



## **United States of America**

Confidence Building Measure Return covering 2009

Convention on the Prohibition of the Development, Production and Stockpiling of  
Bacteriological (Biological) and Toxin Weapons and on their Destruction

Submitted to the United Nations on  
April 15, 2010

**Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange**

<b>Measure</b>	<b>Nothing to declare</b>	<b>Nothing new to declare</b>
A, part 2 (i)		
A, part 2 (ii)		
A, part 2 (iii)		
B (i)		
B (ii)		
C		
D		
E		
F		√
G		

Date: April 15, 2010

State Party to the Convention: United States of America

April 15, 2010

**Report of the United States of America to the United Nations Department for Disarmament Affairs**

Pursuant to the procedural modalities agreed upon in April 1987 at the “Ad Hoc Meeting of Scientific and Technical Experts for STATES Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction,” the United States of America submits the following information under Article V of the Convention:

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**Confidence Building Measure A, Part 2**

Exchanges of information on national biological defence research and development programmes

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**Confidence Building Measure B**

Exchange of information on all outbreaks of infectious diseases and similar occurrences caused by toxins

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Declaration of past activities in offensive and/or defensive biological research and development programmes pages 247, 248

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List of the Biological Select Agents and Toxins, and NIAID Category A, B and C Priority Pathogens pages 260-264

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**Form A – Part 1**

**BWC - Confidence Building Measure**

Exchange of data on research centres and laboratories

United States of America

April 15, 2010

**Exchange of data on research centres and laboratories**

In accordance with the agreement at the Third Review Conference that States Parties provide data on “research centres and laboratories that meet very high national or international safety standards established for handling, for permitted purposes, biological materials that pose a high individual and community risk or specialize in permitted biological activities directly related to the Convention,” the United States is providing data on all facilities designated biosafety level 4 (BSL-4) that were operational during 2009. Data on BSL-4 facilities currently under construction, including two at the National Interagency Biodefense Campus in Frederick Maryland, will be included in future U.S. CBM submissions beginning with the submission covering the year each such facility becomes operational.

In addition to the BSL-4 facilities described above, the United States is providing data on Plum Island Animal Disease Center (PIADC) due to its historical significance.

**Exchange of data on research centres and laboratories<sup>1</sup>**

**1. Name(s) of facility<sup>2</sup>**

Viral Immunology Center, Georgia State University  
National B Virus Resource Laboratory

**2. Responsible public or private organization or company.**

Georgia State University

**3. Location and postal address.**

P. O. Box 4118  
Atlanta, GA 30302-4118

**4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

U.S. Department of Defense (partly)  
National Institutes of Health  
Georgia Research Alliance

**5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>).**

One BSL-4 Laboratory 60 m<sup>2</sup>

**6. If no maximum containment unit, indicate highest level of protection.**

Not applicable.

**7. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

The Viral Immunology Center provides a global resource to assist in the identification of zoonotic disease transmissions and to develop enhanced strategies to detect viral infections in macaques. Current projects in the National B Virus Resource Laboratory are focused on the molecular biology of human and non-human primate alphaherpesviruses and the diseases

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<sup>1</sup> The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>2</sup> For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".

<sup>3</sup> In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent.

they cause. Studies focus on the mechanisms by which virus kills the host and how that process can be circumvented with:

- early identification - research focuses on the design and development of new approaches to more effectively identify these agents in both natural and foreign hosts;
- appropriate antiviral drugs – researchers continually screen the efficacy of existing as well as novel antiviral agents to inhibit the growth of viruses that can potentially cross into the human population, either through occupational exposure or through more subtle contact; and
- in the future, effective vaccines.

Additional information can be found at:

<http://www2.gsu.edu/~wwwvir/Research/Index.html>

**Exchange of data on research centres and laboratories<sup>1</sup>**

**1. Name of facility<sup>2</sup>.**

The Betty Slick and Lewis J. Moorman, Jr. Laboratory Complex  
Department of Virology and Immunology

**2. Responsible public or private organization or company.**

Southwest Foundation for Biomedical Research

**3. Location and Postal address.**

P.O. Box 760549  
San Antonio, Texas 78245-0549

**4. Source of financing of the reported activity, including indication if an activity is wholly or partly financed by the Ministry of Defence.**

National Institutes of Health  
U.S. Department of Defense  
U.S. Department of Homeland Security  
Private Sector Companies  
Private Donors

**5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size.**

One BSL-4 laboratory 114 m<sup>2</sup>

**6. If no maximum containment, indicate highest level of protection.**

Not applicable.

**7. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate.**

The mission of the Department is: "Through basic and applied research, develop vaccines and therapeutics against viral pathogens, and determine how viruses replicate and spread."

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<sup>1</sup> The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>2</sup> For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".

<sup>3</sup> In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent.

In the BSL-4 laboratory, scientists are studying new and emerging disease threats, possible bioterrorism agents, as well as unknown agents for which there is not a biosafety classification. SFBR has permits from the U.S. Department of Agriculture and the Centers for Disease Control to work on select agents as designated by the CDC.

Additional information can be found at:

<http://www.sfbr.org>

**Exchange of data on research centres and laboratories<sup>1</sup>**

**1. Name of facility<sup>2</sup>.**

Galveston National Laboratory (GNL) Complex including Robert E. Shope Laboratory

**2. Responsible public or private organization or company.**

The University of Texas Medical Branch

**3. Location and Postal address.**

301 University Blvd.  
Galveston, TX 77555

**4. Source of financing of the reported activity, including indication if an activity is wholly or partly financed by the Ministry of Defence.**

National Institutes of Health  
U.S. Department of Homeland Security  
U.S. Department of Defense (not sole source, and overall minority funder)  
U.S. Department of Energy  
Pharmaceutical Industry  
Private Foundations

**5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size.**

One BSL-4 laboratory	186 m <sup>2</sup>	(Shope laboratory)
One BSL-4 laboratory	1021.9 m <sup>2</sup>	(GNL laboratory)

**6. If no maximum containment, indicate highest level of protection.**

Not applicable.

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<sup>1</sup> The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>2</sup> For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".

<sup>3</sup> In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent.

**7. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate.**

The mission of the Galveston National Laboratory is to assist the National Institute of Allergy and Infectious Diseases and the nation in the development of an improved means for the prevention, diagnosis and treatment of potentially life-threatening diseases caused by naturally emerging and purposefully disseminated infectious agents. To accomplish this goal GNL conducts multidisciplinary research into the causes, modes of transmission, and mechanisms of infectious diseases. Studies focus on a number of pathogens requiring BSL-4 containment, primarily those that cause viral hemorrhagic fevers, as well as some zoonotic viruses requiring enhanced BSL-3 containment. Products likely to emerge from research and investigations within the GNL include novel diagnostic assays, improved therapeutics and treatment models, and preventative measures such as vaccines.

Additional information can be found at:

<http://www.utmb.edu/gnl/>

**Exchange of data on research centres and laboratories<sup>1</sup>**

**1. Name(s) of facility<sup>2</sup>**

Plum Island Animal Disease Center (PIADC)

Declared in accordance with Form A, part 2(iii)

**2. Responsible public or private organization or company.**

U.S. Department of Homeland Security,  
Science and Technology Directorate,  
Office of National Laboratories

**3. Location and postal address.**

40550 Rte. 25  
Orient Point, NY 11957

DHS PIADC  
P.O. Box 848  
Greenport, NY 11944-0848 USA

**4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

U.S. Department of Homeland Security  
U.S. Department of Agriculture

**5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>).**

There are no maximum containment units (i.e. BSL-4 or equivalent).

The facility includes an enhanced BSL-3 and BSL-3 Agriculture level of biocontainment.

There are a total of 17,643 square meters of BSL-3 floor space, broken down as follows:

BSL-3 Lab Space	2630.09 m <sup>2</sup>
BSL-3 Animal Room Space	2960.54 m <sup>2</sup>
BSL-3 Support Space	12,052 m <sup>2</sup>

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<sup>1</sup> The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>2</sup> For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".

<sup>3</sup> In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent.

**6. If no maximum containment unit, indicate highest level of protection.**

*The Center has the following features which represent an enhancement of BSL-3 space:* biowaste thermal treatment plant; clothing change and shower facilities; double door autoclaves at building exit zones; laboratory and animal biocontainment room areas are HEPA filtered exhaust air, some laboratory and animal room areas are HEPA filtered in and out, and a limited number of animal rooms in BSL-3 biocontainment are deep-bed filtered exhaust air (non-infectious animal work); incinerators for pathological waste disposal.

*The Center lacks the following features required for BSL-4 biocontainment:* Class III gas-tight glove box hoods within enhanced BSL-3 containment space and / or ventilated positive pressure personnel safety suits and safety suit room within biocontainment space; personnel suit chemical decontamination airlocks; check valve systems on gas and fluid supply piping; independent dedicated waste water decontamination unit for BSL-4 zone; and HEPA in and double (in series) HEPA exhaust ventilation.

**7. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

PIADC provides research, development and diagnostic capability for specific high-consequence, contagious, foreign animal diseases of livestock. The focus of the research is on pathogens that infect animals, not those of humans. The facility also maintains a reference repository of animal disease agents (and diagnostic capabilities to recognize them should they occur in the U.S.) and trains veterinarians to field diagnose high consequence foreign animal disease.

Additional information can be found at:

[http://www.dhs.gov/files/labs/editorial\\_0901.shtm](http://www.dhs.gov/files/labs/editorial_0901.shtm)

<http://www.ars.usda.gov/AboutUs/AboutUs.htm?modecode=19-40-00-00>

[http://www.ars.usda.gov/research/projects\\_programs.htm?modecode=19-40-00-00](http://www.ars.usda.gov/research/projects_programs.htm?modecode=19-40-00-00)

[http://www.aphis.usda.gov/animal\\_health/lab\\_info\\_services/about\\_faddl.shtml](http://www.aphis.usda.gov/animal_health/lab_info_services/about_faddl.shtml)

**Exchange of data on research centres and laboratories<sup>1</sup>**

**1. Name(s) of facility<sup>2</sup>**

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

Declared in accordance with Form A, part 2(iii)

**2. Responsible public or private organization or company.**

U.S. Army Medical Research and Materiel Command

**3. Location and postal address.**

1425 Porter St  
Fort Detrick,  
Frederick, Maryland 21702-5011

**4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

U.S. Department of Defense

**5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>).**

One BSL-4 laboratory    1,093 m<sup>2</sup>

**6. If no maximum containment unit, indicate highest level of protection.**

Not applicable

**7. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

USAMRIID conducts research to develop strategies, products, information, procedures and training programs for medical defense against biological warfare threats and infectious diseases. Medical products developed to protect military personnel against biological agents include vaccines, drugs, diagnostic capabilities and various medical management procedures.

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<sup>1</sup> The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>2</sup> For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".

<sup>3</sup> In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent.

**Exchange of data on research centres and laboratories<sup>1</sup>**

**1. Name(s) of facility<sup>2</sup>**

Integrated Research Facility (IRF) – Rocky Mountain Laboratories (RML)

Declared in accordance with Form A, part 2 (iii).

**2. Responsible public or private organization or company.**

National Institutes of Health, U.S. Department of Health and Human Services

**3. Location and postal address.**

903 South 4th St.  
Hamilton, MT 59840

**4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

U.S. Department of Health and Human Services

**5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>).**

Three BSL-4 laboratories            630.85 m<sup>2</sup> (Total)

There are no fixed patient treatment modules integrated with these laboratories.

**6. If no maximum containment unit, indicate highest level of protection.**

Not Applicable

**7. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

Research activities involving viruses, bacteria, rickettsia and prions revolve around pathogenesis studies, vaccinology, and development of therapeutic agents and rapid diagnostic assays in support of the civilian biodefense program.

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<sup>1</sup> The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>2</sup> For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark “Declared in accordance with Form A, part 2 (iii)”.

<sup>3</sup> In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent.

Additional information can be found at:

<http://www.niaid.nih.gov/about/organization/dir/rml/Pages/default.aspx>

<http://www.niaid.nih.gov/about/organization/dir/rml/pages/overview.aspx>

**Exchange of data on research centres and laboratories<sup>1</sup>**

**1. Name(s) of facility<sup>2</sup>**

Coordinating Center for Infectious Diseases (CCID)

Declared in accordance with Form A, part 2 (iii).

**2. Responsible public or private organization or company.**

Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

**3. Location and postal address.**

1600 Clifton Road N.E.  
Atlanta, GA 30333

**4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

U.S. Department of Health and Human Services  
U.S. Department of Homeland Security

**5. Number of maximum containment units<sup>3</sup> within the research centre and/or laboratory, with an indication of their respective size (m<sup>2</sup>).**

6 BSL-4 Laboratories      937 m<sup>2</sup> (Total)

There are no fixed patient treatment module integrated with these laboratories

**6. If no maximum containment unit, indicate highest level of protection.**

Not Applicable

**7. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

Activities include testing and diagnostic assay development, molecular and antigenic characterization, decontamination studies, vaccine development, pathogenesis and natural

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<sup>1</sup> The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.

<sup>2</sup> For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".

<sup>3</sup> In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent.

history studies. CCID performs work with HHS/USDA select agents, with the exception of certain biological toxins.

Additional information can be found at:

[http://www.cdc.gov/fmo/topic/Budget%20Information/CIO\\_Overviews/cio\\_overviews\\_pdf/CCID.pdf](http://www.cdc.gov/fmo/topic/Budget%20Information/CIO_Overviews/cio_overviews_pdf/CCID.pdf)

<http://www.federallabs.org/labs/profile/?id=1880>

**Form A - Part 2**

**BWC - Confidence Building Measure**

Exchanges of information on national biological defence research  
and development programmes

United States of America

April 15, 2010

**National biological defence research and development programme declaration:**

**I. Declaration**

**Is there a national programme to conduct biological defence research and development within the territory of the State Party, under its jurisdiction or control anywhere? Activities of such a programme would include prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research?**

Yes

No

If the answer is yes, complete Form A, part 2 (ii) which will provide a description of the programme.

**Additional Information**

For more information on U.S. Government strategies related to biodefense including biological threat preparedness and response please consult:

- *Management of Domestic Incidents* (HSDP-5) and the related *National Response Framework*;
- *National Preparedness* (HSPD-8);
- *National Strategy for Defense of United States Agriculture and Food* (HSPD-9);
- *National Biodefense Strategy* (HSPD-10/National Security Presidential Directive-33);
- *Medical Countermeasures against Weapons of Mass Destruction* (HSPD-18);
- *Public Health and Medical Preparedness* (HSPD-21);
- *National Strategy for Countering Biological Threats*

Web links to the Homeland Security Presidential Directives (HSPD), issued by the President on matters pertaining to homeland security, can be found at:

[http://www.dhs.gov/xabout/laws/editorial\\_0607.shtm](http://www.dhs.gov/xabout/laws/editorial_0607.shtm)

The *National Strategy for Countering Biological Threats* can be found at:

[http://www.whitehouse.gov/sites/default/files/National\\_Strategy\\_for\\_Countering\\_BioThreats.pdf](http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf)

**Form A – Part 2 (ii)**

**BWC - Confidence Building Measure**

National biological defence research and development programme - Description

United States of America

April 15, 2010

**National biological defence research and development programme**

**II. Description**

- 1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

The Biological Countermeasures Program in the Science and Technology (S&T) Directorate of the Department of Homeland Security (DHS) is an applied research and development program that focuses emerging science and technology to provide the understanding, technologies, and systems needed to protect against biological attacks on the U.S. population, agriculture or infrastructure. The program focuses on the conduct of research, development, testing, and evaluation (RDT&E) and on the transition to deployment of the needed technologies and systems. The five principal areas of study are: 1) systems studies and decision support tools, 2) threat awareness, 3) surveillance and detection research and development (R&D), 4) forensics, and 5) response and restoration. The program supports other U.S. federal agencies in overall coordination of national biodefense efforts.

Programs conducted during 2009 include systems studies and decision tools, risk assessments, the biodefense knowledge management, biological warning and detection systems for critical infrastructure and urban areas, decontamination of transit systems, national bioforensic analysis, the National Biodefense Analysis and Countermeasures Center (a DHS program that serves as national resource to understand the scientific basis of the risks posed by biological threats and to attribute their use in bioterrorism or biocrime events), biological threat characterization, development of response plans and risk communication, and, at the Plum Island Animal Disease Center, development of vaccines and diagnostics for foreign animal diseases.

- 2. State the total funding for the programme and its source.**

The total CY09 funding of the DHS S&T Biological Countermeasures Program was:  
\$134,000,000 U.S. Department of Homeland Security

- 3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

Yes

**4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

100%

**5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

As previous stated, the Biological Countermeasures program utilizes multiple activities to carry out its mission. In the systems studies and decision tool area, research includes conducting system studies and net assessments that are used to identify effective measures for deterrence, detection, and mitigation of biological terrorism acts against the U.S. population and infrastructure.

For threat awareness, efforts are underway to characterize threats posed by biological weapons, anticipate future threats, and conduct comprehensive threat and risk assessments to guide prioritization of the Nation's biodefense investments. DHS programs on threat awareness include the National Biodefense Analysis and Countermeasures Center (NBACC)'s Biological Threat Characterization Center (BTCC).

Within the area of surveillance and detection R&D, performers are developing next-generation detectors for biological threat agents, including fully autonomous detection capabilities for the third generation (Gen 3) BioWatch system. In addition, other efforts are underway to develop the assays (i.e. signatures or fingerprints of biological agents) needed by detectors to accurately recognize a biological agent. Another focus is on developing detect-to-protect systems specifically for use indoors as well as detection systems for protecting food products.

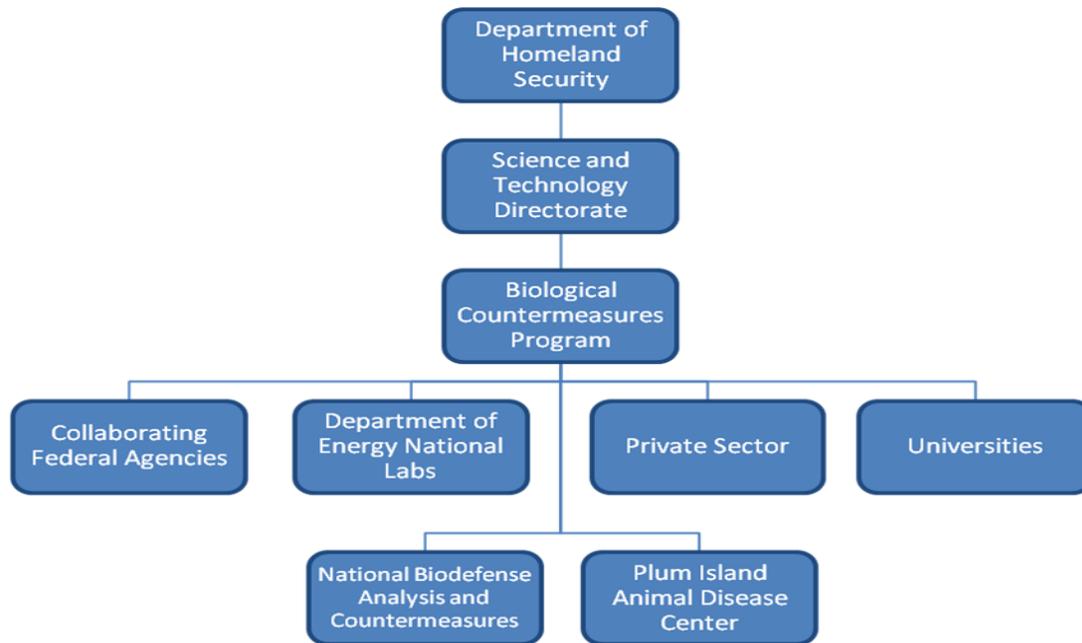
Under the microbial forensics area, funding is devoted to operate the NBACC's National BioForensics and Analysis Center (NBFAC) and conduct bioforensics research in support of criminal investigations and attribution by the appropriate Federal agency. Other DHS activities provide facilities, tools (i.e. assays, protocols, and strain libraries), analyses, and rigorous chain-of-custody controls needed to support the FBI and others in their investigation of potential biocrimes or acts of bioterrorism.

Lastly, the Biological Countermeasures Program has a response and restoration element that provides advanced planning, develops concepts-of-operation, and funds exercises and training for responding to and recovering from a large-scale biological attack. Biological agents have the potential to contaminate large portions of a city, covering multiple city blocks and facilities therein. The objective is to provide a more rapid and less expensive post-attack cleanup and restoration in such situations. This program is developing a systems approach for the restoration of citywide areas and of critical facilities, such as major transportation hubs, and is not developing specific decontamination technologies. Restoration demonstrations, which bring together Federal, State, and local partners to

develop, test, and then share the concepts-of-operations for key scenarios, are at the heart of this approach.

**6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)**

The structure existed through 2009.



**7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

In accordance with Form A part 2 (iii):

- Plum Island Animal Disease Center.

National biological defence research and development programme

**II. Description**

- 1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

The program objective is to identify or prepare and characterize “reactive materials” to produce self-disinfecting and/or self-decontaminating materials for incorporation into protective gear and other materiel in order to provide personnel and equipment protection against both environmental and weaponized pathogens.

- 2. State the total funding for the programme and its source.**

\$2,508,500	U.S. Department of Defense
\$ 473,000	Other Governmental Agencies

- 3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

Yes

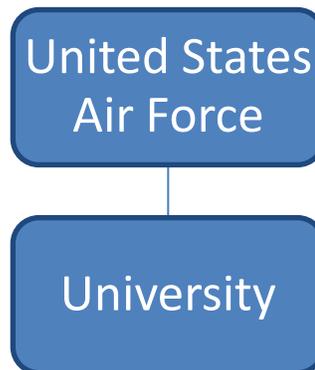
- 4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

60%.

- 5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

To classify the particle size distribution of bioaerosols, building precision aerosol deposition devices and studying post-capture fate of iodine on bioaerosol particles.

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in the programme).



7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

Not applicable

**National biological defence research and development programme**

**II. Description**

- 1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

The purpose of the Threat Agent Cloud Tactical Intercept and Countermeasure (TACTIC) Program is to provide the United States (US) military with the capability to identify and effectively defeat/neutralize a biological threat agent cloud on the battlefield.

- 2. State the total funding for the programme and its source.**

\$26,200,000

U.S. Department of Defense

- 3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

Yes

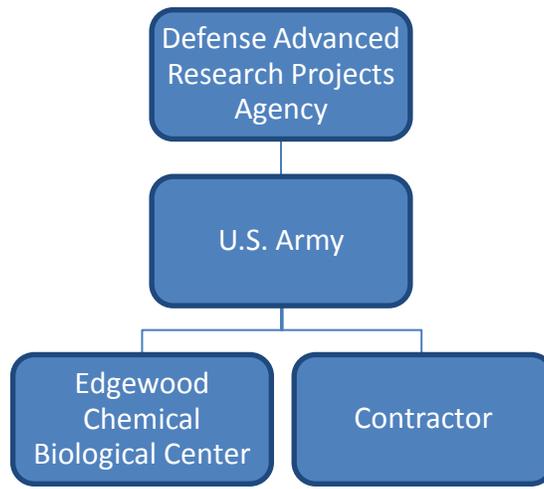
- 4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

100%

- 5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

Provide independent testing and evaluation of a countermeasure solution against a biological warfare agent stimulant. The research area for this work is decontamination.

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme).



7. Provide a declaration in accordance with Form A, part 2 (ii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

In accordance with Form A, Part 2(iii).

- Edgewood Chemical Biological Center (ECBC)

**National biological defence research and development programme**

**II. Description**

- 1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

The Rapid Vaccine Assessment (RVA) Program developed an Artificial Immune System (AIS) that will serve as an *in vitro* test platform to accurately test the human response to vaccines. The AIS reproduces human immune responses to experimental vaccines and drugs using a low-cost, high-throughput automated system. The platform is fully developed, capable of testing a number of vaccines against large numbers of human cells.

- 2. State the total funding for the programme and its source.**

\$74,900,000                      U.S. Department of Defense

- 3. Are aspects of this programme conducted under contract with industry, academic institutions, or in other non-defense facilities**

Yes

- 4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

100%

- 5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

Vaccination Site

- Antigen presentation by dendritic cell
- Innate response profile of vaccines
- Immunosuppressant evaluation
- Innate response to biologics

Lymphoid Tissue Equivalent

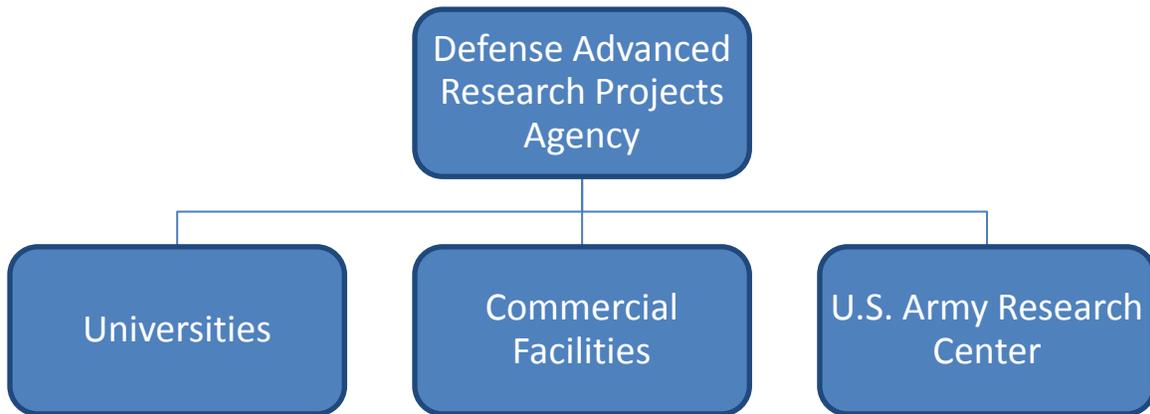
- Antigen-specific cell responses
- Responses to naïve and recall antigens
- Human primary antibody response – sub-class switching

Artificial Immune System

- Developing cell response detection system

- Novel rapid microneutralization assays for membrane fusion and endocytosis viral entry
- Optimization of high thru-put (HTP) testing
- Integration of robotic controls
- Confirmation of consistent results
- Automation of blood processing, vaccination site, development provides approximately 4X savings in time
- Second core automation system brought to aid in system analysis

**6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in the programme).**



**7. Provide a declaration in accordance with Form A: part 2(iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

Not applicable

**National biological defence research and development programme**

**II. Description**

- 1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

The Accelerated Manufacture of Pharmaceuticals (AMP) Program is creating a U.S.-based vaccine and antibody manufacturing platform capable of producing three million doses of vaccines or monoclonal antibodies (mAb) within 12 weeks. AMP produces life-saving vaccines and antidotes such as monoclonal antibodies (mAbs) when the pathogen itself is not available. AMP is designed to address key shortfalls in current vaccine manufacturing.

- 2. State the total funding for the programme and its source.**

\$71,000,000                      U.S. Department of Defense

- 3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defense facilities:**

Yes

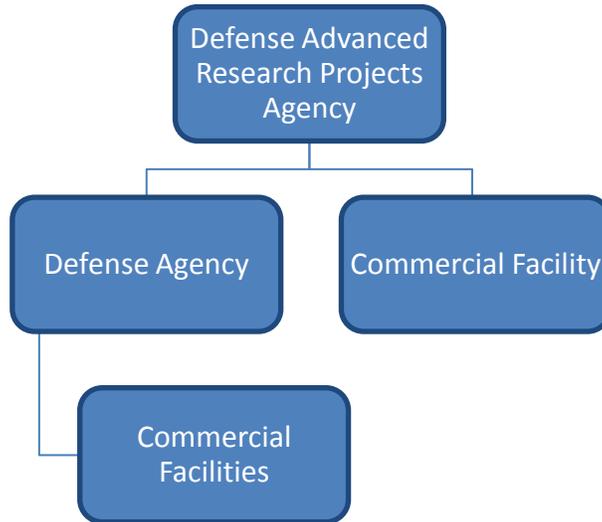
- 4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

100%

- 5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified under paragraph 4.**

The AMP program seeks to produce bulk doses of vaccine quality recombinant protein and monoclonal therapies "on demand," and in large quantities against established and new biological threats. The goal of the program is to create an extremely rapid, flexible, and cost-effective production system capable of producing 3 million bulk doses of protein for any vaccine or monoclonal antibody therapy (mAB) within 12 weeks of notification.

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in the programme).



7. Provide a declaration in accordance with Form A: part 2(iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

Not Applicable

National biological defence research and development programme

**II. Description**

- 1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

**Joint Biological Point Detection System.** Produce and field a fully automated system for point sampling, detecting, and identifying biological agents in an aerosolized environment.

**Joint Biological Tactical Detection System.** Develop, produce and field a man-portable family of systems for point sampling, detecting, and identifying biological agents in an aerosolized environment.

**Joint Biological Stand-off Detection System.** Develop, produce and field a system for detecting biological agent clouds at certain stand-off distances.

- 2. State the total funding for the programme and its source.**

\$177,000,000                      U.S. Department of Defense

- 3. Are aspects of this programme conducted under contract with industry, academic institutions, or in other non-defense facilities?**

Yes

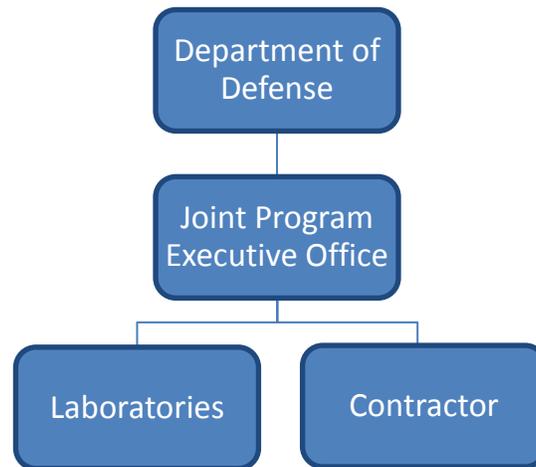
- 4. If yes, what proportion of the total funds for the program is expended in these contracted or other facilities?**

70%

- 5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified under paragraph 4.**

- 1) Produce components and systems
- 2) Develop and test new sensor hardware and software components;
- 3) Develop system test methods

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in the programme).



7. Provide a declaration in accordance with Form A: part 2(iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

Not Applicable

**National biological defence research and development programme**

**II. Description**

- 1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

Environmentally Friendly Aircraft Decontamination System (EFADS). Develop a prototype system for biological decontamination of aircraft.

- 2. State the total funding for the programme and its source.**

\$1,400,000                      U.S. Department of Defense

- 3. Are aspects of this programme conducted under contract with industry, academia institutions, or in other non-defense facilities?**

Yes

- 4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

100%

- 5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4:**

Modify a current system and verify performance.

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme).



7. Provide a declaration in accordance with Form A, part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

Not applicable

**National biological defence research and development programme**

**II. Description**

- 1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

The Environmental Protection Agency (EPA)'s mission is to protect public health and the environment. The National Homeland Security Research Center (NHSRC), part of the EPA's Office of Research and Development, conducts and reports on research to improve capacity to respond to and recover from environmental contamination of water infrastructure, buildings and outdoor areas by chemical, biological, radiological and nuclear (CBRN) agents. The NHSRC biodefense program focuses on EPA's two biodefense responsibilities:

- 1) assistance in the protection of the American water supply, and
- 2) decontamination of indoor and outdoor areas should the U.S. suffer a contamination incident.

EPA is designated as the government's lead sector-specific agency for water, and is responsible for protecting water systems and detecting and recovering from terrorist attacks affecting them. EPA's homeland security research is responsible for developing products and providing expertise to protect, detect, respond to, and recover from terrorist attacks on the nation's water and wastewater infrastructure.

EPA is also the lead federal agency for the remediation of areas contaminated by terrorist events involving the release of biological organisms, biotoxins, chemical warfare agents, toxic industrial chemicals, toxic industrial materials, and radiological materials. Terrorist acts may involve biological, chemical, and radiological agents not previously encountered as environmental pollutants. EPA's homeland security research is responsible for providing procedures and methods that will assist EPA's responders in the detection and containment of contamination, and in the remediation of sites following terrorist attacks.

- 2. State the total funding for the programme and its source.**

\$10,490,000	Environmental Protection Agency Science and Technology appropriation
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- 3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

Yes

**4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

39%

**5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

NHSRC has research being conducted by contractors to assess risks of biological agents. Exposure studies are being conducted to estimate doses that result in adverse health effects from biological hazards. To address the need for remediating contaminated sites, NHSRC has been evaluating as well as developing analytical methods for biological agents.

**6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)**



**7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting Stated, or under its jurisdiction or control anywhere.**

Not Applicable

National biological defence research and development programs

**II. Description**

- 1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

Improving our nation's defenses against bioterrorism is a key part of the U.S. government's homeland security effort. The Department of Health and Human Services (HHS) supports activities to improve local and state public health systems, to expand existing biosurveillance efforts, and to fund research on medical countermeasures against potential bioterror agents.

**The NIH biodefense program** is supported by funding from the U.S. Department of Health and Human Services. The National Institutes of Health and specifically the National Institute of Allergy and Infectious Diseases (NIAID) has the primary responsibility within the United States Government for civilian biodefense research. The intent of the program is to provide countermeasures to be used to protect the U.S. civilian population through the development of vaccines, therapeutic agents and rapid, agent-specific assays.

- 2. State the total funding for the programme and its source.**

\$61,776,210      U.S. Department of Health and Human Services

- 3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

No

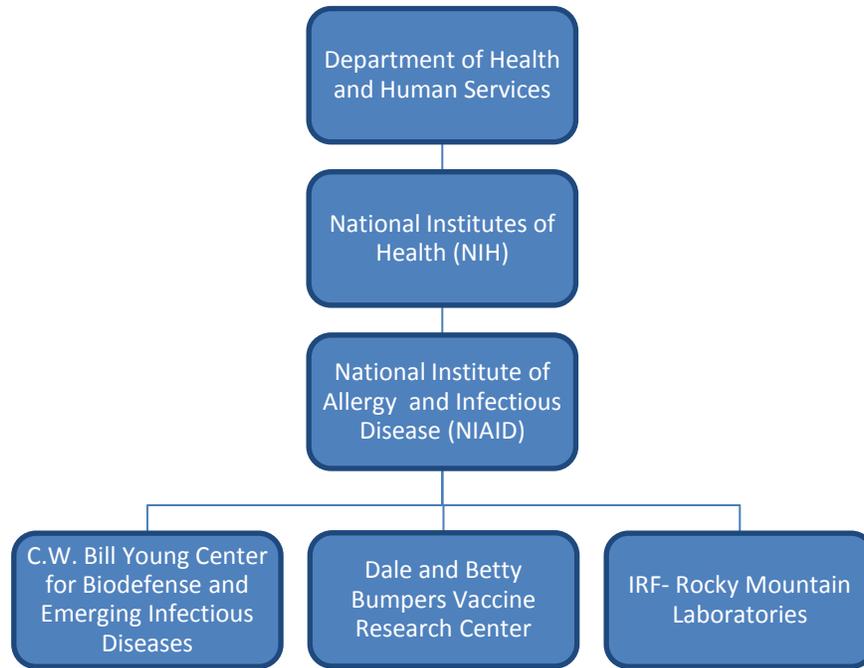
- 4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

Not Applicable

- 5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

Not Applicable

**6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)**

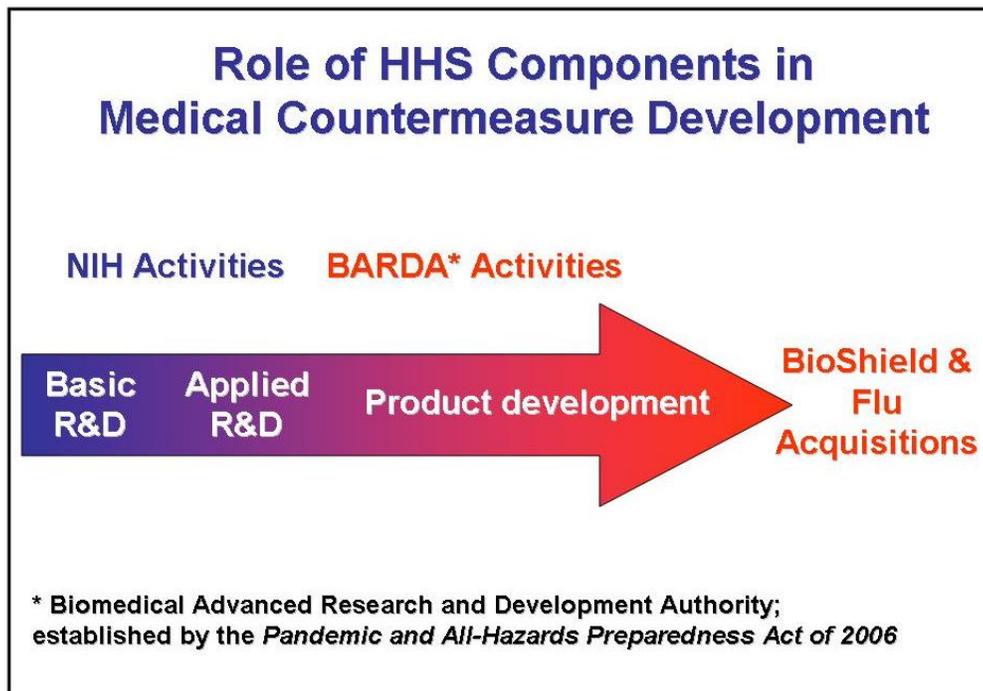


**Background information on the integration of NIH biodefense program into the US Department of Health and Human Service (HHS) biodefense program and activities:**

The National Institutes of Health (NIH), and specifically the National Institute of Allergy and Infectious Diseases (NIAID), conducts and supports much of the research aimed at developing new and improved medical countermeasures against potential bioterrorism agents. The NIH/NIAID *Strategic Plan for Biodefense Research* is available online at: <http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Documents/biosp2007.pdf>.

The NIH biodefense program is integrated into the HHS biodefense program and activities. Overall responsibility for coordination of HHS development, acquisition, storage, maintenance, deployment, and guidance for using biodefense products resides with the Biomedical Advanced Research and Development Authority (BARDA), a component of the Office of the Assistant Secretary for Preparedness and Response (ASPR), at the US Department of Health and Human Service (HHS). BARDA was established by the Pandemic and All-Hazards Preparedness Act of 2006 (Public Law 109-417) to facilitate collaboration among the U.S. government, industry, and academia in the development of medical countermeasures for public health emergencies, support the advanced research and development of medical countermeasure (MCM), and promote innovation to reduce the time and cost of MCM development. BARDA manages Project BioShield, which includes the acquisition and procurement of medical countermeasures for chemical, biological, radiological, and nuclear agents, as well as the advanced development and procurement of

medical countermeasures for pandemic influenza and other emerging infectious diseases that fall outside the auspices of Project BioShield.



The HHS *Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy for Chemical, Biological, Radiological and Nuclear Threats*, the HHS *PHEMCE Implementation Plan*, and the Homeland Security Presidential Directive (HSPD)-18, “*Medical Countermeasures Against Weapons of Mass Destruction*”, outline strategies for identifying medical countermeasure requirements and establishing priorities for their research, development, and acquisition.

For additional information on the integration of HHS biodefense program components from R&D to acquisition (procurement), please refer to the following websites:

<http://www.niaid.nih.gov/topics/biodefenserelated/biodefense/about/Pages/default.aspx>

<http://www.hhs.gov/aspr/barda>

<https://www.medicalcountermeasures.gov/>

The large investment in biodefense research and product development will significantly benefit other areas of medicine. Many of the organisms under study and a host of other emerging infectious diseases and drug-resistant microbes are significant public health threats, both within the United States and in other parts of the world. Research on microbial biology and pathogenesis will enhance understanding of these and other naturally occurring infectious diseases. Advances in developing diagnostics, vaccines, and therapeutics with broad spectrum activity will have direct relevance to many naturally occurring diseases, as well as spin-off benefits for developing other broad spectrum products. Broad spectrum technologies that improve product stability, potency, and ease of use will benefit many classes of new diagnostics, vaccines, and therapeutics, regardless of the disease target. The

most obvious gain will be for interventions to prevent, diagnose, and treat major killers such as malaria, tuberculosis, HIV/AIDS, and a spectrum of emerging and reemerging diseases. This is especially important in countries where public health infrastructure cannot support delivery of products that require a cold chain, multiple doses of a vaccine, or advanced diagnostic equipment. Broad spectrum platforms have the potential to reduce time and cost of developing new products for many medical conditions. Basic research on host defenses will greatly enhance our understanding of the molecular and cellular mechanisms of the innate immune system and its relationship to the adaptive immune system, and lead to improvements in treatment and prevention of immune-mediated diseases, such as systemic lupus erythematosus, rheumatoid arthritis, and other autoimmune diseases. Finally, improved understanding of mechanisms of regulation of the human immune system will have positive spinoffs for diseases such as cancer, immune-mediated neurological diseases, and allergic and hypersensitivity diseases, as well as for preventing rejection of transplanted organs [Reference: NIH/NIAID *Strategic Plan for Biodefense Research*, online at: <http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Documents/biosp2007.pdf> ]

**7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

In accordance with Form A part 2 (iii):

- C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases
- Dale and Betty Bumpers Vaccine Research Center
- IRF- Rocky Mountain Laboratories

**National biological defence research and development programme**

**II. Description**

- 1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

**The CDC Division of Vector-borne Infectious Diseases (DVBID)** focuses on development and implementation of epidemiology and surveillance, prevention and control and improved diagnostics for diagnosis, detection and characterization of several vector-borne pathogens including various bacteria and alphaviruses.

