United States of America

Confidence Building Measure Return covering 2018

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, 2019

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

Measure	Nothing to declare	Nothing new to declare	Year of last declaration if nothing new to declare
A, part 1			
A, part 2 (i)			
A, part 2 (ii)			
A, part 2 (iii)			
B			
C			
E			
F		√	1997
G			

Date: April 15, 2019

State Party to the Convention: United States of America

Date of ratification/accession to the Convention: March 26, 1975

National point of contact: Mr. Christopher Park, Department of State

Inquiries may be directed to ISN-BPS-DL@state.gov.

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:

Form A, Part 1

BWC - Confidence Building Measure

Exchange of data on research centres and laboratories

United States of America

April 15, 2019

Form A, Part 1 (i)

Exchange of data on research centres and laboratories[*]

1. Name(s) of facility.
National Biodefense Analysis and Countermeasures Center (NBACC)
[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
Operated by Battelle National Biodefense Institute LLC

3. Location and postal address.
8300 Research Plaza, Fort Detrick, Maryland 21702

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 (DHS)
U.S. Department of Justice (DOJ)
U.S. Department of State (DOS)
U.S. Department of Health and Human Services (HHS)

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m^2).
BSL 4 Laboratory 980 m^2

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.
NBACC conducts studies to better understand current and future biological threats; to assess vulnerabilities; and to determine potential impacts to guide the development of biological countermeasures such as detectors, drugs, vaccines, and decontamination technologies. When needed, NBACC conducts experimental programs to better characterize the benefits and risks of changes in U.S. biodefense preparations. NBACC also develops bioforensic assays and provides operational bioforensic analysis to support the attribution of biocrime and bioterrorism. (http://bnbi.org/)

The types of agents registered for use at NBACC are BSL-2 toxins, BSL-2 gram positive and gram negative bacterial agents, BSL-2 viral agents, BSL-3 gram positive and gram negative bacterial agents, BSL-3 viral agents, and BSL-4 viral agents.

[*] The Viral Immunology Center – National B Virus Resource Laboratory is not listed, as the BSL 4 and BSL 3 spaces in this facility have not been operational since 2015 due to remodeling delays.

Exchange of data on research centres and laboratories

1. Name(s) of facility.
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 Street, 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 (DoD) – Partly
U.S. Department of Homeland Security (DHS)
U.S. Department of Health and Human Services (DHHS)
U.S. Department of Agriculture (USDA)
Universities
Private sector companies

5. Number of maximum containment units[3] within the research centre and/or laboratory, with an indication of their respective size (m^2).
BSL 4 Laboratory 1186 m^2

6. 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.

Additional information can be found at: http://www.usamriid.army.mil/

Exchange of data on research centres and laboratories

1. Name(s) of facility.
Centers for Disease Control (CDC), Deputy Director for Infectious Disease (DDID)
[Declared in accordance with Form A, Part 2 (iii)]

2. Responsible public or private organization or company.
Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

3. Location and postal address.
1600 Clifton Road N.E., Atlanta, Georgia, 30329

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 (HHS)

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m^2).
BSL-4 Laboratory = 127 m^2
BSL-4 Laboratory = 279 m^2
BSL-4 Laboratory = 127 m^2

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.
Activities include developing diagnostic assays for public health, developing and validating methods to differentiate and characterize organisms and the toxins that they produce, developing environmental sampling methods for recovery of agents from porous and nonporous surfaces for public health, routine reference antimicrobial susceptibility testing of clinical isolates, conducting molecular and antigenic characterization of organisms, determining pathogenicity and virulence of infectious agents, development of culture-independent point of care diagnostics, maintaining emergency response laboratory expertise and capacity, evaluating vaccines and medical countermeasures, determining the natural history of infectious organisms, assessing immune correlates of protection, and conducting epidemiologic studies and surveillance for diseases. Additional information can be found at: http://www.cdc.gov/oid/. Please note, in 2018, 127 square meters of the reported BSL-4 space was utilized as BSL-3 Enhanced (BSL-3E) space, but remained capable of being used as BSL-4 space.

Biodefense activities include those with select agents (the select agents list is available at: http://www.selectagents.gov/SelectAgentsandToxinsList.html).

Form A, Part 1 (i)

Exchange of data on research centres and laboratories

1. Name(s) of facility
Integrated Research Facility at Fort Detrick (IRF – Frederick)
[Declared in Accordance with Form A, Part 2 (iii)]

2. Responsible public or private organization or company
National Institutes of Health, Department of Health and Human Services
Operated by Battelle Memorial Institute

3. Location and postal address
8200 Research Plaza, Frederick, Maryland 21702

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence
Department of Health and Human Services (HHS)

5. Number of maximum containment units[3] within the research centre and/or laboratory, with an indication of their respective size (m^2)
BSL 4 Laboratory = 1305 m^2

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate
The Integrated Research Facility at Fort Detrick in Frederick, Maryland (IRF-Frederick) is a component of the Division of Clinical Research of the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH). The mission of the IRF-Frederick is to manage, coordinate, and facilitate the conduct of emerging infectious disease and biodefense research to develop vaccines, countermeasures, and improved medical outcomes for patients. Research emphasis is placed on elucidating the nature of high consequence pathogens. Additional information can be found at: https://www.niaid.nih.gov/about/dir.

Exchange of data on research centres and laboratories

1. Name(s) of facility
Integrated Research Facility at Rocky Mountain Laboratories (IRF-RML)
[Declared in Accordance with Form A, Part 2 (iii)]

2. Responsible public or private organization or company
National Institutes of Health (NIH), Department of Health and Human Services (HHS)

3. Location and postal address
903 South 4th Street, Hamilton, Montana 59840 United States

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence
Department of Health and Human Services (HHS)

5. Number of maximum containment units[3] within the research centre and/or laboratory, with an indication of their respective size (m^2)
BSL-4 Laboratory = 1145 m^2

6. Scope and general description of activities, including type(s) of micro-organisms and/or toxins as appropriate
Rocky Mountain Laboratories (RML) is a component of the Division of Intramural Research of the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH). The RML mission is to play a leading role in the nation's efforts to develop diagnostics, vaccines, and therapeutics to combat emerging and re-emerging infectious diseases. Research at the Integrated Research Facility at Rocky Mountain Laboratories (IRF-RML) is dedicated to understanding the mechanisms of pathogenesis of microbial agents associated with or likely to cause serious or lethal human diseases using molecular methods and animal model systems. Additional information can be found at: https://www.niaid.nih.gov/about/rocky-mountain-laboratories.

Exchange of data on research centres and laboratories

1. Name(s) of facility[2]
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 Boulevard, Galveston, Texas 77555

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence
State of Texas and the University of Texas Medical Branch
U.S. Department of Agriculture (USDA)
Private Foundations
Pharmaceutical and Biotechnology Industries
U.S. Department of Energy (DOE)
U.S. Department of Defense (DOD)
U.S. Department of Homeland Security (DHS)
National Institutes of Health (NIH)
Centers for Disease Control and Prevention (CDC)

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m^2)
BSL-4 Laboratory = 186 m^2 (Shope Laboratory)
BSL-4 Laboratory = 1022 m^2 (GNL Laboratory)

6. Scope and general description of activities, including type(s) of microorganisms 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

1. Name(s) of facility
The Betty Slick and Lewis J. Moorman, Jr. Laboratory Complex

2. Responsible public or private organization or company
Texas Biomedical Research Institute

3. Location and postal address
P.O. Box 760549, San Antonio, Texas 78245-0549

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence
Department of Health and Human Services (HHS)
Department of Defense (DOD) - partly
Department of Homeland Security (DHS)
Private Sector Companies
Private Donors

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m^2)
BSL 4 Laboratory = 114 m^2

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.
The mission of the Laboratory is to develop vaccines and therapeutics against viral pathogens, and to determine how viruses replicate and spread. Scientists are studying new and emerging disease threats, possible bioterrorism agents, and as-yet uncharacterized agents for biodefense. TXBiomed (formerly Southwest Foundation for Biomedical Research) has permits from the U.S. Department of Agriculture and the Centers for Disease Control to work on select agents. Additional information can be found at: https://www.txbiomed.org/about/extraordinary-resources/.

Form A, Part 1 (i)

Exchange of data on research centres and laboratories

1. Name(s) of facility.
The Boston University National Emerging Infectious Diseases Laboratories (NEIDL)

2. Responsible public or private organization or company:
Boston University

3. Location and postal address.
620 Albany Street, Boston, MA 02118

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.
National Institute of Allergly and Infectious Disease (NIAID), U.S. National Institute of Health (NIH)
Boston University
U.S. Department of Health and Human Services (DHHS)
Pharmaceutical and Biotechnology companies
Private foundations

5. Number of maximum containment units[3] within the research centre and/or laboratory, with an indication of their respective size (m^2).
BSL-2 Laboratory = 2,470 m^2
BSL-3 Laboratory = (5 suites + 7 animal rooms) 960 m^2
BSL-4 Laboratory = (All ABSL-4 spaces are integrated with 6 suites + 7 animal rooms) 968 m^2

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.
The mission of the Boston University National Emerging Infectious Diseases Laboratories (NEIDL) is to generate and translate fundamental knowledge on high priority emerging infectious diseases for the benefit of the public health, locally, nationally, and globally.