As the national reference laboratory for these pathogens, DVBID observes new trends, identifies deficiencies and finds solutions that improve the ability to provide more credible service to the public. Enhanced and reliable detection is critical for identifying illnesses that may be related to bioterrorism and improving the ability of the Laboratory Response Networks (LRN) to diagnose these life-threatening conditions. Improved diagnostic capacity also strengthens DVBID's ability to serve as subject matter experts for the deliberate use of these agents.

DVBID provides CDC with a critical means for preventing the animal-and vector-borne spread of these pathogens from a site of initial release during a bioterrorism event. Implementation of adequate control measures also will greatly reduce the risks that secondary human cases of disease which could arise from contact with infected animals or exposure to the bites of infectious vector arthropods.

- 2. State the total funding for the programme and its source.**

\$1,781,885                      Direct allocation from the CDC Office of Terrorism, Preparedness and Emergency Response program.

- 3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

No

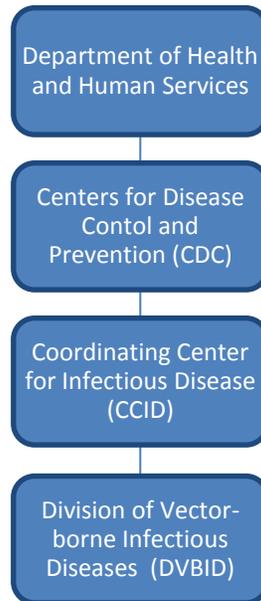
- 4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

Not Applicable

5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.

Not Applicable

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme).



7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

In accordance with Form A part 2 (iii):

- Division of Vector-borne Infectious Diseases (DVBID)

**National biological defence research and development programme**

**II. Description**

- 1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

**The CDC Mass Spectrometry Toxin Laboratory** is developing toxin assays that are critical for the public health response to biological toxins. The laboratory uses advanced mass spectrometry techniques to measure peptides and proteins that are in the pathogenic pathway of the infectious agent or toxin and uses these measurements to identify and track infection or poisoning.

- 2. State the total funding for the programme and its source.**

\$3,700,000            U.S. Government obligated funds (allocation from CDC/Office of  
Terrorism, Preparedness and Emergency Response)

- 3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

Yes

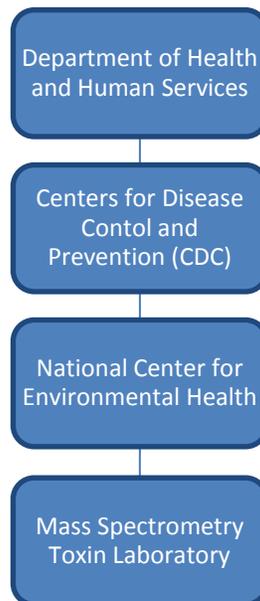
- 4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

10%

- 5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

Manufacture of botulinum neurotoxin antibodies for use in detection assays.

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)



7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

In accordance with Form A part 2 (iii):

- Mass Spectrometry Toxin Laboratory

National biological defence research and development programme

**II. Description**

- 1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

The variety of activities in **CDC Coordinating Center for Infectious Diseases (CCID)** include diagnostic techniques, assay development, molecular and antigenic characterization of microorganisms, evaluation of decontamination methods, pathogenicity, virulence, natural history, and vaccine development for select agents (select agents list available at: <http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html>).

- 2. State the total funding for the programme and its source.**

\$31,000,000 (estimated) U.S. Department of Health and Human Services  
\$ 350,000 (estimated) The Environmental Protection Agency (EPA) for CDC projects, including some carried out at CCID.

- 3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

Yes

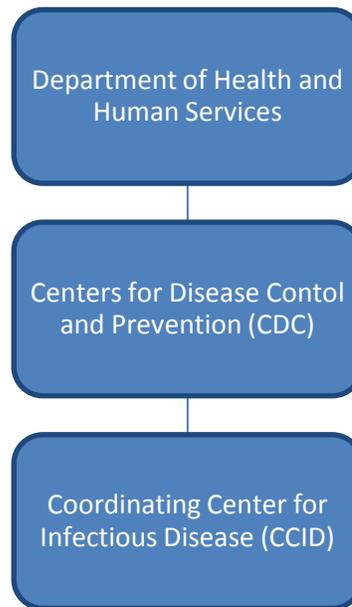
- 4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

Approximately 35%

- 5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

Anthrax vaccine efficacy trials, bioterrorism preparedness and response activities, avian influenza preparedness, disease surveillance in CDC field locations.

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)



7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

In accordance with Form A part 2 (iii):

- Coordinating Center for Infectious Disease (CCID)

**National biological defence research and development programme**

**II. Description**

- 1. State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

United States Department of Agriculture - Agriculture Research Service (USDA ARS)

**Background**

Foreign animal diseases represent a major threat to U.S. agriculture. Introduction of these agents, either accidental or deliberate, has devastating social and economic effects not only in the country's agricultural systems but also in a wide range of economic activities. Diseases of concern include but are not limited to Foot-and-Mouth Disease, Avian Influenza, Rift Valley Fever, Classical Swine Fever, African Swine Fever, Exotic Newcastle disease, Vesicular stomatitis, and Exotic Bluetongue.

Animal health officials define an exotic or foreign animal disease (FAD) as an important transmissible livestock or poultry disease believed to be absent from the U.S. and its territories that has a potential significant health or economic impact. Foreign animal diseases are considered a threat to the U.S. when they significantly affect human health or animal production and when there is an appreciable cost associated with disease control and eradication efforts. To protect the long-term health and profitability of U.S. animal agriculture, incursions of a FAD must be rapidly controlled.

In the U.S., control usually means disease eradication. Disease eradication is currently accomplished by eliminating the animal, resulting in loss of protein, loss of income to the farm community, public opposition and environmental disruption. In addition to control costs, one of the most immediate and severe consequences of a FAD occurrence in the U.S. will be the loss of export markets. As we move into the 21st century, many new issues and factors are affecting FAD prevention, control, management, and recovery. These factors include free trade agreements, free trade blocks, regionalization, increased international passenger travel, intensification of animal production, the constant evolution of infectious agents, and the uncertain impact of biotechnology and bioterrorism.

Current methods for prevention and control of high consequence diseases, including prevention, detection, control and eradication, are not socially or economically acceptable. Rapid detection and characterization tools for prevention, control and eradication of foreign animal diseases are inadequate or not currently available. Our understanding of pathogenesis, transmission, and immune response is insufficient to rapidly control and eradicate foreign animal diseases. Effective measures to prevent, control and eradicate foreign animal diseases are lacking or inadequate.

## **Strategic Objectives**

- Establish Agriculture Research Service (ARS) laboratories into a fluid, highly effective research network, to maximize use of core competencies and resources
- Access to specialized high containment facilities to study zoonotic and emerging diseases
- Develop an integrated animal and microbial genomics research program
- Establish centers of excellence in animal immunology
- Launch a biotherapeutic discovery program providing alternatives to animal drugs
- Build a technology-driven vaccine and diagnostic discovery research program
- Develop core competencies in field epidemiology and predictive biology
- Develop internationally recognized OIE expert collaborative research laboratories
- Establish best in class training center for our nation's veterinarians and scientists
- Develop a model technology transfer program to achieve the full impact of our research discoveries

## **Research Needs**

In order to control foreign animal disease, a wide variety of agent detection platforms need to be developed and validated. Information for design of these platforms will come in part from further knowledge of pathogen genomics and proteomics and in part from understanding the evolution and genetic variability of disease agents. Although many of the foreign animal diseases have existed for many years in many countries there is still much more fundamental knowledge of these agents that is required. There is still a lack of understanding in host range and tissue tropism, carrier state, duration and routes of shedding, transmission mechanisms, (e.g. vectors, fomites, aerosols), ecology and epidemiology (e.g., wildlife reservoirs). If these diseases should occur in the U.S. more effective prevention and control tools such as identifying suitable control strategies compatible with short time and cost of recovery from disease outbreaks (DIVA compatible) need to be developed. There is a need for development of vaccines and biotherapeutics suitable for strategic stockpiles, integrated methods of disease control including vector control and animal management, which all lead to a better capability to regain country disease-free status and retain economic sustainability.

## **Expected Outputs:**

- Better anticipation of introduction of foreign animal diseases
- Capability to advise regulatory officials on scientific procedures for the prevention of introduction of FADs
- Better capability to produce effective products to control and eliminate foreign animal diseases
- Real-time detection of agents in a wide range of farm matrices
- Searchable databases of genome and proteome information for major known FAD agents
- Improved ability to predict or anticipate emergence or introduction FAD agents
- Discovery of effective candidate biotherapeutics
- Discovery of effective candidate vaccines that allow differentiation of infected animals from vaccinated animals (DIVA)
- Viable integrated vector control strategies that minimize losses

The USDA-ARS biodefense research program is intramural and implemented in ARS high containment facilities in the following locations: Ames, Iowa; Orient Point, New York; Athens, Georgia; Frederick, Maryland.

**2. State the total funding for the programme and its source.**

\$16,645,000                      U.S. Department of Agriculture

**3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

No

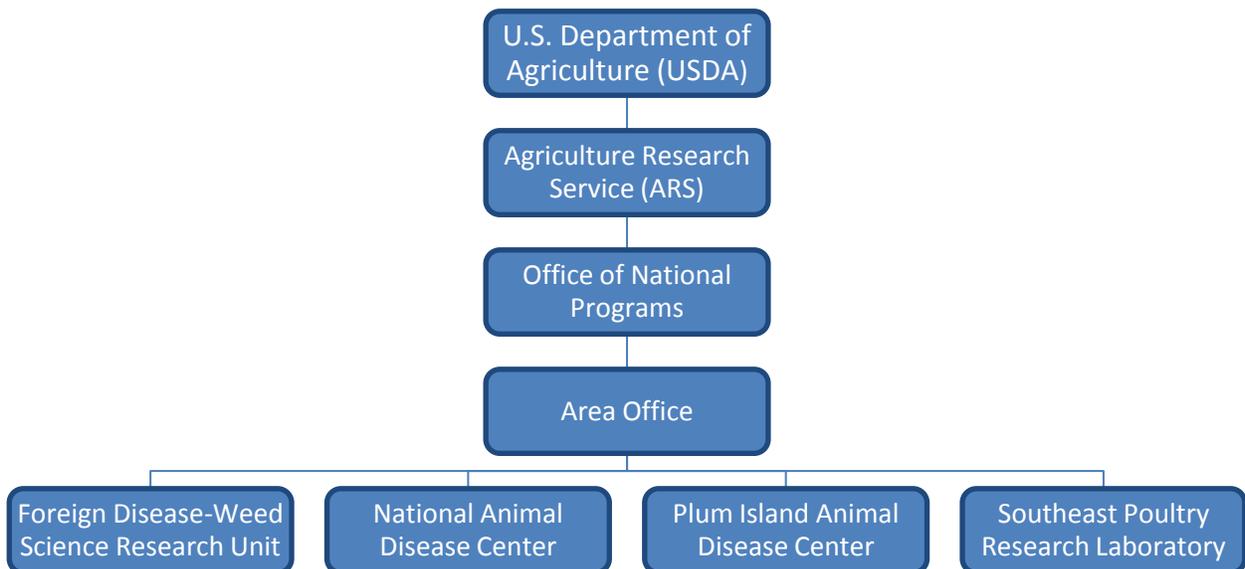
**4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

Not applicable

**5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

Not applicable

**6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)**



- 7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

In accordance with Form A part 2 (iii):

- Foreign Disease-Weed Science Research Unit
- National Animal Disease Center
- Plum Island Animal Disease Center
- Southeast Poultry Research Laboratory

**Form A – part 2 (iii)**

**BWC - Confidence Building Measure**

National biological defence research and development programme - Facilities

United States of America

April 15, 2010

**National biological defence research and development programme**

In preparing the 2009 CBM Return, the U.S. Government identified potential concerns associated with public release of information on the identity of biological agents at specific facilities.

To balance these concerns with a desire to promote transparency, in Form A Part 2(iii) the U.S. submission characterizes the agents used for biological defense research at each facility by identifying:

- whether there are **Biological Select Agent and Toxins** (Select Agent) present at the facility, and if so, which subcategories (HHS, Overlap, USDA, and USDA PPA) are represented;
- for each Select Agent subcategory, whether these agents are also listed under **NIAID Category A, B, or C Priority Pathogens**;
- whether there are non-Select Agent **NIAID Category A, B or C Priority Pathogens** present at the facility; and
- other relevant information as appropriate.

**Biological Select Agents and Toxins** (Select Agents) are biological agents or toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products, whose possession, use and transfer are regulated by the Select Agent Rules.

Additional information on Select Agents can be found at:

<http://www.selectagents.gov>.

The **NIAID list of Category A, B and C Priority Pathogens** identifies specific pathogens as priorities for additional research efforts as part of the NIAID biodefense research agenda.

Additional information on NIAID Category A, B and C Priority Pathogens can be found at:

<http://funding.niaid.nih.gov/ncn/glossary/default5.htm>

<http://pathema.jcvi.org/pathema/AbcGenomes.shtml>

<http://www.fas.org/irp/threat/cbw/niaid0803.pdf>

<http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Documents/categorybandc.pdf>

Using the two lists to categorize the agents at a facility offers greater transparency into the types of agents than using either list alone. Lists of **Biological Select Agents and Toxins**, and **NIAID Category A, B, C Priority Pathogens** can be found in the Appendix of the CBM submission (pages 260-264). A compiled list of biological agents and toxins used for biological defense research at the facilities reported in Form A Part 2(iii) can be found in Appendix B of the CBM submission (pages 265-271)

To maintain our existing high level of transparency to States Parties we are making available, to all States Parties, information on agents consistent with previous submissions.

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

Plum Island Animal Disease Center

**2. Where is it located?**

40550 Rte. 25  
Orient Point, NY 11957

**3. Floor area of laboratory areas by containment level:**

BL2 (sqM)	234
BL3 (sqM)	17,643
BL4 (sqM)	0
Total (sqM)	17,877

**4. The organizational structure of each facility.**

**I Total number of personnel** 358

**II Division of personnel:**

Military	0
Civilian	358

**III Division of personnel by category:**

Scientists	86
Engineers	2
Technicians	115
Administrative and support staff	155

**IV List the scientific disciplines represented in the scientific/engineering staff.**

Biology  
Chemistry  
General Engineering  
Microbiology  
Molecular computational biology  
Molecular biology  
Veterinary Clinical Research

Veterinary Medicine

**V Are contractor staff working in the facility? If so, provide an approximate number.**

Yes                      Number:              214

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Research is funded by the U.S. Federal government, specifically:  
U.S. Department of Agriculture  
U.S. Department of Homeland Security

**VII What are the funding levels for the following program areas:**

Research	\$ 4,000,000 (approximately)
Development	\$ 7,000,000 (approximately)
Test and evaluation	\$ 4,000,000 (approximately)
Total	\$15,000,000 (approximately)

**VIII Briefly describe the publication policy of the facility:**

DHS scientific research staff are expected to publish papers in open literature. Papers are peer reviewed and approved by DHS prior to submittal to journals. DHS has no official publication policy.

USDA ARS has several publication policies (website links in parenthesis):

- Policy Number 150.1 “Dissemination of Public Information by ARS”  
<http://www.afm.ars.usda.gov/ppweb/PDF/150-01.pdf>;
- Number 113.1 “Publishing (Print and Electronic Material)”  
[www.afm.ars.usda.gov/ppweb/2010/113-1-ARS.pdf](http://www.afm.ars.usda.gov/ppweb/2010/113-1-ARS.pdf); and
- Number 152.1 “Procedures for Publishing Manuscripts and Abstracts with Non-USDA Publishers (Outside Publishing)”  
<http://www.afm.ars.usda.gov/ppweb/pdf/152-01.pdf>

**IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)**

Alves M.P., Guzylack-Piriou L., Juillard V., Audonnet J.C., Doel T., Dawson H., Golde W.T., Gerber H., Peduto N., McCullough K.C., Summerfield A. Innate immune defenses induced by CpG do not promote vaccine-induced Protection against foot and mouth disease virus in pigs. (2009) *Clinical and Vaccine Immunology*, August 2009, 16(8) :1151-1157. DOCUMENT TYPE: Article

Arzt, J., Gregg D. A., Clavijo A., Rodriguez L.L. Optimization of immunohistochemical and fluorescent antibody techniques for localization for foot and mouth disease virus in animal tissues. *Journal of Veterinary Diagnostic Investigation*, 21: 779-792. DOCUMENT TYPE: Article

Barrette R.W., Metwally S.A., Rowland J.M., Xu L., Zaki S.R., Nichol S.T., Rollin P.E., Towner J.S., Shieh W.J., Batten B., Sealy T.K., Carrillo C., Moran K.E., Bracht A.J., Mayr G.A., Sirios-Cruz M. Discovery of swine as a host for the *Reston ebolavirus*. *Science*, July 10, 2009, 325, pp. 204-206 DOCUMENT TYPE: Article

Brockmeier S.L., Lager K.M., Grubman M.J., Brough D.E., ETTYREDDY D., SACCO R.E., GAUGER P.C., LOVING C.L., VORWALD A.C., KEHRLI M.E., LEHMKUHL H.D. Adenovirus-mediated expression of interferon- $\alpha$  delays viral replication and reduces disease signs in swine challenged with porcine reproductive and respiratory syndrome virus. (2009) *Viral Immunology*, 22, (3), pp. 173-180 DOCUMENT TYPE: Article

De los Santos, T., Diaz-San Segundo F., Zhu J., Koster M., Dias C.C.A., Grubman M.J. A conserved domain in the leader proteinase of Foot-and-Mouth Disease Virus is required for proper subcellular localization and function. *Journal of Virology*, 83 (4), pp. 1800-1810 DOCUMENT TYPE: Article

Diaz-San Segundo, F., Moraes M.P., de los Santos T., Dias C.C.A., Grubman M.J. Interferon-induced protection against foot-and-mouth disease virus correlates with enhanced tissue specific innate immune cell infiltration and interferon stimulated gene expression. *Journal of Virology*, February 2010, p. 2063-2077, Vol. 84, No. 4 DOCUMENT TYPE: Article

Fernandez-Sainz I., Holinka L.G., GAVRILOV B.K., PRARAT M.V., GLADUE D., LU Z., JIA W., RISATTI G.R., BORCA M.V. Alteration of the N-linked glycosylation condition in E1 glycoprotein of Classical Swine Fever Virus strain Brescia alters virulence in swine. *Virology*, 36 (1) pp. 210-216 DOCUMENT TYPE: Article

Fernandez-Sainz I., Gladue D.P., Holinka L.G., O'Donnell V.O., Gudmundsdottir I., Prarat M.W., Patch J.R., Golde W.T., Lu Z., Zhu J., Carrillo C., Risatti G.R., Borca M.V. Mutations in NS4B of Classical Swine Fever Virus affect virulence in swine. *Journal of Virology* 2010 Feb;84(3):1536-49. Epub 2009 Nov 18 DOCUMENT TYPE: Article

Grubman M.J., Moraes M.P., Schutta C., Barrera J., Nielan J., ETTYREDDY D., BUTMAN B.T., BROUGH D.E., BRAKE D.A. Replication-defective human adenovirus serotype 5-vectored foot-and-mouth disease subunit vaccines: the first decade. *Future Virology*, 5(1), pp. 1-14. DOCUMENT TYPE: Review

Holinka L.G., Fernandez-Sainz I., O'Donnell V., Prarat M.V., Gladue D.P., Lu Z., Risatti G.R., Borca M.V. Development of a live attenuated antigenic marker classical swine fever vaccine. *Virology*, 384 (1), pp. 106-113 DOCUMENT TYPE: Article

Junior A.S., Castro L.A., Neto O.C., Silva F.M.F., Vidigal P.M.P., Moraes M.P., Almeida M.R. Development and evaluation of a recombinant DNA vaccine candidate expressing porcine circovirus 2 structural protein. *Pesquisa veterinaria Brasileira*, January 2009, 29 (1), pp. 76-82. DOCUMENT TYPE: Article

Lawrence P., Rieder E. Identification of RNA helicase A as a new host factor in the replication cycle of Foot-and-Mouth Disease Virus. *Journal of Virology*, Nov. 2009, 883 (21) pp. 11356-11366 DOCUMENT TYPE: Article

Mason P.W., Grubman M.J., Foot-and-Mouth Disease. Chapter 22 from the book titled "Vaccines for Biodefense and Emerging and Neglected Diseases," by Alan D.T. Barrett and Lawrence R. Stanberry. Academic Press, c2009. ISBN: 9780123694089. PP. 361-377. DOCUMENT TYPE: Article

Mead D.G., Rainwater Lovett K., Murphy M.D., Pauszek S.J., Smoliga G., Gray E.W., Noblet R., Overmyer J., Rodriguez L.L. Experimental transmission of vesicular stomatitis New Jersey virus from simulim vittatum to cattle: clinical outcome is influenced by site of insect feeding. *Journal of Medical Entomology* 46(4) : 866-872. DOCUMENT TYPE: Article

O'Donnell V., Pacheco J.M., Gregg D., Baxt B. Analysis of Foot-and Mouth Disease Virus integrin receptor expression in tissues from naïve and infected cattle. (2009) *Journal of Comparative Pathology*, 141: pp. 98-112. DOCUMENT TYPE: Article

Overend C.C., Ambrogio J., He D., Grubman M.J. Garemendia A.E. The antiviral state induced by IFN $\beta$  differs in MARC-145 cells and PAMs as demonstrated by infection outcomes with different PRRRSV isolates. (2009) *Abstracts/Veterinary Immunology and Immunopathology*, 128, pp. 326-327. DOCUMENT TYPE: Abstract

Perez A.M., Pauszek S.J., Jimenez D., Kelley W.N., Whedbee Z., Rodriguez L.L. Spatial and phylogenetic analysis of vesicular stomatitis virus over-wintering in the United States. *Preventive Veterinary Medicine*, 2010 Mar 1;93(4):258-64. Epub 2009 Dec 3. DOCUMENT TYPE: Article

Piccone M.E., Pauszek S., Pacheco J., Rieder E., Kramer E., Rodriguez L.L. Molecular characterization of a Foot-and-Mouth Disease Virus containing a 57 nucleotide insertion in the 3'untranslated region. (2009) *Archives of Virology*, 154 (4), pp. 671-676.

Piccone M.E., Pacheco J.M., Pauszek S.J., Kramer E., Rieder E., Borca M.V., Rodriguez L.L. The region between the two polyprotein initiation codons of foot-and- mouth disease virus is critical for virulence in cattle. (2010) *Virology*, 396: 152-159. DOCUMENT TYPE: Article

Rainwater-Lovett K., Pacheco J.M., Packer C., Rodriguez L.L. Detection of Foot-and-Mouth Disease Virus infected cattle using infrared thermography. *The Veterinary Journal*, June 2009, 180, (3), pp. 317-324. DOCUMENT TYPE: Article

Rodriguez L.L., Grubman M.J. Foot-and-Mouth Disease: novel technologies improve detection and control. *Agricultural Research* (April 2009), pp. 14-15. DOCUMENT TYPE: Article

Rodriguez L.L., Grubman M.J. Foot and Mouth disease virus vaccines. *Vaccine*, 27, D90-D94 DOCUMENT TYPE: Review

Toka F.N., Nfon C.K., Dawson H., Estes D.M., Golde W.T. Activation of porcine natural killer cells and lysis of Foot-and-Mouth Disease Virus infected cells. *Journal of Interferon & Cytokine Research*, 29 (3), pp. 47-60. DOCUMENT TYPE: Article

Toka, F.N., Nfon C.K., Dawson H., Golde W.T. Natural killer cell dysfunction during acute infection with foot-and-mouth disease virus (FMDV). (2009) *Clinical Vaccine Immunology*, Dec. 2009, v16(12) : 1738-1749.

Valarcher J.F., Knowles N.J., Zakharov V., Scherbakov A., Zhang Z., Shang Y.J., Liu Z.X., Liu X.T., Sanyal A., Hamadri D., Tosh C., Rasool Ferris N.P. Roeder P.L., Paton D.J. Multiple origins of foot-and-mouth disease virus serotype asia I outbreaks, 2003-2007. *Emerging Infectious Diseases*, July 2009, v15 (7) : 1046-1051. DOCUMENT TYPE: Article

Wilson W.C., Letchworth G.J., Jimenez C., Herrero M.V., Navarro R., Paz P., Cornish T.E., Smoliga G., Pauszek S.J., Dornak C., George M., Rodriguez L.L. Field evaluation of a multiplex real-time reverse transcription polymerase chain reaction assay for detection of vesicular stomatitis virus. *Journal of Veterinary Diagnostic Investigation*, 21, pp. 179-186 DOCUMENT TYPE: Article

Xu L., Guo L., Shen Z., Loss G., Gish R., Wasilenko S., Mason A.L. Duplication of MER115 on chromosome 4 in patients with primary biliary cirrhosis. *Liver International*, 2009 Mar, 29(3), pp. 375-383. DOCUMENT TYPE: Article

**Briefly describe the biological defense work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols:**

### **I Objectives**

PIADC provides research, development and diagnostic capability for specific high-consequence, contagious, foreign animal diseases of livestock. The focus of the research is on pathogens that infect animals, not those of humans. The facility also trains veterinarians to field diagnose high consequence foreign animal disease.

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\* Including viruses and prions.

## **II Agents**

- **USDA Select Agents and Toxins**

The facility maintains a reference repository of animal disease agents (and diagnostic capabilities to recognize them should they occur in the U.S.).

## **III Outdoor Studies**

None – all work confined to biocontainment facilities, BSL-2 and BSL-3.

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

Tyndall AFB

**2. Where is it located?**

3000 Research Road  
Tyndall AFB, FL 32403

**3. Floor area of laboratory areas by containment level:**

BL2 (sqM)	55
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	55

**4. The organizational structure of each facility.**

**I Total number of personnel:** 5

**II Division of personnel:**

Military	0
Civilian	5

**III Division of personnel by category:**

Scientists	3
Engineers	0
Technicians	2
Administrative and support staff	0

**IV List the scientific disciplines represented in the scientific/engineering staff.**

Microbiology

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number: 4

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense

**VII What are the funding levels for the following program areas:**

Research	\$586,000
Development	\$ 0
Test and evaluation	\$195,000
Total	\$781,000

**VIII Briefly describe the publication policy of the facility:**

Unlimited release, prefer peer-reviewed journals for research results; limit to government for test and evaluation and proprietary data.

**IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)**

Heimbuch, B.; Wu, C.Y.; Wander, J.; Viral Penetration of HEPA Filters; AFRL-RX-TY-TP-2009-4567

Salter, B.; Kinney, K.; Wallace, W.; Lumley, A.; Heimbuch, B.; Wander, J.; Analysis of Chemical Off-Gassing From Filtering Facepiece Respirators after Decontamination; AFRL-RX-TY-TP-2009-4565

Riemenschneider, L.; Wu, C.Y.; Lundgren, D.; Lee, J.; Li, H.; Wander, J.; Heimbuch, B.; Characterization of Reaerosolization From Impingers in an Effort to Improve Airborne Virus Sampling; AFRL-RX-TY-TP-2009-4525

Lee, J.; Assessment of the Performance of Iodine-Treated Biocidal Filters and Characterization of Virus Aerosols; AFRL-RX-TY-TM-2009-4551

**5. Briefly describe the biological defense work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols:**

**I Objectives**

The facility houses and supports a bioaerosol test chamber in which aerosols containing biological simulants are used to classify the size distribution of bioaerosol challenges as needed.

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\* Including viruses and prions.

## **II Agents**

- **Other pathogens or toxins**  
Including non-Select Agent, NIAID Category B Priority Pathogens
- **Simulants**

## **III Outdoor Studies**

None

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

Tyndall AFB

**2. Where is it located?**

139 Barnes Drive  
Tyndall AFB, FL 32403

**3. Floor area of laboratory areas by containment level:**

BL2 (sqM)	52.5
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	52.5

**4. The organizational structure of each facility.**

**I Total number of personnel:** 8

**II Division of personnel:**

Military	0
Civilian	8

**III Division of personnel by category:**

Scientists	4
Engineers	1
Technicians	1
Administrative and support staff	2

**IV List the scientific disciplines represented in the scientific/engineering staff.**

Chemistry  
Environmental Engineering

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number:        5

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense

**VII What are the funding levels for the following program areas:**

Research	\$1,000,000
Development	\$1,300,000
Test and evaluation	\$ 0
Total	\$2,300,000

**VIII Briefly describe the publication policy of the facility:**

Unlimited release, prefer peer-reviewed journals for research results; limit to government for test and evaluation and proprietary data.

**IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)**

Ren, Z.; Kocer, H.; Worely, S.; Broughton, R.; Huang, T.; Rechargeable Biocidal Cellulose: Synthesis and Application of 3-(2,3-dihydroxypropyl)-5,5-dimethylimidazolidine-2,4-dione; AFRL-RX-TY-TP-2009-4517

**5. Briefly describe the biological defense work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols:**

**I Objectives**

This facility supports the preparation and characterization of novel chemicals expected to exhibit antimicrobial properties. It also supports research into degradation products formed by exposure of samples of reactive materials to surrogate threat agents.

**II Agents**

None

**III Outdoor Studies**

None

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\* Including viruses and prions.

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

Lothar Salomon Life Sciences Test Facility (LSTF)

**2. Where is it located?**

2029 Burns Rd  
Dugway, UT 84022-5006

**3. Floor area of laboratory areas by containment level:**

BL2 (sqM)	744
BL3 (sqM)	414
BL4 (sqM)	0
Total (sqM)	1158

**4. The organizational structure of each facility.**

**I Total number of personnel:** 65

**II Division of personnel:**

Military	0
Civilian	65

**III Division of personnel by category:**

Scientists	42
Engineers	0
Technicians	10
Administrative and Support Staff	13

**IV List the scientific disciplines represented in the scientific/engineering staff.**

Aerobiology  
Bacteriology  
Biochemistry  
Immunology  
Microbiology  
Molecular Biology  
Toxicology

Virology

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number:        19

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense

**VII What are the funding levels for the following program areas?**

Research	\$ 35,000
Development	\$ 0
Test and Evaluation	\$4,500,000
Total	\$4,535,000

**VII Briefly describe the publication policy of the facility.**

Professional scientists are encouraged to publish worthy papers in peer-reviewed journals. All publications must obtain the necessary command permission before submission. Technical papers receive in-house peer review before the article is submitted for publication in accordance with Army regulations.

**IX Provide a list of publicly available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)**

C. Fairfield-Estill, P. A. Baron, J. K. Beard, M. J. Hein, L. D. Larsen, L. Rose, F. W. Schaefer III, J. Noble-Wang, Hodges, H. D. Alan Lindquist, G. J. Deye, and M. J. Arduino. July 2009. Recovery Efficiency and Limit of Detection of Aerosolized *Bacillus anthracis* Sterne from Environmental Surface Samples. Applied and Environmental Microbiology. Vol. 75 No. 13, pp. 4297–4306.

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**I Objectives:**

Testing of battlefield detection and identification methods, protective equipment, and decontamination systems, to include interferent testing of biological detectors and development/validation of aerosol particle dispersion models.

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\* Including viruses and prions.

## **II Agents:**

- **HHS Select Agents and Toxins**  
Including NIAID Category A and B Priority Pathogens
- **Overlap Select Agents**  
Including NIAID Category A and B Priority Pathogens
- **Other pathogens or toxins**  
Including non-Select Agent, NIAID Category B Priority Pathogens
- **Simulants**  
Includes inactivated agents

## **III Outdoor studies:**

Yes - using biological simulants

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

U.S. Army Edgewood Chemical and Biological Center (ECBC)

**2. Where is it located?**

5183 Blackhawk Rd  
Aberdeen Proving Ground, MD 21010-5424

**3. Floor area of laboratory areas by containment level:**

BL2 (sqM)	532
BL3 (sqM)	177
BL4 (sqM)	0
Total (sqM)	709

**4. The organizational structure of each facility.**

**I Total number of personnel:** 279

**II Division of personnel:**

Military	1
Civilian	278

**III Division of personnel by category:**

Scientists	173
Engineers	41
Technicians	29
Administrative and support staff	36

**IV List the scientific disciplines represented in the scientific/engineering staff:**

Aerobiology  
Aerospace Engineering  
Biological Science  
Biology  
Biochemistry  
Biomedical Engineering  
Biotechnology

Chemical Engineering  
Chemistry  
Computer Engineering  
Electronic Engineering  
General Engineering  
Immunology  
Mathematics  
Mechanical Engineering  
Microbiology  
Molecular Biology  
Operations Research Analysis  
Physical Science  
Physics  
Physiology  
Statistics  
Toxicology  
Toxinology  
Virology

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number:        155

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense

**VII. What are the funding levels for the following program areas:**

Research:	\$ 1,417,000
Development:	\$20,330,000
Testing and Evaluation:	\$        0
Total	\$21,747,000

**VIII Briefly describe the publication policy of the facility:**

Technical papers receive in-house peer review before the article is submitted for publication in accordance with Army regulations.

**IX. Provide a list of publicly-available papers and reports resulting from work during the previous 12 months. (To include authors, titles and full references.)**

Ben-David A, Davidson CE, and Embury JF. Radiative transfer model for aerosols at infrared wavelengths for passive remote sensing applications: revisited. *Appl. Opt.*, 47(31):5924-5937, Nov 1, 2008. Erratum in: *Appl. Opt.*, 48(5):903, Feb 10, 2009.

Edmonds JM. Efficient methods for large-area surface sampling of sites contaminated with pathogenic microorganisms and other hazardous agents: current state, needs, and perspectives. *Appl. Microbiol. Biotechnol.*, 84(5):811-816, Oct 2009. Epub Jul 31, 2009.

Henderson TJ. Feasibility study for the rapid screening of target molecules using translational diffusion coefficients: diffusion-ordered NMR spectroscopy of biological toxins. *Anal. Bioanal. Chem.*, Dec 24, 2009. [Epub ahead of print]

Poore C, Clark P, and Emanuel PA. An evaluation of suspicious powder screening tools for first responders. *J. Hazard Mater.*, 172(2-3):559-565, Dec 30, 2009. Epub Jun 9, 2009.

Rastogi VK, Wallace L, Smith LS, Ryan SP, and Martin B. Quantitative method to determine sporicidal decontamination of building surfaces by gaseous fumigants, and issues related to laboratory-scale studies. *Appl. Environ. Microbiol.*, 75(11):3688-3694, Jun 2009. Epub Apr 3, 2009.

Sagripanti JL, Levy A, Robertson J, Merritt A, and Inglis TJ. Inactivation of virulent *Burkholderia pseudomallei* by sunlight. *Photochem. Photobiol.*, 85(4):978-986, Jul-Aug 2009.

Samuels AC, Snyder AP, Emge DK, Amant D, Minter J, Campbell M, and Tripathi A. Classification of select category A and B bacteria by Fourier transform infrared spectroscopy. *Appl. Spectrosc.*, 63(1):14-24, Jan 2009.

Tripathi A, Jabbour RE, Guicheteau JA, Christesen SD, Emge DK, Fountain AW, Bottiger JR, Emmons ED, and Snyder AP. Bioaerosol Analysis with Raman Chemical Imaging Microspectroscopy. *Anal. Chem.*, Jul 14, 2009. [Epub ahead of print]

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**I Objectives**

Development of non-medical defensive materiel against biological agents, to include: research, development, and engineering for methods of rapid detection, identification, decontamination, and physical protection of/from biological threat agents.

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\* Including viruses and prions.

## II Agents

- **HHS Select Agents and Toxins**  
Including NIAID Category A, B, and C Priority Pathogens
- **Overlap Select Agents**  
Including NIAID Category A and B Priority Pathogens
- **Other pathogens or toxins**  
Including non-Select Agent, NIAID Category B Priority Pathogens
- **Simulants**

## III Outdoor Studies:

None

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)

**2. Where is it located?**

3100 Ricketts Point Road  
Aberdeen Proving Ground, MD 21010-5400

**3. Floor area of laboratory areas by containment level:**

BL2 (sqM)	400
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	400

**4. The organizational structure of each facility.**

**I Total number of personnel:** 13

**II Division of personnel:**

Military	2
Civilian	11

**III Division of personnel by category:**

Scientists	7
Engineers	0
Technicians	6
Administrative and support staff	0

**IV List the scientific disciplines represented in the scientific/engineering staff:**

Biochemistry  
Biology  
Molecular Biology  
Pharmacology  
Physiology

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes.                      Number:        6

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense

**VII What are the funding levels for the following program areas:**

Research:	\$ 250,000
Development:	\$1,200,000
Test and evaluation:	\$ 0
Total	\$1,450,000

**VIII Briefly describe the publication policy of the facility:**

Technical papers receive in-house peer review before the article is submitted for publication in accordance with Army regulations.

**IX. Provide a list of publicly-available papers and reports resulting from work during the previous 12 months. (To include authors, titles and full references.)**

Zhang, P., Ray, R., Singh, B.R., Adler, M. and Ray, P. (2009). An efficient drug delivery vehicle for botulism countermeasure. *BMC Pharmacol.* 9, 12-19.

Stahl, A.M., Adler, M., Millard, C.B. and Gilfillan, L. (2009). Accelerating botulism therapeutic product development in the Department of Defense. *Drug Development Research* 70:303-326.

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**I Objectives:**

The mission involves research on medical defenses against neurotoxins.

**II Agents:**

- **HHS Select Agents and Toxins**  
Including NIAID Category A Priority Pathogens

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\* Including viruses and prions.

**III Outdoor studies:**  
None

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

**2. Where is it located?**

1425 Porter St.  
Fort Detrick, MD 21702-5011

**3. Floor area of laboratory areas by containment level:**

BL2 (sqM)	26,026
BL3 (sqM)	3,139
BL4 (sqM)	1,093
Total (sqM)	30,258

**4. The organizational structure of each facility.**

**I Total number of personnel:** 956

**II Division of personnel:**

Military	191
Civilian	765

**III Division of personnel by category:**

Scientists	309
Engineers	3
Technicians	348
Administrative and support staff	296

**IV List the scientific disciplines represented in the scientific/engineering staff:**

Aerobiology  
Biochemistry  
Biology  
Chemistry  
Clinical Immunology  
Entomology  
Genetics

Immunology  
Infectious Disease  
Internal Medicine  
Microbiology  
Molecular Biology  
Preventive Medicine  
Toxicology  
Veterinary Medicine  
Virology

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes.                      Number:        397

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense

**VII What are the funding levels for the following program areas:**

Research	\$ 3,948,000
Development	\$62,068,000
Test and evaluation	\$            0
Total	\$66,016,000

**VIII Briefly describe the publication policy of the facility:**

Technical papers receive in-house peer review before the article is submitted for publication in accordance with Army regulations.

The research program is unclassified and scientists are encouraged to publish their results in the peer reviewed scientific literature as well as present their work at national and international professional meetings.

**IX Provide a list of publicly-available papers and reports resulting from work during the previous 12 months. (To include authors, titles and full references.)**

Baldwin CD, GB Howe, R Sampath, LB Blyn, H Matthews, V Harpin, TA Hall, JJ Drader, SA Hofstadler, MW Eshoo, K Rudnick, K Studarus, D Moore, S Abbott, JM Janda, CA Whitehouse. 2009. Usefulness of multilocus polymerase chain reaction followed by electrospray ionization mass spectrometry to identify a diverse panel of bacterial isolates. *Dign Microbiol Infect Dis* 63:403 – 408.

Cote CK, J Bozue, N Twenhafel, SL Welkos. 2009. Effects of altering the germination potential of *Bacillus anthracis* spores by exogenous means in a mouse model. *J Med Microbiol* 58:816 – 825.

DiMezzo TL, G Ruthel, EE Brueggemann, HB Hines, WJ Ribot, CE Chapman, BS Powell, SL Welkos. 2009. In vitro intracellular trafficking of virulence antigen during infection by *Yersinia pestis*. *PLoS One* 4:e6281.

Dupuy LC, CP Locher, M Paidhungat, MJ Richards, CM Lind, R Bakken, MD Parker, RG Whalen, CS Schmaljohn. 2009. Directed molecular evolution improves the immunogenicity and protective efficacy of a Venezuelan equine encephalitis virus DNA vaccine. *Vaccine* 27:4152 – 4160.

Eshoo MW, CA Whitehouse, A Nalca, S Zoll, JA Ecker, TA Hall, TT Pennella, DD Duncan, A Desai, EK Moradi, K Rudnick, B Libby, R Rankin, R Sampath, SA Hofstadler, DJ Ecker, LB Blyn. 2009. Rapid and high-throughput pan-Orthopoxvirus detection and identification using PCR and mass spectrometry. *PLoS One* 4:e6342.

Ezzell JW, TG Abshire, R Panchal, D Chabot, S Bavari, EK Leffel, B Purcell, AM Friedlander, WJ Ribot. 2009. Association of *Bacillus anthracis* capsule with lethal toxin during experimental infection. *Infect Immun* 77:749 – 755.

Friedlander AM, SF Little. 2009. Advances in the development of next-generation anthrax vaccines. *Vaccine* 27:D28 – D32.

Garza NL, JM Hatkin, V Livingston, DK Nichols, PJ Chaplin, A Volkmann, D Fisher, A Nalca. 2009. Evaluation of the efficacy of modified vaccinia Ankara (MVA)/IMVAMUNE against aerosolized rabbitpox virus in a rabbit model. *Vaccine* 27:5496 – 5504.

Gelhaus HC, DA Rozak, WC Nierman, D Chen, JJ Varga, RL Ulirsch, JJ Adamovicz. 2009. Exogenous *Yersinia pestis* quorum sensing molecules N-octanoyl-homoserine lactone and N-(3-oxooctanoyl)-homoserine lactone regulate the LcrV virulence factor. *Microb Pathog* 46:283 – 287.

Hartman LJ, EB Selby, CA Whitehouse, SR Coyne, JG Jaissle, NA Twenhafel, YL Burke, DA Kulesh. 2009. Rapid real-time PCR assays for detection of *Klebsiella pneumoniae* with the *rmpA* or *magA* genes associated with the hypermucoviscosity phenotype. Screening of nonhuman primates. *J Mol Diagn* (pub ahead of print).

Howe GB, BM Loveless, D Norwood, P Craw, D Waag, M England, JR Lowe, BC Courtney, ML Pitt, DA Kulesh. 2009. Real-time PCR for the early detection and quantification of *Coxiella burnetii* as an alternative to the murine bioassay. *Mol Cell Probes* 23:127 – 131.

Huang J, AJ D'Souza, JB Alarcon, JA Mikszta, BM Ford, MS Ferriter, M Evans, T Stewart, K Amemiya, RG Ulrich, VJ Sullivan. 2009. Protective immunity in mice achieved with dry

powder formulation and alternative delivery of plague F1-V vaccine. *Clin Vaccine Immunol* 16:719 – 725.

Huggins J, A Goff, L Hensley, E Mucker, J Shamblin, C Wlazloski, W Johnson, J Chapman, T Larsen, N Twenhafel, K Kareem, IK Damon, CM Byrd, TC Bolken, RN Jordan, D Hrubby. 2009. Nonhuman primates are protected from smallpox virus or monkeypox virus challenges by the antiviral drug ST-246. *Antimicrob Agents Chemother* 53:2620 – 2625.

Hughes MA, DL Burns, SJ Juris, WJ Tang, KH Clement, LJ Eaton, CD Kelly-Cirino, ML McKee, BS Powell, ML Bishop, TL Rudge, N Shine, A Verma, MS Willis, SA Morse. 2009. The case for developing consensus standards for research in microbial pathogenesis: *Bacillus anthracis* toxins as an example. *Infect Immun* (epub ahead of print).

Jenkins AL, PL Worsham, SL Welkos. 2009. A strategy to verify the absence of the *pgm* locus in *Yersinia pestis* strain candidates for select agent exemption. *J Microbial Methods* (epub ahead of print).

Jordan R, A Goff, A Frimm, ML Corrado, LE Hensley, CM Byrd, E Mucker, J Shamblin, TC Bolken, C Wlazlowski, W Johnson, J Chapman, N Twenhafel, S Tyavanagimatt, A Amantana, J Chinsangaram, DE Hrubby, J Huggins. 2009. ST-246(R) Antiviral efficacy in a non-human primate monkeypox model: determination of the minimal effective dose and human dose justification. *Antimicrob Agents Chemother* (epub ahead of print).

Kalb SR, J Lou, C Garcia-Rodriguez, IN Geren, TJ Smith, H Moura, JD Marks, LA Smith, JL Pirkle, JR Barr. 2009. Extraction and inhibition of enzymatic activity of botulinum neurotoxins/A1, /A2, and /A3 by a panel of monoclonal anti-BoNT/A antibodies. *PLoS One* 4:e5355.

Keasey SL, KE Schmid, MS Lee, J Meegan, P Tomas, M Minto, AP Tikhonov, B Schweitzer, RG Ulrich. 2009. Extensive antibody cross-reactivity among infectious gram-negative bacteria revealed by proteome microarray analysis. *Mol Cell Proteomics* 8:924 – 935.

Koeller CA. 2009. Comparison of buprenorphine and butorphanol analgesia in the eastern red-spotted newt (*Notophthalmus viridescens*). *J Am Asso Lab Anim Sci* 48:171 – 175.

Krakauer T, MJ Buckley, LM Huzella, DA Alves. 2009. Critical timing, location and duration of glucocorticoid administration rescue mice from superantigen-induced shock and attenuate lung injury. *Int Immunopharmacol* (epub ahead of print).

Lee MS, FJ Lebeda, MA Olson. 2009. Fold prediction of VP24 protein of Ebola and Marburg viruses using de novo fragment assembly. *J Struct Biol* 167:136 – 144.

Loveless BM, EM Mucker, C Hartmann, PD Craw, J Huggins, DA Kulesh. 2009. Differentiation of *Variola major* and *Variola minor* variants by MGB-Eclipse probe melt curves and genotyping analysis. *Mol Cell Probes* 23:166 – 170.

McKinney MD, SJ Moon, DA Kulesh, T Larsen, RJ Schoepp. 2009. Detection of viral RNA from paraffin-embedded tissues after prolonged formalin fixation. *J Clin Virol* 44:39 – 42.

Mohamadzadeh M. 2009. Potential factors induced by filoviruses that lead to immune suppression. *Curr Mol Med* 9:174 – 185.

Mohamadzadeh M, T Duong, SJ Sandwick, T Hoover, TR Klaenhammer. 2009. Dendritic cell targeting of *Bacillus anthracis* protective antigen expressed by *Lactobacillus acidophilus* protects mice from lethal challenge. *Proc Natl Acad Sci USA* 106:4331 – 4336.

Natesan M, MA Cooper, JP Tran, VR Rivera, MA Poli. 2009. Quantitative detection of staphylococcal enterotoxin B by resonant acoustic profiling. *Anal Chem* 81:3896 – 3902.

O'Guinn ML, TA Klein, JS Lee, AL Richards, HC Kim, SJ Ha, SH Shim, LJ Baek, KJ Song, ST Chong, MJ Turell, DA Burkett, A Schuster, IY Lee, SH Yi, WJ Sames, JW Song. 2009. Serological surveillance of scrub typhus, murine typhus, and leptospirosis in small mammals captured at firing points 10 and 60, Gyeonggi Province, Republic of Korea, 2001-2005. *Vector Borne Zoonotic Dis* (epub ahead of print).

Panchal RG, RL Ulrich, SB Bradfute, D Lane, G Ruthel, TA Kenny, PL Iverson, AO Anderson, R Gussio, WC Raschke, S Bavari. 2009. Reduced expression of CD45 protein-tyrosine phosphatase provides protection against anthrax pathogenesis. *J Biol Chem* 284:12874 – 12885.

Panchal RG, RL Ulrich, D Lane, MM Butler, C Houseweart, T Opperman, JD Williams, NP Peet, DT Moir, T Nguyen, R Gussio, T Bowlin, S Bavari. 2009. Novel broad-spectrum bis-(imidazolinyndole) derivatives with potent antibacterial activity against antibiotic-resistant strains. *Antimicrob Agents Chemother* (epub ahead of print).

Ravel J, L Jiang, ST Stanley, MR Wilson, RS Decker, TD Read, P Worsham, PS Keim, SL Salzberg, CM Fraser-Liggett, DA Rashko. 2009. The complete genome sequence of *Bacillus anthracis* Ames "Ancestor." *J Bacteriol* 191:445-446.

Roxas-Duncan V, I Enyedy, VA Montgomery, VS Eccard, MA Carrington, H Lai, N Gul, DC Yang, LA Smith. 2009. Identification and biochemical characterization of small-molecule inhibitors of *Clostridium botulinum* neurotoxin serotype A. *Antimicrob Agents Chemother* 53:3478 – 3486.

Rusnak JM, WR Byrne, KN Chung, PH Gibbs, TT Kim, EF Boudreau, T Cosgriff, P Pittman, KY Kim, MS Erlichman, DF Rezvani, JW Huggins. 2009. Experience with intravenous ribavirin in the treatment of hemorrhagic fever with renal syndrome in Korea. *Antiviral Res* 81:68 – 76.

Rusnak JM, LA Smith. 2009. Botulinum neurotoxin vaccines: past history and recent developments. *Hum Vaccin* (epub ahead of print).

Pittman PR, CT Liu, TL Cannon, JA Mangiafico, PH Gibbs. 2009. Immune interference after sequential alphavirus vaccine vaccinations. *Vaccine* 27:4879 – 4882.

Schmaljohn C. 2009. Vaccines for hantaviruses. *Vaccine* 27:D61 – D4.

Spring MD, JF Cummings, CF Ockenhouse, S Dutta, R Reidler, E Angov, E Bergmann-Leitner, VA Stewart, S Bittner, L Juompan, MG Kortepeter, R Nielson, U Krzych, E Tierney, LA Ware, M Dowler, CC Hernsen, RW Sauerwein, SJ de Vlas, O Ofori-Anylnam, DE Lanar, JL Williams, KE Kester, K Tucker, M Shi, E Malkin, C Long, CL Diggs, L Solsson, M-C Dubois, WR Ballou, J Cohen, DG Heppner Jr. 2009. Phase 1/2a study of the malaria vaccine candidate apical membrane antigen-1 (AMA-1) administered in adjuvant system AS01B or AS02A. *PLoS One* 4:e5254.

Steele KE, AO Anderson, M Mohamadzadeh. 2009. Fibroblastic reticular cells and their role in viral hemorrhagic fevers. *Expert Rev Anti Infect Ther* 7:423 – 435.

Swenson DL, KL Warfield, TK Warren, C Lovejoy, JN Hassinger, G Ruthel, RE Blouch, HM Moulton, DD Weller, PL Iverson, S Bavari. 2009. Chemical modifications of antisense morpholino oligomers enhance their efficacy against Ebola virus infection. *Antimicrob Agents Chemother* 53:2089 – 2099.

Toth SI, LA Smith, SA Ahmed. 2009. Extreme sensitivity of botulinum neurotoxin domains towards mild agitation. *J Pharm Sci* 98:3302 – 3311.

Tournier J-N, RG Ulrich, A Quesnel-Hellmann, A Mohamadzadeh, BG Stiles. 2009. Anthrax, toxins and vaccines: a 125-year journey targeting *Bacillus anthracis*. *Expert Rev Anti Infect Ther* 7:219 – 236.

Twenhafel N, DA Alves, BK Purcell. 2009. Pathology of inhalational *Francisella tularensis* spp. *tularensis* SCHU S4 infection in African green monkeys (*Chlorocebus aethiops*). *Vet Pathol* 46:698 – 706.

Warfield KL, SB Bradfute, J Wells, L Lofts, MT Cooper, DA Alves, DK Reed, SA VanTongeren, CA Mech, S Bavari. 2009. Development and characterization of a mouse model for Marburg hemorrhagic fever. *J Virol* 83:6404 – 6415.

Warfield KL, EM Deal, S Bavari. 2009. Filovirus infections. *J Am Vet Med Assoc* 234:1130 – 1139.

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**I Objectives**

To develop medical countermeasures, to include candidate vaccines, diagnostic tests and drug or immunological therapies for biological agents. Perform exploratory studies and advanced development of protective and therapeutic countermeasures and agent identification technologies.

**II Agents**

- **HHS Select Agents and Toxins**  
Including NIAID Category A and B Priority Pathogens
- **Overlap Select Agents**  
Including NIAID Category A and B Priority Pathogens
- **Other pathogens or toxins**  
Including non-Select Agents, NIAID Category A and B Priority Pathogens
- **Simulants**

**III Outdoor studies**

None

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\* Including viruses and prions.

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

Walter Reed Army Institute of Research (WRAIR)

**2. Where is it located?**

503 Robert Grant Avenue  
Silver Spring, MD 20910

**3. Floor area of laboratory areas by containment level:**

BL2 (sqM)	397
BL3 (sqM)	165
BL4 (sqM)	0
Total (sqM)	562

**4. The organizational structure of each facility.**

**I Total number of personnel:** 23

**II Division of personnel:**

Military	1
Civilian	22

**III Division of personnel by category:**

Scientists	15
Engineers	0
Technicians	8
Administrative and support staff	0

**IV List the scientific disciplines represented in the scientific/engineering staff.**

Biochemistry  
Chemistry  
Immunology  
Microbiology  
Molecular Biology  
Neuroscience

Pharmacology  
Veterinary Medicine

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number:        15

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense

**VII What are the funding levels for the following program areas:**

Research	\$ 3,083,000
Development	\$            0
Test and evaluation	\$            0
Total	\$ 3,083,000

**VIII Briefly describe the publication policy of the facility:**

Technical papers receive in-house peer review before the article is submitted for publication in accordance with Army regulations.

**IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)**

Lindita S. Tabaku, Roberta R. Owens, Ankit V. Patel, Richard K. Gordon. A Novel Targeted Liposomal Delivery System for Botulinum Toxin Therapeutics. WRAIR, Division of Regulated Activities, Department of Regulated Laboratories, Silver Spring, MD 20910-7500 IBRCC, Alexandria, Virginia 19-22 October, 2009.

L.S. Tabaku, R. R. Owens, R. K. Gordon. Development of a Liposomal Delivery System for Botulinum Toxin Therapeutics. WRAIR, Division of Regulated Activities, Department of Regulated Laboratories, Silver Spring, MD 20910-7500 CBD S&T, Dallas, Texas 16-20 November 2009.

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**I Objectives:**

The Walter Reed Army Institute of Research conducts studies to develop therapeutics against neurotoxins. Also conducted is biodefense research on bacterial threat agents.

**II Agents:**

- **HHS Select Agents and Toxins**  
Including NIAID Category A and B Priority Pathogens
- **Overlap Select Agents**  
Including NIAID Category A and B Priority Pathogens

**III Outdoor studies:**

None

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\* Including viruses and prions.

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

Edgewood Chemical Biological Center

**2. Where is it located?**

5183 Blackhawk Road  
Aberdeen Proving Ground, MD 21010-5424

**3. Floor area of laboratory areas by containment level:**

BL2 (sqM)	2,000
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	2,000

**4. The organizational structure of the facility:**

**I Total number of personnel:** 6

**II Division of personnel:**

Military	0
Civilian	6

**III Division of personnel by category:**

Scientists:	3
Engineers:	3
Technicians	0
Administrative and support staff	0

**IV List the scientific disciplines represented in the scientific/engineering staff:**

Aerosol Science  
Biology  
Chemistry  
Engineering  
Materials Science  
Physics

Polymer Science

**V Are contractor staff working in the facility? If so, provide an approximate number:**

No

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense

**VII What are the funding levels for the following program areas?**

Research:	\$	0
Development:	\$	0
Testing and Evaluation:	\$1,171,000	
Total	\$1,171,000	

**VIII Briefly describe the publication policy of the facility:**

The publication policy requires prior review by Edgewood Chemical Biological Center's public affairs and security offices prior to submission

**IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)**

None

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**I Objective**

Conduct mixed reactor testing for the evaluation of the efficacy of the countermeasure solution against a biological warfare agent simulant to determine if agent neutralization can be achieved.

**II Agent**

- **Simulants**

**III Outdoor Studies**

None

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\* Including viruses and prions.

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

Battelle Biomedical Research Center

**2. Where is it located?**

1425 State Route 142  
West Jefferson, OH 43162

**3. Floor area of laboratory areas by containment level**

BL2 (sqM)	212
BL3 (sqM)	114
BL4 (sqM)	0
Total (sqM)	326

**4. The organizational structure of each facility:**

**I Total number of personnel:** 57

**II Division of personnel:**

Military	0
Civilian	57

**III Division of personnel by category:**

Scientists:	14
Engineers:	0
Technical:	38
Administrative and support staff:	5

**IV List the scientific disciplines represented in the scientific/engineering staff.**

Aerobiology  
Biochemistry  
Biomedical Engineering  
Chemistry  
Microbiology  
Molecular Biology Molecular Toxicology  
Pathology

Pharmacology  
Statistics  
Toxicology  
Toxinology  
Veterinary Medicine  
Virology

**V Are contractor staff working in the facility? If so, provide an approximate number:**

No

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense

**VII What are the funding levels for the following program areas:**

Research	\$	0
Development	\$34,589,000	
Test and Evaluation	\$	0
Total	\$34,589,000	

**VIII Briefly describe the publication policy of the facility:**

Publication is based on permission from the study sponsor. Battelle has a peer review of publications prior to release.

**IX Provide a list of publicly-available papers and reports resulting from work during the previous 12 months. (To include authors, titles and full references.)**

Development of a Mouse and Rhesus Macaque Aerosol Challenge Model for Evaluation of Recombinant Botulinum Vaccine Efficacy.; D. Sanford, R. Barnewall, M. Vassar, N. Niemuth, K. Metcalfe, I. Henderson and J. Shearer. Aerobiology in Biodefense III Conference. July 2009.

Cynomolgus Macaque Model for Pneumonic Plague.; Richard Warren<sup>1</sup>, Hank Lockman<sup>1</sup>, Roy Barnewall<sup>1</sup>, Robert Krile<sup>1</sup>, Oscar Bermeo Blanco<sup>2</sup>, Daphne Vasconcelos<sup>2</sup>, Jessica Price<sup>3</sup>, Mark Bolanowski<sup>3</sup>, and Patricia Fellows<sup>3</sup>, <sup>1</sup>Battelle Biomedical Research Center, 505 King Ave, Columbus, Ohio 43201, <sup>2</sup>Battelle Toxicology Columbus, 505 King Ave, Columbus, Ohio 43201, <sup>3</sup>DynPort Vaccine Company LLC, a CSC Company, Frederick, MC 21702.

Development of the Rhesus Macaque Aerosol Challenge Model for Evaluation of Recombinant Botulinum Vaccine Efficacy.; D. Sanford, R. Barnewall, M. Vassar, N. Niemuth, K. Metcalfe, I. Henderson and J. Shearer. Aerobiology in Biodefense III Conference. July 2009.

Development of the Mouse Aerosol Challenge Model for Evaluation of Recombinant Botulinum Vaccine Efficacy.; Michelle L. Vassar<sup>1</sup>, Roy E. Barnewall<sup>1</sup>, Michael C. Babin<sup>1</sup>, Nancy Niemuth<sup>1</sup>, Karen Metcalfe<sup>2</sup>, Ian Henderson<sup>2</sup> and Jeffry Shearer<sup>2</sup>, Battelle Biomedical Research Center, West Jefferson, Ohio, <sup>2</sup>DynPort Vaccine Company LLC, a CSC company, Frederick, Maryland.

Development of Nonhuman Primate and Rodent Aerosol Systems for Generation, Delivery and Collection of Botulinum Neurotoxins A1 and B1; Roy Barnewall<sup>1</sup>, Edward Heller<sup>1</sup>, Patricia Reuther<sup>1</sup>, Gary Sparks<sup>1</sup> and Jeffry Shearer<sup>2</sup>, <sup>1</sup>Battelle Biomedical Research Center, West Jefferson, Ohio; <sup>2</sup>DynPort Vaccine Company LLC, a CSC company, Frederick, Maryland

Efficacy of Recombinant Botulinum Vaccine (rBV A/B) in Rhesus Macaques to Aerosol Exposure with Botulinum Neurotoxin Complex Serotypes BoNT/A1 and BoNT/B1; Jeffry Shearer<sup>1</sup>, Karen Metcalfe<sup>1</sup>, Roy Barnewall<sup>2</sup>, Michelle Vassar<sup>2</sup>, Daniel Sanford<sup>2</sup>, <sup>1</sup>DynPort Vaccine Company LLC (DVC), a CSC company, Frederick, MD and <sup>2</sup>Battelle, 505 King Ave., Columbus, OH.

Validation of a Mouse Assay for Evaluation of Recombinant Botulinum Vaccine Potency; Jeffry Shearer<sup>1</sup>, Michelle Vassar<sup>2</sup>, Nancy Niemuth<sup>2</sup>, Karen Metcalfe<sup>1</sup>, Ian Henderson<sup>1</sup>; <sup>1</sup>DynPort Vaccine Company LLC (DVC), A CSC Company, Frederick MD and <sup>2</sup>Battelle, 505 King Ave., Columbus, OH

Evaluation of the Botulinum Neurotoxin Neutralizing Efficiency in Immunoglobulin Purified from Clinical Volunteers Vaccinated with Recombinant Botulinum Vaccine; Jeffry Shearer<sup>1</sup>, Michelle L. Vassar<sup>2</sup>, Nancy Niemuth<sup>2</sup>, William Swiderski<sup>1</sup> and Karen Metcalfe<sup>1</sup>, <sup>1</sup>DynPort Vaccine Company LLC, a CSC company, Frederick, Maryland, <sup>2</sup>Battelle Biomedical Research Center, West Jefferson, Ohio

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**I Objectives**

Test and evaluation of medical countermeasures against biological threat/terrorism agents.

**II Agents**

- **HHS Select Agents and Toxins**

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\* Including viruses and prions.

Including NIAID Category A Priority Pathogens

**III Outdoor Studies**

None

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

Naval Surface Warfare Center—Dahlgren Division

**2. Where is it located?**

6149 Welsh Road  
Dahlgren, VA 22448-5162

**3. Floor area of laboratory areas by containment level:**

BL2 (sqM)	190
BL3 (sqM)	26
BL4 (sqM)	0
Total (sqM)	216

**4. The organizational structure of each facility:**

**I Total number of personnel:** 163

**II Division of personnel:**

Military	0
Civilian	163

**III Division of personnel by category:**

Scientists	58
Engineers	53
Technicians	11
Administrative and support staff	41

**IV List the scientific disciplines represented in the scientific/engineering staff:**

Aerospace Engineering  
Biology  
Chemical Engineering  
Chemistry  
Computer Engineering  
Computer Science

Electronic Engineering  
General Engineering  
Industrial Engineering  
Mathematician  
Mechanical Engineering  
Microbiology  
Molecular Biology  
Operations Research Analyst  
Physical Science  
Physics  
Software Engineering  
Toxicology

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number:        28

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense

**VII What are the funding levels for the following program areas?**

Research	\$ 4,131,000
Development	\$ 2,772,000
Test and evaluation	\$ 7,716,000
Total	\$14,619,000

**VIII Briefly describe the publication policy of the facility:**

Employees are encouraged to publish. Employees must follow appropriate U.S. Department of Defense guidelines for publishing information related to biological defense efforts and have all publications approved.

**IX Provide a list of publicly available papers and reports from work during the previous 12 months. (To include authors, titles and full references.)**

Barnette, H., Application of Metamodels in the Development of the Joint Expeditionary Collective Protection (JECPC) System Performance Model (SPM), Presentation/Publication, June 2009

Bauer, T., VLSTRACK Modeling Approach to Chemical Agent Fate, Presentation, April 2009

Bauer, T., Issues with use of Toxicity Values for Emergency Response, Presentation, January 2009

Dave, G., JECP SPM for Operational Test and Evaluation, Publication, May 2009

Dave, G., Chemical, Biological, & Radiological (CBR) Modeling & Simulation Overview, Presentation/Publication, June 2009

Gutting, B., Dose-Dependent Host-Pathogen Interactions in the Rabbit Following Inhalation of Aerosolized Ames strain Bacillus anthracis Spores, Abstract, April 2009

Hill, M., (Boise Technologies), Slice-Selective NMR Spectroscopy of a Biphasic System Manuscript for publication in Concepts in Magnetic Resonance, Publication, March 2009

Hornbaker, M., CBR Concepts & Experimentation Branch, Presentation, April 2009

Khan, M.J., (MIT Lincoln Lab) and K. Jewell, Ultra-sensitive, room-temperature THz detector using nonlinear parametric upconversion, Presentation, February & June 2009

Warder, R., Homeland Defense partnership: Major City Fire Departments Reach Out to Shipboard Collective Protection Expertise, Publication, April 2009

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols:**

**I Objectives**

Efforts at this defense laboratory are focused on biological detection systems, collective protection systems, decontamination solutions and filtration devices.

**II Agents**

- **HHS Select Agents and Toxins**  
Including NIAID Category A and B Priority Pathogens
- **Overlap Select Agents**  
Including NIAID Category A Priority Pathogens
- **Other pathogens or toxins**
- **Simulants**  
Includes inactivated agents

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\* Including viruses and prions.

### **III Outdoor Studies**

None

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

Naval Research Laboratory (NRL)

**2. Where is it located?**

4555 Overlook Ave., SW  
Washington, DC 20375

**3. Floor area of Laboratory areas by containment level:**

BL2 (sqM)	835
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	835

**4. The Organizational structure of each facility**

**I Total number of personnel:** 73

**II Division of personnel:**

Military	2
Civilian	71

**III Division of personnel by category**

Scientists	57
Engineers	8
Technicians	7
Administrative and support staff	1

**IV List the scientific disciplines represented in the scientific/engineering staff:**

Biology  
Biochemistry  
Biophysics  
Chemistry  
Chemical Engineering  
Mechanical Engineering

Molecular Biology  
Microbiology  
Engineering  
Electrical Engineering  
Immunology  
Physics

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number:        19

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense

**VII What are the funding levels for the following program areas?**

Research:	\$ 3,420,000
Development:	\$ 6,169,000
Test and evaluation	\$ 700,000
Total	\$10,289,000

**VIII Briefly describe the publication policy of the facility?**

Unlimited release, prefer peer-reviewed journals for research results; limit to government for test and evaluation and proprietary data.

**IX Provide a list of publicly available papers and reports resulting from work during the previous 12 months. (To include authors, titles and full references.)**

Vasanthi Sivaprakasam, Timothy Pletcher, John E. Tucker, Alan L.Huston, Joseph McGinn, David Keller, and Jay D. Eversole, "Classification and selective collection of individual aerosol particles using laser-induced fluorescence," Appl. Opt. 48(4), B126-B136 (2009).

Vasanthi Sivaprakasam, Alan L. Huston, Abraham Schultz and Jay D. Eversole, "A novel method of aerosol particle velocimetry using polarized elastic scattering," (submitted to Aerosol Science and Technology)

Aniruddha S. Weling, et al., "Infrared Trigger Sensor for Bio-aerosol Threat Detection," presented at the Dept. Homeland Security 2009 Annual Chemical and Biological R&D Technologies Conference, San Antonio, TX, 26-29 Jan., 2009.

Charles D. Merritt, Cathy S. Scotto, Horn-Bond Lin, Vasanthi Sivaprakasam and Jay D. Eversole, "Biological Aerosol Background Characterization and Aerosol Collection Methods," Poster presented at the Aerobiology in Biodefense III Conference, Cumberland, MD, 13-16 Jul., 2009.

Matthew B. Hart, Horn-Bond Lin, Jay D. Eversole, and Charles D. Merritt, "Defeating the Background: On-the-Fly Labeling of Chemical and Biological Aerosols Using Fluorescent Beacons for Rapid Identification," 3rd National Conference on Environmental Sampling and Detection for Bio-Threat Agents

Kim, J.S., G.P. Anderson, J.S. Erickson, J.P. Golden, M. Nasir, and F.S. Ligler (2009) Multiplexed detection of bacteria and toxins using a microflow cytometer, *Anal.Chem.*, 81, 5426-5432.

Golden, J.P., J.S. Kim, J.S. Erickson, L.R. Hilliard, P.B. Howell, G.P. Anderson, M. Nasir, and F.S. Ligler (2009) Multi-wavelength microflow cytometer using groove-generated sheath flow, *Lab Chip* 9, 1942-1950.

Ligler, F.S., J.S. Erickson, J.P. Golden, J.S. Kim, M. Nasir, P.J. Howell, A.L. Thangawng, L.R. Hilliard, and G. P. Anderson (2009) Microflow Cytometer. *SPIE* 7167, 22(1) – 22(5).

Wojciechowski, J., L.C. Shriver-Lake, M. Yamaguchi, E. Fuereder, R. Pieler, M. Schamesberger, C. Winder, H. Prall, M. Sonnleitner, and F.S. Ligler (2009) Organic Photodiodes for Biosensor Miniaturization, *Anal.Chem.* 81, 3455-3461.

Taitt, CR, North, SH, Kulagina, NK. 2009. Antimicrobial peptide arrays for detection of inactivated biothreat agents. *Meth. Mol. Biol.* 570, 233-255.

Charles PT, Stubbs VR, Soto CM, Martin BD, White BJ, Taitt CR. 2009. Reduction of non-specific protein adsorption using poly(ethylene) glycol (PEG) modified polyacrylate hydrogels in immunoassays for staphylococcal enterotoxin B detection. *Sensors* 9(1), 645-655.

Goldman E.R. Anderson, G.P., Bernstein, R.D., Swain, M.D. 2009 Amplification of Immunoassays using Phage-Displayed Single Domain Antibodies *Journal of Immunological Methods* (published on-line)

Goldman, E.R., Liu, J.L., Bernstein, R.D., Swain, M.D., Mitchell, S.Q., Anderson, G.P. 2009 Ricin Detection using Phage Displayed Single Domain Antibodies. *Sensors* 9:542-555.

Leski TA, Lin B, Malanoski AP, Wang Z, Long NC, Meador CE, Barrows B, Ibrahim S, Hardick JP, Aitichou M, Schnur JM, Tibbetts C, Stenger DA. Testing and validation of high density resequencing microarray for broad range biothreat agents detection. *PLoS One.* 2009 Aug 11;4(8):e6569.

Leski TA, Caswell CC, Pawlowski M, Klinke DJ, Bujnicki JM, Hart SJ, Lukomski S. Identification and classification of bcl genes and proteins of *Bacillus cereus* group organisms

and their application in Bacillus anthracis detection and fingerprinting. *Appl Environ Microbiol.* 2009 Nov;75(22):7163-72.

Vora, GJ. Comparative genomic analyses identify the *Vibrio harveyi* genome sequenced strains BAA-1116 and PSU 2529 as *Vibrio campbellii*. *Environmental Microbiology Reports*.

Alex Terray, Joseph D. Taylor, and Sean J. Hart\*, "Cascade Optical Chromatography for Sample Fractionation", *Biomicrofluidics*, 3, 044106, 2009.

Leski T.A., C.C. Caswell, M. Pawlowski, J.M. Bujnicki, S.J. Hart, and S. Lukomski, "bcl-gene Polymorphism in the Genomes of the Members of Bacillus cereus Group: Feasibility Studies of Anthrax Detection and Strain Fingerprinting," *Appl. Environ. Microbiol.*, doi:10.1128 / AEM.01069-09, in press, 2009.

Alex Terray, H.D. Ladoucer, Mark Hammond, and Sean J. Hart\*, "Simulation of an Optical Chromatographic Separator," *Optics Express*, Vol. 17, Issue 3, pp. 2024-2032, January 30, 2009.

S. P. Mulvaney, C. N. Ibe, C. R. Tamanaha, L. J. Whitman. Direct Detection of Genomic DNA with Semi-Homogeneous Fluidic Force Discrimination Assays. *Anal. Biochem.* 392 (2009) 139–144.

C. R. Tamanaha, M. P. Malito, S. P. Mulvaney, L. J. Whitman. Reusable, compression-sealed fluid cells for surface mounting to planar substrates. *Lab Chip* 9 (2009) 1468–1471.

J. C. Rife, J. P. Long, J. Wilkinson, L. J. Whitman. Particle tracking single protein-functionalized quantum dot diffusion and binding at silica surfaces. *Langmuir* 25 (2009) 3509–3518.

R. Stine, D. Y. Petrovykh. Oriented self-assembled monolayers of bifunctional molecules on InAs. *J. Electron Spect. Rel. Phenom.* 172 (2009) 42–46.

Goldman - February 24, 2009 Oral presentation at the ASM Biodefense and Emerging Diseases Research Meeting (Baltimore, MD) Improved toxin detection using Single Domain Antibodies.

Goldman - April 27, 2009 invited presentation at Single domain antibody workshop, Frederick Maryland, Single domain antibodies for toxin detection.

Goldman - May 1, 2009 invited presentation 2009 Biothreat Agent Workshop at Chapel Hill, North Carolina, Single domain antibodies for biothreat detection

Goldman - June 25, 2009 invited presentation at 14th international conference Biodetection Technologies 2009 Baltimore, Maryland, Single domain antibodies for biothreat detection

Goldman - September 29, 2009 invited talk at Nanoelectronic Devices for Defense & Security Conference (Fort Lauderdale, Florida) Single domain antibodies as robust recognition elements.

Goldman - November 10, 2009 Oral presentation at the 1st Bio-Sensing Technology Conference (Bristol UK) Llama derived single domain recognition reagents specific for toxins.

Goldman - November 18, 2009 Poster presentation at the 2009 Chemical and Biological Defense Science and Technology Conference (Dallas, Texas) Characterization of toxin specific llama derived single domain antibodies.

Goldman - August 21, 2009 Oral presentation at the 3rd annual Botulinum Symposium (Dartmouth MA) Single domain antibodies specific for botulinum A toxin and complex.

Taitt, North - Design of antimicrobial peptides for Gram-specific binding behavior. Chemical Biological Defense Physical Science and Technology Conf in Dallas, TX/Nov 16-20, 2009.

Anderson, Goldman - Single Domain Antibodies as Robust Recognition Elements. 2009 Chemical and Biological Defense Science and Technology Conference, Nov 16-20, 2009, Dallas TX.

Vora - Vib Comparative genomic analyses of environmental and clinical *Vibrio harveyi* isolates reveal a highly heterogeneous species. VIBRIO 2009 in Rio de Janeiro, Brazil/Nov 4-6, 2009.

Grun, Kunapareddy, Nikitin, Gillis, Wang, Lunsford, Manka, Bowles; Two-Dimensional Resonance-Raman Signatures for Identification of Cells and Bacteria in Complex Environments. European Conferences on Biomedical Optics (ECBO) 14-18 June 2009 at ICM-International Congress Centre Munich, in Munich, Germany.

“Label-Free Biosensing with AlGaIn/GaN Quantum Well Devices,” R. Stine, S. Mulvaney, J. Rife, C. Tamanaha, 2009 Chemical and Biological Defense Science and Technology Conference, Dallas, TX, 16–20 November 2009.

“Detection of Non-Amplified Genomic Samples Using Fluidic Force Discrimination,” S. Mulvaney, K. Myers, C. Tamanaha, 2009 Chemical and Biological Defense Science and Technology Conference, Dallas, TX, 16–20 November 2009.

“Single Nanoparticle/Molecule Tracking of Diffusion and Binding at Surfaces,” J. Rife, 2009 Chemical and Biological Defense Science and Technology Conference, Dallas, TX, 16–20 November 2009.

“Atomic-Level Unfolding Dynamics of Ubiquitin in Uniform Flow,” G. Wang, W. Sandberg, J. Rife, 2009 Chemical and Biological Defense Science and Technology Conference, Dallas, TX, 16–20 November 2009.

“Labeled and Label-Free Biosensing Strategies at NRL,” C. R. Tamanaha, S. P. Mulvaney, J. C. Rife, R. Stine, 1<sup>st</sup> Bio-Sensing Technology Conference, Bristol, UK, 10–12 November 2009.

“Evolution of a Magnetic-Based Biomolecular Detection System,” C. R. Tamanaha, S. P. Mulvaney, J. C. Rife, 31<sup>st</sup> Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Minneapolis, MN, 2–6 September 2009.

“Microparticle Labels Enabling Attomolar Detection of Biothreats in Minutes,” S. P. Mulvaney, M. Malito, K. Myers, C. Tamanaha, Symposium on Nanoparticles and Microparticles in Homeland Security for the 238th ACS National Meeting, Washington, DC, 16–20 August 2009.

“Attomolar Molecular Diagnostics in Minutes with the Compact Bead Array Sensor System (cBASS<sup>®</sup>),” S. P. Mulvaney, C. R. Tamanaha, P. E. Sheehan, Pittcon 2009, Chicago, IL, 8–12 March 2009.

**5. Briefly describe the biological defence work carried out at the facility, including types(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**I Objectives**

The objectives are to develop and test reliable systems for the detection of biological warfare agents in order to provide early warning and contamination avoidance information.

**II Agents**

- **HHS Select Agents and Toxins**  
Including NIAID Category B Priority Pathogens
- **Overlap Select Agents**  
Including NIAID Category A Priority Pathogens
- **Other pathogens or toxins**  
Including non-Select Agent, NIAID Category A Priority Pathogens
- **Simulants**  
Includes inactivated agents

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\* Including viruses and prions.

### **III Outdoor studies**

None

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

Naval Medical Research Center (NMRC)

**2. Where is it located?**

503 Robert Grant Avenue  
Silver Spring, MD 20910

**3. Floor area of laboratory areas by containment level:**

BL2 (sqM)	100
BL3 (sqM)	35
BL4 (sqM)	0
Total (sqM)	135

**4. The organizational structure of the facility:**

**I Total number of personnel:** 79

**II Division of personnel:**

Military	15
Civilian	64

**III Division of personnel by category:**

Scientists	19
Engineers	0
Technicians	52
Administrative and support staff	8

**IV List the scientific disciplines represented in the scientific/engineering staff:**

Biochemistry  
Microbiology  
Molecular Biology  
Parasitology

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number:        33

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense

**VII What are the funding levels for the following program areas:**

Research:	\$3,078,900
Development:	\$        0
Test and Evaluation:	\$        0
Total	\$3,078,900

**VIII Briefly describe the publication policy of the facility:**

Professional scientists are encouraged to publish worthy papers in peer- reviewed journals. All publications must obtain the necessary command permission before submission.

**IX Provide a list of publicly available papers and reports resulting from work during the previous 12 months:**

None

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins, as well as outdoor studies of biological aerosols.**

**I Objectives**

The goal of the program is the development of rapid diagnostic assays which would increase the rapid detection and diagnosis of infectious diseases.

**II Agents**

- **HHS Select Agents and Toxins**  
Including NIAID Category A and B Priority Pathogens
- **Overlap Select Agents**  
Including NIAID Category A and B Priority Pathogens
- **Other pathogens or toxins**

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\* Including viruses and prions.

- **Simulants**

### **III Outdoor Studies**

None

**National biological defence research and development programme**

**III. Facilities**

**1. Name of the facility:**

Brookhaven National Laboratory

**2. Where is it located?**

Brookhaven National Laboratory  
Biology Department  
Upton, NY 11973-5000

**3. Floor area of laboratory areas by containment level:**

BL1 (sqM)	0
BL2 (sqM)	58
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	58

**4. The organizational structure of each facility:**

**I Total number of personnel:** 3

**II Division of Personnel:**

Military	0
Civilian	3

**III Division of personnel by category (include on-site contractors):**

Scientists	3
Engineers	0
Technicians	0
Administrative and support staff	0

**IV List the scientific disciplines represented in the scientific/engineering staff:**

Biochemistry  
Microbiology  
Molecular Biology  
Structural Biology

**V Are contractor staff working in the facility? If so, provide an approximate number:**

No

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Department of Defense

**VII What are the funding levels for the following program areas:**

Research and Development:	\$750,000
Test and Evaluation:	\$ 0
Total	\$750,000

**VIII Briefly describe the publication policy of the facility:**

It is the policy of Brookhaven National Laboratory that the results of research be published unless publication is expressly restricted by a written agreement and that such publication is an essential part of the work of the Laboratory. The preparation of reviews, articles, monographs, etc. requested by sponsoring organizations and related to sponsored work is considered part of the regular duties of scientific and technical staff members. Scientists are required to publish their results in the peer reviewed scientific literature as well as present their work at national and international meetings.

**IX Provide a list of publicly available papers and reports resulting from work during the previous 12 months:**

Agarwal, R., Schmidt, J. J., Stafford, R. G., and Swaminathan, S. Mode of VAMP substrate recognition and inhibition of Clostridium botulinum neurotoxin F. *Nature Structural and Molecular Biology* 16(7): 789-794 (July, 2009).

Kumaran, D., Eswaramoorthy, S., Furey, W., Navaza, J., Sax, M., and Swaminathan, S. Domain organization in Clostridium botulinum neurotoxin type E is unique: Its implication in faster translocation. *Journal of Molecular Biology* 386(1): 233-245 (February, 2009).

Swaminathan, S. Molecular structures and functional relationships of botulinum neurotoxins. *Botulinum Toxin: Therapeutic Clinical Practice and Science*, J. Jankovic, A. Albanese, M. Z. Atassi, J. O. Dolly, M. Hallett, and N. H. Mayer, Editors, Chapter 2, pp. 15-29, Saunders Elsevier Inc., Philadelphia, PA (February, 2009).

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro- organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**I Objectives**

The overall objective of the work is to develop countermeasures for biowarfare agents. The specific aim of the projects is to determine the three-dimensional structures of the agents. The purified agents are crystallized using standard crystallization techniques and brought to the National Synchrotron Light Source (also located at Brookhaven National Laboratory) for x-ray diffraction studies. These results can lead to vaccine development, treatment, and/or diagnosis.

**II Agents**

- **HHS Select Agents and Toxins**

Including NIAID Category A Priority Pathogens

Work only involves one toxin (which is both a Select Agent Toxin and NIAID Category A Pathogen)

**III Outdoor studies**

None

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\* Including viruses and prions.