Emerging infectious diseases are defined as those that have newly appeared and been recognized in the population, or have existed but are rapidly increasing in incidence or in geographic range. To meet this mission the NEIDL will:
1. Perform innovative basic, translational, and clinical research on emerging infectious diseases, especially those identified as high priority category A, B, and C agents (http://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens), in order to develop diagnostics tests, treatments and vaccines to promote public health.
2. Provide education and training in these areas of research, in order to develop the next generation of scientists in this field, and to support a national response in the event of a biodefense emergency.
3. Establish a research facility with the highest attention to community and laboratory safety and security.
Types of microorganisms currently being used are BSL-4 viruses.
Additional information can be found at: http://www.bu.edu/today/2017/neidl-bsl-4-lab-approved/

Form A, Part 2 (i)

BWC - Confidence Building Measure

National biological defence research and development programmes - Declaration

United States of America

April 15, 2019

Form A, Part 2 (i)

National biological defence research and development programme: Declaration

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

Yes	X
No	

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

Form A, Part 2 (ii)

BWC - Confidence Building Measure

National biological defence research and development programmes - Description

United States of America

April 15, 2019

National biological defence research and development programmes: Overview

On September 18, 2018, the United States issued the National Biodefense Strategy, which contains goals and objectives that will guide the United States in assessing, preventing, detecting, preparing for, responding to, and recovering from a biological incident, whether deliberate, naturally occurring, or accidental in origin, and the accompanying Presidential Memorandum on Support for National Biodefense (NSPM-14) (see https://www.phe.gov/Preparedness/biodefense-strategy/Pages/default.aspx and https://www.whitehouse.gov/presidential-actions/presidential-memorandum-support-national-biodefense/; see also Form A, Part 2 (ii) and Form E). Integral to the strategy is a variety of research and development programs aimed at protecting against the deliberate use of biological materials to cause harm. These programs focus on the identification of harmful pathogens and outbreaks of infectious diseases, and their containment, treatment, and elimination from the environment. The programs are managed by several agencies with direct stakes in national security, environmental protection, and human and animal health and safety, including the Departments of Agriculture, Defense, Energy, Health and Human Services, Homeland Security, and the Environmental Protection Agency.

Historically, certain pathogens were selected for use as biological weapons because of their pathogenicity and other characteristics. Research on these pathogens, including study of molecular mechanisms and related diagnostic, vaccine and therapeutic development work, not only increases U.S. biodefense preparedness, but also offers inherent benefits for broader public health needs. Efforts to improve medical product stability, potency and ease-of-use that cut across disease targets could yield significant benefits for public health systems that cannot support existing treatments that require refrigeration, multiple doses or sophisticated diagnostic techniques. Similarly, biodefense initiatives to improve human and animal host defenses, to monitor emerging infectious diseases and drug-resistant microbes, and to clean up the site of a biological weapons attack benefit public health services, such as epidemiological disease surveillance and environmental remediation.

To promote the benefits gained by these programs and to ensure that the research is available to the scientific community both domestically and internationally, the United States Government encourages the publication of research funded by its biodefense programs.

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

- Management of Domestic Incidents (Homeland Security Presidential Directive 5 [HSPD-5]) and the related National Response Framework;
- Presidential Policy Directive 8: National Preparedness (PPD-8);
- National Strategy for Defense of United States Agriculture and Food (HSPD-9);
- Medical Countermeasures against Weapons of Mass Destruction (HSPD-18);
- Public Health and Medical Preparedness (HSPD-21);
- Executive Order 13527 ("Establishing Federal Capabilities for the Timely Provision of Medical Countermeasures following a Biological Attack").

National biological defence research and development programmes:

1. State the objectives and funding of each 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, toxinology, physical protection, decontamination and other related research.

The Department of Defense Chemical and Biological Defense Program develops capabilities to enable the U.S. Armed Forces to deter, prevent, protect from, mitigate, respond to, and recover from the effects of chemical, biological, and radiological (CBR) threats as part of a layered, integrated defense. The Program is an integral contributor to a global and systems approach for Countering Weapons of Mass Destruction (CWMD), Global Health Security, and other pertinent mission areas.

The Program works to counter biological threats by providing complementary sets of sensors, protective equipment, and medical countermeasures to counter known and unknown threats, including novel and naturally-occurring emerging infectious diseases that may also pose a biological weapons threat. Current research focuses on host-pathogen interactions; capabilities for pre- and post-exposure therapeutics for bacterial biological select agents and novel threats; testing battlefield detection and identification methods, protective systems, and decontamination systems; the development of rapid and deployable detection assays for troop protection; and medical defenses against neurotoxins.

The Program also works on producing self-disinfecting and/or self-decontaminating materials, as well as developing, producing, and fielding capabilities for sampling, detecting, and identifying biological agents.

Biological defense related work conducted by the Department of Defense is carried out by the military services and biological defense program-focused agencies. These include funding agencies and service laboratories within the Departments of the Air Force, Army, and Navy, and the Defense Threat Reduction Agency/Joint Science and Technology Office, the Joint Program Executive Office for Chemical and Biological Defense, and the Defense Advanced Research Projects Agency.

2. State the total funding for each programme and its source.
$558,651,000 U.S. Department of Defense (DOD)

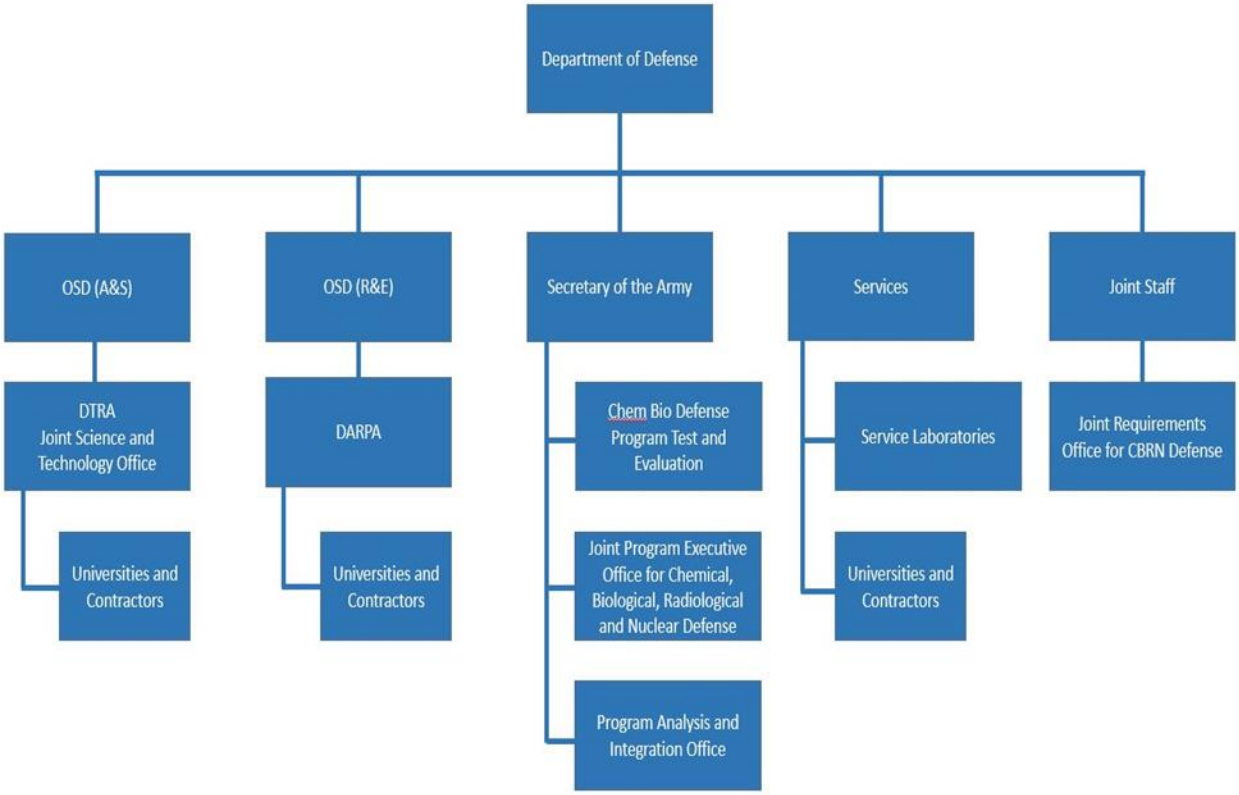
3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?
Yes

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?
58.0 %

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

- Provide support and capabilities to protect the U.S. Armed Forces against biological warfare threats
- Development, testing, and manufacturing of vaccines, therapeutics, and diagnostic systems
- Development of self-disinfecting and/or self-decontaminating materials
- Development and testing of detection and identification methods, protective equipment, and decontamination systems

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



This chart reflects funding relationships

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 each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

- Naval Medical Research Center (NMRC) – Page 44
- Naval Research Laboratory (NRL) – Page 46
- Naval Surface Warfare Center-Dahlgren Division Chemical, Biological, Radiological (CBR) Defense Laboratory – Page 48
- Lothar Salomon Life Sciences Test Facility (LSTF) – Page 42
- U.S. Army Research Development and Engineering Command Edgewood Chemical Biological Center (RDECOM ECBC) – Page 50
- U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) – Page 53
- U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) – Page 56
- U.S. Army Natick Soldier Research Development and Engineering Center (NSRDEC) – Page 66

Air Force Research Laboratory (AFRL) received no funding for biodefense work in 2018 and is not included in the 2018 Confidence Building Measures

National biological defense research and development programmes:

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, 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 characterization and containment of contamination, and in the remediation of sites following terrorist attacks.