**National biological defence research and development programme**

**III. Facilities**

**1. Name of the facility:**

Idaho National Laboratory

**2. Where is it located?**

Idaho National Laboratory  
2525 Fremont Ave.  
Idaho Falls, ID 83415-2203

**3. Floor area of laboratory areas by containment level:**

BL1 (sqM)	150
BL2 (sqM)	90
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	240

**4. The organizational structure of each facility:**

**I Total number of personnel:** 4

**II Division of personnel:**

Military	0
Civilian	4

**III Division of personnel by category (include on-site contractors):**

Scientists	4
Engineers	0
Technicians	0
Administrative and support staff	0

**IV List the scientific disciplines represented in the scientific/engineering staff:**

Bioinformatics  
Microbiology  
Molecular Biology

**V Are contractor staff working in the facility? If so, provide an approximate number:**

No

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Homeland Security

**VII What are the funding levels for the following program areas:**

Research and Development:	\$140,000
Test and Evaluation:	\$ 0
Total	\$140,000

**VIII Briefly describe the publication policy of the facility:**

Publications are prepared in accordance with contractor and Department of Energy requirements for control of externally released information and export control. Any additional requirements imposed by sponsors are also adhered to. The research program is unclassified and scientists are encouraged to publish their results in the peer-reviewed literature as well as present their work at national and international professional meetings. Assay details are considered sensitive as they could be exploited for defeat and may not be published or released without permission from the Department of Homeland Security.

**IX Provide a list of publicly available papers and reports resulting from work during the previous 12 months:**

None

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**I Objectives**

Idaho National Laboratory (INL) principal investigators have developed reliable and robust methods to detect biological threat agents. Using molecular methods, unique DNA signatures are being identified that distinguish individual species and isolates from one another, supporting both detection and forensic capabilities. Researchers are developing high resolution forensic (genotyping) techniques and species-specific real-time PCR assays. In addition, researchers conduct cross-lab validation of real-time PCR assays.

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\* Including viruses and prions.

## **II Agents**

- **HHS Select Agents and Toxins**  
Including NIAID Category A Priority Pathogens (genetic material only)
- **OVERLAP Select Agents and Toxins**  
NIAID Category B Priority Pathogens

## **III Outdoor studies**

None

## **General Comments**

Reported lab area and staff numbers account for labs used for two projects and staff working on both projects.

**National biological defence research and development programme**

**III. Facilities**

**1. Name of the facility:**

Los Alamos National Laboratory

**2. Where is it located?**

Los Alamos National Laboratory  
P. O. Box 1663  
Los Alamos, NM 87545

**3. Floor area of laboratory areas by containment level:**

BL1 (sqM)	676
BL2 (sqM)	786
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	1462

**4. The organizational structure of each facility:**

**I Total number of personnel:** 55

**II Division of personnel:**

Military	0
Civilian	55

**III Division of personnel by category (include on-site contractors):**

Scientists	32
Engineers	0
Technicians	23
Administrative and support staff	0

**IV List the scientific disciplines represented in the scientific/engineering staff:**

Biochemistry  
Bioinformatics  
Biology  
Chemistry  
Environmental Science

Genetics  
Genomics  
Microbiology  
Molecular Biology  
Proteomics

**V Are contractor staff working in the facility? If so, provide an approximate number:**

No

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense  
U.S. Department of Health and Human Services (including NIH, CDC)  
U.S. Department of Homeland Security  
Internal (Laboratory Directed Research and Development [LDRD])

**VII What are the funding levels for the following program areas:**

Research and Development:	\$14,102,000
Test and Evaluation:	\$ 0
Total	\$14,102,000

**VIII Briefly describe the publication policy of the facility:**

As a U.S. Department of Energy/National Nuclear Security Administration (DOE/NNSA) facility, Los Alamos National Laboratory (LANL) is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment.

The Laboratory has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. The Laboratory also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others.

Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access.

**IX Provide a list of publicly available papers and reports resulting from work during the previous 12 months:**

Nag, K. and A. Chaudhary, "Mediators of Tyrosine Phosphorylation in Innate Immunity: from Host Defense to Inflammation onto Oncogenesis" Invited Review: Current Signal Transduction Therapy, 4(2), 76-81 (2009).

Gabbard, J, Velappan N, Di Niro, R, Schmidt, J, Jones, C, Tompkins SM, Bradbury ARM. A humanized anti-M2 scFv shows protective in vitro activity against influenza. PROTEIN ENGINEERING DESIGN & SELECTION (MAR 2009) Vol.22, iss.3, p.189-198.

Nag, K; Chaudhary, A. Mediators of Tyrosine Phosphorylation in Innate Immunity: From Host Defense to Inflammation onto Oncogenesis. Current Signal Transduction Therapy (2009) Vol.4, iss.2, p.76-81.

Hill, KK; Xie, G; Foley, BT; Smith, TJ; Munk, AC; Bruce D; Smith LA; Brettin TS; Detter JC. Recombination and insertion events involving the botulinum neurotoxin complex genes in Clostridium botulinum types A, B, E and F and Clostridium butyricum type E strains. BMC Biology, 2009, 7:66.

Lauer, S; Kunde, YA; Apodaca, TA; Goldstein, B ; Hong-Geller, E. Soluble MD2 increases TLR4 levels on the epithelial cell surface. CELLULAR IMMUNOLOGY (2009) Vol.255, iss.1-2, p.8-16.

Hong-geller E; Valdez YE; Shou Y; Yoshida TM; Marrone BL; Dunbar JM. Sample collection of virulent and non-virulent B. anthracis and Y. pestis for bioforensics analysis. Letters in Applied Microbiology. (2009) Vol. 50, Iss 4, p.431-437.

Ward, NL; Challacombe, JF; Janssen, PH; Henrissat, B; Coutinho, PM; et al. Three Genomes from the Phylum Acidobacteria Provide Insight into the Lifestyles of These Microorganisms in Soils. Applied And Environmental Microbiology (Apr 1 2009) Vol.75, iss.7, p.2046-2056.

Marrone, B.L. Flow Cytometry: A Multipurpose Technology for a Wide Spectrum of Global Biosecurity Applications. JALA - Journal of the Association for Laboratory Automation (2009) Vol.14, iss.3, p.148-156.

Rich, RL; Papalia, GA; Flynn, PJ; Furneisen, J; Quinn, J; et al. A global benchmark study using affinity-based biosensors. Analytical Biochemistry (MAR 15 2009) Vol.386, iss.2, p.194-216.

Stubben, CJ ; Duffield, ML ; Cooper, IA ; Ford, DC ; Gans, JD; Karylshev AV; Lingard B; Oyston PCF; Rochefort A de; Song J; Wren BW; Titball RW; Wolinsky M. Steps toward broad-spectrum therapeutics: discovering virulence-associated genes present in diverse human pathogens. BMC Genomics (Oct 29 2009) Vol.10 501.

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro- organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**I Objectives**

The biological defense work at the Los Alamos National Laboratory includes the following areas: pathogen signature identification, host-pathogen interactions, biothreat agent virulence study, and pathogen detection technology development.

The main objectives for these research and development activities are:

- to study molecular, chemical, and physical signatures of pathogens for detection, assay development, and characterization;
- to improve sample collection techniques;
- to develop environmental sample analysis and pathogen fate analysis techniques;
- to develop high throughput assays for host-pathogen protein interactions screening; and
- to identify host molecular targets as potential therapeutic candidates.

**II Agents**

- **HHS Select Agents and Toxins**  
Including NIAID Category A, B and C Priority pathogens, genetic materials or purified proteins
- **OVERLAP Select Agents and Toxins**  
Including NIAID Category A, B Priority pathogens, genetic materials, or purified proteins
- **Other pathogens or toxins**  
Including non-Select Agent, NIAID Category B Priority Pathogens

**III Outdoor studies**

None

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\* Including viruses and prions.

**National biological defence research and development programme**

**III. Facilities**

**1. Name of the facility:**

Lawrence Livermore National Laboratory

**2. Where is it located?**

Lawrence Livermore National Laboratory  
7000 East Avenue  
Livermore, California 94550

**3. Floor area of laboratory areas by containment level:**

BL1 (sqM)	3795.4
BL2 (sqM)	1231.8
BL3 (sqM)	88.5
BL4 (sqM)	0
Total (sqM)	5115.7

**4. The organizational structure of each facility:**

**I Total number of personnel:** 128

**II Division of personnel:**

Military	0
Civilian	128

**III Division of personnel by category (include on-site contractors):**

Scientists	99
Engineers	13
Technicians	16
Administrative and support staff	0

**IV List the scientific disciplines represented in the scientific/engineering staff:**

Biochemistry  
Bioinformatics  
Biology  
Biophysics  
Chemical Engineering  
Chemistry

Computer Science  
Genetics  
Immunology  
Microbiology  
Microfluidics  
Molecular Biology  
Proteomics

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number:        1

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense  
U.S. Department of Energy  
U.S. Department of Homeland Security  
Environmental Protection Agency (EPA)  
Federal Bureau of Investigation (FBI)  
Internal (Laboratory Directed Research and Development [LDRD])

**VII What are the funding levels for the following program areas:**

Research and Development:	\$39,314,000
Test and Evaluation:	\$12,186,000
Total	\$51,500,000

**VIII Briefly describe the publication policy of the facility:**

The Laboratory has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others. Every year, authors at Lawrence Livermore National Laboratory (LLNL) create thousands of documents. These documents are widely varied in scientific, technical, programmatic, and administrative content and scope. Some documents are written for the scientific community outside the Laboratory and some are written for the general public. Some documents are written for a more limited audience.

Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access. The LLNL Information Management Policy ensures that unclassified and classified scientific and

technical information resulting from LLNL research is identified, processed, disseminated, and preserved in accordance with our contract and DOE requirements.

**IX Provide a list of publicly available papers and reports resulting from work during the previous 12 months:**

LLNL-JRNL-414983; The Use Of Single Nucleotide Polymorphism (Snp) and Multiple Locus Variable Number Tandem Repeat (Mlva) Analyses to Study the Population Genetics of Pathogenic Microbes; Paul J. Jackson, LLNL;

LLNL-TR-409644; Multiplex Upgrade (Panel 4) Report; P. Naraghi-Arani, LLNL;

LLNL-TR-411387-DRAFT; LDRD 2008 Final Report: Characterizing Hypothetical Proteins from Uncultivated Microbial Communities; Michael Thelen, LLNL;

LLNL-PRES-411481; Probing the Architecture and Structure-Function Relationships of Microbial and Cellular Systems by High-Resolution in vitro Atomic Force Microscopy; A.J. Malkin, LLNL;

LLNL-PRES-416392; In vitro High-Resolution Architecture and Structural Dynamics of Bacterial Systems; A.J. Malkin, LLNL; M.Plomp, LLNL; T.J. Leighton, Children's Hospital Oakland Research Institute, 5700 Martin Luther King Way, Oakland, CA; B.Vogelstein, The Johns Hopkins Sidney Kimmel Cancer Center, 1650 Orleans Str., Baltimore, MD 21231; P. Setlow, University of Connecticut; H.Y. Holman, Lawrence Berkeley National Laboratory;

LLNL-ABS-415463; In vitro High-Resolution Architecture and Structural Dynamics of Bacterial Systems; A. J. Malkin, LLNL; M. Plomp, LLNL; T. J. Leighton, Children's Hospital Oakland Research Institute; B. Vogelstein, The John Hopkins Kimmel Cancer Center; H.-Y. Holman, Lawrence Berkeley National Laboratory;

LLNL-POST-415340; Molecular Needles, Glowing Plasmids, Laser Tweezers, and Plague Nicole M. Turner, LLNL; Maher Elskeikh, LLNL; Peter Pauzaskie, LLNL; Brett Chromy, LLNL;

LLNL-JRNL-420436-DRAFT; Conjugation to Nickel-Chelating Nanolipoprotein Particles Increases the Potency and Efficacy of Subunit Vaccines to Prevent West Nile Encephalitis; Nicholas O. Fischer, LLNL; Ernesto Infante, University of Texas, Medical Branch Galveston; Tomohiro Ishikawa, University of Texas, Medical Branch Galveston; Craig D. Blanchette, LLNL; Nigel Bourne, University of Texas, Medical Branch Galveston; Paul D. Hoeplich, LLNL; Peter W. Mason, University of Texas, Medical Branch Galveston;

LLNL-JRNL-420683-DRAFT; Isolation, Characterization, and Stability of Discretely-Sized Nanolipoprotein Particles Assembled with Apolipoprotein-III; Nicholas O. Fischer, LLNL; Craig D. Blanchette, LLNL; Brent W. Segelke, LLNL; Michele Corzett, LLNL; Brett A. Chromy, LLNL; Edward A. Kuhn, LLNL; Graham Bench, LLNL; Paul D. Hoeplich, LLNL;

LLNL-JRNL-415696-DRAFT; Identification and Optimization of DNA Aptamer Binding Regions Using DNA Microarrays; Nicholas O. Fischer, LLNL; Theodore M. Tarasow, Tethys Bioscience;

LLNL-PRES-418092; Development and Application of Functional Nanolipoprotein Particles; Nicholas O. Fischer, LLNL;

LLNL-POST-412422; Nickel-Chelating Nanolipoprotein Particles (NiNLPs) as Versatile Platforms for Vaccine Development; Nicholas O. Fischer, LLNL; Craig D. Blanchette, LLNL; Peter W. Mason, UTMB; Paul D. Hoeprich, LLNL;

LLNL-POST-415205; Expression, Purification, and Crystallization of a novel *Francisella tularensis* protein, REPP24 (Rapid Encystment Phenotype Protein, 24 kD); Jennifer Bilka, Arthur A. Benjamin Health Professions H.S.; Michael Sana, Waipahu High School; Michele Corzett, LLNL; Sahar El-Etr, LLNL; Amy Rasley, LLNL; Brent Segelke, LLNL;

LLNL-POST-414979; Isolation and Characterization of Antimicrobials Against MRSA; S.E. Edgar-Lee, Livermore High School; F.A. Bourguet, LLNL; B.E. Souza, LLNL; P.J. Jackson, LLNL; M.A. Coleman, LLNL;

LLNL-JRNL-413261-DRAFT; In Vitro Double Transposition for DNA Identification; Nicholas J. Heredia, LLNL; N. Reginald Beer, LLNL; Christine A. Hara, LLNL; Amy L. Hiddessen, LLNL; Christopher G. Bailey, LLNL;

LLNL-PRES-418364; System-level analysis of cellular metabolism using constraint-based methods; Ali Navid, LLNL;

LLNL-PRES-410026; From Albuminomics to Zyomyx: An Overview of Omics Science for the Biodefense Researcher; Brett A. Chromy, LLNL;

LLNL-ABS-416404; Repurposing and Combination of FDA-approved Drugs to Counter Select Agent Pathogens; Paul Hoeprich, LLNL; Brett Chromy, LLNL;

LLNL-POST-417512; Analyses of Cellular Metabolism Using Computational Constraint-based Methods; Ali Navid, LLNL; Benjamin Stewart, LLNL; Eivind Almaas, Norwegian University of Science and Technology; Ed Kuhn, LLNL; Ken Turteltaub, LLNL;

LLNL-TR-415195-DRAFT; Comparative Host Immune Response to Disparate *Yersinia* Strains During Aerosol Challenge in Mice; Duncan Parsons, LLNL; Amy Rasley, LLNL;

LLNL-ABS-416407; Repurposing and Combining of Currently Licensed Drug Molecules for Prophylactic and Therapeutic Use against One or More Biodefense Threat Agents; Paul Hoeprich, LLNL; Brett Chromy, LLNL;

LLNL-ABS-410717; Select agent pathogens *Yersinia pestis*, *Brucella melitensis* and *Francisella tularensis* induce markedly different cytokine patterns in human THP-1

monocytes; Duncan Parsons, LLNL; Sahar El-Etr, LLNL; Christelle Roux, UC Davis; Renee Tsolis, UC Davis; Amy Rasley, LLNL;

LLNL-JRNL-412375; Molecular Dynamics Simulations of Highly Charged Green Fluorescent Proteins; E. Y. Lau, LLNL; J. L. Phillips, UC Merced; M. E. Colvin, UC Merced;

LLNL-POST-414553; Microbes with Substantial Tolerance to Ionic Liquids Isolated from Compost; John Gladden, LLNL; Amitha Reddy, UC Davis; Jean VanderGheynst, UC Davis; Blake Simmons, Sandia National Laboratory; Steven Singer, LLNL;

LLNL-JRNL-414198; Bioelectronic Silicon Nanowire Devices Utilizing Functional Membrane Proteins; Nipun Misra, UC Berkeley; Julio Martinez, LLNL; Jay Huang, LLNL; Yinmin Wang, LLNL; Costas Grigoropoulos, UC Berkeley; Pieter Stroeve, UC Davis; Aleksandr Noy, LLNL;

LLNL-POST-413644; Imaging Mineral Modification by Peptides: Inhibition, Acceleration, and Hysteretic Growth Kinetics; R. W. Friddle, LLNL; M. L. Weaver, UC Davis; S. R. Qiu, LLNL; A. Wierzbicki, Univ of South Alabama; W. H. Casey, UC Davis; J. J. DeYoreo, Lawrence Berkeley National Laboratory;

LLNL-POST-410894; D-lipid bilayers on Nanowire and Nanotube Templates; Nipun Misra, UC Berkeley; Julio Martinez, UC Davis; Jay Huang, LLNL; Pieter Stroeve, UC Davis; J. Woody Ju, UCLA; Costas Grigoropoulos, UC Berkeley; Aleksandr Noy, LLNL;

LLNL-POST-410477; Exploring Variation Detection Within a Wide Range of Bioenergy-Relevant Species Via Short Read Technology; D. Hillman, LLNL; W. Schackwitz, Lawrence Berkeley National Laboratory; J. Martin, Lawrence Berkeley National Laboratory; S. Sunkara, Lawrence Berkeley National Laboratory; M. Shin, Lawrence Berkeley National Laboratory; A. Lipzen, Lawrence Berkeley National Laboratory; C. Wright, Lawrence Berkeley National Laboratory; F. Chen, Lawrence Berkeley National Laboratory; L. Pennachio, Lawrence Berkeley National Laboratory;

LLNL-JRNL-410804-DRAFT; An adaptable, miniature microarray reader for biodetection; Deanna L. Thompson, UC Davis; Francesca Pearson, LLNL; Cynthia Thomas, LLNL; Rupa Rao, UC Davis; Dennis Matthews, UC Davis; Joanna S. Albala, UC Davis; Sebastian Wachsmann-Hogiu, UC Davis; Matthew A. Coleman, LLNL;

LLNL-POST-411597; Probing plant cell wall architecture during deconstruction in single cells from *Zinnia elegans*; Catherine Lacayo, LLNL; Hoi-Ying Holman, Lawrence Berkeley National Laboratory; Mona Hwang, LLNL; Alexander Malkin, LLNL; Michael Thelen, LLNL;

LLNL-POST-410346; Probing the Architecture of the Plant Cell Wall during Deconstruction in Single Cells from *Zinnia elegans*; C. I. Lacayo, LLNL; H-Y. N. Holman, Lawrence Berkeley National Laboratory; M. Hwang, LLNL; A. Hiddessen, LLNL; A. J. Malkin,

LLNL; M. P. Thelen, LLNL;

LLNL-POST-414978; Characterization Of Novel Francisella tularensis Genes Involved in Both Environmental Persistence and Virulence; Raynes, Sonja, Turlock High School; El-etr, Sahar, LLNL; Rasley, Amy, LLNL;

LLNL-ABS-412957; Fast Fluid Flow and Electrolyte Transport in Carbon Nanotube Pores; F. Fornasiero, LLNL; S. Kim, LLNL; J.B. In, UC Berkeley; H.G. Park, LLNL; J.K. Holt, LLNL; M. Stadermann, LLNL; C.P. Grigoropoulos, UC Berkeley; A. Noy, LLNL; O. Bakajin, LLNL;

LLNL-POST-413482; FAST FLOW AND ION TRANSPORT IN SUB 2-NM CARBON NANOTUBE PORES; F. Fornasiero, LLNL; S. Kim, UC Davis; J.B. In, UC Berkeley; H.G. Park, LLNL; J.K. Holt, LLNL; M. Stadermann, LLNL; C.P. Grigoropoulos, UC Berkeley; A. Noy, LLNL; O. Bakajin, LLNL;

LLNL-PRES-414065; Rejection of Single and Binary Electrolyte Solutions by Carbon Nanotube Pores; F. Fornasiero, LLNL; H.G. Park, LLNL; J.K. Holt, LLNL; M. Stadermann, LLNL; S. Kim, UC Davis; J.B. In, UC Berkeley; C.P. Grigoropoulos, UC Berkeley; A. Noy, LLNL; O. Bakajin, LLNL;

LLNL-PRES-411033; Performance-Based Design Considerations in Development of Loop-Mediated Isothermal Amplification (LAMP) Assays for Pathogen Detection B. R. Baker, LLNL;

LLNL-POST-413562; Point-of-Care Detection of Methicillin Resistant Staphylococcus aureus (MRSA) in Human Whole Blood; B. R. Baker, LLNL; S. B. Hall, LLNL; C. L. Torres, LLNL; L. C. Dugan, LLNL; W. H. Benner, LLNL; E. A. Vitalis, LLNL; J. M. Dzenitis, LLNL;

LLNL-PRES-413116; Loop-mediated isothermal Amplification (LAMP) Assays for Point-of-Care Detection of Bloodstream Infections; B. R. Baker, LLNL;

LLNL-POST-412840; Loop-Mediated Isothermal Amplification (LAMP): A Novel Nucleic Acid Recognition Technique for Rapid Pathogen Identification in Patients with Septicemia; N. L. Gentile, UC Davis; B. R. Baker, LLNL; S. B. Hall, LLNL; E. A. Vitalis, LLNL; R. F. Louie, UC Davis; N. K. Tran, UC Davis; J. M. Dzenitis, LLNL; G. J. Kost, UC Davis;

LLNL-JRNL-412175-DRAFT; Human Variation in Regions Predisposed to Deep Evolutionary Conservation; G.G. Loots, LLNL; I. Ovcharenko, NCBI;

LLNL-JRNL-421456-DRAFT; pH-Tunable Ion Selectivity in Carbon Nanotube Pores; F. Fornasiero, LLNL; J.B. In, UC Berkeley; S. Kim, Porifera Inc.; H.G. Park, ETH; Y. Wang, LLNL; C.P. Grigoropoulos, UC Berkeley; A. Noy, LLNL; O. Bakajin, Porifera Inc.;

LLNL-PRES-418855-DRAFT; Fast Fluid Flow and Electrolyte Transport in Carbon

Nanotube Pores; F. Fornasiero, LLNL; S. Kim, Porifera Inc.; J. B. In, UC Berkeley; H. G. Park, ETH Zurich; J. K. Holt, NanOasis Inc.; M. Stadermann, LLNL; C. P. Grigoropoulos, UC Berkeley; A. Noy, LLNL; O. Bakajin, Porifera Inc.;

LLNL-PRES-417810-DRAFT; Nanofluidics in Carbon Nanotube Pores; F. Fornasiero, LLNL;

LLNL-ABS-418587; Fast Fluid Flow and Transport Selectivity in Carbon Nanotube Channels F. Fornasiero, LLNL; S. Kim, Porifera Inc; J. B. In, UC Berkeley; H. G. Park, ETH Zurich; C. P. Grigoropoulos, UC Berkeley; A. Noy, LLNL; O. Bakajin, Porifera Inc;

LLNL-POST-416302; Antibiotic resistance in Bacillus anthracis Lisa M. Vergez, LLNL; Patrick Chain, LLNL; Aubree Hinckley, LLNL; Crystal Jaing, LLNL; Kevin McLaughlin, LLNL; Cheryl Strout, LLNL; Paul Jackson, LLNL;

LLNL-PRES-410366; Visualizing two-component interactions using fluorescence: cases of in vivo protein labeling and pathogen entry into host-cells; Younhi Woo, LLNL;

LLNL-PRES-415283; A Unique Approach to Simulating the Fluorescence Characteristics of Microorganisms Using Biodegradable Microsphere Technology; George Farquar, LLNL;

LLNL-POST-411822; Pesticide detection using Single Particle Aerosol Mass Spectrometry (SPAMS); Zach Barker, Mount Union College; Veena Vankatachalam, MIT; Audrey Martin, LLNL; Matthias Frank, LLNL; George Farquar, LLNL;

LLNL-PROP-412453; Rapid High Efficiency Trace Particle and Gas Collection For Explosives Detection; George Farquar, LLNL;

LLNL-TR-414873; BIOCOMPATIBLE FLUORESCENT MICROSPHERES: SAFE PARTICLES FOR MATERIAL PENETRATION STUDIES; G. Farquar, LLNL; R. Leif, LLNL;

LLNL-TR-415069; BIOCOMPATIBLE FLUORESCENT MICROSPHERES: SAFE PARTICLES FOR MATERIAL PENETRATION STUDIES (TAS Review Brief); G. Farquar, LLNL; R. Leif, LLNL;

LLNL-ABS-417208; Molecular Dynamics Simulations Of The Type A GABA Receptor; T. S. Carpenter, LLNL; F. C. Lightstone, LLNL;

LLNL-PROP-419725-DRAFT; Bacillus anthracis Sample Matching using Structural and Morphological Data; A.J. Malkin, LLNL; S.Elhadj, LLNL; S. Velsko, LLNL;

LLNL-POST-415334; An Interspecies Comparison of Butyrylcholinesterase; W.R. Corning, Deer Valley High School; B.J. Bennion, LLNL;

LLNL-ABS-419035-DRAFT; Determining the Cause of Species Toxicity Differences of

Traditional Chemical Weapons Agents by Computational Free Energy Calculations; B.J. Bennion, LLNL; F.C. Lightstone, LLNL; J. Fattebert, LLNL; E.R. Schwegler, LLNL; E. Lau, LLNL;

LLNL-POST-418727; Designing Enzymes Ab Initio; G. Kiss, UC Los Angeles; K. N. Houk, UC Los Angeles; F. C. Lightstone, LLNL;

LLNL-POST-415236; Assay Development for the Detection of Hemorrhagic Fever Viruses; K. M. Ethier, UC Davis; P. Naraghi-Arani, LLNL; A. C. Carrillo, LLNL;

LLNL-POST-412657; Aspergillus fumigatus JF1- An Ionic Liquid Tolerant Fungus Isolated from Compost; Steven W. Singer, LLNL; John M. Gladden, LLNL; Amitha P. Reddy, UC Davis; Jean S. Vanderghenst, UC Davis; Blake A. Simmons, Sandia National Laboratory;

LLNL-POST-413623; Bioprospecting Compost for Lignocellulose-degrading Microbes and Enzymes; John Gladden, LLNL; Becky Rutherford, Lawrence Berkeley National Laboratory; Steven Singer, LLNL; Blake Simmons, Sandia National Laboratory;

LLNL-PRES-415127; Towards preventing antibacterial resistance S. E. Wong, LLNL; B. W. Segelke, LLNL; M. H. Corzett, LLNL; C. A. Valdez, LLNL; F. C. Lightstone, LLNL;

LLNL-POST-413630; Analysis of metabolism in Yersinia pestis using new theoretical tools Ali Navid, LLNL; Patrik D'haeseleer, LLNL; Eivind Almaas, LLNL;

LLNL-JRNL-415374-DRAFT; Reconstitution of the Yersinia pestis, Yop B and YopD Translocon Complex; Jenny A. Cappuccio, LLNL; Craig D. Blanchette, LLNL; Erin S. Arroyo, LLNL; Angela K. Hinz, LLNL; Feliza A. Bourguet, LLNL; Paul D. Hoepflich, LLNL; Brett A. Chromy, LLNL; Matthew A. Cole, LLNL;

LLNL-JRNL-419924; Constrained DNA-Protamine Toroids Exert Force; Laurence R Brewer, Washington State; Laura Cree, Washington State; Michele Corzett, LLNL; Rod Balhorn, UC Davis;

LLNL-JRNL-415388; LIVE WIRES: BioNanoElectronics with 1D Materials; Aleksandr Noy, LLNL; Alexander Artyukhin, U of Texas; Nipun Misra, UC Berkeley;

LLNL-JRNL-418363; Bionanoelectronics with functional membrane proteins; Aleksandr Noy, LLNL; Nipun Misra, LLNL; Julio Martinez, LLNL;

LLNL-POST-415351 Mining the Human Urine Proteome for Biomarkers; Martha Rodriguez Villalpando, LLNL; Jennifer Montgomery, LLNL; Chi-yuan Hsu, UCSF; Brett Chromy, LLNL;

LLNL-PRES-415632; Homeland Security One Particle at a Time: Single Particle Aerosol Mass Spectrometry, Detecting Threats and Understanding Backgrounds; George Farquar, LLNL;

LLNL-ABS-415300; High Throughput Single Particle Nanoaerosol mass spectrometry for Long Term Temporal Aerosol Studies; G. Farquar, LLNL;

LLNL-JRNL-417813; Carbon nanotube devices controlled by an ion pump; Shih-Chieh Huang, LLNL; Alexander Artyukhin, U. of Texas; Nipun Misra, UC Berkeley; Julio Martinez, LLNL; Pieter Stroeve, UC Davis; Costas Grigoropoulos, UC Berkeley; Jiann Wen Ju, UCLA; Aleksandr Noy, LLNL;

LLNL-ABS-421248; Cell Wall Assembly and Deconstruction Revealed through Multi-Platform Imaging in the *Zinnia elegans* Model System; C. Lacayo, LLNL; A. Malkin, LLNL; H.-Y. Holman, Lawrence Berkeley National Laboratory; S.-Y. Ding, National Renewable Energy Laboratory; M. Hwang, LLNL; M. Thelen, LLNL;

LLNL-ABS-420907; Sub-Proteomic Analyses and Structural Modeling of Proteins Expressed in Acidophilic Microbial Communities; Y. Jiao, LLNL; P. Yelton, UC Berkeley; P. D'haeseleer, LLNL; A. Zelma, LLNL; B. Dill, Oakridge National Laboratory; N. Verberkmoes, Oakridge National Laboratory; R. Hettich, Oakridge National Laboratory; J. Banfield, UC Berkeley; M. Thelen, LLNL;

LLNL-ABS-411820; Homeland Security One Particle at a Time: Single Particle Aerosol Mass Spectrometry, Detecting Threats and Understanding Backgrounds; G. Farquar, LLNL; M. Frank, LLNL; A. Martin, LLNL; M. Bogan, SLAC; K. Coffee, LLNL; D. Fergenson, Livermore Instruments; E. Gard, LLNL; V. Riot, LLNL; P. Steele, LLNL;

LLNL-JRNL-409916; Genome-scale reconstruction of the metabolic network in *Yersinia pestis*, strain 91001; A. Navid, LLNL; E. Almaas, LLNL;

LLNL-MI-417220; Neutralization Procedure for Chemical Agents and Toxins Miscellaneous, C. Koester, LLNL; A. Alcaraz, LLNL

LLNL-ABS-420155; BioThreat Response Vehicle: High-Throughput Analysis of Environmental Samples; T. Bunt, LLNL; P. Althouse, LLNL; W. Hoppes, LLNL;

LLNL-MI-410265; BioNet DNA Extraction and Cleanup DNA Extraction and Cleanup Vacuum Filter Extraction Method; Cheryl Strout, LLNL;

LLNL-ABS-415415; Dielectrophoretic Focusing of Particles in Microfluidic Devices for Complex Sample Preparation; A. G. Varallo, LLNL; K. A. Rose, LLNL;

LLNL-ABS-415413; Modeling Acoustic Focusing of Particles in Microfluidic Channels, Douglas A. Wajda, LLNL; Klint A. Rose, LLNL;

LLNL-VIDEO-421423; Automated Sample Preparation for the Viral Discovery Platform (Animation); Klint A. Rose;

LLNLLLNL-PRES-412959; Emerging Applications: Biodefense Presentation/Viewgraphs 5/13/2013 J. M. Dzenitis, LLNL;

LLNL-TR-413046; Baseline Signal Technical Status, Autonomous Pathogen Detection System; J. M. Dzenitis, LLNL;

LLNL-TM-416925; Instrument Operations, Autonomous Pathogen Detection System Standard Operating Procedure; J. M. Dzenitis, LLNL;

LLNL-TR-410831; Baseline Test Report for APDS306, Autonomous Pathogen Detection System; T. H. Weisgraber, LLNL; J. M. Dzenitis, LLNL; A. J. Makarewicz, LLNL;

LLNL-JRNL-410104; The Autonomous Pathogen Detection System; J. M. Dzenitis, LLNL; A. J. Makarewicz, LLNL;

LLNL-TM-416893; Monitoring Instrument Signals, Autonomous Pathogen Detection System Standard Operating Procedure; J. M. Dzenitis, LLNL;

LLNL-ABS-410390; Genetic inference for viral forensics: inferring host to host transmission events with viral genome sequence data Abstract/Summary 2/6/2013; J. Allen, LLNL; S. Velsko, LLNL; S. Gardner, LLNL; T. Slezak, LLNL;

LLNL-JRNL-420969; Amino acid and structural variability of Yersinia pestis LcrV protein, A. P. Anisimov, State Research Center for Applied Microbiology and Biotechnology, 142279, Obolensk, Moscow Region, Russia; S. V. Dentovskaya, State Research Center for Applied Microbiology and Biotechnology, 142279, Obolensk, Moscow Region, Russia; E. A. Panfertsev, State Research Center for Applied Microbiology and Biotechnology, 142279, Obolensk, Moscow Region, Russia; T. E. Svetoch, State Research Center for Applied Microbiology and Biotechnology, 142279, Obolensk, Moscow Region, Russia; P. K. Kopylov, State Research Center for Applied Microbiology and Biotechnology, 142279, Obolensk, Moscow Region, Russia; B. W. Segelke, LLNL; A. Zemla, LLNL; M. V. Telepnev, Department of Microbiology and Immunology, University of Texas Medical Branch, Galveston, Texas 77555, USA; V. L. Motin, Department of Microbiology and Immunology and Department of Pathology, University of Texas Medical Branch, Galveston, Texas 77555, USA;

LLNL-JRNL-412667-DRAFT; A Microbial Detection Array (MDA) for Viral and Bacterial Detection; S.N. Gardner, LLNL; C. J. Jaing, LLNL; K.S. McLoughlin, LLNL; T.R. Slezak, LLNL;

LLNL-JRNL-413646; LAVA: An Open-Source Approach To Designing LAMP (Loop-Mediated Isothermal Amplification) DNA Signatures; Clinton Torres, LLNL; Elizabeth Vitalis, LLNL; Brian Robert Baker, LLNL; Shea Gardner, LLNL; Marisa Lam, LLNL; John Dzenitis, LLNL;

LLNL-JRNL-409735; Conserved amino acid markers from past influenza pandemic strains,

J. E. Allen, LLNL; S. N. Gardner, LLNL; E. A. Vitalis, LLNL; T. R. Slezak, LLNL;

LLNL-POST-409721; Arrays for Microbial Detection and Genotyping; S.N. Gardner, LLNL; C. Jaing, LLNL; K. McLoughlin, LLNL; M. Lam, LLNL; T. Slezak, LLNL;

LLNL-POST-415347-DRAFT; Annotation of Virulence Regulatory Networks of Yersinia Pestis; L. Pnag, CSU East Bay; P. D'haeseleer, LLNL; A. Navid, LLNL;

LLNL-POST-413437-DRAFT; The Metabolism of the Plague Bacterium Yersinia pestis, A. Navid, LLNL; P. D'haeseleer, LLNL;

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**I Objectives**

LLNL is performing work in the area of biological agent detection, therapeutics development, virulence mechanism elucidation, structural characterization, agent viability testing, response planning, restoration, and forensics.

The biological detection platforms being developed at LLNL include multiplex assays, the Autonomous Pathogen Detection System (APDS), Biological Aerosol Mass Spectrometry (BAMS), Enhanced Biological Aerosol Detection System (EBADS), and the Viral Discovery Platform (VDP). These platforms use PCR, immunoassay, mass spectrometry, and genomic sequencing to gather useful information about the biological species present in the sampling environment. LLNL is also working to support and upgrade the biological detection network put in place by DHS which is known as Biowatch. Personnel from LLNL play an important role in the bioinformatics required to develop new detection assays for the various detection platforms. The development and screening of new DNA/RNA based assays is also a core area of expertise at LLNL. Testing and validation of new hardware components, and training for the Biowatch network is another area where LLNL supports the DHS mission.

In addition to the detection platforms LLNL is also working on tools that will help to restore normal activities in the event that a biological agent is used. These include developing rapid viability testing, decontamination strategies, and biological response plans for DHS, DOD, and EPA. We also have substantial activities in developing forensic assays to help determine where an agent may have come from and who might be responsible for the use of that agent.

Beyond detection, response, recovery, and attribution LLNL also has ongoing research projects whose goal is to help elucidate the mechanisms of host-pathogen interactions. The goal of this research is to understand how an organism is able to defeat or circumvent the host immune system. This will enable the development of new intervention strategies that are specifically targeted to steps in the organism life cycle. LLNL is also involved in

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\* Including viruses and prions.

the search for new anti-bacterial compounds that can be used as effective intervention strategies as well as the development of novel vaccine strategies for disease prevention.

## **II Agents**

- **HHS Select Agents and Toxins**  
Including NIAID Category A, B and C Priority Pathogens
- **OVERLAP Select Agents and Toxins**  
Including NIAID Category A, B Priority Pathogens
- **Simulants**  
Simulants of HHS, USDA and OVERLAP Select Agents and Toxins including less pathogenic strains and killed or inactivated variants as well as other non-select agents or derivatives from any of the microorganisms or toxins.

## **III Outdoor studies**

The Biowatch program is an outdoor monitoring system.

National biological defence research and development programme

**III. Facilities**

**1. Name of the facility:**

Oak Ridge National Laboratory

**2. Where is it located?**

Oak Ridge National Laboratory  
P. O. Box 2008  
Oak Ridge, TN 37831

**3. Floor area of laboratory areas by containment level:**

BL1 (sqM)	0
BL2 (sqM)	0
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	0

No laboratory work is involved

**4. The organizational structure of each facility:**

**I Total number of personnel** 1

**II Division of personnel**

Military	0
Civilian	1

**III Division of personnel by category (include on-site contractors):**

Scientists	1
Engineers	0
Technicians	0
Administrative and support staff	0

**IV List the scientific disciplines represented in the scientific/engineering staff:**

Biochemistry  
Bioinformatics  
Chemistry

Computer Science  
Electrical Engineering  
Microbiology

**V Are contractor staff working in the facility? If so, provide an approximate number:**

No

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Internal (Laboratory Directed Research and Development [LDRD])

**VII What are the funding levels for the following program areas:**

Research and Development:	\$100,000
Test and Evaluation:	\$ 0
Total	\$100,000

**VIII Briefly describe the publication policy of the facility:**

Scientists are encouraged to publish their unclassified results in peer-reviewed scientific literature and present their results at national and international scientific meetings. All manuscripts and presentations are subject to review by the sponsor and a classification review prior to release

**IX Provide a list of publicly available papers and reports resulting from work during the previous 12 months:**

No publications this year

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**I Objectives**

The program at Oak Ridge National Laboratory (ORNL) is in two areas: R&D to improve detection of biological agents, with complementary work in bioinformatics and biological forensics. The mass spectrometry detector efforts for biological weapons (Block II Chemical Biological Mass Spectrometer Program [CBMS-II program]) have halted except for exploratory efforts to detect genetically modified organisms using BSL-1 models.

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\* Including viruses and prions.

## **II Agents**

ORNL has no active work requiring registration with the Select Agent Program. There are no Select Agents in current use and all toxins associated with the CBMS II program requiring registration with the Select Agent Program were destroyed as part of the project closeout process. There is some work with exempt vaccine strains and some toxins below the *de minimus* level and thus exempt.

## **III Outdoor studies**

None

**National biological defence research and development programme**

**III. Facilities**

**1. Name of the facility:**

Pacific Northwest National Laboratory

**2. Where is it located?**

Pacific Northwest National Laboratory  
P. O. Box 999  
Richland, WA 99352

**3. Floor area of laboratory areas by containment level:**

BL1 (sqM)	1737
BL2 (sqM)	2105
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	3842

**4. The organizational structure of each facility:**

**I Total number of personnel:** 40

**II Division of personnel:**

Military	0
Civilian	40

**III Division of personnel by category (include on-site contractors):**

Scientists	31
Engineers	1
Technicians	0
Administrative and support staff	8

**IV List the scientific disciplines represented in the scientific/engineering staff:**

Analytical chemistry  
Biochemistry  
Biology  
Biophysics  
Bioinformatics

Chemical Engineering  
Genetics  
Laser Electro-optics  
Microbiology  
Microbial forensics  
Molecular Biology

**V Are contractor staff working in the facility? If so, provide an approximate number:**

No

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense  
U.S. Department of Health & Human Services (including NIH, CDC)  
U.S. Department of Homeland Security  
Internal (Laboratory Directed Research and Development [LDRD])

**VII What are the funding levels for the following program areas:**

Research and Development:	\$1,822,000
Test and Evaluation:	\$ 649,000
Total	\$2,471,000

**VIII Briefly describe the publication policy of the facility:**

Pacific Northwest National Laboratory (PNNL) staff are encouraged to publish the results of their work in the peer-reviewed scientific literature, however scientific and technical information developed by staff and non-staff must be reviewed and receive an Information Release number before being distributed outside PNNL.