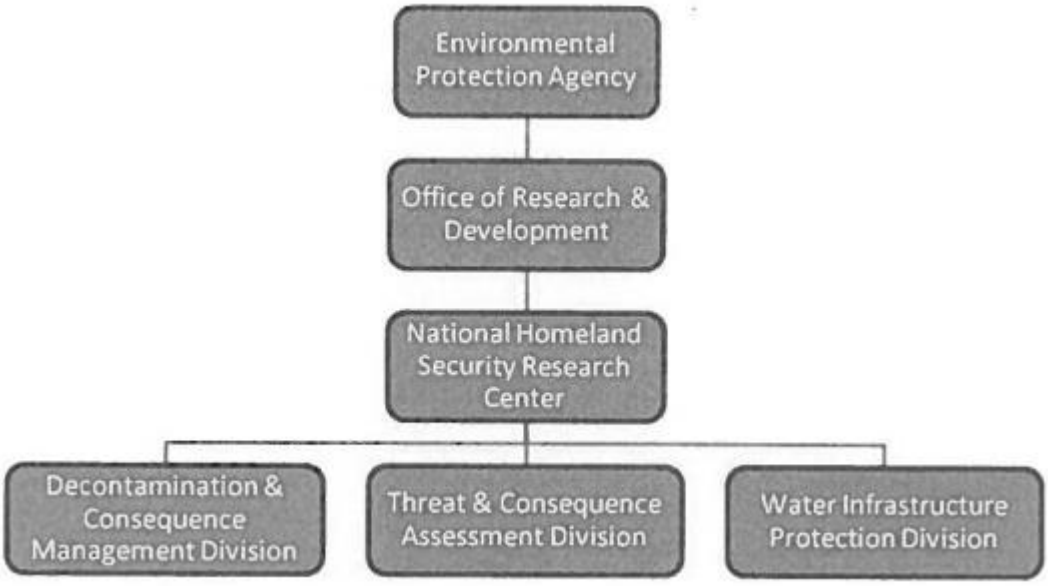
2. State the total funding for the programme and its source.
$7,100,000 U.S. Environmental Protection Agency (EPA)

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
30 %

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 address capabilities related to EPA’s indoor/outdoor remediation mission, NHSRC, through intramural and extramural avenues, conducts research related to characterization methods, risk assessment, decontamination methods, and waste management. Specifically the program develops and evaluates 1) sampling and analytical methods for environmental matrices, 2) decontamination methods for complex environments, and 3) treatment methods for solid and liquid waste. Supporting such capabilities, NHSRC has been addressing the fate and transport of biological agents and developing exposure assessment information and methods to support risk assessment decisions.

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 defense research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

Not Applicable

National biological defence research and development programmes:

1. State the objectives and funding of each 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 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 National Institutes of Health (NIH) biodefense program is supported by funding from HHS. The NIH, and specifically the National Institute of Allergy and Infectious Diseases (NIAID), has the primary responsibility within the U.S. 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.

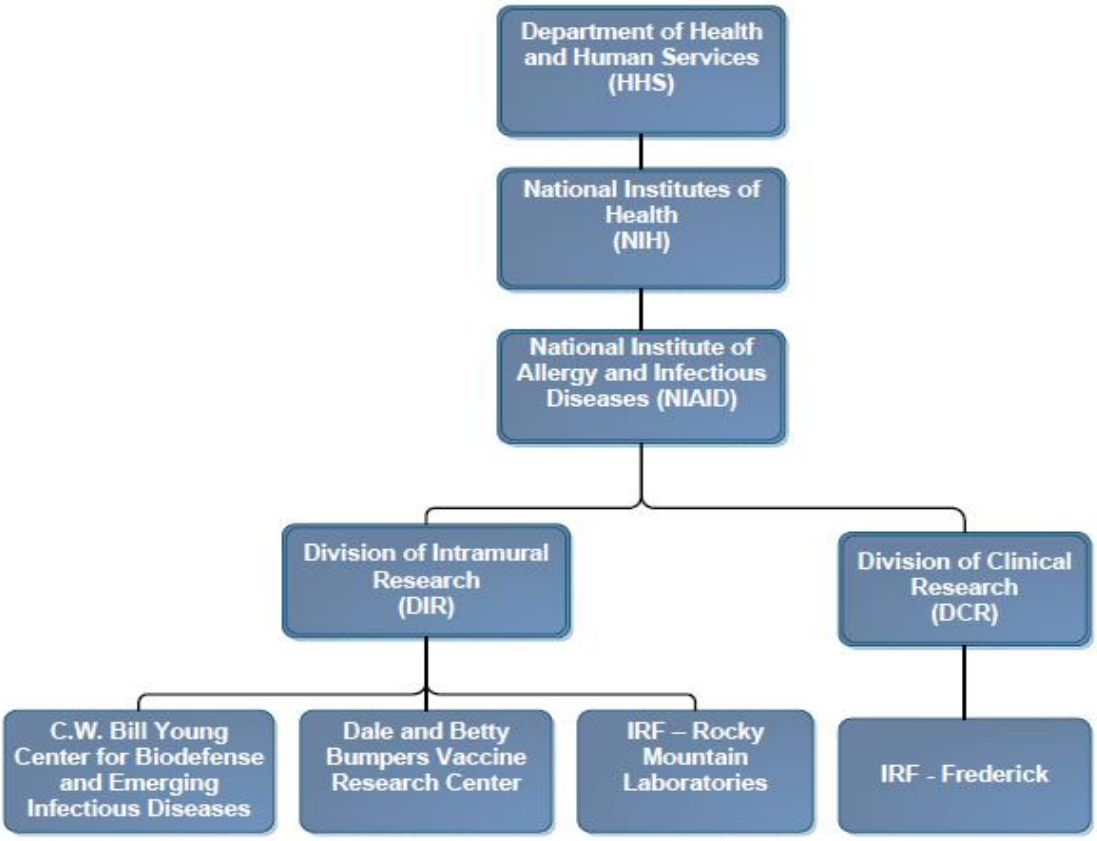
2. State the total funding for each programme and its source.
$87,671,966 Department of Health and Human Services (HHS)

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?
Yes

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?
17.5%

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.
Battelle Memorial Institute facilitates scientific research at the Integrated Research Facility at Fort Detrick (IRF-Frederick), including refinement of animal models to facilitate countermeasure development, with direction from the IRF Scientific Steering Committee.

6. Provide a diagram of the organizational structure of each 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 each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

- Integrated Research Facility at Rocky Mountain Laboratories (IRF - RML) – Page 93
- Integrated Research Facility at Fort Detrick (IRF - Frederick) – Page 103
- C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases – Page 107
- Dale and Betty Bumpers Vaccine Research Center – Page 117

Form A, Part 2 (ii)

National biological defence research and development programmes:

1. State the objectives and funding of each 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 objective of the Mass Spectrometry Toxin Laboratory and the Chemical Threats Method Development Laboratory within CDC's National Center for Environmental Health, Division of Laboratory Sciences is to develop methods for measuring selected toxins to help improve detection and diagnosis during a public health response to biological toxins.

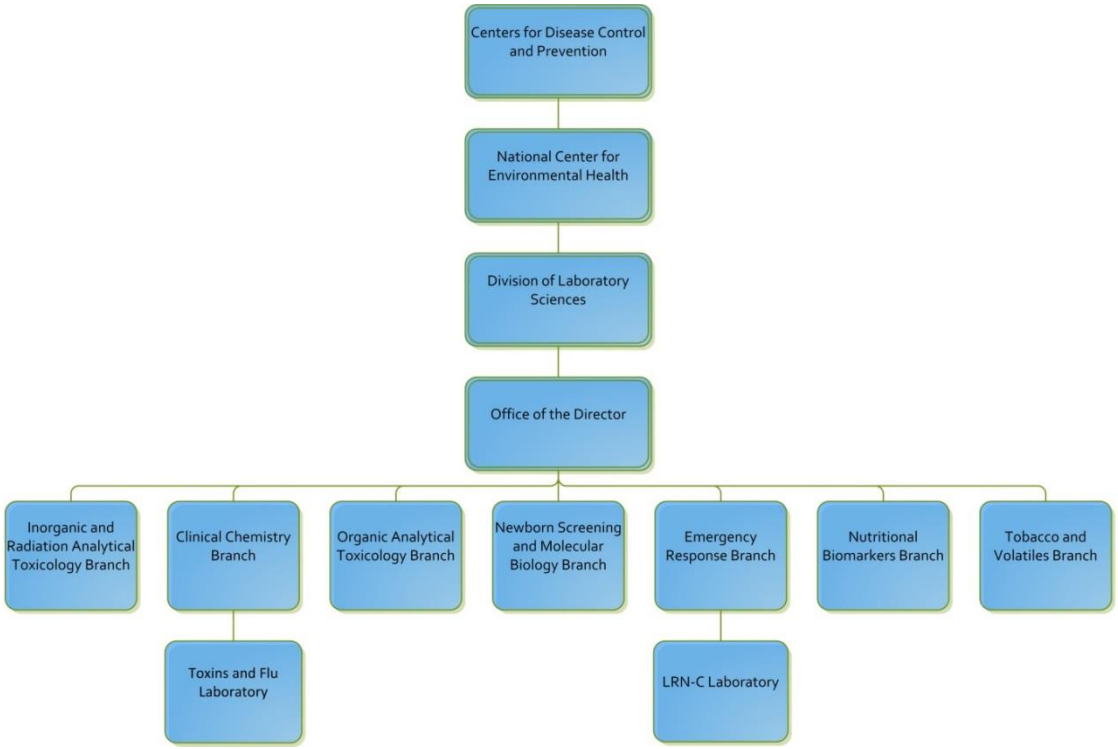
2. State the total funding for each programme and its source.
$3,921,686 Centers for Disease Control and Prevention (CDC)

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?
No

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

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

6. Provide a diagram of the organizational structure of each 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 each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

CDC, National Center for Environmental Health (NCEH), Division of Laboratory Sciences (DLS) – Page 80

Form A, Part 2 (ii)

National biological defence research and development programmes:

1. State the objectives and funding of each 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, toxinology, physical protection, decontamination and other related research.