The information release process is not required for proposals, internal communications or for speeches and publications unrelated to PNNL or its clients. A publication grid is available to help authors determine if a product needs to go through ERICA.

ERICA, an acronym for "Electronic Records and Information Capture Architecture" is PNNL's online system that:

- automates and tracks the Information Release process from the time that an information release form is initiated, through approvals, to the point of publication/external release;
- assigns an Information Release number to each product;
- captures information about what is being released outside PNNL (to clients or to the public) by PNNL authors;

- makes this information available, when appropriate, to the PNNL external publications web site and to DOE's Office of Scientific and Technical Information (OSTI);
- Makes this information available, when appropriate, to Laboratory users for SDRs, Annual Reports, bibliometric analysis, etc.

Reviewers include, but are not limited to, subject-matter experts, clients, and intellectual property experts, as well as Authorized Derivative Classifiers who determine if the product might contain national security or business sensitive information requiring classification or modification.

**IX Provide a list of publicly available papers and reports resulting from work during the previous 12 months:**

Ozanich RM, KC Antolick, CJ Bruckner-Lea, KJ Bunch, BP Dockendorff, JW Grate, CL Warner, and MG Warner. 2009. "Bead-Based Assays for Biodetection: From Flow-Cytometry to Microfluidics." In Optics and Photonics in Global Homeland Security V and Biometric Technology for Human Identification VI (Proceedings Volume) Proceedings of SPIE, vol. 7306, p. Art. No. 730601. Society of Photo-Optical Instrumentation Engineers, Bellingham, WA. doi:10.1117/12.819951

Warner CL, GJ Posakony, NB Valentine, RM Ozanich, LJ Bond, JW Grate, TM Straub, MM Matzke, BP Dockendorff, CO Valdez, PLJ Valdez, SL Owsley, Jr, and CJ Bruckner-Lea. 2009. "A flow-through ultrasonic lysis system for the disruption of bacterial spores." Journal of the Association for Laboratory Automation 14:277-284.

Grate JW, MG Warner, RM Ozanich, KD Miller, HA Colburn, BP Dockendorff, KC Antolick, NC Anheier, Jr, MA Lind, J Lou, JD Marks, and CJ Bruckner-Lea. 2009. "Renewable Surface Fluorescence Sandwich Immunoassay Biosensor for Rapid Sensitive Botulinum Toxin Detection in an Automated Fluidic Format." Analyst 134(5):987 - 996. doi:10.1039/B900794F

Ozanich RM, CJ Bruckner-Lea, MG Warner, KD Miller, KC Antolick, JD Marks, J Lou, and JW Grate. 2009. "Rapid Multiplexed Flow Cytometric Assay for Botulinum Neurotoxin Detection Using an Automated Fluidic Microbead-Trapping Flow Cell for Enhanced Sensitivity." Analytical Chemistry 81(14):5783-5793.

Warner MG, JW Grate, AJ Tyler, RM Ozanich, KD Miller, J Lou, JD Marks, and CJ Bruckner-Lea. 2009. "Quantum dot immunoassays in renewable surface column and 96-well plate formats for the fluorescence detection of Botulinum neurotoxin using high-affinity antibodies." Biosensors and Bioelectronics 25(1):179-184.

Boschek CB, DO Apiyo, TA Soares, HE Engelmann, NB Pefaur, TP Straatsma, CL Baird. "Engineering an ultra-stable affinity reagent based on Top7." Protein Eng Des Sel. 2009 May; 22(5):325-32. Epub 2009 Mar 25.

Gray SA, KM Weigel, KD Miller, J Ndung'u, P Büscher, T Tran, C Baird, GA Cangelosi. "Flow cytometry-based methods for assessing soluble scFv activities and detecting antigens in solution." *Biotechnol Bioeng.* 2009 Dec 1;105(5):973-981. [Epub ahead of print]

Wahl KL, H. Colburn, DS Wunschel, CE Petersen, KH Jarman, and NB Valentine, "Residual Agar Determination in Bacterial Spores by Electrospray Ionization Mass Spectrometry", in *Press Anal. Chem.* 2010.

Kreuzer, H., JH Wahl, CN Metoyer, HA Colburn, and KL Wahl. "Detection of Acetone Processing of Castor Bean Mash." 2010. *J. Forensic Sci.*, in press.

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**I Objectives**

Enhanced Bioaerosol Detection System: Measure the optical fluorescence of a range of biothreat surrogates and potential interferents at 288nm and 355nm excitation wavelength. Biothreat simulants/near neighbors were used.

Botulinum Toxin Detection system: develop antibody-assays for the rapid detection of botulinum toxin in complex samples. Use the non-toxic heavy chain fragment of botulinum toxin for assay development and testing.

Develop affinity reagents to bind and detect biothreat targets including toxins and bacteria.

Develop analytical methods for identifying organic signatures of processing methods, procedures, materials used in culturing and preparation of biological hazards. Work with vaccine strains for bacterial pathogens that are all BSL2 or lower, also received some certified killed organisms from other organizations that have BSL3 capabilities to test for preparation signatures.

Conduct studies on castor seed mash and related inactivate preparations to detect methods of preparation.

Develop real-time PCR assays for *Francisella tularensis*, using *F. tularensis* genetic material, tests inclusivity, exclusivity, and environmental DNA panels.

Test and evaluate nucleic acid and immunologic assays developed by DHS performers. Tests inclusivity, exclusivity, and environmental DNA and/or protein panels.

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\* Including viruses and prions.

## **II Agents**

- **HHS Select Agents and Toxins**  
Including NIAID Category A and B Priority Pathogens  
NIAID Category A Priority Pathogens are not fully virulent organisms but genetic material, proteins and/or vaccine strains
- **Overlap Select Agents**  
Including NIAID Category A and B Priority Pathogens

## **III Outdoor studies**

None

**National biological defence research and development programme**

**III. Facilities**

**1. Name of the facility:**

Sandia National Laboratories

**2. Where is it located?**

Sandia National Laboratories  
P. O. Box 5800  
Albuquerque, NM 871853

**3. Floor area of laboratory areas by containment level:**

BL1 (sqM)	656
BL2 (sqM)	991.4
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	1647.4

**4. The organizational structure of each facility:**

**I Total number of personnel:** 124

**II Division of personnel:**

Military	0
Civilian	124

**III Division of personnel by category (include on-site contractors):**

Scientists	63
Engineers	11
Technicians	46
Administrative and support staff	4

**IV List the scientific disciplines represented in the scientific/engineering staff:**

Biochemistry  
Bioengineering, virology  
Bioinformatics  
Biology  
Biophysics

Chemical Engineering  
Chemistry  
Electrical Engineering  
Environmental Science  
Genetics  
Immunology  
Laser Electro-optics  
Microbiology  
Molecular Biology  
Molecular Spectroscopy and Imaging  
Nanotechnology  
Neuroscience  
Proteomics

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number:        21

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Defense  
U.S. Department of Energy  
U.S. Department of Health & Human Services (including NIH, CDC)  
U.S. Department of Homeland Security  
Internal (Laboratory Directed Research and Development [LDRD])

**VII What are the funding levels for the following program areas:**

Research and Development:	\$38,125,000
Test and Evaluation:	\$            0
Total	\$38,125,000

**VIII Briefly describe the publication policy of the facility:**

Scientists are encouraged to publish their results in the peer reviewed scientific literature as well as present their work at national and international professional meetings.

**IX Provide a list of publicly available papers and reports resulting from work during the previous 12 months:**

Carroll-Portillo, A., and Bachand, G.D. (2008). Directed attachment of antibodies to kinesin-powered molecular shuttles. *Biotechnol. Bioeng.* 104(6): 1182-1188.

Carroll-Portillo, A., Bachand, M., Greene, A.C, and Bachand, G.D. (2009). Capture and

transport of protein analytes with kinesin-based nanoharvesters. *Small* 5(16): 1835-1840.

Bachand, G.D., Hess, H., Ratna, B., Satir, P., and Vogel, V. (2009). "Smart Dust" biosensors powered by biomolecular motors. *Lab Chip* 9(12): 1661 – 1666 (Invited review).

Tucker, R., Saha, A., Katira, P., Bachand, M., Bachand, G.D., and Hess, H. (2009). Temperature-compensation for hybrid devices: Kinesin's  $K_m$  is temperature-independent. *Small* 5(11): 1279-1282.

Rios, L. and Bachand, G.D. (2009). Multiplex transport and detection of cytokines using kinesin-driven molecular shuttles. *Lab Chip* 9: 1005-1010.

E.C. Carnes, D.M. Lopez, H. Greshan, A. Cheung, G.S. Timmins, and C. J. Brinker, "Confinement-Induced Quorum Sensing of Individual *Staphylococcus aureus* Bacteria," *Nature Chemical Biology* (2009, November, published online).

J. W. Liu, A. Stace-Naughton, X. M. Jiang, and C. J. Brinker, "Porous Nanoparticle Supported Lipid Bilayers (Protocells) as Delivery Vehicles," *Journal of the American Chemical Society* 131 (4), 1354-+ (2009).

J. W. Liu, A. Stace-Naughton, and C. J. Brinker, "Silica nanoparticle supported lipid bilayers for gene delivery," *Chemical Communications* (34), 5100-5102 (2009).

J. W. Liu, X. M. Jiang, C. Ashley, and C. J. Brinker, "Electrostatically Mediated Liposome Fusion and Lipid Exchange with a Nanoparticle-Supported Bilayer for Control of Surface Charge, Drug Containment, and Delivery," *Journal of the American Chemical Society* 131 (22), 7567-+ (2009).

D. R. Dunphy, T. M. Alam, M. P. Tate, H. W. Hillhouse, B. Smarsly, A. D. Collord, E. Carnes, H. K. Baca, R. Kohn, M. Sprung, J. Wang, and C. J. Brinker, "Characterization of Lipid-Templated Silica and Hybrid Thin Film Mesophases by Grazing Incidence Small-Angle X-ray Scattering," *Langmuir* 25 (16), 9500-9509 (2009).

Eric C. Carnes, Jason C. Harper, Carlee E. Ashley, DeAnna M. Lopez, Lina M. Brinker, Juewen Liu, Seema Singh, Susan M. Brozik, and C. Jeffrey Brinker, "Cell-Directed Localization and Orientation of a Functional Foreign Transmembrane Protein within a Silica Nanostructure," *Journal of the American Chemical Society* 131 (40), 14255-14257 (2009).

R. W. Davis, J. A. Timlin, R. Noek, J. N. Kaiser, H. D. T. Jones & T. W. Lane, "Accurate detection of low levels of fluorescence emission in autofluorescent background: Francisella infected macrophage cells," *Microscopy & Microanalysis*, submitted, 2009.

A. Carroll-Portillo, K. Spendier, K. Lidke, J. Pfeiffer, D. Lidke, J. Thomas, B. Wilson & J. A. Timlin, "FcεRI Membrane Dynamics upon Binding Mobile or Immobile Ligands on Surfaces: Formation of a Mast Cell Synapse," *Journal of Immunology*, submitted, 2009.

J. N. Kaiser, J. A. Timlin, R. W. Davis, R. Noek & T. W. Lane, "Clustering and Subcellular Localization of Components of a Type Six Secretion System in *Francisella novicida*," *Journal of Bacteriology*, submitted, 2009.

J. A. Timlin, L. E. Martin, C. R. Lyons, B. Hjelle & M. K. Alam, "Dynamics of Cellular Activation as Revealed by Attenuated Total Reflectance Infrared Spectroscopy," *Vibrational Spectroscopy* 50, 78-85, 2009.

James CD, Moorman MW, Carson BD, Branda CS, Lantz JW, Manginell RP, Martino A, Singh AK. Nuclear translocation kinetics of NF-kappaB in macrophages challenged with pathogens in a microfluidic platform. *Biomed Microdevices*. 2009 Jun;11(3):693-700. PubMed PMID: 19169824.

Altman, S. J., L. K. McGrath, C. A. Souza, J. Murton and A. Camper, Integration and decontamination of *Bacillus cereus* in *Pseudomonas fluorescens* biofilms, *J. Appl. Microbiol.*, 107(1), 287-299, 2009.

Altman, S. J., M. Cappelle, P. G. Clem, A. W. Cook, C. H. Cornelius, W. E. Hart, M. R. Hibbs, C. K. Ho, H. D. T. Jones, S. S. Khalsa, R. Noek, A. C. Sun, S. W. Webb, L. K. McGrath, A. Sanchez, D. L. James, A. Adout, M. Elimelech, and S. Kang, Analysis of Micromixers and Biocidal Coatings on Water-Treatment Membranes to Minimize Biofouling, SAND2009-8316, Sandia National Laboratories, Albuquerque, NM, 2009.

Altman, S. J., L. K. McGrath, C. A. Souza, J. Murton and A. Camper, Integration and decontamination of *Bacillus cereus* in *Pseudomonas fluorescens* biofilms, *J. Appl. Microbiol.*, 107(1), 287-299, 2009.

Altman, S. J., M. Cappelle, P. G. Clem, A. W. Cook, C. H. Cornelius, W. E. Hart, M. R. Hibbs, C. K. Ho, H. D. T. Jones, S. S. Khalsa, R. Noek, A. C. Sun, S. W. Webb, L. K. McGrath, A. Sanchez, D. L. James, A. Adout, M. Elimelech, and S. Kang, Analysis of Micromixers and Biocidal Coatings on Water-Treatment Membranes to Minimize Biofouling, SAND2009-8316, Sandia National Laboratories, Albuquerque, NM, 2009.

T.A. Stewart, D.E. Trudell, T.M. Alam, C.A. Ohlin, W.H. Casey, S. Jett and M. Nyman, "Enhanced Water Purification: A Single Atom Makes a Difference," *Environmental Science and Technol.*, 21(11), 2201-2208, 2009.

E.C. Carnes, D.M. Lopez, H. Greshan, A. Cheung, G.S. Timmins, and C. J. Brinker, "Confinement-Induced Quorum Sensing of Individual *Staphylococcus aureus* Bacteria," *Nature Chemical Biology* (2009, November, published online).

J. W. Liu, A. Stace-Naughton, X. M. Jiang, and C. J. Brinker, "Porous Nanoparticle Supported Lipid Bilayers (Protocells) as Delivery Vehicles," *Journal of the American Chemical Society* 131 (4), 1354-+ (2009).

J. W. Liu, A. Stace-Naughton, and C. J. Brinker, "Silica nanoparticle supported lipid bilayers

for gene delivery," *Chemical Communications* (34), 5100-5102 (2009).

J. W. Liu, X. M. Jiang, C. Ashley, and C. J. Brinker, "Electrostatically Mediated Liposome Fusion and Lipid Exchange with a Nanoparticle-Supported Bilayer for Control of Surface Charge, Drug Containment, and Delivery," *Journal of the American Chemical Society* 131 (22), 7567-+ (2009).

D. R. Dunphy, T. M. Alam, M. P. Tate, H. W. Hillhouse, B. Smarsly, A. D. Collord, E. Carnes, H. K. Baca, R. Kohn, M. Sprung, J. Wang, and C. J. Brinker, "Characterization of Lipid-Templated Silica and Hybrid Thin Film Mesophases by Grazing Incidence Small-Angle X-ray Scattering," *Langmuir* 25 (16), 9500-9509 (2009).

Eric C. Carnes, Jason C. Harper, Carlee E. Ashley, DeAnna M. Lopez, Lina M. Brinker, Juewen Liu, Seema Singh, Susan M. Brozik, and C. Jeffrey Brinker, "Cell-Directed Localization and Orientation of a Functional Foreign Transmembrane Protein within a Silica Nanostructure," *Journal of the American Chemical Society* 131 (40), 14255-14257 (2009).

D. E. Huber, M. L. Markel, S. Pennathur, K. D. Patel. "Oligonucleotide Hybridization and Free-Solution Electrokinetic Separation in a Nanofluidic Device," *Lab Chip*, 2009, (20),2933-2940 DOI: 10.1039/b901739a

G.J. Sommer, A.K. Singh, A.V. Hatch. "Enrichment and Fractionation of Proteins via Microscale Pore Limit Electrophoresis," *Lab on a Chip*, 9, 2729-2737 (2009).

G.J. Sommer and A.V. Hatch, "Isoelectric Focusing in Microfluidic Devices," *Electrophoresis*, 30, 742-757 (2009). Invited Review.

Somin Eunice Lee, Darryl Y. Sasaki, Thomas D. Perroud, Daniel Yoo, Kamlesh D. Patel, and Luke P. Lee, J. "Biologically Functional Cationic Phospholipid-Gold Nanoplasmonic Carriers of RNA," *J. Am. Chem. Soc* 2009, 131(39), 14066 - 14074.

Carl C. Hayden, Jane S. Hwang, Elisa A. Abate, Michael S. Kent, Darryl Y. Sasaki, J. "Directed Formation of Lipid Membrane Microdomains as High Affinity Sites for His-Tagged Proteins," *J. Am. Chem. Soc.* 2009, 131(25), 8728 - 8729.

Orendorff, C. J.; Alam, T. M.; Sasaki, D. Y.; Bunker, B. C.; Voigt, J. A. "Phospholipid-Gold Nanorod Composites," *ACS Nano* 2009, 3, 971 – 983.

C. M. Yip, M. S. Kent, D. Y. Sasaki, "Protein-Membrane Interactions on Supported Lipid Membranes," *Soft Nanomaterials*, H.S. Nalwa (Ed.), vol. 2, American Scientific Publishers, Stevenson Ranch, 2009, pp. 67 - 121.

Perroud, T. D.; Meagher R. J.; Kanouff, M. P.; Renzi, R. F.; Wu, M.; Singh, A. K.; Patel, K. D. "Isotropically Etched Radial Micropore for Cell Concentration, Immobilization, and Picodroplet Generation," *Lab on a Chip* 9, 507-515 (2009). Featured on journal back cover.

N'Diaye EN, Branda CS, Branda SS, Nevarez L, Colonna M, Lowell C, Hamerman JA, Seaman WE. TREM-2 (triggering receptor expressed on myeloid cells 2) is a phagocytic receptor for bacteria. (2009) *J Cell Biol.* Jan 26;184(2):215-23.

James CD, Moorman MW, Carson BD, Branda CS, Lantz JW, Manginell RP, Martino A, Singh AK. (2009) Nuclear translocation kinetics of NF-kappaB in macrophages challenged with pathogens in a microfluidic platform. *Biomed Microdevices.* 2009 Jan 24.

ET Yu, Zendejas F, Lane PD, Gaucher SP, Simmons BA, Lane TW. 2008. "Triacylglycerol Accumulation and Profiling in the Model Diatoms *Thalassiosira pseudonana* and *Phaeodactylum tricornutum* (Baccilariophyceae) During Starvation." *J. Applied Phycol.* (published online January 2009).

Y.J. Tang, R. Sapra, D. Joyner, T.C. Hazen, S. Myers, D. Reichmuth, H. Blanch, J.D. Keasling, "Analysis of Metabolic Pathways and Fluxes in a Newly Discovered Thermophilic and Ethanol-Tolerant *Geobacillus* Strain," *Biotechnology and Bioengineering*, vol 102, pp 1377-1386 (2009).

C.A. Ramseier, J.S. Kinney, A.E. Herr, T. Braun, J.V. Sugai, C.A. Shelburne, L.A. Rayburn, H.M. Tran, A.K. Singh, W.V. Giannobile, "Identification of pathogen and host-response markers correlated with periodontal disease," *J Periodontol*, 2009, 80, 3, 436-446.

N. Srivastava, J. S. Brennan, R. F. Renzi, M. Wu, S. S. Branda, A. K. Singh, and A. E. Herr, "Fully Integrated Microfluidic Platform Enabling Automated Phosphoproteomics of Macrophage Response," *Anal. Chem.*, 81, 3261–3269, 2009.

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols.**

**I Objectives**

The Sandia Chem/Bio Defense Program is an applied research program designed to develop and demonstrate technologies and systems that can be used to mitigate the impact of attacks on civilian populations with chemical or biological agents. Specific aims include:

- Analyze pathogenic mechanisms caused by toxins interacting with cell membranes.
- Develop detector technologies for toxins, bacteria, and viruses by applying microseparations technology.
- Develop diagnostic technologies for toxins, bacteria, and viruses by applying microseparations technology.

**II Agents**

Sandia National Laboratories (SNL) does not work with any pathogens or amounts of toxins requiring registration with the U.S. Select Agent Program. All work is with exempt

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\* Including viruses and prions.

vaccine strains, killed or inactivated variants, as well as other non-select agents as simulants. There are some toxins below the *de minimus* level and thus exempt.

- **HHS Select Agents and Toxins**  
Including NIAID Category A and B Priority Pathogens  
Only exempt strains or simulants
- **Overlap Select Agents**  
Including NIAID Category B Priority Pathogens  
Only exempt strains or simulants
- **Other pathogens or toxins**  
Sandia also conducts basic and applied research with a range of yeast, fungi, viruses, and bacteria (such as different species of thermophilic bacteria) that are nonpathogenic or minimally pathogenic.

### **III Outdoor studies**

None

#### **General Comments:**

This report also covers activities at the SNL-Livermore site.

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

C. W. Bill Young Center for Biodefense and Emerging Infectious Diseases,  
National Institutes of Health, U.S. Department of Health and Human Services

**2. Where is it located?**

9000 Rockville Pike  
Bethesda, Maryland, USA 20892

**3. Floor area of laboratory areas by containment level:**

BL2 (sqM)	2493.3
BL3 (sqM)	1090.9
BL4 (sqM)	0
Total (sqM)	3584.2

**4. The organizational structure of each facility.**

**I Total number of personnel:** 111

**II Division of personnel:**

Military	0
Civilian	111

**III Division of personnel by category:**

Scientists	77
Engineers	0
Technicians	34
Administrative and support staff	0

**IV List the scientific disciplines represented in the scientific/engineering staff.**

Bacteriology  
Biology  
Chemistry  
Medicine  
Pathogenesis  
Virology

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number:        30

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Health and Human Services (Appropriated Funding)

**VII What are the funding levels for the following program areas:**

Research	\$ 36,444,385
Development	\$            0
Test and evaluation	\$            0
Total	\$ 36,444,385

**VIII. Briefly describe the publication policy of the facility:**

All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (<http://publicaccess.nih.gov/policy.htm>) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the National Library of Medicine's digital archive PubMed Central upon acceptance for publication. To help advance science and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

**IX. Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)**

Anthrax toxin uptake by primary immune cells as determined with a lethal factor-beta-lactamase fusion protein. Hu H, Leppla SH. PLoS One. 2009 Nov 23;4(11):e7946.

Potent neutralization of anthrax edema toxin by a humanized monoclonal antibody that competes with calmodulin for edema factor binding. Chen Z, Moayeri M, Zhao H, Crown D, Leppla SH, Purcell RH. Proc Natl Acad Sci U S A. 2009 Aug 11;106(32):13487-92. Epub 2009 Jul 27.

Cellular and systemic effects of anthrax lethal toxin and edema toxin. Moayeri M, Leppla SH. Mol Aspects Med. 2009 Dec;30(6):439-55. Epub 2009 Jul 26. Review.

CA-074Me protection against anthrax lethal toxin. Newman ZL, Leppla SH, Moayeri M. Infect Immun. 2009 Oct;77(10):4327-36. Epub 2009 Jul 27.

Capillary morphogenesis protein-2 is the major receptor mediating lethality of anthrax toxin in vivo. Liu S, Crown D, Miller-Randolph S, Moayeri M, Wang H, Hu H, Morley T, Leppla SH. Proc Natl Acad Sci U S A. 2009 Jul 28;106(30):12424-9. Epub 2009 Jul 15.

Quantitative high-throughput screening identifies inhibitors of anthrax-induced cell death. Zhu PJ, Hobson JP, Southall N, Qiu C, Thomas CJ, Lu J, Inglese J, Zheng W, Leppla SH, Bugge TH, Austin CP, Liu S. Bioorg Med Chem. 2009 Jul 15;17(14):5139-45. Epub 2009 May 29.

Novel chimpanzee/human monoclonal antibodies that neutralize anthrax lethal factor, and evidence for possible synergy with anti-protective antigen antibody. Chen Z, Moayeri M, Crown D, Emerson S, Gorshkova I, Schuck P, Leppla SH, Purcell RH. Infect Immun. 2009 Sep;77(9):3902-8. Epub 2009 Jun 15.

A new minimal replicon of Bacillus anthracis plasmid pXO1. Pomerantsev AP, Camp A, Leppla SH. J Bacteriol. 2009 Aug;191(16):5134-46. Epub 2009 Jun 5. Erratum in: J Bacteriol. 2009 Oct;191(19):6192.

The heart is an early target of anthrax lethal toxin in mice: a protective role for neuronal nitric oxide synthase (nNOS). Moayeri M, Crown D, Dorward DW, Gardner D, Ward JM, Li Y, Cui X, Eichacker P, Leppla SH. PLoS Pathog. 2009 May;5(5):e1000456. Epub 2009 May 29.

Dissecting the urokinase activation pathway using urokinase-activated anthrax toxin. Liu S, Bugge TH, Frankel AE, Leppla SH. Methods Mol Biol. 2009;539:175-90.

Imaging specific cell surface protease activity in living cells using reengineered bacterial cytotoxins. Hobson JP, Liu S, Leppla SH, Bugge TH. Methods Mol Biol. 2009;539:115-29.

Matrix metalloproteinase-activated anthrax lethal toxin inhibits endothelial invasion and neovasculature formation during in vitro morphogenesis. Alfano RW, Leppla SH, Liu S, Bugge TH, Meininger CJ, Lairmore TC, Mulne AF, Davis SH, Duesbery NS, Frankel AE. Mol Cancer Res. 2009 Apr;7(4):452-61.

Pathophysiology of anthrax. Frankel AE, Kuo SR, Dostal D, Watson L, Duesbery NS, Cheng CP, Cheng HJ, Leppla SH. Front Biosci. 2009 Jan 1;14:4516-24. Review.

Norepinephrine increases blood pressure but not survival with anthrax lethal toxin in rats. Li Y, Cui X, Su J, Haley M, Macarthur H, Sherer K, Moayeri M, Leppla SH, Fitz Y, Eichacker PQ. Crit Care Med. 2009 Apr;37(4):1348-54.

Codon-optimized fluorescent proteins designed for expression in low-GC gram-positive bacteria. Sastalla I, Chim K, Cheung GY, Pomerantsev AP, Leppla SH. Appl Environ Microbiol. 2009 Apr;75(7):2099-110. Epub 2009 Jan 30.

PapR peptide maturation: role of the NprB protease in Bacillus cereus 569 PlcR/PapR global gene regulation. Pomerantsev AP, Pomerantseva OM, Camp AS, Mukkamala R, Goldman S, Leppla SH. FEMS Immunol Med Microbiol. 2009 Apr;55(3):361-77. Epub 2009 Jan 12.

Detection of anthrax toxin by an ultrasensitive immunoassay using europium nanoparticles. Tang S, Moayeri M, Chen Z, Harma H, Zhao J, Hu H, Purcell RH, Leppla SH, Hewlett IK. Clin Vaccine Immunol. 2009 Mar;16(3):408-13. Epub 2009 Jan 7.

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**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols:**

**I Objectives:**

At the C.W. Bill Young Center, the Laboratory of Infectious Diseases (LID) focuses on viral vaccine development, host immune response to viruses, and viral molecular biology and genetics. Newer programs focus on developing vaccines, from basic research to clinical trials.

The Laboratory of Bacterial Diseases (LBD) studies bacterial diseases related to biodefense pathogens. Research focuses on identification and analysis of bacterial virulence factors and their genetic regulation; structure-function analysis of bacterial proteins and other factors; disease pathogenesis; and development of diagnostics, vaccines, and therapeutics.

The Laboratory of Viral Diseases (LVD) studies the basic mechanisms of viral entry into cells, regulation of viral gene expression, viral DNA replication, assembly and transport of viral proteins and particles, viral virulence, and humoral and cellular immunity.

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\* Including viruses and prions.

Applied research includes development of recombinant expression vectors, candidate vaccines, and antiviral agents. DNA and RNA viruses are studied.

## **II Agents:**

- **HHS Select Agents and Toxins**  
Including NIAID Category A and C Priority Pathogens
- **Overlap Select Agents**  
Including NIAID Category A Priority Pathogens
- **USDA Select Agents**
- **Other pathogens or toxins**  
Including non-Select Agent, NIAID Category A, B and C Priority Pathogens  
Including other non-Select Agent, non-NIAID Category A, B and C Priority Pathogens
- **Simulants**

## **III Outdoor Studies:**

None

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

Integrated Research Facility-Rocky Mountain Laboratories (RML)  
National Institutes of Health, US Department of Health and Human Services

**2. Where is it located?**

903 South 4<sup>th</sup> Street  
Hamilton, MT 59840, USA

**3. Floor area of laboratory areas by containment level:**

BL2(sqM)	1361
BL3(sqM)	55.7
BL4(sqM)	630.85
Total (sqM)	2047.55

**4. The organizational structure of each facility.**

**I Total number of personnel:** 87

**II Division of personnel:**

Military	0
Civilian	87

**III Division of personnel by category:**

Scientists	61
Engineers	0
Technicians	26
Administrative and support staff	0

**IV List the scientific disciplines represented in the scientific/engineering staff.**

Bacteriology  
Biology  
Chemistry  
Medicine  
Prionology  
Rickettsiology

Virology

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number:        5

**VI. What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Health and Human Services (Appropriated Funding)

**VII. What are the funding levels for the following program areas:**

Research	\$ 24,591,429
Development	\$            0
Test and evaluation	\$            0
Total	\$ 24,591,429

**VIII Briefly describe the publication policy of the facility:**

All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (<http://publicaccess.nih.gov/policy.htm>) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the National Library of Medicine's digital archive PubMed Central upon acceptance for publication. To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

**IX. Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)**

The Francisella tularensis pathogenicity island encodes a secretion system that is required for phagosome escape and virulence. Barker JR, Chong A, Wehrly TD, Yu JJ, Rodriguez SA, Liu J, Celli J, Arulanandam BP, Klose KE. Mol Microbiol. 2009 Dec;74(6):1459-70.

Restricted cytosolic growth of Francisella tularensis subsp. tularensis by IFN- $\gamma$  activation of macrophages. Edwards JA, Rockx-Brouwer D, Nair V, Celli J. Microbiology. 2009 Nov 19. [Epub ahead of print]

Acid phosphatases do not contribute to the pathogenesis of type A Francisella tularensis. Child R, Wehrly TD, Rockx-Brouwer D, Dorward DW, Celli J. Infect Immun. 2010 Jan;78(1):59-67. Epub 2009 Oct 26.

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A Legionella pneumophila effector protein encoded in a region of genomic plasticity binds to Dot/Icm-modified vacuoles. Ninio S, Celli J, Roy CR. PLoS Pathog. 2009 Jan;5(1):e1000278. Epub 2009 Jan 23.

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Structure of the flexible amino-terminal domain of prion protein bound to a sulfated glycan. Taubner LM, Bienkiewicz EA, Copié V, Caughey B. J Mol Biol. 2010 Jan 22;395(3):475-90. Epub 2009 Nov 10.

Distinct structures of scrapie prion protein (PrP<sup>Sc</sup>)-seeded versus spontaneous recombinant prion protein fibrils revealed by hydrogen/deuterium exchange. Smirnovas V, Kim JI, Lu X, Atarashi R, Caughey B, Surewicz WK. J Biol Chem. 2009 Sep 4;284(36):24233-41. Epub 2009 Jul 13.

Human variant Creutzfeldt-Jakob disease and sheep scrapie PrP(res) detection using seeded conversion of recombinant prion protein. Orrú CD, Wilham JM, Hughson AG, Raymond LD, McNally KL, Bossers A, Ligios C, Caughey B. Protein Eng Des Sel. 2009 Aug;22(8):515-21. Epub 2009 Jul 1.

Getting a grip on prions: oligomers, amyloids, and pathological membrane interactions. Caughey B, Baron GS, Chesebro B, Jeffrey M. Annu Rev Biochem. 2009;78:177-204. Review.

Recent advances in prion chemotherapeutics. Sim VL, Caughey B. Infect Disord Drug Targets. 2009 Feb;9(1):81-91. Review.

Ultrastructures and strain comparison of under-glycosylated scrapie prion fibrils. Sim VL, Caughey B. Neurobiol Aging. 2009 Dec;30(12):2031-42. Epub 2008 Apr 3.

Susceptibilities of nonhuman primates to chronic wasting disease. Race B, Meade-White KD, Miller MW, Barbian KD, Rubenstein R, LaFauci G, Cervenakova L, Favara C, Gardner D, Long D, Parnell M, Striebel J, Priola SA, Ward A, Williams ES, Race R, Chesebro B. Emerg Infect Dis. 2009 Sep;15(9):1366-76.

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Cells expressing anchorless prion protein are resistant to scrapie infection. McNally KL, Ward AE, Priola SA. J Virol. 2009 May;83(9):4469-75. Epub 2009 Feb 18.

Prion protein misfolding and disease. Moore RA, Taubner LM, Priola SA. Curr Opin Struct Biol. 2009 Feb;19(1):14-22. Epub 2009 Jan 20. Review.

Burkholderia mallei cluster 1 type VI secretion mutants exhibit growth and actin polymerization defects in RAW 264.7 murine macrophages. Burtneck MN, DeShazer D, Nair V, Gherardini FC, Brett PJ. Infect Immun. 2010 Jan;78(1):88-99. Epub 2009 Nov 2.

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A systematic approach to evaluate humoral and cellular immune responses to Coxiella burnetii immunoreactive antigens. Chen C, Bouman TJ, Beare PA, Mertens K, Zhang GQ, Russell-Lodrigue KE, Hogaboam JP, Peters B, Felgner PL, Brown WC, Heinzen RA, Hendrix LR, Samuel JE. Clin Microbiol Infect. 2009 Mar 11. [Epub ahead of print] No abstract available

Host cell-free growth of the Q fever bacterium Coxiella burnetii. Omsland A, Cockrell DC, Howe D, Fischer ER, Virtaneva K, Sturdevant DE, Porcella SF, Heinzen RA. Proc Natl Acad Sci U S A. 2009 Mar 17;106(11):4430-4. Epub 2009 Feb 25.

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Characterization of a Coxiella burnetii ftsZ mutant generated by Himar1 transposon mutagenesis. Beare PA, Howe D, Cockrell DC, Omsland A, Hansen B, Heinzen RA. J Bacteriol. 2009 Mar;191(5):1369-81. Epub 2008 Dec 29.

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Sustained activation of Akt and Erk1/2 is required for Coxiella burnetii antiapoptotic activity. Voth DE, Heinzen RA. Infect Immun. 2009 Jan;77(1):205-13. Epub 2008 Nov 3.

Adaptive immunity to the obligate intracellular pathogen Coxiella burnetii. Shannon JG, Heinzen RA. Immunol Res. 2009;43(1-3):138-48. Review.

The presence of CD14 overcomes evasion of innate immune responses by virulent Francisella tularensis in human dendritic cells in vitro and pulmonary cells in vivo. Chase JC, Bosio CM. Infect Immun. 2010 Jan;78(1):154-67. Epub 2009 Oct 19.

A novel role for plasmin-mediated degradation of opsonizing antibody in the evasion of host immunity by virulent, but not attenuated, Francisella tularensis. Crane DD, Warner SL, Bosio CM. J Immunol. 2009 Oct 1;183(7):4593-600. Epub 2009 Sep 14.

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Intracellular biology and virulence determinants of Francisella tularensis revealed by transcriptional profiling inside macrophages. Wehrly TD, Chong A, Virtaneva K, Sturdevant DE, Child R, Edwards JA, Brouwer D, Nair V, Fischer ER, Wicke L, Curda AJ, Kupko JJ 3rd, Martens C, Crane DD, Bosio CM, Porcella SF, Celli J. Cell Microbiol. 2009 Jul;11(7):1128-50. Epub 2009 Mar 18.

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Disease modeling for Ebola and Marburg viruses. Bente D, Gren J, Strong JE, Feldmann H. Dis Model Mech. 2009 Jan-Feb;2(1-2):12-7.

The Ebola virus ribonucleoprotein complex: a novel VP30-L interaction identified. Groseth A, Charton JE, Sauerborn M, Feldmann F, Jones SM, Hoenen T, Feldmann H. Virus Res. 2009 Mar;140(1-2):8-14. Epub 2008 Dec 16.

Chimeric human parainfluenza virus bearing the Ebola virus glycoprotein as the sole surface protein is immunogenic and highly protective against Ebola virus challenge. Bukreyev A, Marzi A, Feldmann F, Zhang L, Yang L, Ward JM, Dorward DW, Pickles RJ, Murphy BR, Feldmann H, Collins PL. Virology. 2009 Jan 20;383(2):348-61. Epub 2008 Nov 17.

Limited transcriptional responses of Rickettsia rickettsii exposed to environmental stimuli. Ellison DW, Clark TR, Sturdevant DE, Virtaneva K, Hackstadt T. PLoS One. 2009;4(5):e5612. Epub 2009 May 19.

Induction of Salmonella Pathogenicity Island 1 under different growth conditions can affect Salmonella-host cell interactions in vitro. Ibarra JA, Knodler LA, Sturdevant DE, Virtaneva K, Carmody AB, Fischer ER, Porcella SF, Steele-Mortimer O. Microbiology. 2009 Dec 24. [Epub ahead of print]

Salmonella--the ultimate insider. Salmonella virulence factors that modulate intracellular survival. Ibarra JA, Steele-Mortimer O. Cell Microbiol. 2009 Nov;11(11):1579-86. Epub 2009 Sep 23. Review.

Ubiquitination of the bacterial inositol phosphatase, SopB, regulates its biological activity at the plasma membrane. Knodler LA, Winfree S, Drecktrah D, Ireland R, Steele-Mortimer O. Cell Microbiol. 2009 Nov;11(11):1652-70. Epub 2009 Jul 13.

The capsid proteins of Aleutian mink disease virus (AMDV) activate caspases and are specifically cleaved during infection. Cheng F, Chen AY, Best SM, Bloom ME, Pintel D, Qiu J. J Virol. 2009 Dec 30. [Epub ahead of print]

Potential impact of a 2-person security rule on BioSafety Level 4 laboratory workers. LeDuc JW, Anderson K, Bloom ME, Carrion R Jr, Feldmann H, Fitch JP, Geisbert JB, Geisbert TW, Holbrook MR, Jahrling PB, Ksiazek TG. Emerg Infect Dis. 2009 Jul;15(7):e1.

Tick-borne flaviviruses: dissecting host immune responses and virus countermeasures. Robertson SJ, Mitzel DN, Taylor RT, Best SM, Bloom ME. Immunol Res. 2009;43(1-3):172-86.

Analysis of protein levels of 24 cytokines in scrapie agent-infected brain and glial cell cultures from mice differing in prion protein expression levels. Tribouillard-Tanvier D, Striebel JF, Peterson KE, Chesebro B. J Virol. 2009 Nov;83(21):11244-53. Epub 2009 Aug 26.

Prion infectivity in fat of deer with chronic wasting disease. Race B, Meade-White K, Race R, Chesebro B. J Virol. 2009 Sep;83(18):9608-10. Epub 2009 Jul 1.

Prion protein on astrocytes or in extracellular fluid impedes neurodegeneration induced by truncated prion protein. Race B, Meade-White K, Race R, Baumann F, Aguzzi A, Chesebro B. Exp Neurol. 2009 Jun;217(2):347-52. Epub 2009 Mar 28.

Getting a grip on prions: oligomers, amyloids, and pathological membrane interactions. Caughey B, Baron GS, Chesebro B, Jeffrey M. Annu Rev Biochem. 2009;78:177-204. Review.

Phosphoglucosyltransferase of Yersinia pestis is Required for Autoaggregation and Polymyxin B Resistance. Felek S, Muszynski A, Carlson RW, Tsang TM, Hinnebusch BJ, Krukoni ES. Infect Immun. 2009 Dec 22. [Epub ahead of print]

The Yersinia pestis caf1M1A1 fimbrial capsule operon promotes transmission by flea bite in a mouse model of bubonic plague. Sebbane F, Jarrett C, Gardner D, Long D, Hinnebusch BJ. Infect Immun. 2009 Mar;77(3):1222-9. Epub 2008 Dec 22.

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols:**

**I Objectives:**

NIH RML scientists broadly study pathogens that cause viral hemorrhagic fevers, viral encephalitis, and certain respiratory diseases. This work employs investigations in cell culture; animal models, including nonhuman primates; reservoir species; and arthropod hosts in order to elucidate the viral pathogenesis, immune responses, molecular evolution, cellular and molecular biology, and vector-host interactions. Specifically, studies include pathogenesis and pathophysiology of high-containment pathogens using molecular technologies; immune responses to infection and vaccination of viral pathogens; vector/reservoir transmission of viral pathogens and development of new vaccine candidates; *in vitro* and *in vivo* systems to study the interactions between viral pathogens or viral components and host cells; and epidemiology and ecology of pathogens.

Research activities address pathogenesis studies, vaccinology, and development of therapeutic countermeasures and rapid diagnostic assays in support of the civilian biodefense program.

**II Agents:**

- **HHS Select Agents and Toxins**  
Including NIAID Category A, B and C Priority Pathogens
- **Overlap Select Agents**  
Including NIAID Category A and B Priority Pathogens
- **Other pathogens or toxins**  
Including non-Select Agent, NIAID Category A, B and C Priority Pathogens  
Including other non-Select Agent, non-NIAID Category A, B and C Priority Pathogens
- **Simulants**

**III Outdoor Studies:**

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\* Including viruses and prions.