The activities of the CDC Deputy Director for Infectious Disease (DDID) include developing diagnostic assays for public health, conducting molecular and antigenic characterization of microorganisms, evaluating decontamination methods, determining pathogenicity and virulence of infectious agents, determining the natural history of infectious organisms, and conducting epidemiologic studies and surveillance for diseases. Biodefense activities include those with select agents. DDID includes the National Center for Emerging Zoonotic Infectious Diseases (NCEZID) and the National Center for Immunization and Respiratory Diseases (NCIRD).

The select agents list is available at: http://www.selectagents.gov/SelectAgentsandToxinsList.html

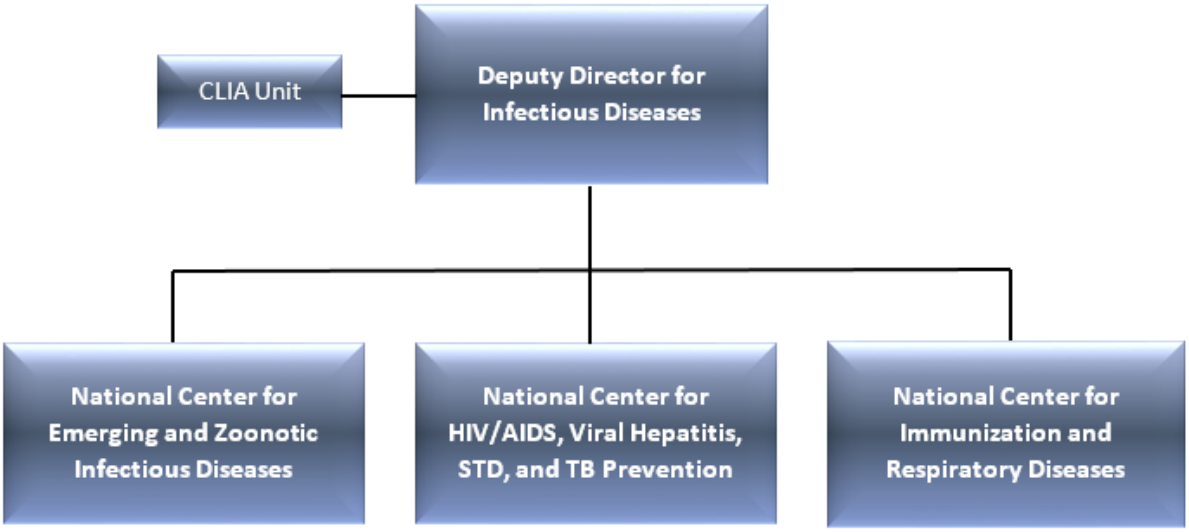
2. State the total funding for each programme and its source.
$26,139,975 Centers for Disease Control and Prevention (CDC)

3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?
Yes

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?
5%

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.
Vaccine efficacy trials, reagent development, bioterrorism preparedness and response activities, avian influenza preparedness, and disease surveillance in CDC field locations.

6 Provide a diagram of the organizational structure of each 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 each national biological defence research and development programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

- CDC, Deputy Director for Infectious Diseases (DDID) – Page 83
- CDC, Deputy Director for Infectious Diseases (DDID), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Vector Borne Diseases (DVBD) - Ft. Collins – Page 91

National biological defence research and development programmes:

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.

Background

The U.S. Department of Agriculture's Agricultural Research Service (USDA-ARS), National Animal Health Action Plan, provides the program direction for biodefense research. Biodefense research programs at ARS address foreign pathogens of plants and animals that represent a major threat to U.S. agriculture. Introduction of these agents, either accidental or deliberate, could have devastating effects on animal or plant health, and in some cases, human health. These devastating effects extend to social and economic impacts — 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 wheat rust, Foot-and-Mouth Disease, Avian Influenza, Rift Valley Fever, Classical Swine Fever, African Swine Fever, Exotic Newcastle disease, Vesicular stomatitis, and Exotic Bluetongue.

Plant and Animal health officials define an exotic or foreign plant or animal disease as important infectious diseases of crops, livestock or poultry believed to be absent from the U.S. and its territories that has a potential significant health or economic impact. In addition, zoonotic foreign animal diseases pose a threat to human health and animal production, potentially resulting in appreciable costs due to expensive disease control and eradication efforts. To protect the long-term health and profitability of U.S. animal agriculture, incursions of a foreign animal disease must be rapidly controlled.

In theUnited States, control is the first step towards disease eradication. Disease eradication is currently accomplished by eliminating crops or animals, resulting in loss of foods, 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 foreign animal disease occurrence in the United States will be the loss of export markets. As we approach the third decade of the 21st century, many new issues and factors are affecting prevention, control, management, and recovery from foreign disease outbreaks. These factors include free trade agreements, free trade blocks, regionalization, increased international passenger travel, intensification of plant and animal production, increased climate instability, the constant evolution of infectious agents, and the uncertain impact of biotechnology and bioterrorism.

The USDA-ARS biodefense program focuses its research efforts on the prevention, detection, control, and eradication of high consequence foreign plant and animal diseases. Research efforts include furthering our understanding of pathogenesis, transmission, and host responses to emerging plant and animal diseases to enhance rapid detection and developing effective countermeasures.

Strategic Objectives

- Establish Agricultural Research Service (ARS) laboratories into a fluid, highly effective research network, to maximize the use of core competencies and resources
- Access specialized high containment research 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 conventional animal drugs
- Build a technology-driven vaccine and diagnostic discovery research program
- Develop core competencies in field epidemiology and predictive biology

- Develop internationally recognized World Organisation for Animal Health (OIE) collaborative research centers
- Establish a 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
- Determine basic knowledge of the biology, pathology, and epidemiology of selected plant Oomycete pathogens as the basis for development of improved control/management strategies

Research Needs

In order to control foreign animal disease, a wide variety of agent detection platforms needs 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). Lack of reagents, and the lack of stockpiling of diagnostic kits and supplies present vulnerabilities in detection and response preparedness. Effective prevention and control tools need to be developed in order to prepare for the possibility of a foreign animal disease outbreak in the United States. These could include tools for identifying suitable control strategies, which take into account the short amount of time available and the cost of recovery from disease outbreaks. There is a need for development of vaccines and biotherapeutics suitable for strategic stockpiles and for integrated methods of disease control (including vector control and animal management), which 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 (FADs)
- 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 FADs
- 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
- In-depth knowledge of pathogen biology, taxonomy, genetics, ecology, and pathology of emerging Oomycete pathogens that can be used to develop novel and effective exclusion, control and management strategies

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; and Frederick, Maryland.

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

$21,425,000 U.S. Department of Agriculture (USDA)

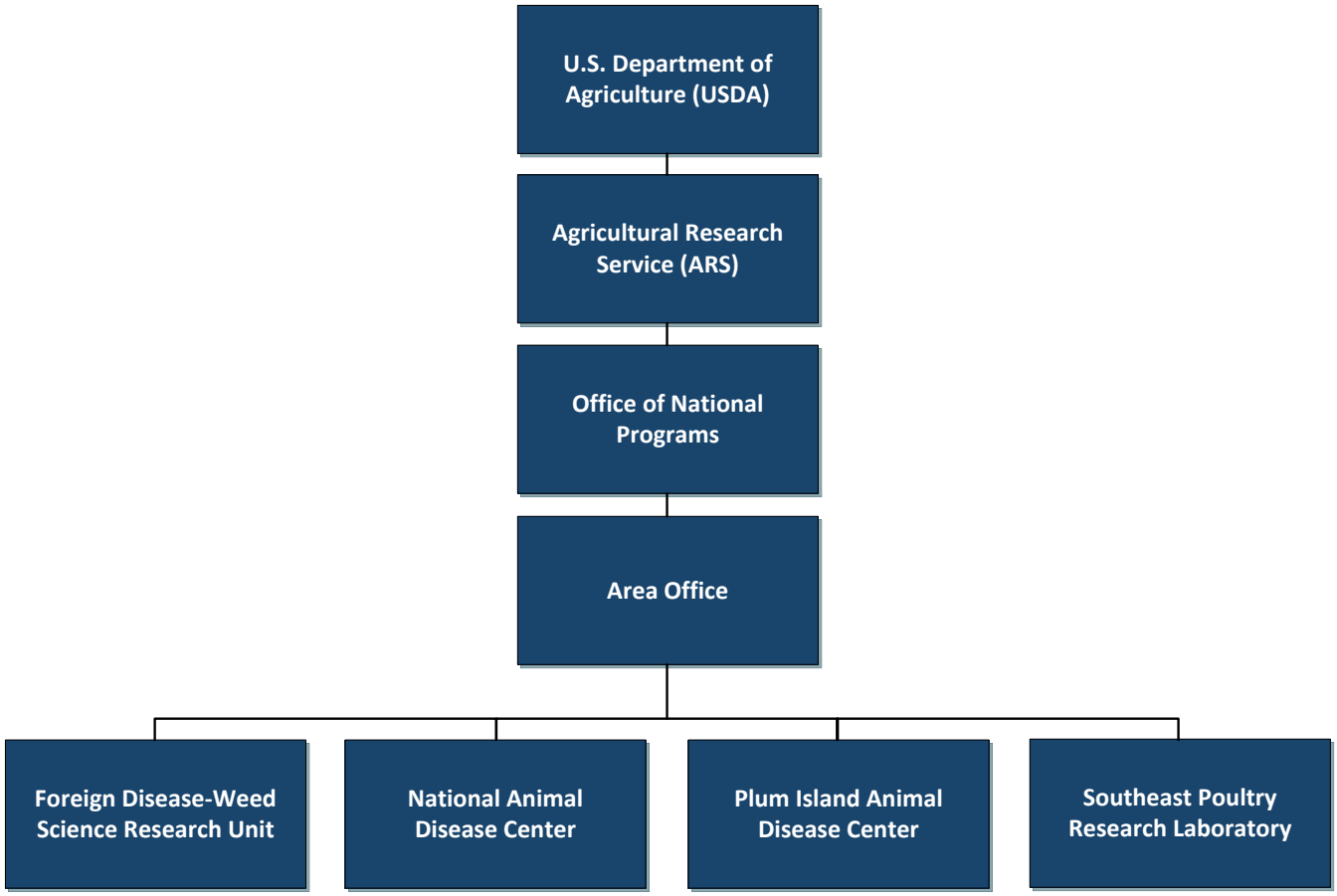
3. Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?

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.

- Foreign Disease-Weed Science Research Unit – Page 119
- National Animal Disease Center (NADC) – Page 121
- Southeast Poultry Research Laboratory – Page 124
- Plum Island Animal Disease Center (PIADC) – Page 37

National biological defence research and development programmes:

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.**

   Preventing terrorism and enhancing security, including protection against biological terrorism, is one of the five key Department of Homeland Security (DHS) mission areas. This includes efforts to: prevent terrorist attacks, including biological attacks; prevent the unauthorized acquisition, importation, movement, or use of, *inter alia*, biological materials and capabilities within the United States; and reduce the vulnerability of critical infrastructure to terrorist attacks and other hazards. These efforts are further guided by the National Biodefense Strategy, which outlines five goals: enable risk awareness to inform decision-making across the biodefense enterprise; ensure biodefense enterprise capabilities to prevent bioincidents; ensure biodefense enterprise preparedness to reduce the impacts of bioincidents; rapidly respond to limit the impacts of bioincidents; and facilitate recovery to restore the community, the economy, and the environment after a bioincident.

   The goal of the DHS biodefense program is to leverage emerging technologies to protect against biological attacks targeting the U.S. population, agriculture, or infrastructure. The DHS Biodefense program focuses on scenario modelling, agent release detection, training in responding to biological events, biological countermeasures research, development, testing, and evaluation (RDT&E) efforts, and on the transition of resultant technologies to operational use. The five main 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.

   Efforts conducted during 2018 included comprehensive threat and risk assessments to guide prioritization of the Nation's biodefense investments, biodefense knowledge management, the development of next-generation detectors for biological threat agents for critical infrastructure and urban areas, decontamination of transit systems, and bioforensics research in support of criminal investigations and attribution. Efforts at the National Biodefense Analysis and Countermeasures Center included biological threat characterization and forensic analysis for attribution, and, at the Plum Island Animal Disease Center, development of vaccines and diagnostics for foreign animal diseases.

   The DHS Compliance Review Group, chaired by the DHS Deputy Secretary, met in 2018 to review all relevant DHS-funded biological defense projects for compliance with the provisions of the Biological Weapons Convention and associated U.S. domestic laws and policies.

2. **State the total funding for the programme and its source.**
   $80,029,641 U.S. Department of Homeland Security (DHS)

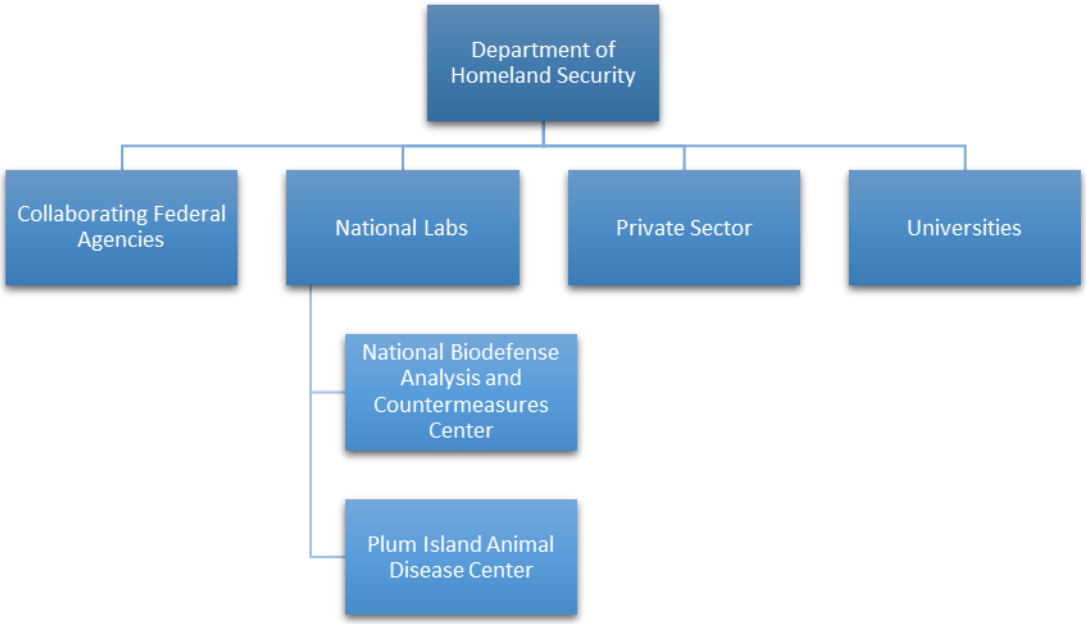
3. **Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

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.**
   Identical to answer provided in question 1.

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.**

   - National Biodefense Analysis and Countermeasures Center (NBACC) – Page 34
   - Plum Island Animal Disease Center (PIADC) – Page 37

Form A, Part 2 (iii)

BWC - Confidence Building Measure

National biological defence research and development programmes - Facilities

United States of America

April 15, 2019

Form A, Part 2 (iii)

National biological defence research and development programme

For each facility detailed on Form A, Part 2 (iii), the entries given for question 3, "Floor area of laboratory areas by containment level (m2)" represent lab space used for biodefense R&D purposes during CY18. Year-to-year variations in programming may result in variations in laboratory space reported rather than alterations to the physical laboratory space.

The U.S. Government identified potential concerns associated with public release of information regarding the presence of highly pathogenic microorganisms and toxins at specific facilities. To balance these concerns with a desire to promote transparency, rather than listing the specific microorganisms and toxins at individual facilities, the U.S. public CBM return characterizes microorganisms and toxins studied at each facility on Form A, Part 2 (iii) simply as "Select Agents" and/or "NIAID Category A pathogens." The full lists of Select Agents and NIAID pathogens are found in Appendix A. 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. Possession, use and transfer of Select Agents are regulated by the Select Agent Rules. Detailed information on Select Agents and their regulation can be found at: http://www.selectagents.gov. The NIAID designated Category A pathogens as priorities for additional research efforts as part of the NIAID biodefense research agenda. Detailed information about NIAID Category A pathogens can be found at: http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Pages/CatA.aspx.

The U.S. public CBM also includes an Appendix B, which is a combined list of all of the specific microorganisms and toxins studied for biodefense research and development at *all* facilities reported on Form A, part 2 (iii) below. To maintain a high level of transparency to States Parties, the United States makes available, via the restricted-access portion of the ISU website, a Supplement containing information on the microorganisms and toxins studied at each individual facility reported on Form A, part 2 (iii).

Brookhaven National Laboratory (BNL) received no funding for biodefense work in 2018 and is not included in the 2018 Confidence Building Measures

Form A, Part 2 (iii)

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
National Biodefense Analysis and Countermeasures Center (NBACC)

2. Where is it located (provide both address and geographical location)?
8300 Research Plaza, Fort Detrick, Maryland 21702

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	1,307 m^2
BSL-3:	2,564 m^2
BSL-4:	980 m^2
Total laboratory floor area:	4,851 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 175

(ii) Division of personnel:

Military	0
Civilian	175

(iii) Division of personnel by category:

Scientists	29
Engineers	40
Technicians	60
Administrative and support staff	46

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Aerobiology, Bacteriology, Biochemistry, Bioinformatics, Biological Science, Biomedical Science, Biophysics, Biotechnology, Cell Biology, Chemistry, Computer Science, Genetics, Immunology, Molecular Biology, Toxicology, Veterinary Medicine, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number:
Yes Number: 175

(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 (DHS)
U.S. Department of Justice (DoJ)
U.S. Department of State (DOS)
U.S. Department of Health and Human Services (HHS)

(vii) What are the funding levels for the following program areas:

Research	$ 10,717,078
Development	$ 12,419,435
Test and evaluation	$ 0
Total	$ 23,136,513

(viii) Briefly describe the publication policy of the facility:

The NBACC publication policy is to present research results to the greater scientific community as widely as possible. As a Federally Funded Research and Development Center (FFRDC) engaged in research with select agents/regulated pathogens, NBACC has established a formal, multi-tiered review system to ensure compliance and conformance with U.S. Government laws, regulations and policies including: export control regulations under Export Administration Regulations (EAR) and International Traffic in Arms Regulations (ITAR); the Biological Weapons Convention (BWC), and internal U.S. Department of Homeland Security (DHS) policies. Prior to submittal to journals or release, all publications are reviewed by NBACC and DHS for security, clarity, and accuracy with regard to the description of the work. The DHS Management Directive for Review of External Publications can be found at https://www.dhs.gov/sites/default/files/publications/mgmt_directive_2260.1_review_of_external_publications.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.):