None

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

Dale and Betty Bumpers Vaccine Research Center  
National Institutes of Health, US Department of Health and Human Services

**2. Where is it located?**

9000 Rockville Pike  
Bethesda, Maryland, USA 20892

**3. Floor area of laboratory areas by containment level:**

BL2(sqM)	88.5
BL3(sqM)	0
BL4 (sqM)	0
Total (sqM)	88.5

**4. The organizational structure of each facility.**

**I Total number of personnel:** 7

**II Division of personnel:**

Military	0
Civilian	7

**III Division of personnel by category:**

Scientists	7
Engineers	0
Technicians	0
Administrative and support staff	0

**IV List the scientific disciplines represented in the scientific/engineering staff.**

Biology  
Biochemistry  
Immunology  
Infectious Disease  
Microbiology  
Molecular Biology

Virology

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number:        2

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Health and Human Services

**VII What are the funding levels for the following program areas:**

Research	\$ 740,396
Development	\$ 0
Test and evaluation	\$ 0
Total	\$ 740,396

**VIII Briefly describe the publication policy of the facility:**

All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (<http://publicaccess.nih.gov/policy.htm>) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the National Library of Medicine's digital archive PubMed Central upon acceptance for publication. To help advance science and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

**IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)**

Correlates of protective immunity for Ebola vaccines: implications for regulatory approval by the animal rule. Sullivan NJ, Martin JE, Graham BS, Nabel GJ. *Nat Rev Microbiol.* 2009 May;7(5):393-400. Review. Erratum in: *Nat Rev Microbiol.* 2009 Sep;7(9):684.

Philosophy of science. The coordinates of truth. Nabel GJ. *Science.* 2009 Oct 2;326 (5949):53-4.

Public health. Rethinking influenza. Rappuoli R, Del Giudice G, Nabel GJ, Osterhaus AD, Robinson R, Salisbury D, Stöhr K, Treanor JJ. *Science.* 2009 Oct 2;326 (5949):50.

Graham BS, Ledgerwood JE, Nabel GJ. Vaccine development in the twenty-first century: changing paradigms for elusive viruses. *Clin Pharmacol Ther.* 2009 Sep;86 (3):234-6.

Ledgerwood JE, Graham BS. DNA vaccines: a safe and efficient platform technology for responding to emerging infectious diseases. *Hum Vaccin*. 2009 Sep;5(9):623-6.

Moore J., Roederer M. The flow cytometry shared resource laboratory: best practices to assure a high-quality, cost-effective partnership with biomedical research laboratories. *Cytometry A*. 2009 Aug;75(8):643-9.

Sun Y, Bailer RT, Rao SS, Mascola JR, Nabel GJ, Koup RA, Letvin NL. Systemic and mucosal T-lymphocyte activation induced by recombinant adenovirus vaccines in rhesus monkeys. *J Virol*. 2009 Oct;83(20):10596-604.

Santra S, Sun Y, Koriath-Schmitz B, Fitzgerald J, Charbonneau C, Santos G, Seaman MS, Ratcliffe SJ, Montefiori DC, Nabel GJ, Ertl HC, Letvin NL. Heterologous prime/boost immunizations of rhesus monkeys using chimpanzee adenovirus vectors. *Vaccine*. 2009 Sep 25;27(42):5837-45. Epub 2009 Aug 4.

The Size of the Viral Inoculum Contributes to the Outcome of Hepatitis B Virus Infection. Asabe S, Wieland SF, Chattopadhyay PK, Roederer M, Engle RE, Purcell RH, Chisari FV. *J Virol*. 2009 Jul 22.

Different Vaccine Vectors Delivering the Same Antigen Elicit CD8+ T Cell Responses with Distinct Clonotype and Epitope Specificity. Honda M, Wang R, Kong WP, Kanekiyo M, Akahata W, Xu L, Matsuo K, Natarajan K, Robinson H, Asher TE, Price DA, Douek DC, Margulies DH, Nabel GJ. *J Immunol*. 2009 Jul 20.

Protecting against future shock--inhalational anthrax. Nabel GJ *N Engl J Med*. 2009 Jul 9;361(2):191-3.

Flow cytometry and the future of vaccine development. Bolton DL, Roederer M *Expert Rev Vaccines*. 2009 Jun;8(6):779-89.

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols:**

**I Objectives:**

The research focus of the Biodefense Research Laboratory, Vaccine Research Center (VRC) comprises three areas:

1. Development of vaccines and antivirals
2. Studies of the mechanism of vaccine-induced immune protection
3. Basic research to understand the mechanism of virus replication (entry) and neutralization

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\* Including viruses and prions.

## **II Agents:**

- **HHS Select Agents and Toxins**  
Including NIAID Category A, B, and C Priority Pathogens
- **Overlap Select Agents**  
Including NIAID Category B Priority Pathogens
- **Other pathogens or toxins**  
Including non-Select Agent, NIAID Category A, B and C Priority Pathogens  
Including other non-Select Agent, non-NIAID Category A, B and C Priority Pathogens
- **Simulants**

## **III Outdoor Studies:**

None

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

Coordinating Center for Infectious Diseases (CCID)  
Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

**2. Where is it located?**

1600 Clifton Road N.E.  
Atlanta, GA 30333  
USA

**3. Floor area of laboratory areas by containment level:**

BL2(sqM)	328
BL3(sqM)	1975
BL4(sqM)	937
Total(sqM)	3240

**4. The organizational structure of each facility.**

**I Total number of personnel:** 699

**II Division of personnel:**

Military	0
Civilian	699

**III Division of personnel by category:**

Scientists	253
Engineers	5 (maintenance & security system engineers)
Technicians	45
Administrative and support staff	396

**IV List the scientific disciplines represented in the scientific/engineering staff.**

Biology  
Environmental engineering  
Epidemiology  
Medicine  
Microbiology

Molecular biology  
Public health  
Statistics

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number:        117 (approximately)  
                                 20 scientific staff (approximately)  
                                 49 technicians and support staff (approximately)  
                                 48 security personnel also have clearance (approximately)

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Centers for Disease Control and Prevention (most)  
Environmental Protection Agency (EPA) (some)

**VII What are the funding levels for the following program areas:**

Total funding:  
\$31,000,000 (estimated) Centers for Disease Control and Prevention  
\$ 350,000 (estimated) The Environmental Protection Agency (EPA) for CDC projects,  
including some carried out at CCID.

Research	88%
Development	6%
Test and evaluation	6%
Total	100%

**VIII Briefly describe the publication policy of the facility:**

Publication is encouraged and managed by editorial and clearance policies conducted at all levels of the Agency.

The clearance policy for information products disseminated outside CDC for public use is available online at: <http://www.cdc.gov/od/science/policies/clearance.htm>

CDC Policy on "Oversight and clearance of dual use research of concern" is available online at: <http://www.cdc.gov/OD/foia/policies/policy516.pdf>

**IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)**

Azziz-Baumgartner E, Smith N, Gonzalez-Alvarez R, Daves S, Layton M, Linares N, Richardson-Smith N, Bresee J, Mounts A. National pandemic influenza preparedness planning. *Influenza and Other Respiratory Viruses*. 2009;3:189-96.

Baskin CR, Bielefeldt-Ohmann H, Tumpey TM, Sabourin PJ, Long JP, Garcia-Sastre A, Tolnay AE, Albrecht R, Pyles JA, Olson PH, Aicher LD, Rosenzweig ER, Murali-Krishna K, Clark EA, Kotur MS, Fornek JL, Proll S, Palermo RE, Sabourin CL, Katze MG. Early and sustained innate immune response defines pathology and death in nonhuman primates infected by highly pathogenic influenza virus. *Proceedings of the National Academy of Science*. 2009;106(9):3455-60.

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Belser JA, Wadford DA, Xu J, Katz JM, Tumpey TM. Ocular infection of mice with influenza A (H7) viruses: A site of primary replication and spread to the respiratory tract. *Journal of Virology*. 2009;83(14):7075-84.

Belser JA, Lu X, Katz JM, Wurtman DF, Yu M, Fang F. (Reply) DAS181 and H5N1 virus infection. *Journal of Infectious Diseases*. 2009;199:1250-1.

Belser JA, Bridges CB, Katz JM, Tumpey TM. Past, present, and possible future human infection with influenza virus A subtype H7. *Emerging Infectious Diseases*. 2009;15(6):859-65.

Billharz R, Zeng H, Proll SC, Korth MJ, Lederer S, Albrecht R, Goodman AG, Rosenzweig E, Tumpey TM, Garcia-Sastre A, Katze MG. The NS1 protein of the 1918 pandemic influenza virus blocks host interferon and lipid metabolism pathways. *Journal of Virology*. 2009;83(20):10557-70.

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**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols:**

**I Objectives:**

Activities include testing and diagnostic assay development, molecular and antigenic characterization, decontamination studies, vaccine development, pathogenesis and natural history studies.

**II Agents:**

- **HHS Select Agents and Toxins**  
Including NIAID Category A, B, and C Priority Pathogens
- **Overlap Select Agents**  
Including NIAID Category A, B, and C Priority Pathogens
- **Other pathogens or toxins**  
Including non-Select Agent, NIAID Category A, B, and C Priority Pathogens  
Including other non-Select Agents, non-NIAID Category A, B, and C Priority Pathogens
- **Simulants**

**III Outdoor Studies:**

None

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\* Including viruses and prions.

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

Division of Vector-borne Infectious Diseases (DVBID)  
Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

**2. Where is it located?**

3150 Rampart Road  
Fort Collins, CO 80521  
USA

**3. Floor area of laboratory areas by containment level:**

BL2(sqM)	65.84
BL3(sqM)	1141.57
BL4(sqM)	0
Total(sqM)	1207.41

**4. The organizational structure of each facility.**

**I Total number of personnel:** 154

**II Division of personnel:**

Military	0
Civilian	154

**III Division of personnel by category:**

Scientists	86
Engineers	6
Technicians	0
Administrative and support staff	68

**IV List the scientific disciplines represented in the scientific/engineering staff.**

Biology  
Ecology  
Electrical Engineering  
Entomology



**IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)**

Eisen RJ, Yockey B, Young J, Reese SM, Piesman J, Schriefer ME, Beard CB, Petersen JM. Short Report: Time Course of Hematogenous Dissemination of *Francisella tularensis* A1, A2, and Type B in Laboratory Mice. *Am. J. Trop. Med. Hyg.*, 80(2), 2009 Feb, pp. 259-262

Claudia R. Molins, Jennifer K. Carlson, Jana Coombs, Jeannine M. Petersen. Identification of *Francisella tularensis* subsp. *tularensis* A1 and A2 infections by real-time polymerase chain reaction. *Diagnostic Microbiology and Infectious Disease* 2009 May;64(1):6-12. Epub 2009 Feb 18

Erik Machado-Ferreira, Joseph Piesman, Nordin S. Zeidner, and Carlos A. G. Soares. *Francisella*-Like Endosymbiont DNA and *Francisella tularensis* Virulence-Related Genes in Brazilian Ticks (Acari: Ixodidae). *J Med Entomol.* 2009 Mar;46(2):369-374(6)

Petersen JM, Mead PS, Schriefer ME. *Francisella tularensis*: an arthropod-borne pathogen. *Vet Res.* 2009 Mar-Apr;40(2):7. Epub 2008 Oct 28

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Kugeler KJ, Mead PS, Janusz AM, Staples JE, Kubota KA, Chalcraft LG, Petersen JM. Molecular Epidemiology of *Francisella tularensis* in the United States. *Clin Infect Dis.* 2009 Apr 1;48(7):863-70

Eisen RJ, Gage KL. Adaptive strategies of *Yersinia pestis* to persist during inter-epizootic and epizootic periods. *Vet Res.* 2009 Mar-Apr;40(2):1. Epub 2008 Sep 23.

Champion MD, Zeng Q, Nix EB, Nano FE, Keim P, Kodira CD, Borowsky M, Young S, Koehrsen M, Engels R, Pearson M, Howarth C, Larson L, Whie J, Alvarado L, Forsman M, Bearden SW. Comparative genomic characterization of *Francisella tularensis* strains belonging to low and high virulence subspecies. *PLoS Pathog.* 2009 May;5(5):e1000459. Epub 2009 May 29

Bearden SW, Sexton C, Pare J, Fowler JM, Arvidson CG, Yerman L, Viola RE, Brubaker RR. Attenuated enzootic (pestoides) isolates of *Yersinia pestis* express active aspartase. *Microbiology* 2009 Jan;155 (Pt 1):198-209

Enscore R. Flea Diversity and Infestation Prevalence on Rodents in a Plague-Endemic Region of Uganda. *Am. J. Trop. Med. Hyg.* 81(4), 2009, pp 718-724

Eisen, RJ. Studies of vector competency and efficiency of North American fleas for *Yersinia pestis*: state of the field and future research needs. *J Med Entomol* 2009 Jul; 46(4): 737-44

Mead PS. Plague (Bubonic, Pneumonic, Septicemic). Book: Chapter 5 - Plague (Bubonic, Pneumonic, Septicemic) - 2010 Yellow Book, CDC Travelers' Health

Petersen, JM. Primary Pneumonic Plague Contracted from a Mountain Lion Carcass. *Clinical Infectious Diseases* 2009 Aug 1; 49:e33-8

Lowell J. Colorado animal-based plague surveillance systems: relationships between targeted animal species and prediction efficacy of areas at risk for humans. *Journal of Vector Ecology* 34(1): 22-31, 2009

Colman RE, Vogler AJ, Lowell JL, Gage KL, Morway C, Reynolds PJ, Ettestad P, Keim P, Kosoy MY, Wagner DM. Fine-scale Identification of the Most Likely Source of a Human Plague Infection. *Emerg Infect Dis.* 2009 Oct;15(10):1623-5

Stapp P, Salkeld DJ, Franklin HA, Kraft JP, Tripp DW, Antolin MF, Gage KL. Evidence for the involvement of an alternate rodent host in the dynamics of introduced plague in prairie dogs. *J Anim Ecol.* 2009 Jul;78(4):807-17. Epub 2009 Mar 17

Tripp DW, Gage KL, Montenieri JA, Antolin MF. Flea abundance on black-tailed prairie dogs (*Cynomys ludovicianus*) increases during plague epizootics. *Vector Borne Zoonotic Dis.* 2009 Jun; 9(3):313-21

Robinson JB, Telepnev MV, Zudina IV, Bouyer D, Montenieri JA, Bearden SW, Gage KL, Agar SL, Foltz SM, Chauhan S, Chopra AK, Motin VL. Evaluation of a *Yersinia pestis* mutant impaired in a thermoregulated type VI-like secretion system in flea, macrophage and murine models. *Microb Pathog.* 2009 Nov;47(5):243-51. Epub 2009 Aug 27

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols:**

**I Objectives:**

Activities address assay development, molecular and antigenic characterization, decontamination studies, vaccine development, pathogenesis and natural history studies.

**II Agents:**

- **HHS Select Agents and Toxins**  
Including NIAID Category A, B, and C Priority Pathogens
- **Overlap Select Agents**  
Including NIAID Category A and B Priority Pathogens

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\* Including viruses and prions.

- **USDA Select Agents**  
Including NIAID Category B Priority Pathogen
- **Other pathogens or toxins**  
Including non-Select Agent, NIAID Category A and B Priority Pathogens  
Including other non-Select Agent, non-NIAID Category A, B and C Priority Pathogens
- **Simulants**

**III Outdoor Studies:**

None

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

Mass Spectrometry Toxin Laboratory  
Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

**2. Where is it located?**

4770 Buford Highway  
Mail stop F-47  
Atlanta, GA 30341

**3. Floor area of laboratory areas by containment level:**

BL2(sqM)	114
BL3(sqM)	0
BL4(sqM)	0
Total(sqM)	114

**4. The organizational structure of each facility.**

**I Total number of personnel:** 30

**II Division of personnel:**

Military	0
Civilian	30

**III Division of personnel by category:**

Scientists	27
Engineers	0
Technicians	0
Administrative and support staff	3

**IV List the scientific disciplines represented in the scientific/engineering staff.**

Analytical Chemistry  
Biochemistry  
Mass spectrometry  
Microbiology

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number:        4

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

Centers for Disease Control and Prevention

**VII What are the funding levels for the following program areas:**

Total funding:  
\$3,700,000              Centers for Disease Control and Prevention

Research	100%
Development	
Test and evaluation	
Total	100%

**VIII Briefly describe the publication policy of the facility:**

Scientists are encouraged to publish their results in the peer reviewed scientific literature as well as present their work at national and international professional meetings.

The clearance policy for information products disseminated outside CDC for public use is available online at: <http://www.cdc.gov/od/science/policies/clearance.htm>

CDC Policy on "Oversight and clearance of dual use research of concern," is available online at: <http://www.cdc.gov/OD/foia/policies/policy516.pdf>

**IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)**

Boyer AE, Quinn CP, Hoffmaster AR, Kozel TR, Saile E, Marston CK, Percival A, Plikaytis BD, Woolfitt AR, Gallegos M, Sabourin P, McWilliams LG, Pirkle JL, Barr JR. Kinetics of lethal factor and poly-D-glutamic acid antigenemia during inhalation anthrax in rhesus macaques. *Infect Immun.* 2009 Aug; 77(8):3432-41.

Kalb SR, Barr JR. Mass spectrometric detection of ricin and its activity in food and clinical samples. *Anal Chem.* 2009 Mar 15;81(6):2037-42.

Kalb SR, Lou J, Garcia-Rodriguez C, Geren IN, Smith TJ, Moura H, Marks JD, Smith LA, Pirkle JL, Barr JB. Extraction and Inhibition of Enzymatic Activity of BoNT A1, A2, and A3 by a Panel of Monoclonal anti-BoNT A Antibodies. *PLoS One*, 2009, 4(4), e5355.

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols:**

**I Objectives:**

The CDC Mass Spectrometry Toxin Laboratory has successfully developed toxin assays that are critical for better detection and diagnosis during a public health response to biological toxins. The laboratory uses advanced mass spectrometry techniques to measure peptides and proteins that are in the pathogenic pathway of the infectious agent or toxin and uses these measurements to identify and track infection or poisoning.

**II Agents:**

- **HHS Select Agents and Toxins**  
Including NIAID Category A and B Priority Pathogens

**III Outdoor Studies:**

None

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\* Including viruses and prions.

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

Foreign Disease-Weed Science Research Unit  
Agricultural Research Service, United States Department of Agriculture

**2. Where is it located?**

1301 Ditto Avenue,  
Fort Detrick, Maryland, 21702, USA

**3. Floor area of laboratory areas by containment level:**

BL2 (sqM)	105	BL-2 laboratories; enhanced by HEPA air filtration.
BL3 (sqM)	950	BL3 plant pathogen containment facility with HEPA air filtration, steam sterilization of wastewater and personnel shower-out procedures.
BL4 (sqM)	0	
Total (sqM)	1055	

**4. The organizational structure of each facility.**

**I Total number of personnel:** 44

**II Division of personnel:**

Military 0  
Civilian 44

**III Division of personnel by category:**

Scientists 13 (Principal Investigators)  
Engineers 0  
Technicians 24  
Administrative and support staff 7

**IV List the scientific disciplines represented in the scientific/engineering staff.**

Agronomy  
Biological control  
Horticulture  
Plant Biochemistry

Plant Molecular Biology  
Plant Pathology (including plant virology, bacteriology, and mycology)  
Plant Physiology  
Weed Science

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number:              1 (Janitorial)

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Agriculture, Agricultural Research Service (100%)

**VII What are the funding levels for the following program areas:**

Research	\$5,600,000
Development	\$ 0
Test and evaluation	\$ 0
Total	\$5,600,000

**VIII Briefly describe the publication policy of the facility:**

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and publish in books and proceedings. No classified research is conducted at this facility.

**IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)**

Luster, D.G., Fletcher, J., Melcher, U., Sherwood, J. 2008. Microbial Forensics and Plant Pathogens. Wiley Handbook of Science Technology for Homeland Security. DOI: 10.1002/9780470087923.hhs391 (online posting)

Kolomiets, T., Mukhina, Z., Matveeva, T., Bogomaz, D., Berner, D.K., Cavin, C.A., Castlebury, L.A. 2009. First report of stem canker of *Salsola tragus* caused by *Diaporthe* in Russia. Plant Disease. 93:110.

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**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols:**

**I Objectives:**

- Develop detection arrays and diagnostic systems for new and emerging plant pathogens;
- Identify genomic and phenotypic elements to characterize emerging and foreign plant pathogens;
- Investigate molecular and biological factors in pathogen/host/vector systems that affect host adaptation, vector adaptation, and evolution of new pathogenic forms;
- Investigate critical factors that influence developmental and circulative processes of vector transmission in new or emerging plant pathogenic diseases;
- Identify germplasm resistant to new and emerging pathogens; and
- Develop Oomycete management strategies.

**II Agents:**

- **USDA (PPQ) Select Agents and Toxins**

The agents studied are foreign and/or emerging pathogens of plants that have an agricultural base. The agents studied include viruses, bacteria, and fungi. The majority of the agents studied are not classified by USDA as select agents. The agents classified as select agents are pathogens that pose a threat to our plant production systems, our agricultural economy, and exports.

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\* Including viruses and prions.

**III Outdoor Studies:**  
None

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

National Animal Disease Center (NADC)  
Agricultural Research Service, United States Department of Agriculture

**2. Where is it located?**

1920 Dayton Avenue,  
Ames, IA 50010

**3. Floor area of laboratory areas by containment level:**

**Laboratory**

BL2 (sqM)	4410
BL3 (sqM)	509
BL4 (sqM)	0
Total (sqM)	4919

**Animal**

BSL3Ag (sqM)	1980
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BSL3Ag Large Animal Space - enhancements include HEPA-filtered supply air; dual HEPA filtered exhaust; air-tight doors; shower-in /out of each animal room; Heat-treated waste; Steam-treated rendering for carcasses; stainless steel penning and gating systems; epoxy-coated floors, epoxy-covered surfaces.

**4. The organizational structure of each facility.**

**I Total number of personnel:** 297

**II Division of personnel:**

Military	0
Civilian	297

**III Division of personnel by category:**

Scientists	49
Engineers	0
Technicians	70
Administrative and support staff	178

**IV List the scientific disciplines represented in the scientific/engineering staff.**

Immunology  
Microbiology  
Molecular Biology  
Physiology  
Veterinary Medicine  
Virology

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number:        3 (Cafeteria Employees)

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Agriculture, Agricultural Research Service (100%)

**VII What are the funding levels for the following program areas:**

Research	\$32,100,000
Development	\$            0
Test and evaluation	\$            0
Total	\$32,100,000

**VIII Briefly describe the publication policy of the facility:**

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and publish in books and proceedings. No classified research is conducted at this facility.

**IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)**

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Zuerner, R.L., Cameron, C.E., Raverty, S., Robinson, J., Colegrove, K., Norman, S.A., Lambourn, D., Jeffries, S., Alt, D.P., Gulland, F. 2009. Geographical Dissemination of *Leptospira interrogans* serovar Pomona During Seasonal Migration of California Sea Lions. *Veterinary Microbiology*. 137(1-2):105-110.

**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols:**

**I Objectives:**

Provide scientific information to solutions in the control and eradication of national and international exotic, emerging, zoonotic, and endemic infectious diseases of animals through a comprehensive research program emphasizing basic and applied research in diagnostics, prevention, and control strategies, prediction of disease outbreaks, molecular epidemiology, and understanding disease pathogenesis.

The objectives of the research programs are to produce new research knowledge and technology to:

- prevent, reduce or eliminate losses from impaired performance, and increased deaths and condemnations;

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\* Including viruses and prions.

- develop more sensitive, specific and faster diagnostic tests;
- develop vaccines designed for the control and, when feasible, the eradication of disease;
- improve our understanding of the ecology and epidemiology of pathogens at the domestic-wild life interface; and
- improve our understanding of the genetic and pathobiological basis of virulence.

This research provides government regulatory agencies and the livestock industries with improved intervention strategies against priority diseases.

## **II Agents:**

- **USDA Select Agents and Toxins**
- **USDA OVERLAP Select Agents and Toxins**  
Including NIAID Category B priority pathogens
- **Other pathogens or toxins**  
Including non-Select Agent, NIAID Category B priority pathogens

The agents studied are endemic and emerging viruses and bacteria that cause diseases in livestock and poultry. The majority of the agents studied are not classified by USDA as select agents. The agents classified as select agents are pathogens that are zoonotic agents (diseases transmitted from animals to people) that pose a threat to our animal production systems, our agricultural economy, and agricultural exports.

## **III Outdoor Studies:**

No research work is done outdoors with infectious organisms. Outdoor studies are conducted only for ecological purposes and monitoring of bacteria, viruses, and prions in wild life.

**National biological defence research and development programme**

**III. Facilities**

**1. What is the name of the facility?**

Southeast Poultry Research Laboratory  
Agricultural Research Service, United States Department of Agriculture

**2. Where is it located?**

934 College Station Road  
Athens GA 30605 USA

**3. Floor area of laboratory areas by containment level:**

BL2 (sqM)	1138 (non-Select Agent research)
BL3 (sqM)	624
BL4 (sqM)	0
Total (sqM)	1762

**4. The organizational structure of each facility.**

**I Total number of personnel:** 43

**II Division of personnel:**

Military	0
Civilian	43

**III Division of personnel by category:**

Scientists	11
Engineers	0
Technicians	19
Administrative and support staff	13

**IV List the scientific disciplines represented in the scientific/engineering staff.**

Immunologist  
Microbiologist  
Molecular Biologist  
Veterinarian  
Virologist

**V Are contractor staff working in the facility? If so, provide an approximate number:**

Yes                      Number              3

**VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?**

U.S. Department of Agriculture, Agricultural Research Service (80%)

Extramural (20%):

Centers for Disease Control

U.S. Department of Homeland Security

USAID

Non-profit Associations

Private companies

**VII What are the funding levels for the following program areas:**

Research	\$5,800,000
Development	\$ 0
Test and evaluation	\$ 0
Total	\$5,800,000

**VIII Briefly describe the publication policy of the facility:**

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and publish in books and proceedings.

No classified research is conducted at this facility.

**IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles and full references.)**

Adcock, N.J., Rice, E.W., Sivaganesan, M., Brown, J.D., Stallknecht, D.E., Swayne, D.E. 2009. The use of bacteriophages of the family Cystoviridae as surrogates for H5N1 highly pathogenic avian influenza viruses in persistence and inactivation studies. *Journal of Environmental Science and Health, Part A*, 44(13):1362-1366.

Bogoyavlenskiy, A., Berezin, V., Prilipov, A.G., Usachev, E.V., Lyapina, O.V., Korotetskiy, I.S., Zaitceva, I.A., Asanova, S.E., Kydyrmanov, A., Daulbaeva, K., Shakhvorostova, L.M., Sayatov, M.K., King, D.J. 2009. Newcastle disease outbreaks in Kazakhstan and Kyrgyzstan during 1998, 2000, 2001, 2003, 2004 and 2005 were caused by viruses of the genotypes VIIb and VIIc. *Virus Genes*. 39:94-101.

Brown, J.D., Stallknecht, D.E., Swayne, D.E. 2009. Infectious and lethal doses of H5N1 highly pathogenic avian influenza virus for house sparrows (*Passer domesticus*) and rock pigeons (*Columbia livia*). *Journal of Veterinary Diagnostic Investigation*. 21:437-445.

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Day, J.M. 2009. The diversity of the orthoreoviruses: molecular taxonomy and phylogenetic divides. *Infection, Genetics and Evolution*. 9:390-400.

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Faust, C., Stallknecht, D.E., Swayne, D.E., Brown, J. 2009. Filter-Feeding bivalves can remove avian influenza viruses from water and reduce infectivity. *Proceedings of the Royal Society B: Biological Sciences* 276:3727-3735.

Kapczynski, D.R., Gonder, E., Liljebjelke, K.A., Lippert, R., Petkov, D., Tilley, B. 2009. Vaccine induced protection from egg production losses in commercial turkey breeder hens following experimental challenge with a triple reassortant H3N2 avian influenza virus. *Avian Diseases*. 53:7-15.

Kwon, Y.K., Lipatov, A.S., Swayne, D.E. 2009. Bronchointerstitial pneumonia in guinea pigs following inoculation with H5N1 high pathogenicity avian influenza virus. *Veterinary Pathology* 46:138-141.

Layton, S.L., Kapczynski, D.R., Cox, M.M., Higgins, S., Higgins, J., Wolfenden, A.D., Liljebjelke, K.A., Bottje, W.G., Swayne, D., Berghman, L.R., Kwon, Y.M., Hargis, B.M., Cole, K. 2009. Recombinant salmonella expressing M2e and CD154 increase protection against avian influenza in chickens, *Poultry Science* 88(11):2244-52.

Lipatov, A.S., Kwon, Y.K., Pantin-Jackwood, M., Swayne, D.E. 2009. Pathogenesis of H5N1 influenza virus infections in mice and ferret models differ between respiratory and digestive system exposure. *Journal of Infectious Diseases* 199(1 March):717-725.

Matsuoka, Y., Swayne, D.E., Rameix-Welti, M.A., Naffakh, N., Warnes, C., Altholtz, M., Donis, R., Subbarao, K. 2009. Neuraminidase stalk length and additional glycosylation of the hemagglutinin of H5N1 viruses influence the virulence of H5N1 viruses for mice. *Journal of Virology* 83(9):4704-4708.

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- Szretter, K.J., Gangappa, S., Zeng, H., Chen, H., Matsuoka, Y., Sambhara, S., Tumpey, T.M., Swayne, D.E., Katz, J.M. 2009. Early Control of H5N1 Influenza Virus Replication by the Type I Interferon Response in Mice. *Journal of Virology* 83(11):5825-5834.
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**5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms\* and/or toxins studied, as well as outdoor studies of biological aerosols:**

**I Objectives:**

Provide scientific solutions to national and international exotic, emerging and endemic poultry viral diseases through a comprehensive research program emphasizing basic and applied research in diagnostics, prevention, and control strategies, prediction of disease outbreaks, molecular epidemiology, and understanding disease pathogenesis.

The objectives of the research program are to produce new research knowledge and technology to:

- prevent, reduce or eliminate losses from impaired performance and increased deaths and condemnations;
- develop more sensitive, specific and faster diagnostic tests;
- develop vaccines designed for the control and, when feasible, the eradication of disease;
- improve our understanding of the ecology and epidemiology of viruses at the wild bird-domestic poultry interface; and
- improve our understanding of the genetic and pathobiological basis of virulence.

This research provides government regulatory agencies and the poultry industries with improved intervention strategies against poultry viral diseases. The Laboratory has two research units: 1) Exotic and Emerging Avian Viral Diseases Research Unit, and 2) Endemic Poultry Viral Diseases Research Unit.

**II Agents:**

- **USDA Select Agents and Toxins**  
Including NIAID Category B priority pathogens
- **Other pathogens or toxins**  
Including non-Select Agent, NIAID Category B priority pathogens

The agents studied are foreign and emerging viruses that cause diseases in poultry. The majority of the agents studied are classified by USDA as select agents. Some of the agents classified as select agents are pathogens that are zoonotic agents (diseases

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\* Including viruses and prions.

transmitted from animals to people) that pose a threat to our poultry production systems, our agricultural economy, and agricultural exports.

### **III Outdoor Studies:**

No research work is done outdoors with infectious organisms. Outdoor studies are conducted only for ecological purposes and monitoring of viruses in free flying wild birds.

**Form B**

**BWC - Confidence Building Measure**

Exchange of Information on all Outbreaks of Infectious Diseases and  
Similar Occurrences Caused by Toxins

United States of America

April 15, 2010

**Form B (i)**

**BWC - Confidence Building Measure**

Background Information on Outbreaks of Reportable Infectious Diseases

United States of America

April 15, 2010

Background information on outbreaks of reportable infectious diseases

<b>Human Disease</b>	<b>Total cases reported for previous years</b>				
	<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>
Anthrax	---	1	1	---	---
Botulism, total	135	165	144	145	96
Botulism, foodborne	19	20	32	17	11
Botulism, infant	85	97	85	109	62
Brucellosis	120	121	131	80	110
Chancroid	17	33	23	25	46
Cholera	8	9	7	5	8
Cyclosporiasis	543	137	93	139	127
Diphtheria	---	---	---	---	---
Domestic arboviral diseases					
California serogroup virus disease	80	67	55	62	47
Eastern equine encephalitis virus disease	21	8	4	4	4
Powassan virus disease	1	1	7	2	4
St. Louis encephalitis virus disease	13	10	9	13	11
Western equine encephalitis virus disease	---	---	---	---	---
<i>Haemophilus influenzae</i> , invasive disease (age <5 yrs):					
serotype b	9	29	22	30	27
nonserotype b	135	175	199	244	215
unknown serotype	217	179	180	163	230
Hansen disease	87	66	101	80	62
Hantavirus pulmonary syndrome	26	40	32	18	13
Hemolytic uremic syndrome, postdiarrheal	221	288	292	330	228
HIV infection, pediatric (age <13 yrs)	380	---	---	---	---
Influenza-associated pediatric mortality	45	43	77	90	360
Listeriosis	896	884	808	759	783
Measles	66	55	43	140	65
Meningococcal disease, invasive					
A, C, Y, and W-135	297	318	325	330	282
serogroup B	156	193	167	188	148
other serogroup	27	32	35	38	23
unknown serogroup	765	651	550	616	477
Mumps	314	6,584	800	454	1,444

Novel influenza A virus infections	NN	NN	4	2	43,771
Plague	8	17	7	3	8
Poliomyelitis, paralytic	1	---	---	---	---
Polio virus Infection, nonparalytic	NN	NN	---	---	---
Psittacosis	16	21	12	8	9
Q fever, total	136	169	171	120	101
acute	---	---	---	106	85
chronic	---	---	---	14	16
Rabies, human	2	3	1	2	4
Rubella	11	11	12	16	3
Rubella, congenital syndrome	1	1	---	---	1
SARS-CoV	---	---	---	---	---
Smallpox	---	---	---	---	---
Streptococcal toxic-shock syndrome	129	125	132	157	134
Syphilis, congenital (age <1 yr)	329	349	430	431	302
Tetanus	27	41	28	19	16
Toxic-shock syndrome (staphylococcal)	90	101	92	71	74
Trichinellosis	16	15	5	39	11
Tularemia	154	95	137	123	89
Typhoid fever	324	353	434	449	344
Vancomycin-intermediate <i>Staphylococcus aureus</i>	2	6	37	63	71
Vancomycin-resistant <i>Staphylococcus aureus</i>	3	1	2	---	---
Vibriosis (noncholera <i>Vibrio</i> species infections)	NN	NN	549	588	654
Viral Hemorrhagic Fever	NN	NN	NN	NN	NN
Yellow fever	---	---	---	---	---

**Form B (i)**

Background information on outbreaks of reportable infectious diseases

<b>Animal Diseases</b>	<b>Occurance during previous years</b>				
	<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>
<b><u>Multiple species diseases</u></b>					
Anthrax	+	+	+	+	Yes
Aujeszky's disease	+	+	+	+	Yes <sup>1</sup>
Bluetongue	+	+	+	+	Yes
Brucellosis ( <i>Brucella abortus</i> )	+	-	+	+	Yes <sup>2</sup>
Brucellosis ( <i>Brucella melitensis</i> )	-	-	-	-	No
Brucellosis ( <i>Brucella suis</i> )	-	-	+	+	Yes <sup>3</sup>
Crimean Congo haemorrhagic fever	-	-	-	-	No
Echinococcosis/hydatidosis	+	-	-	+	No*
Foot-and-mouth disease	-	-	-	-	No
Heartwater	-	-	-	-	No
Japanese encephalitis	-	-	-	-	No
Leptospirosis	+	+	+	+	Yes
New world screwworm	-	-	-	-	No
Old world screwworm	-	-	-	-	No
Paratuberculosis (Johne's Disease)	+	+	+	+	Yes
Q fever	+	+	+	+	Yes
Rabies	+	+	+	+	Yes
Rift Valley fever	-	-	-	-	No
Rinderpest	-	-	-	-	No
Trichinellosis	-	+	-	-	No*
Tularemia	+	+	+	-	Yes <sup>4</sup>
Vesicular stomatitis	+	+	-	-	Yes <sup>5</sup>
West Nile fever/encephalitis	+	+	+	+	Yes
<b><u>Cattle diseases</u></b>					
Bovine anaplasmosis	+	+	+	+	Yes
Bovine babesiosis	-	-	-	-	No
Bovine genital campylobacteriosis	-	+	+	+	Yes
Bovine spongiform encephalopathy	-	+	-	-	No <sup>6</sup>
Bovine tuberculosis	+	+	+	+	Yes <sup>7</sup>
Bovine viral diarrhoea	+	+	+	+	Yes
Contagious bovine pleuropneumonia	-	-	-	-	No

Enzootic bovine leukosis	+	+	+	+	Yes
Haemorrhagic septicaemia	-	-	-	-	No*
Infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis	+	+	+	+	Yes
Lumpy skin diseases	-	-	-	-	No
Theileriosis	-	-	-	-	No
Trichomonosis	+	+	+	+	Yes
Trypanosomosis	-	-	-	-	No
<b><u>Sheep and goat diseases</u></b>					
Caprine arthritis/encephalitis	+	+	+	+	Yes
Contagious agalactia	+	+	+	+	Yes <sup>8</sup>
Contagious caprine pleuropneumonia	-	-	-	-	No
Enzootic abortion of ewes (ovine chlamydiosis)	+	+	+	+	Yes
Maedi-visna	+	+	+	+	Yes
Nairobi sheep diseases	-	-	-	-	No
Ovine epididymitis ( <i>Brucella ovis</i> )	+	+	+	+	Yes
Peste des petits ruminants	-	-	-	-	No
Salmonellosis ( <i>S. abortusovis</i> )	+	-	+	-	No*
Scrapie	+	+	+	+	Yes
Sheep pox and goat pox	-	-	-	-	No
<b><u>Equine diseases</u></b>					
African horse sickness	-	-	-	-	No
Contagious equine metritis	-	+	-	+	Yes <sup>9</sup>
Dourine	-	-	-	-	No
Equine encephalomyelitis (Eastern)	+	+	+	+	Yes
Equine encephalomyelitis (Western)	-	-	-	-	No*
Equine infectious anemia	+	+	+	+	Yes
Equine influenza	+	+	+	+	Yes
Equine piroplasmiasis	-	-	-	+	Yes <sup>10</sup>
Equine rhinopneumonitis	+	+	+	+	Yes
Equine viral arteritis	+	+	+	+	Yes
Glanders	-	-	-	-	No
Surra ( <i>Trypanosoma evansi</i> )	-	-	-	-	No
Venezuelan equine encephalomyelitis	-	-	-	-	No
<b><u>Swine diseases</u></b>					
African swine fever	-	-	-	-	No
Classical swine fever (hog cholera)	-	-	-	-	No
Nipah virus encephalitis	-	-	-	-	No

Porcine cysticercosis	-	-	-	-	No
Porcine reproductive and respiratory syndrome	+	+	+	+	Yes
Swine vesicular disease	-	-	-	-	No
Transmissible gastroenteritis	+	+	+	+	Yes
<b><u>Avian diseases</u></b>					
Avian chlamydiosis	-	+	+	+	No*
Avian infectious bronchitis	+	+	+	+	Yes
Avian infectious laryngotracheitis	+	+	+	+	Yes <sup>11</sup>
Avian mycoplasmosis ( <i>M. gallisepticum</i> )	+	+	+	+	Yes <sup>12</sup>
Avian mycoplasmosis ( <i>M. synoviae</i> )	+	+	+	+	Yes <sup>12</sup>
Duck viral hepatitis	-	-	-	-	No
Fowl cholera ( <i>Pasteurella multocida</i> )	+	+	+	+	Yes
Fowl typhoid ( <i>Salmonella gallinarum</i> )	-	-	-	-	No
Highly pathogenic avian influenza	-	-	-	-	No
Low pathogenic avian influenza (poultry)	+	+	+	+	Yes <sup>13</sup>
Infectious bursal disease (Gumboro disease)	+	+	+	+	Yes
Marek's disease	+	+	+	+	Yes
Newcastle disease (Neurotropic and viscerotropic strains)	-	-	-	-	No
Pullorum disease ( <i>Salmonella pullorum</i> )	-	+	-	+	No <sup>14</sup>
Turkey rhinotracheitis	-	+	+	+	No
<b><u>Lagomorph diseases</u></b>					
Myxomatosis	-	-	-	-	No
Rabbit hemorrhagic disease	+	-	-	+	No
<b><u>Bee diseases</u></b>					
Acarapisosis of honey bees	+	+	+	+	Yes
American foulbrood of honey bees	+	+	+	+	Yes
European foulbrood of honey bees	+	+	+	+	Yes
Small hive beetle infestation ( <i>Aethina tumida</i> )	+	+	+	+	Yes
Tropilaelaps infestation of honey bees	-	-	-	-	No
Varroosis of honey bees	+	+	+	+	Yes
<b><u>Other listed disease</u></b>					
Leishmaniosis	-	-	-	-	No*
Camelpox	-	-	-	-	No
<b><u>Fish</u></b>					
Epizootic hematopoietic necrosis	-	-	-	-	No
Epizootic ulcerative syndrome	-	-	-	-	No
Gyrodactylosis ( <i>Gyrodactylus salaricus</i> )	-	-	-	-	No

Infectious hematopoietic necrosis	+	+	+	+	No
Infectious salmon anemia	+	+	-	-	No
Koi herpesvirus disease	<b>n/a</b>	<b>n/a</b>	+	+	Yes
Red sea bream iridoviral disease	-	-	-	-	No
Spring viremia of carp	-	-	-	-	No
Viral hemorrhagic septicaemia	-	+	+	+	Yes <sup>15</sup>
<b><u>Molluscs</u></b>					
Abalone viral mortality	<b>n/a</b>	<b>n/a</b>	-	-	No
Infection with <i>Bonamia exitiosus</i>	-	-	-	-	No
Infection with <i>Bonamia ostreae</i>	-	+	-	-	No
Infection with <i>Marteilia refringens</i>	-	-	-	-	No
Infection with <i>Perkinsus marinus</i>	+	+	+	+	No
Infection with <i>Perkinsus olseni</i>	-	-	-	-	No
Infection with <i>Xenohaliotis californiensis</i>	+	+	-	-	No
<b><u>Crustaceans</u></b>					
Crayfish plague ( <i>Aphanomyces astaci</i> )	-	-	-	-	No
Infectious hypodermal and haematopoietic necrosis	-	-	-	-	No
Infectious myonecrosis	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	-	No
Spherical baculovirus ( <i>Penaeus monodon</i> -type baculovirus)	-	-	-	-	No
Taura syndrome	-	-	-	-	No
Tetrahedral baculovirus ( <i>Baculovirus penaei</i> )	-	+	-	-	No
White spot disease	-	-	+	+	No*
White tail disease	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	-	No
Yellow head disease	-	-	-	-	No
<b><u>Amphibians</u></b>					
Infection with <i>Batrachochytrium dendrobatidis</i> (wild species)	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	Yes
Infection with ranavirus (wild species)	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	Yes

- + One case or more reported  
 - No cases reported  
 n/a Not OIE Listed

1. Aujeszky's disease limited to feral and/or noncommercial production swine. No commercial production swine herd detections in 2009.
2. Brucellosis (*Brucella abortus*) primarily limited to free-ranging bison (*Bison bison*) and wapiti (*Cervus elaphus*) in Greater Yellowstone National Park area. One domestic cattle herd detection in 2009.