1. Amarasinghe GK, Aréchiga Ceballos NG, Banyard AC, et al. Taxonomy of the order Mononegavirales: update 2018. Arch Virol. 2018 Aug; 163(8):2283-2294. doi: 10.1007/s00705-018-3814-x. https://link.springer.com/article/10.1007%2Fs00705-018-3814-x
2. Bazinet AL, Ondov BD, Sommer DD, Ratnayake S. BLAST-based validation of metagenomic sequence assignments. PeerJ. 2018 May 28; 6:e4892. doi: 10.7717/peerj.4892 https://peerj.com/articles/4892/
3. Calisher CH, Briese T, Rodney Brister J, et al. Strengthening the Interaction of the Virology Community with the International Committee on Taxonomy of Viruses (ICTV) by Linking Virus Names and Their Abbreviations to Virus Species. Syst Biol. 2018 Dec 31; doi: 10.1093/sysbio/syy087. https://academic.oup.com/sysbio/advance-article/doi/10.1093/sysbio/syy087/5267841
4. Loreille O, Ratnayake S, Bazinet AL, et al. Biological sexing of a 4,000 year-old Egyptian mummy head to assess the potential of nuclear DNA recovery from the most damaged and limited forensic specimens. Genes (Basel). 2018 Mar 1; 9(3):pii:E135. doi: 10.3390/genes9030135. https://www.mdpi.com/2073-4425/9/3/135
5. Meisel JS, Nasko DJ, Brubach B, et al. Current progress and future opportunities in applications of bioinformatics for biodefense and pathogen detection: report from the Winter Mid-Atlantic Microbiome Meet-up, College Park, MD, January 10, 2018. Microbiome. 2018 Nov 5; 6(1):197. doi: 10.1186/s40168-018-0582-5. https://microbiomejournal.biomedcentral.com/articles/10.1186/s40168-018-0582-5
6. Perfetto SP, Hogarth PJ, Monard S, et al. Novel Impactor and Microsphere-based Assay used to Measure Containment of Aerosols Generated in a Flow Cytometer Cell Sorter. Cytometry A. 2018 Dec 18. doi: 10.1002/cyto.a.23680. https://onlinelibrary.wiley.com/doi/abs/10.1002/cyto.a.23680
7. Smither SJ, Eastaugh L, Filone CM, et al. Two-Center Evaluation of Disinfectant Efficacy against Ebola Virus in Clinical and Laboratory Matrices. Emerg Infect Dis. 2018 Jan; 24(1). doi: 10.3201/eid2401.170504. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5749448/

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

***Objectives*:** The NBACC mission is to provide the nation with the scientific basis for characterization of biological threats and bioforensic analysis to support attribution investigations. NBACC conducts studies to fill in information gaps to better understand current and future biological threats; to assess vulnerabilities; and to determine potential impacts to guide the development of biological countermeasures such as detectors, drugs, vaccines, and decontamination technologies. When needed, NBACC conducts experimental programs to better characterize the benefits and risks of changes in U.S. biodefense preparations. NBACC also develops bioforensic assays and provides operational bioforensic analysis to support the attribution of biocrime and bioterrorism.

***Microorganisms and/or Toxins Studied*:** Select Agents (HHS, Overlap), Select Toxins (HHS), simulants, NIAID Category A pathogens.

***Outdoor Studies*:** No outdoor studies performed.

* Including viruses and prions.

Form A, Part 2 (iii)

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Plum Island Animal Disease Center (PIADC)

2. Where is it located (provide both address and geographical location)?
40550 Route 25, Orient Point, New York 11957

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	292 m^2
BSL-3:	18,046 m^2
BSL-4:	0 m^2
Total laboratory floor area:	18,338 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 367

(ii)Division of personnel:

Military	0
Civilian	367

(iii) Division of personnel by category:

Scientists	68
Engineers	4
Technicians	14
Administrative and support staff	281

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Biological Science, Chemistry, Engineering, Microbiology, Molecular Biology, Computational Biology, Pathology, Veterinary Medicine

(v) Are contractor staff working in the facility? If so, provide an approximate number:
Yes Number: 271

(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 Defense?
U.S. Department of Agriculture (USDA)
U.S. Department of Homeland Security (DHS)

(vii) What are the funding levels for the following program areas:

Research	$ 4,130,372
Development	$ 2,700,000
Test and evaluation	$ 4,637,012
Total	$ 11,467,384

(viii) Briefly describe the publication policy of the facility:
DHS scientific research staffs are expected to publish papers in open literature. Papers are peer reviewed and approved by PIADC and DHS for security, clarity, and accuracy with regard to the description of work prior to submittal to journals or release. USDA Agricultural Research Service (ARS) has several publication policies: 1) Policy Number 150.1 "Dissemination of Public Information by ARS," http://www.afm.ars.usda.gov/ppweb/PDF/150-01.pdf ; 2) Number 113.1 "Publishing (Print

and Electronic), www.afm.ars.usda.gov/ppweb/2010/113-1-ARS.pdf; and 3) 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.

USDA Animal and Plant Health Inspection Service diagnostic staff are encouraged to publish papers in journals or other formats that are available to the public. Papers follow the review process outlined in standard operating procedure (document number SOP-NVSL-0004) titled "Approval of Manuscripts and Abstracts for Publication, and Posters and Presentations for Display."

(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.):

1. Adhikari G, Acharya KP, Upadhyay M, et al. Outbreak investigations of foot and mouth disease virus in Nepal between 2010 and 2015 in the context of historical serotype occurrence. Vet Med Sci. 2018 Nov; 4(4):304-314. doi:10.1002/vms3.120. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6236139/
2. Ahmed Z, Pauszek SJ, Ludi A, et al. Genetic diversity and comparison of diagnostic tests for characterization of foot-and-mouth disease virus strains from Pakistan 2008-2012. Transbound Emerg Dis. 2018 Apr; 65(2):534-546. doi:10.1111/tbed.12737. https://onlinelibrary.wiley.com/doi/abs/10.1111/tbed.12737
3. Alonso C, Borca M, Dixon L, et al. ICTV Virus Taxonomy Profile: Asfarviridae. J Gen Virol. 2018 May; 99(5):613-614. doi:10.1099/jgv.0.001049. https://jgv.microbiologyresearch.org/content/journal/jgv/10.1099/jgv.0.001049#tab2
4. Armson B, Mioulet V, Doel C, et al. Detection of foot-and-mouth disease virus in milk samples by real-time reverse transcription polymerase chain reaction: Optimisation and evaluation of a high-throughput screening method with potential for disease surveillance. Vet Microbiol. 2018 Sep; 223:189-194. doi:10.1016/j.vetmic.2018.07.024. https://doi.org/10.1016/j.vetmic.2018.07.024
5. Arzt J, Belsham GJ, Lohse L, Bøtner A, Stenfeldt C. Transmission of Foot-and-Mouth Disease from Persistently Infected Carrier Cattle to Naive Cattle via Transfer of Oropharyngeal Fluid. mSphere. 2018 Sep 12; 3(5):pii: e00365-18. doi:10.1128/mSphere.00365-18. https://msphere.asm.org/content/3/5/e00365-18
6. Barrera J, Brake DA, Kamicker BJ, et al. Safety profile of a replication-deficient human adenovirus-vectored foot-and-mouth disease virus serotype A24 subunit vaccine in cattle. Transbound Emerg Dis. 2018 Apr; 65(2):447-455. doi:10.1111/tbed.12724. https://onlinelibrary.wiley.com/doi/full/10.1111/tbed.12724
7. Barrera J, Brake DA, Schutta C, et al. Versatility of the adenovirus-vectored foot-and-mouth disease vaccine platform across multiple foot-and-mouth disease virus serotypes and topotypes using a vaccine dose representative of the AdtA24 conditionally licensed vaccine. Vaccine. 2018 Nov 19; 36(48):7345-7352. doi:10.1016/j.vaccine.2018.10.031. https://doi.org/10.1016/j.vaccine.2018.10.031
8. Barrera J, Schutta C, Pisano M, et al. Use of ENABL® adjuvant to increase the potency of an adenovirus-vectored foot-and-mouth disease virus serotype A subunit vaccine. Vaccine. 2018 Feb 14; 36(8):1078-1084. doi:10.1016/j.vaccine.2018.01.026. https://doi.org/10.1016/j.vaccine.2018.01.026
9. Barrionuevo F, Di Giacomo S, Bucafusco D, et al. Systemic antibodies administered by passive immunization prevent generalization of the infection by foot-and-mouth disease virus in cattle after oronasal challenge. Virology. 2018 May; 518:143-151. doi:10.1016/j.virol.2018.02.012. https://doi.org/10.1016/j.virol.2018.02.012
10. Berninger ML, O'Hearn E, Lomkin R, Newens K, Havas KA. A post-infection serologic assessment of cattle herd immune status after a vesicular stomatitis outbreak and the

agreement of antibody assays. J Vet Diagn Invest. 2018 Jul; 30(4):510-516. doi:10.1177/1040638718766214. https://journals.sagepub.com/doi/10.1177/1040638718766214
11. Bertram MR, Bravo de Rueda C, Garabed R, et al. Molecular Epidemiology of Foot-and-Mouth Disease Virus in the Context of Transboundary Animal Movement in the Far North Region of Cameroon. Front Vet Sci. 2018 Dec 14; 5:320. doi:10.3389/fvets.2018.00320. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6301994/
12. Bertram MR, Delgado A, Pauszek SJ, et al. Effect of vaccination on cattle subclinically infected with foot-and-mouth disease virus in Cameroon. Prev Vet Med. 2018 Jul 1; 155:1-10. doi:10.1016/j.prevetmed.2018.04.003. https://doi.org/10.1016/j.prevetmed.2018.04.003
13. Bertram MR, Vu LT, Pauszek SJ, et al. Lack of Transmission of Foot-and-Mouth Disease Virus From Persistently Infected Cattle to Naïve Cattle Under Field Conditions in Vietnam. Front Vet Sci. 2018 Jul 27; 5:174. doi:10.3389/fvets.2018.00174. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6072850/
14. Borca MV, Holinka LG, Berggren KA, Gladue DP. CRISPR-Cas9, a tool to efficiently increase the development of recombinant African swine fever viruses. Sci Rep. 2018 Feb 16; 8(1):3154. doi: 10.1038/s41598-018-21575-8. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5816594/
15. Borca MV, O'Donnell V, Holinka LG, et al. The L83L ORF of African swine fever virus strain Georgia encodes for a non-essential gene that interacts with the host protein IL-1-beta. Virus Res. 2018 Apr 2; 249:116-123. doi:10.1016/j.virusres.2018.03.017. https://doi.org/10.1016/j.virusres.2018.03.017
16. Brito B, Pauszek SJ, Hartwig EJ, et al. A traditional evolutionary history of foot-and-mouth disease viruses in Southeast Asia challenged by analyses of non-structural protein coding sequences. Sci Rep. 2018 Apr 24; 8(1):6472. doi: 10.1038/s41598-018-24870-6. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5915611/
17. Chung CJ, Clavijo A, Bounpheng MA, et al. An improved, rapid competitive ELISA using a novel conserved 3B epitope for the detection of serum antibodies to foot-and-mouth disease virus. J Vet Diagn Invest. 2018 Sep; 30(5):699-707. doi:10.1177/1040638718779641. https://journals.sagepub.com/doi/10.1177/1040638718779641
18. de Los Santos T, Diaz-San Segundo F, Rodriguez LL. The need for improved vaccines against foot-and-mouth disease. Curr Opin Virol. 2018 Apr; 29:16-25. doi:10.1016/j.coviro.2018.02.005. https://doi.org/10.1016/j.coviro.2018.02.005
19. Elias E, McVey DS, Peters D, et al. Contributions of Hydrology to Vesicular Stomatitis Virus Emergence in the Western USA. Ecosystems. 2018. pp 1-18. doi:10.1007/s10021-018-0278-5. https://doi.org/10.1007/s10021-018-0278-5
20. Farooq U, Ahmed Z, Naeem K, et al. Characterization of naturally occurring, new and persistent subclinical foot-and-mouth disease virus infection in vaccinated Asian buffalo in Islamabad Capital Territory, Pakistan. Transbound Emerg Dis. 2018 Dec; 65(6):1836-1850. doi:10.1111/tbed.12963. https://onlinelibrary.wiley.com/doi/abs/10.1111/tbed.12963
21. Gabbert LR, Smith JD, Neilan JG, Ferman GS, Rasmussen MV. Smart Card Decontamination in a High-Containment Laboratory. Health Secur. 2018 Jul/Aug; 16(4):244-251. doi:10.1089/hs.2018.0023. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6156686/
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26. Heimerman ME, Murgia MV, Wu P, et al. Linear epitopes in African swine fever virus p72 recognized by monoclonal antibodies prepared against baculovirus-expressed antigen. J Vet Diagn Invest. 2018 May; 30(3):406-412. doi:10.1177/1040638717753966. https://journals.sagepub.com/doi/10.1177/1040638717753966
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32. Neilan JG, Schutta C, Barrera J, et al. Efficacy of an adenovirus-vectored foot-and-mouth disease virus serotype A subunit vaccine in cattle using a direct contact transmission model. BMC Vet Res. 2018 Aug 29; 14(1):254. doi:10.1186/s12917-018-1582-1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6114537/
33. Puckette M, Smith JD, Gabbert L, et al. Production of foot-and-mouth disease virus capsid proteins by the TEV protease. J Biotechnol. 2018 Jun 10; 275:7-12. doi:10.1016/j.jbiotec.2018.03.012. https://doi.org/10.1016/j.jbiotec.2018.03.012
34. Ramirez-Carvajal L, Pauszek SJ, Ahmed Z, et al. Genetic stability of foot-and-mouth disease virus during long-term infections in natural hosts. PLoS One. 2018 Feb 1; 13(2):e0190977. doi:10.1371/journal.pone.0190977. https://doi.org/10.1371/journal.pone.0190977
35. Stenfeldt C, Arzt J, Pacheco JM, et al. A partial deletion within foot-and-mouth disease virus non-structural protein 3A causes clinical attenuation in cattle but does not prevent subclinical infection. Virology. 2018 Mar; 516:115-126. doi:10.1016/j.virol.2018.01.008. https://doi.org/10.1016/j.virol.2018.01.008
36. Stenfeldt C, Hartwig EJ, Smoliga GR, et al. Contact Challenge of Cattle with Foot-and-Mouth Disease Virus Validates the Role of the Nasopharyngeal Epithelium as the Site of Primary and Persistent Infection. mSphere. 2018 Dec 12; 3(6):pii: e00493-18. doi:10.1128/mSphere.00493-18. https://msphere.asm.org/content/3/6/e00493-18
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in Pigs. Front Microbiol. 2018 Aug 15; 9:1891. doi:10.3389/fmicb.2018.01891. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6104175/
38. Velazquez-Salinas L, Pauszek SJ, Verdugo-Rodriguez A, Rodriguez LL. Complete Genome Sequences of Two Vesicular Stomatitis New Jersey Viruses Representing the 2012 U.S. Epidemic Strain and Its Closest Relative Endemic Strain from Southern Mexico. Genome Announc. 2018 Feb 15; 6(7):pii: e00049-18. doi:10.1128/genomeA.00049-18. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5814489/
39. Velazquez-Salinas L, Ramirez-Medina E, Bracht AJ, et al. Phylodynamics of parapoxvirus genus in Mexico (2007-2011). Infect Genet Evol. 2018 Nov; 65:12-14. doi: 10.1016/j.meegid.2018.07.005. https://doi.org/10.1016/j.meegid.2018.07.005

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

Objectives: PIADC provides the only research and development and confirmatory diagnostic capability for specific high-consequence, contagious, foreign animal diseases of livestock, including foot-and-mouth disease in the United States. Technologies researched and developed are vaccines, antivirals, and diagnostic methods.

Microorganisms and/or Toxins Studied: Select Agents (USDA)

Outdoor Studies: No outdoor studies performed

[*] Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Lothar Salomon Test Facility (LSTF)

2. Where is it located (provide both address and geographical location)?
2029 Burns Road, TEDT-DPW-LS MS#6, Dugway, Utah 84022-5006

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	710 m^2
BSL-3:	336 m^2
BSL-4:	0 m^2
Total laboratory floor area:	1,046 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 39

(ii) Division of personnel:

Military	0
Civilian	39

(iii) Division of personnel by category:

Scientists	31
Engineers	0
Technicians	6
Administrative and support staff	2

(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: 10

(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 (DoD) – Wholly

(vii) What are the funding levels for the following program areas:

Research	$ 0
Development	$ 0
Test and evaluation	$ 436,000
Total	$ 436,000

(viii) Briefly describe the publication policy of the facility:
It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international professional meetings. Such publication is an important part of the Army's research and development program.

Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include:
AR 70-31 “Standards for Technical Reporting”
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r70_31.pdf
AR 360-1 “The Army Public Affairs Program”
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/ARN6644_AR360-1_Admin_WEB_FINAL.pdf
AR 530-1 “Operations Security”
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r530_1.pdf

Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission. Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/523009p.pdf) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.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.):
None

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

Objectives: Testing battlefield detection and identification methods, protective equipment, and decontamination systems, including interferent testing of biological detectors and to develop/validate aerosol particle dispersion models to enhance countermeasure response. https://www.dugway.army.mil/LifeSciences.aspx.

Microorganisms and/or Toxins Studied: None

Outdoor Studies: None

* Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Naval Medical Research Center (NMRC)

2. Where is it located (provide both address and geographical location)?
8400 Research Plaza, Fort Detrick, Maryland 21702

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	2,000 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	2,000 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 80

(ii) Division of personnel:

Military	14
Civilian	66

(iii) Division of personnel by category:

Scientists	11
Engineers	0
Technicians	61
Administrative and support staff	8

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Biochemistry, Computational Biology, Immunology, Microbiology, Molecular Biology

(v) Are contractor staff working in the facility? If so, provide an approximate number:
Yes Number: 56

(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 – Wholly

(vii) What are the funding levels for the following program areas:

Research	$ 21,900,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 21,900,000

(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 and public affairs permission before submission.

Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/523009p.pdf) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.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.):

1. Suttisunhakul V, Hip P, Ouch P, et al. Retrospective analysis of fever and sepsis patients from Cambodia reveals serological evidence of melioidosis. Am J Trop Med Hyg. 2018 Apr; 98(4): 1039-1045. https://www.ncbi.nlm.nih.gov/pubmed/29436341
2. LaVergne S, Hamilton T, Biswas B, et al. Phage therapy for a multidrug resistant *Acinetobacter baumannii* craniectomy site infection. Open Forum Infect Dis. 2018 Apr; 5(4):ofy064. https://doi.org/10.1093/ofid/ofy064
3. Plaut RD, Staab AB, Munson MA, et al. Avirulent *Bacillus anthracis* strain with molecular assay targets as surrogate for irradiation-inactivated virulent spores. Emerg Infect Dis. 2018 Apr;24(4). https://doi.org/10.3201/eid2404.171646
4. Philipson CW, Voegtly LJ, Lueder MR, et al. Characterizing Phage Genomes for Therapeutic Application. Viruses. 2018 April 10; 10(4). Pii: E188. https://doi.org/10.3390/v10040188
5. Schully KL, Young CC, Mayo M, et al. Next generation diagnostics for Melioidosis: Evaluation of a prototype i-STAT cartridge to detect *Burkholderia pseudomallei* biomarkers. Clin Infect Dis. 2018 Oct 31. https://doi.org/10.1093/cid/ciy929 [Epub ahead of print]
6. Duplessis C, Gregory M, Frey K, et al. Evaluating the discriminating capacity of cell death (apoptotic) biomarkers in sepsis. J Intensive Care. 2018 Nov 13;6:72. https://doi.org/10.1186/s40560-018-0341-5
7. LaBreck PT, Rice GK, Paskey AC, et al. Conjugative transfer of a novel Staphylococcal plasmid encoding the biocide resistance gene, qacA. Front Microbiol. 2018 Nov 19;9:2664. https://doi.org/10.3389/fmicb.2018.02664
8. Luke T, Bennett RS, Gerhardt DM, et al. Fully human immunoglobulin G from transchromosomic bovines treats nonhuman primates infected with Ebola virus Makona isolate. J Infect Dis. 2018 Nov 22; 218(suppl5):S636-S648. https://doi.org/10.1093/infdis/jiy377