3. Brucellosis (*Brucella suis*) limited to feral and/or noncommercial production swine. No commercial production swine herd detections in 2009.
4. Tularemia (*Francisella tularensis*) limited primarily to wild rabbits.
5. Vesicular stomatitis OIE Immediate Notification June 12, 2009; resolved August 18, 2009. (Form B (ii))
6. U.S.A. BSE status: 'Controlled Risk'. No detections reported in 2009.
7. Bovine tuberculosis (*Mycobacterium bovis*) sporadic occurrence and limited distribution. National eradication program.
8. Contagious agalactia sporadic occurrence of non Mediterranean form.
9. Contagious equine metritis OIE Immediate Notification December 16, 2008; status-ongoing, no new cases since August 2009. (Form B (ii))
10. Equine piroplasmiasis OIE Immediate Notifications: 1<sup>st</sup> June 11, 2009; resolved August 25, 2009. 2<sup>nd</sup> October 20, 2009; status—ongoing. (Form B (ii))
11. Avian infectious laryngotracheitis sporadic and limited distribution occurrence only (primarily vaccine related)
12. Mycoplasmosis—All commercial poultry breeding flocks are under a surveillance program to confirm infection-free status
13. Low Pathogenic Avian Influenza (LPAI) H5 or H7 subtypes OIE Immediate Notifications both non clinical events: 1<sup>st</sup> event April 6, 2009; resolved July 13, 2009. 2<sup>nd</sup> event August 6, 2009; resolved Dec 15, 2009.
14. Pullorum disease identified sporadically in backyard poultry. No commercial production flock detections in 2009.
15. Viral hemorrhagic septicemia (VHS) detections in wild species only. (Great Lakes area)

\* Sporadic occurrence (uncommon). No detections reported in 2009.

Additional information on OIE Reportable Diseases can be found at:  
<http://www.oie.int/wahis/public.php?page=home>

**Form B (ii)**

**BWC - Confidence Building Measure**

Information on Outbreaks of Infectious Diseases and Similar Occurrences that  
Seem to Deviate from the Normal Pattern\*

\* Information on events reported to the World Health Organization under International Health Regulation (IHR) Public Health Emergency of International Concern (PHEIC); World Organization for Animal Health (OIE); and/or the Food and Agriculture Organization (FAO).

Additional information on OIE Reportable Diseases can be found at:  
<http://www.oie.int/wahis/public.php?page=home>

United States of America

April 15, 2010

Information on outbreaks of infectious diseases and similar occurrences that seem to deviate from the normal pattern

**1. Time of cognizance of the outbreak**

Aware of initial cases of disease on April 13, 2009; CDC lab first identifies 2009 H1N1; pandemic declared by World Health Organizations on June 11, 2009.

**2. Location and approximate area affected**

Worldwide (over 200 countries and territories affected).

**3. Type of disease/intoxication**

Primarily respiratory illness.

**4. Suspected source of disease/intoxication**

Viral respiratory pathogen, evolved via novel triple-reassortant of swine, human, and avian influenza viruses.

**5. Possible causative agent(s)**

Novel H1N1 influenza A virus.

**6. Main characteristics of systems**

Similar to seasonal influenza virus infection—primarily respiratory illness.

**7. Detailed symptoms, when applicable**

- respiratory: cough, runny nose, sore throat, congestion
- circulatory: rare myocarditis
- neurological/behavioural: rare encephalopathy
- intestinal: occasional diarrhea and vomiting
- dermatological:
- nephrological:
- other: fever, myalgias

**8. Deviation(s) from the normal pattern as regards**

- type: novel H1N1 virus
- development: similar
- place of occurrence: similar
- time of occurrence: occurred during atypical influenza months. Two peaks of 2009 H1N1 disease activity occurred in spring 2009 and fall 2009; a typical influenza season has a single peak during a winter month.
- symptoms: similar
- virulence pattern: similar
- drug resistance pattern: similar (depending on comparison influenza strain)
- agent(s) difficult to diagnose: similar
- presence of unusual vectors: none

- other: distribution of illness by age group is different from seasonal influenza. Typically, seasonal influenza causes most severe illness (hospitalizations and deaths) in an elderly population (65 years and older). 2009 pandemic H1N1 influenza caused more severe illness in a younger group of people.

**9. Approximate number of primary cases**

Unknown

**10. Approximate number of total cases**

57 million (April 2009 through January 2010)

**11. Number of deaths**

More than 11,000 lab confirmed from 2009 H1N1 (April 2009 through January 2010)

**12. Development of the outbreak**

Disease initially in discrete areas of United States and Mexico, followed by rapid geographic spread throughout United States and world.

**13. Measures taken**

- Enhanced surveillance
- Implementation of appropriate infection control and non-pharmaceutical intervention strategies (such as surgical mask use, respiratory cohorting, travel advisories, and workplace or school exclusion)
- Standard of care for viral respiratory pathogens
- Antiviral distribution and use
- Rapid development and dissemination of 2009 H1N1-specific vaccine

**Additional information available on the CDC website at:**

[http://www.cdc.gov/h1n1flu/estimates\\_2009\\_h1n1.htm](http://www.cdc.gov/h1n1flu/estimates_2009_h1n1.htm)

Information on outbreaks of infectious diseases and similar occurrences that seem to deviate from the normal pattern

**1. Time of cognizance of the outbreak**

On November 10, 2008, CDC's PulseNet staff noted a small and highly dispersed multistate cluster of 13 *Salmonella typhimurium* isolates with an unusual DNA fingerprint or pulsed-field gel electrophoresis (PFGE) pattern reported from 12 states. On November 25, CDC's OutbreakNet team, working with state and local partners, began an epidemiologic assessment of that cluster, which had increased to 35 isolates. On December 2, CDC and state and local partners began an assessment of a second cluster of 41 *Salmonella typhimurium* isolates. The PFGE patterns of the second cluster were very similar to the patterns in the first cluster and were first noted by PulseNet on November 24, as a cluster of 27 isolates that had subsequently increased to 41 isolates. Neither of these patterns were seen previously in the PulseNet *Salmonella typhimurium* database. The clusters also appeared similar epidemiologically, so the two patterns were grouped together as a single outbreak strain, and the investigations were merged.

**2. Location and approximate area affected**

We identified 714 ill persons from 46 states: The number of ill persons identified in each state is as follows: Alabama (2), Arizona (14), Arkansas (6), California (81), Colorado (18), Connecticut (11), Florida (1), Georgia (6), Hawaii (6), Idaho (17), Illinois (12), Indiana (11), Iowa (3), Kansas (2), Kentucky (3), Louisiana (1), Maine (5), Maryland (11), Massachusetts (49), Michigan (38), Minnesota (44), Missouri (15), Mississippi (7), Montana (2), Nebraska (1), New Hampshire (14), New Jersey (24), New York (34), Nevada (7), North Carolina (6), North Dakota (17), Ohio (102), Oklahoma (4), Oregon (15), Pennsylvania (19), Rhode Island (5), South Dakota (4), Tennessee (14), Texas (10), Utah (8), Vermont (4), Virginia (24), Washington (25), West Virginia (2), Wisconsin (5), and Wyoming (2).

**3. Type of disease/intoxication**

Salmonellosis is an infection with bacteria called *Salmonella*. Most persons infected with *Salmonella* develop diarrhea, fever, and abdominal cramps 12 to 72 hours after infection. The illness usually lasts 4 to 7 days, and most persons recover without treatment. However, in some persons, the diarrhea may be so severe that the patient needs to be hospitalized. In these patients, the *Salmonella* infection may spread from the intestines to the blood stream, and then to other body sites and can cause death unless the person is treated promptly with antibiotics. The elderly, infants, and those with impaired immune systems are more likely to have a severe illness.

**4. Suspected source of disease/intoxication**

Contaminated peanut butter and peanut-products from Peanut Corporation of America facilities in Georgia and Texas

**5. Possible causative agent(s)**

*Salmonella enterica* serotype Typhimurium

## **6. Main characteristics of systems**

The most common symptoms among ill persons were diarrhea, fever, and abdominal cramps. Among persons with available information, 24% reported being hospitalized. Infection may have contributed to nine deaths.

## **7. Detailed symptoms, when applicable**

- respiratory: n/a
- circulatory: n/a
- neurological/behavioural: n/a
- intestinal: see description above (3 & 6)
- dermatological: n/a
- nephrological: n/a
- other : n/a

## **8. Deviation(s) from the normal pattern as regards**

- type: CDC's Emergency Operation Center was activated for this outbreak investigation.
- development: see #1 above for description
- place of occurrence: 46 states across the U.S.
- time of occurrence: Illness onset dates ranged from September 1, 2008 to March 31, 2009; the number of cases peaked between mid-November and mid-December, 2008 and began decreasing in late January, 2009.
- symptoms: see description above (3 & 6)
- virulence pattern: n/a
- drug resistance pattern: pansusceptible
- agent(s) difficult to diagnose: n/a
- presence of unusual vectors: n/a
- other

## **9. Approximate number of primary cases**

701 primary cases (13 secondary cases)

## **10. Approximate number of total cases**

714 ill persons from 46 states

## **11. Number of deaths**

Infection may have contributed to 9 deaths.

## **12. Development of the outbreak**

see description in #1.

## **13. Measures taken**

Two case-control studies not related to institutions (Studies 1 and 2) were performed. In Study 1, illness was associated with eating any peanut butter (matched odds ratio [mOR] =2.53, 95% confidence interval [CI] =1.26-5.31), but not with a specific brand. Institutional cluster investigations prompted testing of Brand X institutional peanut butter (PB) produced

by Peanut Corporation of America (PCA); the outbreak strain was isolated from Brand X PB. Many case-patients who did not eat institutional PB reported eating other PB-flavored products. In Study 2, illness was associated with eating two brands of PB crackers and with eating PB outside the home, but not with major national brands of PB sold in grocery stores. The outbreak strain was isolated from implicated PB crackers, made with peanut paste from PCA, and several other PB-containing products linked to PCA. The PCA plant was closed, and at least 3,910 products were recalled.

Additional information located at:

<http://www.cdc.gov/salmonella/typhimurium/update.html>

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm58e0129a1.htm>

Information on outbreaks of infectious diseases and similar occurrences that seem to deviate from the normal pattern

There were seven World Organization for Animal Health (OIE) immediate reports for animal disease events in 2009 and one ongoing open report from December 2008.

- Two outbreaks of equine piroplasmiasis (EP), *Theileria equi*, were reported to the OIE in 2009.
  - The first outbreak was reported on June 11, 2009, and was resolved August 25, 2009. The outbreak consisted of eight horses in Missouri and Kansas that were confirmed positive for EP. Five of the horses were euthanized, one horse was unable to be relocated after testing, and two horses were illegally removed from quarantine prior to euthanasia. Transmission was most likely caused by management practices.
  - The second EP outbreak was reported on October 20, 2009, and is ongoing at the time of writing. EP positive horses were detected on a ranch in Texas and epidemiological investigation identified 357 positive horses in 2009; 289 of the positive horses were located on the index premises. Positive trace-outs from the index premises were located in 12 additional States. Transmission likely occurred via tick vectors for the EP positive horses directly related to the Texas index premises. In response to the Texas detections, New Mexico instituted an EP screening program for all horses entering race tracks. The screening program identified three positive horses in 2009. Transmission of the New Mexico EP positive horses is thought to be from management practices.
- Vesicular stomatitis (New Jersey strain) was reported to the OIE on June 12, 2009 and was resolved on August 18, 2009. There were a total of seven confirmed equine cases occurring in TX and NM.
- Two incidences of 2009 pandemic A/H1N1 influenza virus were reported to the OIE.
  - The first occurrence of p/H1N1 in swine was reported on November 3, 2009, and was resolved December 1, 2009. The pigs were sent to slaughter after they recovered from illness. The source of the outbreak was thought to be caused by exposure of the swine to humans exhibiting influenza-like illness.
  - The first occurrence of p/H1N1 in turkeys was reported to the OIE on November 30, 2009, and was resolved December 21, 2009. The birds were sent to slaughter after they recovered from illness. The source of the outbreak was thought to be caused by exposure of the turkeys to humans exhibiting influenza-like illness.
- There were two low pathogenic notifiable avian influenza (LPNAI) reports to the OIE in 2009.
  - The first occurrence of LPNAI was reported on April 6, 2009, and was resolved on July 13, 2009. Routine pre-slaughter surveillance detected H7N9 LPNAI in a commercial broiler-breeder operation. No clinical signs other than a modest drop in egg production were noted. The birds were depopulated as a precautionary measure.

- The second occurrence of LPNAI was reported on August 6, 2009, and resolved December 15, 2009. H7N9 LPNAI was detected in a commercial turkey flock in Minnesota. The birds in the flock showed no signs of clinical illness or increased mortality. The birds were depopulated via controlled marketing.
- One ongoing open OIE report from December 2008 of contagious equine metritis (CEM).
  - There have been no new cases of CEM reported since August 2008. As of January 14, 2010, a total of 22 stallions (includes one gelding) and five mares were confirmed positive for *Tylorella equigenitalis* (CEM). All positive animals have successfully completed their treatment and subsequent testing protocol, and are free of *T. equigenitalis*. Overall, 93.5% of epidemiologically linked horses have completed all testing and treatment protocols.

**Form C**

**BWC - Confidence Building Measure**

Encouragement of Publication of Results and Promotion of Use of Knowledge

United States of America

April 15, 2010

Encouragement of Publication of Results and Promotion of Use of Knowledge

**US Department of Health and Human Services (HHS) Open Government Plan (07 April 2010)**

This Open Government Plan represents the official response of the U.S. Department of Health and Human Services (HHS) to the White House's Open Government Directive, issued on December 8, 2009. The plan embraces the idea of working proactively and energetically to advance a culture of Open Government at HHS.

We believe that transparency and data sharing are of fundamental importance to our ability to achieve HHS's strategic goals of advancing the health and well-being of the United States. HHS's vast stores of data are a remarkable national resource which can be utilized to help citizens understand what we do and hold us accountable, help the public hold the private sector accountable, increase awareness of health and human services issues, generate insights into how to improve health and well-being, spark public and private sector innovation and action, and provide the basis for new products and services that can benefit the American people. This plan also seeks to take Open Government to the next level by expanding opportunities for public participation in HHS activities and for collaboration across HHS and with the world outside HHS – especially via the use of new information and communications technologies.

The HHS Open Government Plan is available online at:

[http://www.hhs.gov/open/plan/opengovernmentplan/ourplan\\_openhhs.pdf](http://www.hhs.gov/open/plan/opengovernmentplan/ourplan_openhhs.pdf)

**The Policy on Releasing and Sharing Data at the US Department of Health and Human Services (HHS)**

There are a number of federally mandated regulations and clearance functions that affect the research and practice of HHS (for a list of HHS agencies and offices, please see: <http://www.hhs.gov/about> ). They apply to all HHS employees, contractors, and awardees conducting data collection activities, whether the activities are for research or public health practice or occur in domestic or global settings. Examples include the HHS/FDA regulations for the protection of human research participants and compliance with the federal Animal Welfare Act (AWA) as well as the Public Health Service Policy on Humane Care and Use of Laboratory Animals. In addition, the Paperwork Reduction Act (PRA), the Privacy Act, the Public Health Service Act (PHSA), the E-Government Act of 2002, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, and the Family Educational Rights and Privacy Act (FERPA) all include legislation or regulations that affect the research and public health practice.

Throughout HHS, we believe that public health and scientific advancement are best served when data are released to, or shared with, other public health agencies, academic researchers, and appropriate private researchers in an open, timely, and appropriate way. While recognizing the value of releasing data quickly and widely, we also consider the need to maintain high standards for data quality, the need for procedures that ensure that the privacy of individuals who provide personal information is not jeopardized, and the need to protect information relevant to national

security, criminal investigations, or misconduct inquiries and investigations. The goal is to have a policy on data release and sharing that balances the desire to disseminate data as broadly as possible with the need to maintain high standards and protect sensitive information. The HHS Policy on Releasing and Sharing Data is available at:  
<http://www.cdc.gov/maso/Policy/ReleasingData.pdf>

### **The National Institutes of Health (NIH) Public Access Policy**

The NIH Public Access Policy (<http://publicaccess.nih.gov/policy.htm>) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the National Library of Medicine's digital archive PubMed Central upon acceptance for publication. To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

The NIH also has established a **review mechanism for manuscripts which may involve "dual use research of concern."** Please see <http://www1.od.nih.gov/oir/sourcebook/oversight/pub-clear-form.htm>

NIH ensures that its **researchers are trained in the conduct of responsible science through a mandatory training class** entitled "Science and Social Responsibility - Dual Use Research," which may be viewed at <http://www1.od.nih.gov/oir/sourcebook/ResEthicsCases/2009cases.pdf> .

The **US Food and Drug Administration (FDA)** encourages its scientists to publish their findings in peer-reviewed science journals, books, and related articles. The list of publications (per calendar year) is available at:  
<http://www.fda.gov/AnimalVeterinary/ScienceResearch/ResearchAreas/ucm107413.htm> for publications on Analytical Methods; Animal Health; and Animal and Food Microbiology.

The **FDA's publications on Drug Development and Drug Interactions** are available at:  
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm091806.htm>

The **FDA's National Center for Toxicological Research (NCTR)** lists its publications on the following website:  
<http://www.fda.gov/AboutFDA/CentersOffices/NCTR/WhatWeDo/NCTRPublications/ucm077352.htm>

In addition, the **FDA's Office of Science and Engineering Laboratories (OSEL)** Annual Report provides current information about the Office's organization and intramural science activities; provides a summary of the Office's direct laboratory support for pre-market review and compliance cases; and provides a bibliography of scientific publications, presentations, and

research seminars for the fiscal year; website:

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm109778.htm>

**The Excellence in Science Committee (EISC)** at the **Centers for Disease Control and Prevention (CDC)** promotes the CDC's scientific infrastructure and facilitates communication and collaboration that enhance scientific areas and activities needed for state-of-the-art conduct of science to foster, support, and protect an environment for the promotion of scientific integrity, quality assurance, and the rapid dissemination of scientific innovations, technology, and information with the ultimate goal of improving public health. Website:

<http://www.cdc.gov/od/science/excellence/>

**CDC publishes The Morbidity and Mortality Weekly Report (MMWR) series**, often called “the voice of CDC.” The MMWR series is the agency’s primary vehicle for scientific publication of timely, reliable, authoritative, accurate, objective, and useful public health information and recommendations. MMWR readership predominantly consists of physicians, nurses, public health practitioners, epidemiologists and other scientists, researchers, educators, and laboratorians. The data in the weekly MMWR are provisional, based on weekly reports to CDC by state health departments. The *CDC Surveillance Summaries* provide a means for CDC programs to disseminate surveillance findings, permitting detailed interpretation of trends and patterns based on those findings.

Website: <http://www.cdc.gov/mmwr/publications/index.html>

**CDC publishes *The Emerging Infectious Diseases Journal***, ranked 3 of 51 infectious disease journals. Emerging Infectious Diseases receives more than 1,800 manuscripts per year (most unsolicited, some invited) from authors around the world. It has 17,000 subscribers to print version in more than 100 countries and 33,000 subscribers to electronic table of contents. The journal site receives hundreds of thousands of hits per month (CDC Web Statistics):

<http://www.cdc.gov/ncidod/eid/index.htm>

#### **Public Health Image Library.**

CDC created the Public Health Image Library (PHIL), recognizing that much of the information critical to the communication of public health messages is pictorial rather than text-based. The PHIL offers an organized, universal electronic gateway to CDC's pictures. We welcome public health professionals, the media, laboratory scientists, educators, students, and the worldwide public to use this material for reference, teaching, presentation, and public health messages. The content is organized into hierarchical categories of people, places, and science, and is presented as single images, image sets, and multimedia files.

Website: <http://phil.cdc.gov/phil/home.asp>

**Form D**

**BWC - Confidence Building Measure**

Active Promotion of Contacts

United States of America

April 15, 2010

Active promotion of contacts

**1. Planned international conferences, symposia, seminars, and other similar forums for exchange**

**The NIH events for the 2010 calendar year** are listed at:

<http://calendar.nih.gov/app/MCalWelcome.aspx?SrchType=Year>

**The CDC Laboratory and Public Health Conference Schedules** are available at:

[http://wwwn.cdc.gov/dls/links/links\\_lacs.aspx](http://wwwn.cdc.gov/dls/links/links_lacs.aspx)

March 15-16, 2010

**3rd Annual NIH Conference on the Science of Dissemination and Implementation: Methods and Measurement.**

Bethesda, MD

There is a recognized need to close the gap between research evidence and clinical and public health practice, but how is this best accomplished? Although emerging as a field of research in health and medicine, dissemination and implementation science is as yet underdeveloped. A forum is needed to facilitate growth in the science of dissemination and implementation. The National Institutes of Health is pleased to announce that this year's annual Conference on the Science of Dissemination and Implementation, Methods and Measurement, will provide such a forum. Researchers and evaluators who are interested in identifying opportunities and obstacles for dissemination and implementation research/evaluation are encouraged to attend this meeting. The goal is to engage in dialog, exchange ideas, explore contemporary topics and challenge one another to identify and test research designs, methods and measurement that will advance dissemination and implementation science.

<http://conferences.thehillgroup.com/obssr/DI2010/about.html>

March 17, 2010

Implementation Science and Global Health

**A satellite meeting of the March 2010 NIH Conference on the Science of Dissemination and Implementation (listed above)**

National Institutes of Health, Bethesda, MD,

The NIH Fogarty International Center will host a satellite meeting to this conference on March 17 on Implementation Science and Global Health for Fogarty grantees and trainees working in the field of international implementation science, research training, and curriculum development. The meeting will also explore strategies to build linkages between implementation science researchers to major global healthcare delivery programs (e.g. PEPFAR, PMI).

The primary objectives of this satellite meeting are to:

- Understand the current scope and scale of implementation science and research training in Fogarty-funded programs;
- Encourage collaboration and the exchange of information among Fogarty programs on experiences and best practices in implementation research and research training;

- Identify future areas of research and strategies for implementation science capacity-building; and
- Explore strategies to build and strengthen linkages between researchers and policymakers/implementers of large-scale USG global health initiatives.

<https://meetings.fic.nih.gov/index.cfm?event=home&ID=315>

April 19-23, 2010

**59th Annual Scientific Epidemic Intelligence Service (EIS) Conference**

Atlanta, GA

The EIS hosts an annual scientific conference for the national and international public health community.

- EIS officers' investigation findings are presented
- Current epidemiologic topics are discussed
- Epidemiologic activities at CDC are highlighted
- Public health professionals network and share ideas
- CDC programs recruit new EIS officers

<http://www.cdc.gov/eis/Conference.html>

July 21-23, 2010

**Nanomaterials and Worker Health: Medical Surveillance, Exposure Registries, and Epidemiologic Research**

Keystone, CO

The National Institute for Occupational Safety and Health (NIOSH) and the Mountain and Plains Education and Research Center invite you to attend the conference on "Nanomaterials and Worker Health: Medical Surveillance, Exposure Registries, and Epidemiologic Research." This conference will enable members of the occupational safety and health community concerned with nanomaterials and the health of workers exposed to these materials to address fundamental questions and seek practical solutions for carrying out occupational health surveillance, developing exposure registries, and conducting epidemiological research.

<http://www.cdc.gov/niosh/topics/nanotech/keystone2010/default.html>

**A general list of microbiology conferences, meetings, symposia, workshops and advanced courses for 2010 is available at: <http://microbiologyconference.com/>**

February 6-9 2011

**USDA ARS - 1st International Agricultural Biosafety and Biocontainment Symposium**

Baltimore, MD

The United States Department of Agriculture, Agricultural Research Service (USDA ARS) is planning the 1st International Agricultural Biosafety and Biocontainment Symposium to be held February 6-9 2011 in Baltimore, Maryland. ARS is partnering with The American Biological Safety Association (ABSA) which will be managing the Symposium. The focus of this first symposium will be on animal (livestock, aquaculture and wildlife) health issues associated with

agricultural research, diagnostics and response. Some possible topics will be new and emerging regulatory and compliance issues, livestock and wildlife interface, one world one health, and biosafety and biocontainment issues in the field, industry and research environments. The Symposium will be two and half days and will also feature courses and exhibits of related products and services. Information will become available at [www.absa.org](http://www.absa.org). For more information please contact Ed Stygar at [ed@absaoffice.org](mailto:ed@absaoffice.org)

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The following conferences in the United States are not being hosted by the US Government but US Government researchers and grantees will likely participate:

March 9 - 12, 2010

**14th International Congress on Infectious Diseases (14th ICID) (non-government)**

Miami, FL,

Organized by the International Society for Infectious Diseases. In this ever shrinking world where people, products and pathogens move rapidly around the globe, collective expertise and experience will enable researchers to find answers to the infectious disease challenges confronting society. A scientific program including cutting edge science to state-of-the-art practices to global infectious disease control, all presented by an international faculty.

[http://www.isid.org/14th\\_icid/index.shtml](http://www.isid.org/14th_icid/index.shtml)

March 12 - 14, 2010

**The Clinical Vaccinology Course (non-government)**

San Diego, CA,

Organized by the National Foundation for Infectious Diseases. This course focuses on new developments and issues related to the use of vaccines. Expert faculty will provide the latest information on both current and prospective vaccines through lectures and interactive case presentations. Leading infectious disease experts, pediatricians, and researchers will present newly available vaccines and vaccines in the pipeline, as well as older vaccines whose continued administration is essential to improving disease prevention efforts.

<http://www.nfid.org/pdf/conferences/course310.pdf>

19-22 April 2010

**World Vaccine Congress, (non-government)**

**Chantilly, VA**

The World Vaccine Congress is a forum where the ever-changing dynamics of the industry are discussed and acted upon by the industry's most senior figures.

<http://www.terrapinn.com/2010/wvcdc/>

April 26 - 28, 2010

**13th Annual Conference on Vaccine Research (non-government)**

Baltimore, MD

The latest vaccine-related scientific data, results, and issues are explored via symposia and panel discussions by expert faculty and through oral and poster sessions.

<http://www.nfid.org/conferences/vaccine10/>

May 3-6, 2010

**BIO International Convention, (non-government)**

Chicago, IL

Global leaders like you will gather in Chicago to share ideas, experiences, insights and best practices on biotech innovations that are helping to solve some of the biggest global challenges, including fighting disease and improving health, feeding growing populations and meeting the increased world demand for energy. One third of BIO attendees are from outside the United States. They come ready to share their extensive knowledge and establish relationships. More than 300 international public officials will utilize the convention to make vital connections and drive change on key issues that influence global biotech industry growth and innovation.

<http://convention.bio.org/international/>

May 23 - 27, 2010

**110th General Meeting of the American Society for Microbiology, (non-government)**

San Diego, CA

The scientific program will feature nearly 300 individual colloquia, symposia, roundtable discussions, award lectures, and poster sessions. The 27 Division Chairs and the General Meeting Program Committee have devoted their energies to creating a well-rounded program.

<http://gm.asm.org/>

11-14 July 2010

**International Conference on Emerging Infectious Diseases, (non-government)**

Atlanta, GA

The conference brings together public health professionals to encourage the exchange of scientific and public health information on global emerging infectious disease issues.

<http://www.iceid.org/>

17-21 July 2010

**29th Annual Meeting of the American Society for Virology (non-government)**

Montana State University, Bozeman, MT

The American Society for Virology (ASV) was founded in 1981 to provide a forum for investigators of human, animal, insect, plant, fungal and bacterial viruses, whether the research involves the use of clinical, ecological, biological or biochemical approaches. The Society sponsors an annual meeting, designed to promote discussion and collaboration among scientists active in all aspects of virology.

[www.asv2010.com](http://www.asv2010.com)

**August 1 - 4, 2010 IAFP 2010 (non-government),**  
Anaheim, CA

International Association for Food Protection (IAFP) conference. Annual Meeting features over 550 technical, poster and symposia presentations, detailing current information on a variety of topics relating to food safety. The quantity and quality of presentations provide information on the latest methods and technologies available. Top industry, academic and government food safety professionals attend each meeting.

<http://www.foodprotection.org/about-us/news-releases/63/iafp-2010-call-for-abstracts/>

Active promotion of contacts

## **2. Information regarding other opportunities**

### **Dual Use Concerns in Life Sciences Research: An International Dialogue** (archived videocast)

On October 22, 2009, the United States National Institutes of Health (NIH) sponsored its first regional Webinar on dual use research, hosted by the US National Science Advisory Board for Biosecurity (NSABB). The goal of the event was to foster international engagement of life sciences researchers, biosafety and biosecurity experts, government policy officials, and ethicists on the issue of dual use life sciences research.

Effective global dialogue on concerns and issues regarding dual use life sciences research is key to achieving an effective balance between public health priorities and national security concerns. Numerous national- and international-level activities are currently underway to raise awareness of the risks posed by dual use life sciences research as well as to address or manage these risks while, at the same time, promoting responsible life sciences research. This international Videocast focused on the Americas is the first in a series of internet-based meetings aimed at engaging the international community by region. To learn more about dual use research visit: <http://oba.od.nih.gov/biosecurity/>.

#### View Archived Videocast

To view the archived Videocast in English, click here:  
<http://videocast.nih.gov/Summary.asp?File=15383>

To view the archived Videocast in Spanish, click here:  
<http://videocast.nih.gov/Summary.asp?File=15384>

### **Planned National Science Advisory Board for Biosecurity (NSABB) Meetings**

The purpose of the National Science Advisory Board for Biosecurity (NSABB) is to provide advice, guidance, and leadership regarding biosecurity oversight of dual use research, defined as biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security. The NSABB will advise the Secretary of the Department of Health and Human Services (HHS), the Director of the National Institutes of Health (NIH), and the heads of all federal departments and agencies that conduct or support life science research. The NSABB will advise on and recommend specific strategies for the efficient and effective oversight of federally conducted or supported dual use biological research, taking into consideration both national security concerns and the needs of the research community. NIH shall manage and provide support services for the NSABB

NSABB meetings are planned for: June 22-24, 2010, October 19-21, 2010, February 8-10, 2011. For more information: [http://oba.od.nih.gov/biosecurity/biosecurity\\_meetings.html](http://oba.od.nih.gov/biosecurity/biosecurity_meetings.html)

### **International Training and Career Opportunities available via the NIH John E. Fogarty International Center for Advanced Study in the Health Sciences**

The Fogarty International Center is the international component of the NIH. It addresses global health challenges through innovative and collaborative research and training programs and supports and advances the NIH mission through international partnerships. Fogarty's Research Training Grants provide funding to train researchers, building sustainable research capacity in low- and middle-income countries. Grants are available in a variety of research areas, such as infectious diseases, chronic conditions, population health, informatics, genetics, and clinical, operational and health services. The Division of International Training and Research (DITR) administers research grants, training grants and fellowship programs which are active in over 100 countries (website: <http://www.fic.nih.gov/about/ditr.htm>).

A comprehensive list of Research Training Grant programs is available online at: [http://www.fic.nih.gov/programs/training\\_grants/index.htm](http://www.fic.nih.gov/programs/training_grants/index.htm)

### **FDA Collaborative Scientific Training Program**

The US Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) has a long tradition of improving regulatory pathways and facilitating the availability of safe, effective and high quality biological products. This is accomplished through research conducted by CBER intramural scientists on vaccines; blood and blood products; cell, tissue and gene therapies; and allergenics. CBER established the Collaborative Scientific Training Program (CSTP) to facilitate research and training partnerships that engage scientific partners in pursuing the goals of the Critical Path Initiative of the U.S. Food and Drug Administration (FDA). The FDA Critical Path seeks scientific solutions to the challenges of modernizing existing product evaluation pathways and developing approaches for the evaluation of new products. Attaining these goals will move biomedical discoveries and innovations to the marketplace as safe and effective products providing preventative, therapeutic and diagnostic benefits to the people who need them. CSTP Partnerships will provide **opportunities to bring national and international scientific institutions, experts and trainees together to synergize CBER's unique scientific and regulatory expertise with the complimentary scientific knowledge and skills of Collaborators.** For more details and points of contact:

<http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/CollaborativeScientificTrainingProgram/default.htm>

### **FDA International Programs-Communications**

The overall purpose of the U.S. Food and Drug Administration's (FDA) Office of International Program's (OIP) communications internationally is to effectively communicate FDA policy, regulatory decisions, and programs to counterpart government officials and international organizations around the world, to enhance cooperation with them on public health matters of mutual interest, and provide prompt, accurate, and effective responses to a wide range of requests for program, policy, and technical information. OIP coordinates, organizes and conducts major international conferences, symposia, workshops, and embassy briefings in areas of specific Agency concern, including annual meetings with counterpart agencies. OIP serves as the agency focal point on policies and procedures for sharing public and non-public information. In this regard, OIP is the primary agency liaison with other U.S. Government components, international

and foreign governments (including Washington, D.C. embassies) in disseminating public and non-public information concerning international notifications of recalls in the United States of products that have been distributed abroad. As FDA becomes aware of distribution outside the U.S. of products recalled domestically, the FDA/OIP immediately provides information by e-mail to international regulatory counterparts about these products. These notifications are made directly to the senior executives of our counterpart food and medical product safety agencies, to technical counterparts, and/or to the embassy of the country involved.

<http://www.fda.gov/InternationalPrograms/InternationalCommunications/default.htm>

### **FDA's International Programs-Capacity Building**

FDA's Capacity Building Program includes its technical cooperation and assistance efforts. This includes a range of education, outreach, and other activities where FDA collaborates with our regulatory counterparts of other countries to improve regulatory infrastructures, preventive controls, and production practices to help ensure the safety and quality of imported products into the U.S. These initiatives include in-classroom training, web-based programs, publications, DVDs, and videos and development of other educational training materials that address specific issues and needs as they arise.

FDA's technical assistance includes collaboration with individual countries, as well as investments in broader U.S. or global initiatives, such as:

- Asian Pacific Economic Cooperation (APEC) – Life Sciences Innovation Forum;
- Avian Influenza/Pandemic Preparedness – Workshops conducted on Good Manufacturing Practices (GMPs) and Good Clinical Practices (GCPs);
- Security and Prosperity Partnership (SPP);
- President's Emergency Plan for AIDS Relief (PEPFAR);

For details and point of contact see:

<http://www.fda.gov/InternationalPrograms/CapacityBuilding/default.htm>

### **FDA's International Programs-Beyond Our Borders**

In the past five years, the number of FDA agreements with its regulatory counterparts throughout the world more than doubled and it continues to grow. FDA has over 100 formal agreements with its counterparts in 29 countries, 18 with the European Commission or its European Union members, and two with the World Health Organization.

These agreements allow FDA and its counterparts to

- share human, scientific, and investigational resources and knowledge;
- share scientific expertise;
- promote responsible international standards and regulations.

FDA has more than 30 additional agreements with foreign counterpart agencies, many of which allow the sharing of inspection reports and other otherwise non-public information. FDA intends to use these agreements more extensively to obtain information that can help the agency make more informed judgments on the acceptability of products from foreign sources, in prioritizing FDA's foreign inspection activities, and on detaining unsafe products.

For more details see: <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm103036.htm>

### **FDA's Food Defense and Emergency Response-Training**

FDA works with other government agencies and private sector organizations to help reduce the risk of tampering or other malicious, criminal, or terrorist actions on the food and cosmetic supply. Web-based training resources and additional educational resources are available online at: <http://www.fda.gov/Food/FoodDefense/Training/default.htm>

### **CDC Public Health Training Network**

The Public Health Training Network (PHTN) is a distance learning network of people and resources that takes training and information to the learner. For a listing of distance learning courses and resources, visit <http://www2a.cdc.gov/PHTN/catalog.asp>

### **CDC Emergency Preparedness and Response Training and Educational Resources**

CDC provides resources that are intended to help professionals take an all-hazards approach to preparedness. Website: <http://emergency.cdc.gov/hazards-all.asp>

A list of training resources related specifically to bioterrorism is available at: <http://emergency.cdc.gov/bioterrorism/training.asp>

### **CDC International Laboratory-related Resource and Activity Directory**

This directory includes links to training materials, guidelines, manuals, and resources developed by CDC and partner organizations to promote quality laboratory practices in the global laboratory setting. Website: <http://wwwn.cdc.gov/dls/ILA/default.aspx>

**Form E**

**BWC - Confidence Building Measure**

Declaration of Legislation, Regulations, and other Measures

United States of America

April 15, 2010

Declaration of legislation, regulations and other measures relating to

	Legislation	Regulations	Other	Amended Since Last year
Development, production, stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	YES	YES	YES**	YES
Export of Micro-Organisms and Toxins.	YES	YES	NO	NO
Import of Micro-Organisms and Toxins.	YES	YES	YES*	YES*

On December 7, 2009, HHS published its semiannual regulatory agenda outlining the Obama Administration's planned regulatory initiatives in a number of health policy areas:  
<http://edocket.access.gpo.gov/2009/pdf/E9-28598.pdf> (excerpts below):

\* On August 13, 2009, HHS/CDC posted a Notice of Rescission to lift the HHS/CDC embargo of birds and unprocessed bird products from specified countries to ensure a more coordinated federal response to the control of highly pathogenic avian influenza H5N1. This Notice of Rescission became effective September 14, 2009.  
<http://www.cdc.gov/animalimportation/lawsregulations/BirdEmbargoRescission.html>

**Foreign Quarantine Regulations, Proposed Revision of HHS/CDC Animal Importation Regulations**

By statute, the Secretary of Health and Human Services (HHS) has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. The Secretary has designated the authority to prevent the introduction of diseases from foreign countries to the Director, Centers for Disease Control and Prevention (CDC). CDC also enforces entry requirements for certain animals, etiologic agents and vectors deemed to be of public health significance. CDC is issuing a Notice of Proposed Rulemaking (NPRM) to revise the regulations for importation of certain animals and vectors into the United States (42 CFR parts 71, Subpart F).  
<http://edocket.access.gpo.gov/2009/pdf/E9-28598.pdf>

### **Control of Communicable Diseases, Foreign Quarantine Regulations**

By statute, the Secretary of Health and Human Services (HHS) has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. Quarantine regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. This rule (42 CFR part 71) will update and improve CDC's response to both global and domestic disease threats by creating a multi-tiered illness detection and response process thus substantially enhancing the public health system's ability to slow the introduction, transmission, and spread of communicable disease. The rule will also modify current Federal regulations governing the apprehension, quarantine isolation and conditional release of individuals suspected of carrying a quarantinable disease while respecting individual autonomy.

<http://edocket.access.gpo.gov/2009/pdf/E9-28598.pdf>

### **Revision of 42 CFR Part 34 (Medical Examination of Aliens) Removal of Human Immunodeficiency Virus (HIV) from Definition of Communicable Disease of Public Health Significance – Final Rule**

The Department of Health and Human Services (HHS) and Centers for Disease Control and Prevention (CDC) are removing HIV (human immunodeficiency virus) infection from the list of diseases that keep people who are not U.S. citizens from entering the United States.

HHS has authority to promulgate regulations that establish requirements for the medical examination of aliens (immigrants, refugees, asylees, and parolees) before they may be admitted into the United States. HHS/CDC/Division of Global Migration and Quarantine administers the regulations which include the health-related conditions that make aliens ineligible for entry into the United States. On November 2, 2009, HHS/CDC posted the final rule in the Federal Register regarding these regulations. The effective date of this rule is January 4, 2010.

<http://www.cdc.gov/immigrantrefugeehealth/laws-regs/hiv-ban-removal/final-rule.html>

Specific Laws and Regulations Governing the Control of Communicable Diseases:

<http://www.cdc.gov/quarantine/SpecificLawsRegulations.html>

### **\*\* NIH Proposes Revisions to the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)-04 March 2009**

<http://oba.od.nih.gov/oba/rac/ProposeRevisionsNIHGuidelines-March-4-2009.pdf>

For the purposes of clarification and in acknowledgement of the rapidly developing field of synthetic biology, the NIH is proposing a number of amendments to the current NIH Guidelines. The proposed revisions to the NIH Guidelines include:

- Broadening the scope of the NIH Guidelines, which currently cover laboratory and clinical research involving DNA molecules created via recombinant techniques (i.e., joining of DNA molecules). NIH proposes to encompass nucleic acids that are synthesized chemically or by other means without the use of recombinant technology.
- Revising the criteria for determining when introduction of a drug resistance trait into a microorganism must be reviewed and approved by the NIH Director. NIH proposes to remove the current language regarding a microorganism's ability to acquire the trait naturally, since this criterion may not be determinative of the safety and public health implications of the research. As proposed, this portion of the NIH Guidelines would state,

"the deliberate transfer of a drug resistance trait to microorganisms, if such acquisition could compromise the ability to treat or manage disease caused by that microorganism in human and veterinary medicine, or agriculture." The proposed amendment also contains additional language requiring consideration of the utility of the drug in certain subpopulations.

- Changing the level of review for recombinant or synthetic experiments involving more than half but less than two-thirds of the genome of certain viruses in tissue culture

### **Guidance on the Applicability of the Select Agent Regulations to Issues of Synthetic Genomics**

On 23 February 2009, the US Department of Health and Human Services and the US Department of Agriculture jointly announced the public release of guidance regarding the application of the current Select Agents Regulations to those who create and use synthetic genomic products. The current Select Agent Regulations implement the provisions of the Agricultural Bioterrorism Act of 2002 and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Select Agents are bacteria, viruses, fungi, other microorganisms and toxins that have been deemed to have the potential to pose a significant risk to public health, plant or animal health, or plant or animal production. Regulation of the possession, use, and transfer of select agents is implemented by the U.S. Department of Agriculture Animal and Plant Health Inspection Service (USDA/APHIS) and the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (HHS/CDC). Individuals applying for access to Select Agents must undergo a security risk assessment by the Federal Bureau of Investigation, Criminal Justice Information Service (FBI/CJIS). Information on the Select Agent Regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331) can be found at the national select agent website ([www.selectagents.gov](http://www.selectagents.gov)). The Guidance on the Applicability of the Select Agent Regulations to Issues of Synthetic Genomics is available at:

<http://www.selectagents.gov/resources/Applicability%20of%20the%20Select%20Agents%20Regulations%20to%20Issues%20of%20Synthetic%20Genomics.pdf>

### **Possession, Use and Transfer of Select Agents and Toxins (Section 610 Review)**

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorizes the Secretary of Health and Human Services (HHS) to regulate the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety. These regulations are set forth at 42 CFR 73.3. HHS is proposing to amend the list of HHS select agents and toxins by adding Chapare virus to the list of HHS select agents and toxins based on the conclusion that the Chapare virus has been phylogenetically identified as a Clade B arenavirus and is closely related to other South American arenaviruses that cause haemorrhagic fever, particularly Sabia virus. Risk assessments conducted by arenavirus experts at CDC have resulted in the determination that the manipulation of Chapare virus should be performed only under maximum containment conditions in BSL4 laboratories. Based on these assessments, and the corresponding need to protect public health and safety, HHS has published a proposal to add this agent to the HHS list of select agents and toxins:

<http://www.selectagents.gov/resources/Chapare%20FRN.pdf>

On July 13, 2009, the Department of Health and Human Services (HHS) published in the Federal Register a notice proposing to add SARS-associated coronavirus (SARS-CoV) to the list of HHS Select Agents and toxins found at 42 CFR 73.3. We are proposing this action because (1) SARS-CoV can cause significant mortality, especially in the elderly; (2) the virus has the capability of easily being transmitted from human to human; (3) there is currently no vaccine or antiviral approved for the treatment or prevention of infections caused by the SARS-CoV virus; and (4) it has been documented that the virus may persist in the environment.

[http://www.selectagents.gov/resources/Notice%20of%20proposed%20rulemaking\\_SARS-CoV.pdf](http://www.selectagents.gov/resources/Notice%20of%20proposed%20rulemaking_SARS-CoV.pdf)

**Executive Order 13486 from January 9, 2009- Strengthening Laboratory Biosecurity in the United States:** <http://edocket.access.gpo.gov/2009/E9-818.htm>

The U.S. Government Working Group on Strengthening the Biosecurity of the United States was established by Executive Order 13486 on January 9, 2009 to review existing policies and practices in place at Federal and non-Federal facilities that conduct research on; manage clinical or environmental laboratory operations involving; or handle, store, or transport biological select agents and toxins. The charge to the WG included development of recommendations for new legislation, regulations, guidance, or practices for security and personnel assurance and options for establishing oversight mechanisms. The report represents the culmination of the Working Group members' research and deliberation, including consideration of information obtained from public consultation and laboratory site visits. The Working Group was chaired by officials from U.S. Department of Health and Human Services and the U.S. Department of Defense and included representatives from a broad range of Federal agencies that have responsibility for various aspects of the research on and security of biological select agents and toxins. The report of the U.S. Government Working Group on Strengthening the Biosecurity of the United States is available at: <http://www.hhs.gov/aspr/omsph/biosecurity/biosecurity-report.pdf>

**Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight**

The Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight was established to undertake an intensive analysis of the current framework of biosafety and biocontainment oversight of research activities involving infectious agents and toxins in high- and maximum-containment research facilities with the goal of exploring strategies to address concerns voiced by Congress and the general public. The Task Force is chaired by officials from U.S. Department of Health and Human Services and the U.S. Department of Agriculture and is comprised of representatives from a broad range of Federal departments and agencies that have responsibility for, and oversight of the management of biohazard risks. The task force conducted a comprehensive assessment of the current biosafety/biocontainment oversight framework for these facilities and activities in all sectors; developed specific objectives for improving the current biosafety/biocontainment oversight framework; and developed options and recommendations for achieving the objectives. It is the expectation of the task force that these recommendations will lead to the development and implementation of an optimized framework for biosafety and biocontainment oversight. The report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight is available at:

<http://www.hhs.gov/aspr/omsph/biosafetytaskforce/biosafetycontainmentrpt092009.pdf>

**President's Memorandum on Transparency and Open Government, 21 January 2009**

“...to ensure the public trust and establish a system of transparency, public participation, and collaboration...”

[http://www.whitehouse.gov/the\\_press\\_office/Transparency\\_and\\_Open\\_Government](http://www.whitehouse.gov/the_press_office/Transparency_and_Open_Government)

**President's Memorandum on Science Integrity, 09 March 2009**

“...The public must be able to trust the science and scientific process informing public policy decisions. Political officials should not suppress or alter scientific or technological findings and conclusions. If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking. The selection of scientists and technology professionals for positions in the executive branch should be based on their scientific and technological knowledge, credentials, experience, and integrity...”

[http://www.whitehouse.gov/the\\_press\\_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09](http://www.whitehouse.gov/the_press_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09)

**Form F**

**BWC - Confidence Building Measure**

Declaration of Past Activities in Offensive and/or Defensive  
Biological Research and Development Programmes

United States of America

April 15, 2010

Declaration of past activities in offensive and/or defensive biological research and development programmes

**1. Date of entry into force of the Convention for the State party.**

March 26, 1975

**2. Past offensive biological research and development programmes:**

Nothing new to declare

**Form G**

**BWC - Confidence Building Measure**

Declaration of Vaccine Production Facilities

United States of America

April 15, 2010

Declaration of Vaccine Production Facilities

The following website is provided by the US Food and Drug Administration as a reference for a current list of vaccines licensed in the United States and associated production facilities:

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm>

Data provided in CBM Form G constitute excerpts from the information provided on the publicly available website listed above (as accessed on 28 February 2010). Trade names are included when provided by the manufacturer. Specific and current information about the vaccine and contact information for the manufacturer is available by following the hyperlinks provided on the above website.

Declaration of Vaccine Production Facilities

**1. Name of facility:**

Emergent BioDefense Operations Lansing Inc.

**2. Location (mailing address):**

3500 N. Martin Luther King Jr. Blvd  
Lansing, Michigan 48906

**3. General description of the types of diseases covered:**

Anthrax disease caused by *Bacillus anthracis*.

Vaccine:

- Anthrax Vaccine Absorbed (BioThrax).

Declaration of Vaccine Production Facilities

**1. Name of facility:**

MassBiologics

**2. Location (mailing address):**

University of Massachusetts Medical School  
Boston, MA 02130

**3. General description of the types of diseases covered:**

Diphtheria and tetanus caused by *Corynebacterium diphtheriae* and *Clostridium tetani*.

Vaccine:

- Tetanus and Diphtheria Toxoids, Adsorbed

Declaration of Vaccine Production Facilities

**1. Name of facility:**

MedImmune LLC

**2. Location (mailing address):**

One MedImmune Way  
Gaithersburg, MD 20878

**3. General description of the types of diseases covered:**

Influenza disease caused by pandemic (H1N1) 2009 virus.  
Influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

Vaccine:

- Influenza A (H1N1) 2009 Monovalent Vaccine
- Influenza Vaccine Live, Intranasal (FluMist)

Declaration of Vaccine Production Facilities

**1. Name of facility:**

Merck & Co, Inc.

**2. Location (mailing address):**

One Merck Drive  
P.O. Box 100  
Whitehouse Station, NJ 08889-0100

**3. General description of the types of diseases covered:**

Invasive disease caused by *Haemophilus influenzae*; type b infection caused by all known subtypes of hepatitis B virus; Hepatitis A disease; Vulvar and vaginal cancer and certain diseases caused by Human Papillomavirus (HPV) Types 6, 11, 16, and 18; Measles (rubeola); Mumps; disease caused by *Streptococcus pneumoniae*; Rotavirus disease; Rubella (German measles) disease; Varicella disease caused by the varicella-zoster virus (VZV); Herpes zoster (shingles) disease.

Vaccines:

- Haemophilus b Conjugate (Meningococcal Protein Conjugate) Vaccine (PedvaxHIB)
- Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine (COMVAX)
- Hepatitis A Vaccine, Inactivated (VAQTA)
- Hepatitis B Vaccine (Recombinant) (RECOMBIVAX HB)
- Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant (Gardasil)
- Measles, Mumps, Rubella and Varicella Virus Vaccine Live (ProQuad)
- Measles, Mumps, and Rubella Virus Vaccine, Live (M-M-R II)
- Pneumococcal Vaccine, Polyvalent (Pneumovax 23)
- Rotavirus Vaccine, Live, Oral, Pentavalent (RotaTeq)
- Varicella Virus Vaccine, Live (Varivax)
- Zoster Vaccine, Live (Zostavax)
  
- Measles Virus Vaccine Live (ATTENUVAX) [no longer being made]
- Mumps Virus Vaccine Live, Jeryl Lynn Strain (Mumpsvac) [no longer being made]
- Rubella Virus Vaccine Live (MERUVAX II) [no longer being made]

Declaration of Vaccine Production Facilities

**1. Name of facility:**

Organon Teknika Corporation LLC

**2. Location (mailing address):**

100 Rodolphe Street  
Building 1300  
Durham, NC 27712

**3. General description of the types of diseases covered:**

BCG Vaccine (TICE® BCG) for intravesical use is an attenuated, live culture preparation of the Bacillus (Bacille) of Calmette and Guerin (BCG) strain of *Mycobacterium bovis* that has been used as a therapy for, and prophylaxis against, recurrent tumors in patients with carcinoma in situ (CIS) of the urinary bladder, and to prevent recurrence of Stage TaT1 papillary tumors of the bladder at high risk of recurrence.

Declaration of Vaccine Production Facilities

**1. Name of facility:**

Sanofi Pasteur, Inc

**2. Location (mailing address):**

Discovery Drive  
Swiftwater, PA 18370

**3. General description of the types of diseases covered:**

Diphtheria caused by *Corynebacterium diphtheria*; tetanus caused by *Clostridium tetani*; pertussis diseases; influenza disease caused by pandemic (H1N1) 2009 virus; influenza disease caused by H5N1 subtype; influenza disease caused by influenza virus subtypes A and type B; invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135; meningitis and meningococemia caused by *N. meningitidis*; and Yellow fever acute viral illness caused by a mosquito-borne flavivirus.

Vaccines:

- Diphtheria and Tetanus Toxoids Adsorbed USP (For Pediatric Use) (DT)
- Tetanus and Diphtheria Toxoids Adsorbed For Adult Use (DECAVAC)
- Tetanus Toxoid For Booster Use Only
- Tetanus Toxoid Adsorbed
- Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine, Adsorbed (Tripedia®) (DTaP)
- Influenza A (H1N1) 2009 Monovalent Vaccine
- Influenza Virus Vaccine, H5N1
- Virus Vaccine (Fluzone® and Fluzone High-Dose)
- Meningococcal Polysaccharide (Groups A, C, Y and W-135) Diphtheria Toxoid Conjugate Vaccine (Menactra®)
- Meningococcal Polysaccharide Vaccine, Groups A, C, Y, W135 Combined (Menomune®-A/C/Y/W-135)
- Yellow Fever Vaccine (YF-VAX®)

®- Registered trademarks of Sanofi Pasteur Inc. or an affiliated company

Declaration of Vaccine Production Facilities

**1. Name of facility:**

Sanofi Pasteur Biologics Co.

**2. Location (mailing address):**

38 Sidney Street  
Cambridge, MA 02139

**3. General description of the types of diseases covered:**

Smallpox disease.

Vaccine:

Smallpox (Vaccinia) Vaccine, Live (ACAM2000)

Declaration of Vaccine Production Facilities

**1. Name of facility:**

Wyeth Pharmaceuticals Inc

**2. Location (mailing address):**

Pfizer, Inc.,  
235 East 42nd Street  
New York, NY 10017.

**3. General description of the types of diseases covered:**

Invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F and otitis media caused by Streptococcus pneumoniae serotypes 4, 6B, 9V, 14, 18C, 19F and 23F.

Vaccines:

Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM197 Protein) (Pevnar®)

Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein) (Pevnar 13™)

## **Appendices**

### **BWC - Confidence Building Measure**

United States of America

April 15, 2010

**Biological Select Agents and Toxins**

Biological Select Agents and Toxins are biological pathogens and toxins that the United States has determined have the potential to pose a severe threat to public health and safety, animal and plant health, or animal and plant products. The possession, use, and transfer of these agents is regulated by the U.S. Department of Health and Human Services (HHS) Centers for Disease Control and Prevention and the U.S. Department of Agriculture Animal and Plant Health Inspection Service under the Select Agent Regulations found in Part 73 of Title 42 of the Code of Federal Regulations, Part 331 of Title 7 of the Code of Federal Regulations, and Part 121 of Title 9 of the Code of Federal Regulations.

Information on Biological Select Agents and Toxins can be found on the National Select Agent Registry website: <http://www.selectagents.gov/>

**HHS Select Agents and Toxins**

Abrin	Saxitoxin
Botulinum neurotoxins	Shiga-like ribosome inactivating proteins
Botulinum neurotoxin producing species of <i>Clostridium</i>	Shigatoxin
Cercopithecine herpesvirus 1 (Herpes B virus)	South American Haemorrhagic Fever viruses
<i>Clostridium perfringens epsilon toxin</i>	<ul style="list-style-type: none"><li>• Flexal</li><li>• Guanarito</li><li>• Junin</li><li>• Machupo</li><li>• Sabia</li></ul>
<i>Coccidioides posadasii/Coccidioides immitis</i>	Staphylococcal enterotoxins
Conotoxins	T-2 toxin
<i>Coxiella burnetii</i>	Tetrodotoxin
Crimean-Congo haemorrhagic fever virus	Tick-borne encephalitis complex (flavi) viruses
Diacetoxyscirpenol	<ul style="list-style-type: none"><li>• Central European Tick-borne encephalitis</li><li>• Far Eastern Tick-borne encephalitis</li><li>• Kyasanur Forest disease</li><li>• Omsk Hemorrhagic Fever</li><li>• Russian Spring and Summer encephalitis</li></ul>
Eastern Equine Encephalitis virus	Variola major virus (Smallpox virus)
Ebola virus	Variola minor virus (Alastrim)
<i>Francisella tularensis</i>	<i>Yersinia pestis</i>
Lassa fever virus	
Marburg virus	
Monkeypox virus	
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)	
Ricin	
<i>Rickettsia prowazekii</i>	
<i>Rickettsia rickettsii</i>	

### **OVERLAP Select Agents and Toxins**

*Bacillus anthracis*  
*Brucella abortus*  
*Brucella melitensis*  
*Brucella suis*  
*Burkholderia mallei* (formerly *Pseudomonas mallei*)

*Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*)  
Hendra virus  
Nipah virus  
Rift Valley fever virus  
Venezuelan Equine Encephalitis virus

### **USDA Select Agents and Toxins**

African horse sickness virus  
African swine fever virus  
Akabane virus  
Avian influenza virus (highly pathogenic)  
Bluetongue virus (exotic)  
Bovine spongiform encephalopathy agent  
Camel pox virus  
Classical swine fever virus  
*Ehrlichia ruminantium* (Heartwater)  
Foot-and-mouth disease virus  
Goat pox virus  
Japanese encephalitis virus  
Lumpy skin disease virus  
Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1)

Menangle virus  
*Mycoplasma capricolum* subspecies *capripneumoniae* (contagious caprine pleuropneumonia)  
*Mycoplasma mycoides* subspecies *mycoides* small colony (*Mmm* SC) (contagious bovine pleuropneumonia)  
Peste des petits ruminants virus  
Rinderpest virus  
Sheep pox virus  
Swine vesicular disease virus  
Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3  
Virulent Newcastle disease virus 1

### **USDA PLANT PROTECTION AND QUARANTINE (PPQ) Select Agents and Toxins**

*Peronosclerospora philippinensis*  
(*Peronosclerospora sacchari*)  
*Phoma glycinicola* (formerly *Pyrenochaeta glycines*)  
*Ralstonia solanacearum* race 3, biovar 2  
*Rathayibacter toxicus*

*Sclerophthora rayssiae* var *zeae*  
*Synchytrium endobioticum*  
*Xanthomonas oryzae*  
*Xylella fastidiosa* (citrus variegated chlorosis strain)

**NIAID Category A, B, and C Priority Pathogens**

The National Institute of Allergy and Infectious Disease (NIAID) categorization of pathogens identifies specific pathogens as priorities for additional research efforts as part of the NIAID biodefense research agenda.

Additional information on NIAID Category A, B, and C Priority Pathogens can be found on the NIAID Biodefense website:

<http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/research/Pages/CatA.aspx>

<http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Documents/categorybandc.pdf>  
as well as:

<http://funding.niaid.nih.gov/ncn/glossary/default5.htm>

<http://pathema.jcvi.org/pathema/AbcGenomes.shtml>

<http://www.fas.org/irp/threat/cbw/niaid0803.pdf>

**Category A**

**Bacteria**

- *Bacillus anthracis* (Anthrax)
- *Clostridium botulinum* (Botulism)
- *Francisella tularensis* (Tularemia)
- *Yersinia pestis* (Plague)

**Viruses**

- Variola major (Smallpox) and other pox viruses
- Viral hemorrhagic fevers
  - Arenaviruses
    - Guanarito virus
    - Junin virus
    - Lassa virus
    - Lymphocytic choriomeningitis virus
  - Bunyaviruses
    - Machupo virus
    - Hantaviruses
    - Rift Valley fever virus
  - Flaviruses
    - Dengue fever viruses
  - Filoviruses
    - Ebola virus
    - Marburg virus

**Category B**

**Bacteria**

- *Burkholderia pseudomallei*
- *Burkholderia mallei* (Glanders)
- *Clostridium perfringens* (Epsilon toxin)
- *Coxiella burnetii* (Q fever)
- *Brucella melitensis*, *abortus*, *suis*, and *canis*
- *Staphylococcus aureus* (Enterotoxin B)
- *Rickettsia prowazekii*
- *Chlamydia psittaci*
- Food and Waterborne Pathogens
  - *Escherichia coli* O157:H7
  - *Vibrio cholerae* (Cholera)
  - *Salmonella* species
  - *Shigella* species
  - *Listeria monocytogenes*
  - *Campylobacter jejuni*
  - *Yersinia enterocolitica*

### Viruses

- Viral encephalitis
  - West Nile virus
  - Eastern equine encephalitis virus
  - Western equine encephalitis virus
  - Venezuelan equine encephalitis virus
  - La Crosse virus
  - Japanese encephalitis virus
  - Kyasanur forest virus
  - California encephalitis viruses
- Food and Waterborne Pathogens
  - Caliciviruses (Gastroenteritis)
  - Hepatitis A virus (Hepatitis A)

### Protozoa

- Food and Waterborne Pathogens
  - *Cryptosporidium parvum*
  - *Cyclospora cayatanensis*
  - *Giardia lamblia*
  - *Entamoeba histolytica*
  - *Toxoplasma gondii*
  - *Microsporidia*

### Plants

- *Ricinus communis* Castor bean (Ricin toxin)

## **Category C**

Emerging infectious disease threats such as Nipah virus and additional hantaviruses.  
NIAID priority areas:

### Bacteria

- *Coccidioides immitis* (added February 2008)
- *Coccidioides posadasii* (added February 2008)
- *Mycobacterium tuberculosis* (including multidrug-resistant Tuberculosis)
- Other *Rickettsia*

### Viruses

- Chikungunya virus
- Influenza viruses
- Nipah virus
- Rabies virus
- Severe acute respiratory syndrome associated coronavirus (SARS-CoV)
- Tickborne hemorrhagic fever viruses
  - Crimean-Congo hemorrhagic fever virus
- Tickborne encephalitis viruses
- Yellow fever virus
- Other Hantaviruses

### Prions

Antimicrobial resistance, excluding research on sexually transmitted organisms\*

- Research on mechanisms of antimicrobial resistance
- Studies of the emergence and/or spread of antimicrobial resistance genes within pathogen populations

- Studies of the emergence and/or spread of antimicrobial-resistant pathogens in human populations
- Research on therapeutic approaches that target resistance mechanisms
- Modification of existing antimicrobials to overcome emergent resistance

Antimicrobial research, as related to engineered threats and naturally occurring drug-resistant pathogens, focused on development of broad-spectrum antimicrobials

Innate immunity, defined as the study of nonadaptive immune mechanisms that recognize, and respond to, microorganisms, microbial products, and antigens

**\*NIAID Category C Antimicrobial Resistance—Sexually Transmitted Excluded Organisms**

*Bacterial vaginosis, Chlamydia trachomatis, Cytomegalovirus, Granuloma inguinale, Hemophilus ducreyi, Hepatitis B virus, Hepatitis C virus, Herpes Simplex virus, Human immunodeficiency virus, Human papillomavirus, Neisseria gonorrhoea, Treponema pallidum, Trichomonas vaginalis*

Compiled list of biological agents and toxins used for biodefense research

**Biological Agents**

*Acetivibrio ethanolgignens*  
*Acinetobacter baumannii*  
*Actinobacillus equuli*  
*Actinobacillus lignieresii*  
*Actinobacillus pleuropneumoniae*  
*Actinomyces naeslundii*  
Adenoviruses  
Adenovirus (recombinant)  
Adenovirus type 5  
Adeno-Associated virus  
African Swine Fever  
Aleutian mink disease virus  
*Alternaria spp.*  
*Anaerobiospirillum*  
*Anaeroplasma*  
*Aspergillus flavus*  
*Aspergillus niger*  
*Aspergillus versicolor*  
Avian Influenza virus, high pathogenicity  
Avian Influenza virus, low pathogenicity  
Avian metapneumonvirus

*Bacille Calmette-Guérin*  
*Bacillus anthracis*  
*Bacillus anthracis* (attenuated)  
*Bacillus anthracis* (inactivated)  
*Bacillus anthracis*, Ames strain (CRP inactivated)  
*Bacillus anthracis* Delta Sterne  
*Bacillus anthracis* Sterne strain  
*Bacillus anthracis* V770-NP-1R  
*Bacillus anthracis* (vaccine strain)  
*Bacillus anthracis*, genetic material  
*Bacillus anthracis*, protein  
*Bacillus anthracis*, protein (protective antigen)  
*Bacillus anthracis*, viable organism  
*Bacillus brevis*

*Bacillus cereus* (several strains including inactivated and BSL-1 strains)  
*Bacillus cereus*, genetic material  
*Bacillus circulans*  
*Bacillus globigii* [atrophaeus] spores  
*Bacillus mycoides*  
*Bacillus sphaericus*  
*Bacillus subtilis*  
*Bacillus subtilis*, genetic material  
*Bacillus subtilis*, protein  
*Bacillus subtilis* variant niger  
*Bacillus thuringiensis*  
*Bacillus thuringiensis* Al Hakam  
*Bacillus thuringiensis* (israelensis)  
*Bacillus thuringiensis kurstaki*  
*Bacillus thuringiensis*, genetic material  
*Bacillus thuringiensis*, protein  
bacteriophage MS2  
bacteriophage Q-beta  
bacteriophage T4  
*Bacteroides fragilis*  
*Bartonella quintana* (inactivated nucleic acid)  
Border disease virus  
*Bordetella avium*  
*Bordetella bronchiseptica*  
*Bordetella hinzii*  
*Bordetella pertussis*  
*Borrelia burgdorferi*  
Bovine adenovirus  
Bovine adenovirus D  
Bovine adenovirus E  
Bovine astrovirus  
Bovine calicivirus  
Bovine herpes and retroviruses: Untyped  
Bovine herpesvirus  
Bovine herpesviruses 1,2,4,5,PO38 & PO47  
Bovine lentivirus  
Bovine parainfluenza virus

Bovine parainfluenza virus 3  
 Bovine parvovirus  
 Bovine respiratory syncytial virus  
 Bovine serum albumin (BSA)  
 Bovine spumavirus  
 Bovine viral diarrhea virus  
*Brachyspira alvinipulli*  
*Brachyspira hyodysenteriae*  
*Brachyspira innocens*  
*Brachyspira pilosicoli*  
*Brucella* species  
*Brucella* (killed)  
*Brucella abortus*  
*Brucella canis*  
*Brucella melitensis*  
*Brucella melitensis* (inactivated)  
*Brucella melitensis*, genetic material  
*Brucella melitensis*, protein  
*Brucella neotomae*  
*Brucella ovis*  
*Brucella suis*  
*Burkholderia* spp.  
*Burkholderia andropogonis*  
*Burkholderia caryophylli*  
*Burkholderia cepacia*  
*Burkholderia gladioli*  
*Burkholderia glumae*  
*Burkholderia mallei*  
*Burkholderia mallei* (inactivated)  
*Burkholderia mallei* (killed)  
*Burkholderia pseudomallei*  
*Burkholderia thailandensis*  
*Burkholderia* spp., genetic material  
*Burkholderia* spp., protein  
  
 Cache valley virus  
 Camel Pox virus  
*Campylobacter coli*  
*Campylobacter fetus*  
*Campylobacter jejuni*  
*Campylobacter jejuni*, inactivated nucleic acid  
*Campylobacter lari*  
*Campylobacter* spp.  
*Campylobacter sputorum*  
*Candida albicans*

*Candida glabrata*  
 Canine calicivirus  
 Canine coronavirus  
 Canine parvovirus  
 Caprine adenovirus 2 serotypes  
 Caprine adenovirus A  
 Caprine herpesvirus 1  
 Caprine lentivirus  
 Caprine respiratory syncytial virus  
 Cercopithecine Herpes virus 1  
*Chaetomium globosum*  
 Chikungunya virus  
*Chlamydia trachomatis*  
*Chlorella pyrenoidosa*  
*Chlorella sorokiniana*  
 Chronic wasting disease  
*Cladosporium cladosporioides*  
 Classical Swine Fever  
*Clostridium argentinense*  
*Clostridium botulinum*  
*Clostridium botulinum* (inactivated)  
*Clostridium botulinum*, genetic material  
*Clostridium botulinum*, protein  
*Clostridium butyricum*  
*Clostridium difficile*  
*Clostridium novyi*  
*Clostridium perfringens*  
*Clostridium perfringens*, inactivated nucleic acid  
*Clostridium septicum*  
*Clostridium sordelli*  
*Clostridium sporogenes*  
*Clostridium sporogenes*  
*Clostridium tetani*  
*Clostridium tetani*, inactivated nucleic acid  
*Coccidioides immitis*  
 Congo Hemorrhagic Fever virus  
*Corynebacterium* spp.  
*Corynebacterium bovis*  
*Corynebacterium pseudotuberculosis*  
 Cow Pox virus  
*Coxiella burnetii*  
*Coxiella burnetii* (inactivated)  
*Coxiella burnetii* (killed)  
*Coxiella burnetii*, genetic material

*Cryptosporidium parvum*, inactivated nucleic acid)

Deer adenovirus

*Deinococcus radiodurans* UWO 298

Dengue virus

Dengue virus, nucleic acid

*Dichomitus squalens*

Eastern Equine Encephalitis virus

Eastern Equine Encephalitis virus (killed)

Eastern Equine Encephalitis virus, genetic material

Ebola virus

Ebola virus (killed)

Ebola virus, genetic material

Ebola virus, protein

*Encephalitis*

Enteric viruses of poultry

Epizootic hemorrhagic disease virus

Equine adenovirus

Equine arteritis virus

Equine herpesvirus 1 & 2

*Erwinia herbicola*

*Erwinia herbicola* (inactivated)

*Erwinia herbicola*, genetic material

*Erwinia herbicola*, protein

Erysipelothrix spp.

*Escherichia coli*

*Escherichia coli* K12

*Escherichia coli* BL21

*Escherichia coli* 0157:H7

*Escherichia coli* 0157:H7 (killed)

Feline calicivirus

Feline infectious peritonitis virus

Feline parvovirus

Flexal virus

Foot and Mouth Disease

Foot and Mouth Disease, genetic material

*Francisella novicida* Utah 112 (viable)

*Francisella novicida*-like isolates

*Francisella philomiragia*

*Francisella philomiragia* (inactivated)

*Francisella tularensis* (LVS)

*Francisella tularensis*

*Francisella tularensis* (inactivated)

*Francisella tularensis*, vaccine strain

*Francisella tularensis* holartica (LVS), viable organism

*Francisella tularensis* Schu4 (CRP inactivated)

*Francisella tularensis* genetic material

*Francisella tularensis*, protein

*Francisella* species (non-pathogenic), genetic material

*Fusarium oxysporum*

*Fusobacterium*

*Fusobacterium necrophorum*

Guanarito virus

*Haemophilus avium*

*Haemophilus paragallinarium*

*Haemophilus parainfluenzae*

*Haemophilus parasuis*

*Haemophilus somnus*

*Hafnia alvei*

*Halobacterium solanarium*

Hanta virus

Hendra virus

Herpes simplex virus

Human immunodeficiency virus

Human papillomavirus

Ichinde virus

Influenza virus A and B

*Issatchenkia orientalis*

Japanese Encephalitis virus

Junin virus

*Klebsiella pneumoniae*

*Lactobacillus casei*

*Lactobacillus lactus*

Lassa virus

*Legionella pneumophila*

*Leishmania major*

Lentiviral vectors

Lentivirus Bovine immunodeficiency virus

*Leptospira biflexa*

*Leptospira borgpetersenii*  
*Leptospira inadai*  
*Leptospira interrogans*  
*Leptospira interrogans*, inactivated nucleic acid  
*Leptospira kirschneri*  
*Leptospira noguchii*  
*Leptospira santarosai*  
*Leptospira weilii*  
*Liberabacter africanus*  
*Liberabacter americanus*  
*Liberabacter asiaticus*  
*Listeria monocytogenes*  
 Lymphocytic Choriomeningitis virus  
  
 Machupo virus  
*Magnaporthe grisea*  
*Mannheimia glucosida*  
*Mannheimia haemolytica*  
 Marburg virus  
 Marburg virus (killed)  
 Marburg virus, genetic material  
 Marburg virus, protein  
 Marek's disease herpesvirus  
 Measles virus  
 Mink calicivirus  
 Modified Vaccinia Ankara (MVA) virus  
 Monkey Pox virus  
 Moose adenovirus  
 Moraxella bovis  
 Murine hepatitis virus  
 Murine norovirus  
*Mycobacterium avium*  
*Mycobacterium bovis*  
*Mycobacterium bovis (BCG) vaccine*  
*Mycobacterium kansasii*  
*Mycobacterium paratuberculosis*  
*Mycobacterium smegmatis*  
*Mycobacterium smegmatis, strain MC2*  
*Mycobacterium tuberculosis*  
*Mycobacterium tuberculosis (drug resistant)*  
*Mycobacterium tuberculosis*, inactivated nucleic acid  
*Mycoplasma arginini*  
*Mycoplasma capricolum*  
*Mycoplasma conjunctivae*  
  
*Mycoplasma gallisepticum*  
*Mycoplasma ovipneumoniae*  
*Mycoplasma putrefaciens*  
*Mycoplasma synoviae*  
  
*Nannochloropsis*  
*Neisseria animals NA1*  
*Neisseria lactamica*  
*Neurospora crassa*  
 Newcastle disease virus (low virulent)  
 Newcastle disease virus (virulent)  
 Nipah virus  
  
 Odokoileus adenovirus  
 Orf virus  
*Ornithobacterium rhinotracheale*  
 Ovalbumin  
 Ovine adenovirus  
 Ovine adenovirus A  
 Ovine adenovirus B  
 Ovine adenovirus C  
 Ovine adenovirus D  
 Ovine lentiviruses (OPP & MVV)  
 Ovine parainfluenza virus 3  
 Ovine respiratory syncytial virus  
  
 Parainfluenza virus (types 1,2,3)  
*Pasteurella canis*  
*Pasteurella dagmatis*  
*Pasteurella gallinarum*  
*Pasteurella haemolytica*  
*Pasteurella langae*  
*Pasteurella multocida*  
*Pasteurella pneuematropica*  
*Pasteurella stomatis*  
*Pasteurella trehalosi*  
*Pasteurella ureae*  
*Penicillium chryogenum*  
*Penicillium funiculosum*  
*Peronosclerospora phillipinensis*  
*Peronosclerospora sacchari*  
*Phakopsora pachyrhizi*  
*Phanerochaete chrysosporium*  
*Phytophthora infestans*  
*Phytophthora kernoviae*  
*Phytophthora ramorum*

Pichinde virus  
 Plum Pox Virus  
 Porcine adenovirus  
 Porcine astrovirus  
 Porcine calicivirus  
 Porcine circovirus  
 Porcine enterovirus  
 Porcine hemagglutinating encephalomyelitis  
 virus  
 Porcine parvovirus  
 Porcine reovirus  
 Porcine reproductive and respiratory  
 syndrome virus (PRRS virus, Porcine  
 arterivirus)  
 Porcine respiratory coronavirus  
 Powassan virus  
 Prions  
*Propionibacterium avidum*  
*Pseudomonas aeruginosa*  
*Pseudomonas fluorescens*  
*Pseudomonas oxalacticus*  
*Puccinia graminis tritici*  
*Puccinia striiformis*  
 Puumala virus  
  
*Ralstonia solanacearum* Race 3 biovar 2  
*Rathayibacter toxicus*  
 Respiratory syncytial virus  
*Rhodococcus equi*  
*Rickettsia*  
*Rickettsia prowazekii*  
*Rickettsia prowazekii*, genetic material  
*Rickettsia rickettsii*  
*Rickettsia rickettsii*, genetic material  
 Rift Valley Fever Virus  
  
 Sabia virus  
*Saccharomyces cerevisiae*  
*Saccharomyces cerevisiae* (HB-1/96489;  
 S288C; 966; BK9498; 1651; 1652; HOG1;  
 SSK1; SHO1; WT6899, WLP820,  
 WLP830, WTBY474)  
*Salmonella bongori*  
*Salmonella choleraesuis*  
*Salmonella dublin*  
*Salmonella enterica*

*Salmonella enteritidis*  
*Salmonella Heidelberg*  
*Salmonella mbandaka*  
*Salmonella montevideo*  
*Salmonella pullorum*  
*Salmonella ser braenderup*  
*Salmonella typhimurium*  
*Salmonella typhimurium* (killed)  
 San Miguel sea lion virus  
*Sclerophthora rayssiae* var. *zeae*  
 Semiliki Forest virus  
 Sendai virus  
*Serratia marcescens*  
 Severe acute respiratory syndrome virus  
*Shigella dysenteriae*  
*Shigella* ssp. (inactivated)  
 Simian human immunodeficiency virus  
 Simian immunodeficiency virus  
 Sindbis virus  
 Skunk calicivirus  
 Soybean Dwarf virus (dwarfing strain)  
 Soybean Dwarf virus (yellowing strain)  
*Staphylococcus aureus*  
*Staphylococcus aureus* (inactivated)  
*Staphylococcus aureus*, strains RN6390,  
 RN6911, ALC1743, ALC1740  
*Staphylococcus epidermidis*  
*Staphylococcus hominis*  
*Staphylococcus intermedius*  
*Staphylococcus saprophyticus*  
*Streptococcus agalactiae*  
*Streptococcus bovis*  
*Streptococcus dysgalactiae* ssp.  
*Streptococcus intermedius*  
*Streptococcus intestinalis*  
*Streptococcus pneumoniae*  
*Streptococcus pyogenes*  
*Streptococcus uberis*  
*Streptomyces coelicolor*  
*Streptomyces lividans*, designation FD  
 29404 [TK64]  
 Swine enterovirus  
 Swine influenza virus  
  
 Tacaribe virus  
*Thermomyces lanuginosus*

*Thermus aquaticus*, designation YT-1  
 Tick-borne encephalitis virus  
 Tick-borne flaviviruses  
 Tick-borne Langat virus  
 Tomato mosaic virus  
 Transmissible gastroenteritis virus  
 Transmissible mink encephalopathy  
*Treponema bryantii*  
*Treponema denticola*  
*Treponema hyodysenteriae*  
*Treponema phagedenis*  
*Treponema succinifaciens*

Vaccinia virus  
 Vaccinia virus (Inactivated)  
 Variola virus  
 Variola virus, genetic material  
 Venezuelan equine encephalitis virus  
 Venezuelan equine encephalitis virus  
 (inactivated)  
 Venezuelan Equine Encephalomyelitis virus  
 (TC-83) live  
 Venezuelan Equine Encephalomyelitis virus  
 (TC-83) (killed)  
 Venezuelan equine encephalitis virus,  
 genetic material  
 Vesicular stomatitis virus  
*Vibrio cholerae*  
*Vibrio cholerae* (killed)  
*Vibrio cholerae* 0:139  
*Vibrio cholerae*, inactivated DNA  
*Vibrio fisheri*  
*Vibrio fisheri* 7744, viable organism

*Vibrio harveyi*  
*Vibrio harveyi*, designation BB120  
 Water buffalo adenovirus  
 West Nile virus  
 Western equine encephalitis virus  
 Western equine encephalitis virus (killed)

*Xylella fastidiosa* (CVC strain)

Yellow Fever virus (vaccine strain)  
 Yellow fever virus (17D)  
*Yersinia* species  
*Yersinia bercovieri*  
*Yersinia enterocolitica*  
*Yersinia intermedia*  
*Yersinia pestis*  
*Yersinia pestis* (vaccine strains)  
*Yersinia pestis* (inactivated)  
*Yersinia pestis* (killed)  
*Yersinia pestis*, genetic material  
*Yersinia pestis*, proteins  
*Yersinia pestis* Colorado 92 pgm<sup>-</sup>  
 (attenuated)  
*Yersinia pestis* D27, inactivated nucleic acid  
*Yersinia pestis* (KIM)  
*Yersinia pestis* Lcr-/D1  
*Yersinia pestis* pgm-strain  
*Yersinia pseudotuberculosis*  
*Yersinia rohdei*  
*Yersinia ruckeri*  
*Yersinia pseudotuberculosis* (inactivated)

## **Toxins and Toxoids**

Abrin

Aflatoxins

Brevetoxin

Cholera toxin

*Clostridium botulinum* toxins (serotypes A-G)

*Clostridium botulinum* toxin (inactivated)

*Clostridium botulinum* toxoids [not toxins]

*Clostridium perfringens* toxins

Conotoxins

Deoxynivalenol

Diacetoxyscirpenol

Diphtheria toxin

Domoic acid

Fumonisin

Marine toxins

Microcystin LR

Neosaxitoxin

Ochratoxin

Pertussis toxin

Ricin

Ricin (inactivated)

Ricin A chain

Saxitoxin

Shiga toxin 1 and 2

Shigella Toxin

Staphylococcal enterotoxins (A-E, H, J, K)

Staphylococcal enterotoxin B (SEB) toxoid

T-2 Mycotoxin

Tetrodotoxin