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

Objectives: The goal of the program is the development of rapid and deployable detection assays to protect deployed troops. During 2018, we continued studying clinical cases of sepsis in austere environments with the ultimate goal of understanding host-pathogen interactions, development of new diagnostic assays and better treatment strategies against relevant infectious diseases. Additional information is available at https://www.med.navy.mil/sites/nmrc/NMRC/Pages/NMRC.aspx

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap) and Toxins, NIAID Category A pathogens

Outdoor Studies: None

* Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Naval Research Laboratory (NRL)

2. Where is it located (provide both address and geographical location)?
4555 Overlook Ave., SW, Washington, D.C. 20375

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	589 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	589 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 30

(ii) Division of personnel:

Military	1
Civilian	29

(iii) Division of personnel by category:

Scientists	24
Engineers	2
Technicians	4
Administrative and support staff	0

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Biochemistry, Biophysics, Chemical Engineering, Chemistry, Electrical Engineering, Immunology, Mechanical Engineering, Microbiology, Molecular Biology, Physics

(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 – Wholly

(vii) What are the funding levels for the following program areas:

Research	$ 5,200,000
Development	$ 4,000,000
Test and evaluation	$ 0
Total	$ 9,200,000

(viii) Briefly describe the publication policy of the facility:
Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission. Release of DoD publications is guided by DoD Directive 5230.09 (Clearance of DoD Information for Public Release,

http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/523009p.pdf) and DoD Instruction 5320.29 (Security and Policy Review of DoD Information for Public Release, http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.pdf) for publishing information related to biological defense efforts. Public release of unclassified technical information is subject to sponsor approval.

(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.):

1. Anderson, GP, Shriver-Lake, LC, Liu, JL, Goldman, ER. Orthogonal synthetic zippers as protein scaffolds. ACS Omega. 2018; 3:4810-4815. https://doi.org/10.1021/acsomega.8b00156
2. Anderson, G.P., Shriver-Lake, L.C., Walper, S.A., et al. Genetic Fusion of an Anti-BclA Single-Domain Antibody with Beta Galactosidase. Antibodies. 2018; 7(4):36. https://doi.org/10.3390/antib7040036
3. Balow, R.B., Giles, S.L., Mcgann, C.L., et al. "Rapid Decontamination of Chemical Warfare Agent Simulant with Thermally Activated Porous Polymer Foams", Ind. Eng. Chem. Res. 2018; 57(25): 8630-8634. https://doi.org/10.1021/acs.iecr.8b01546
4. Mcgann, C.L., Daniels, G.C, Giles, S.L., et al. "Ambient activation of self-decontaminating polydicyclopentadiene polyHIPE foams for rapid detoxification of chemical warfare agents", Macromol. Rapid Commun.. 2018 Jun; 39(12):e1800194. https://doi.org/10.1002/marc.201800194
5. Mulvaney, S.P., Fitzgerald, L.A., Hamdan, L.J., et al. Rapid Design and Fielding of Diagnostic Technologies in Sierra Leone, Thailand, Peru, and Australia: Success and Challenges Faced Introducing Four Devices. Sens. Biosens. Res. 2018;20:22-33. https://www.sciencedirect.com/science/article/pii/S2214180418300412
6. Streifel, B.C., Lundin, J.G., Sanders, A.M., et al. Hemostatic and absorbent polyHIPE-kaolin composites for 3D printable wound dressing materials. Macromol. Rapid Commun. 2018; 18(5):e1700414. https://doi.org/10.1002/mabi.201700414
7. White, Taitt, Archibong, Leska. Colorimetric Biosensor: Crosslinker Variations. 2018 NRL Memorandum Report 2018 NRL Memorandum Report #NRL/MR/6930--18-9820. https://apps.dtic.mil/docs/citations/AD1062024
8. White, Taitt, Gleaves, Archibong, Monk, Leska. Colorimetric Biosensor: Porphyrin Variations. 2018 NRL Memorandum Report #NRL/MR/6930--18-9819 https://apps.dtic.mil/docs/citations/AD1061568

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

Objectives: The objectives of research at NRL are to develop and test reliable systems for the detection of chemical and biological (CB) warfare agents in order to provide early warning and contamination avoidance information. Additional information is available at http://www.nrl.navy.mil/research/

Microorganisms and/or Toxins Studied: Simulants

Outdoor Studies: None

* Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Naval Surface Warfare Center-Dahlgren Division, Chemical, Biological, Radiological (CBR) Defense Laboratory

2. Where is it located (provide both address and geographical location)?
6149 Welsh Road, Dahlgren, Virginia 22448

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	180 m^2
BSL-3:	27 m^2
BSL-4:	0 m^2
Total laboratory floor area:	207 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 147

(ii) Division of personnel:

Military	0
Civilian	147

(iii) Division of personnel by category:

Scientists	49
Engineers	38
Technicians	16
Administrative and support staff	44

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Aerospace Engineering, Chemical Engineering, Chemistry, Computer Engineering, Computer Science, Electronic Engineering, Industrial Engineering, Mathematics, Mechanical Engineering, Microbiology, Molecular Biology, Operations Research Analysis, Physics, Toxicology

(v) Are contractor staff working in the facility? If so, provide an approximate number:
Yes Number: 24

(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 (DoD) – Partly
Private Sector Companies
Internal (Laboratory Directed Research and Development [LDRD])
Other Governmental Agencies

(vii) What are the funding levels for the following program areas:

Research	$ 2,867,407
Development	$ 4,710,598
Test and evaluation	$ 396,506
Total	$ 7,974,511

(viii) Briefly describe the publication policy of the facility:

Employees are encouraged to publish. Employees must follow appropriate U.S. DoD guidelines for publishing information related to biological defense efforts and have all publications approved. Public release of unclassified technical information is subject to sponsor approval.

Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/523009p.pdf) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.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.):

1. Coleman, M., Elkins, C., Gutting, B., et al. Microbiota and Dose Response: Evolving Paradigm of Health Triangle. Risk Anal. 2018; 38(10):2013-2028. https://www.ncbi.nlm.nih.gov/pubmed/29900563

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

Objectives: Efforts at this defense laboratory are focused on biological detection systems, collective and individual protection systems, hazard mitigation technologies, risk assessment tools and consequence management planning.

Microorganisms and/or Toxins Studied: Overlap Select Agent + NIAID Category A Simulant

Outdoor Studies: Performance testing of a prototype biosurveillance system using a biological simulant.

* Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
U.S. Army Edgewood Chemical and Biological Center (ECBC)

2. Where is it located (provide both address and geographical location)?
5183 Blackhawk Road, Aberdeen Proving Ground, Maryland 21010-5424

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	532 m^2
BSL-3:	177 m^2
BSL-4:	0 m^2
Total laboratory floor area:	709 m^2

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	62
Engineers	3
Technicians	22
Administrative and support staff	0

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Aerobiology, Aerospace Engineering, Biochemistry, Biomedical Engineering, Biotechnology, Chemical Engineering, Chemistry, Computer Engineering, Immunology, Mathematics, Mechanical Engineering, Microbiology, Molecular Biology, Operations Research Analysis, Physics, Physiology, Toxicology, Toxinology, Virology

(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 (DoD) – Wholly

(vii) What are the funding levels for the following programme areas:

Research	$14,276,000
Development	$ 8,366,000
Test and evaluation	$ 0
Total	$22,642,000

(viii) Briefly describe the publication policy of the facility:
It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international

professional meetings. Such publication is an important part of the Army's research and development program.

Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include:
AR 70-31 "Standards for Technical Reporting"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r70_31.pdf
AR 360-1 "The Army Public Affairs Program"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/ARN6644_AR360-1_Admin_WEB_FINAL.pdf
AR 530-1 "Operations Security"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r530_1.pdf

Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission. Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/523009p.pdf) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.pdf).

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

1. Angelini DJ, Harris JV, Burton LL, et al. Evaluation of commercial-off-the-shelf materials for the preservation of bacillus anthracis vegetative cells for forensic analysis. J Forensic Sci. 2018;63(2):412-9. https://onlinelibrary.wiley.com/doi/abs/10.1111/1556-4029.13549
2. Buckley P. DARPA antibody technology program: standardized test bed for antibody characterization: characterization of an ms2 scfv antibody produced by stablebody technologies. Army Edgewood Chemical Biological Center, Aberdeen Proving Ground, United States. 2018; ECBC-TR-1532. https://apps.dtic.mil/dtic/tr/fulltext/u2/1056465.pdf
3. Buckley P, Madren-Whalley J, Hong C, et alCharacterization of virucidal resistance of DNA viruses. Army Edgewood Chemical Biological Center Aberdeen Proving Ground United States. 2018; ECBC-TR-1539. https://apps.dtic.mil/dtic/tr/fulltext/u2/1060343.pdf
4. Feasel MG, Lawrence RJ, Kristovich RL, Wohlfarth A, Huestis MA. Translational human health assessment of carfentanil using an experimentally refined pbpk model. Army Edgewood Chemical Biological Center Aberdeen Proving Ground United States. 2018; ECBC-TR-1528. https://apps.dtic.mil/dtic/tr/fulltext/u2/1060142.pdf
5. Kong L, Berg F. Investigation of the metabolic biotransformation of cck-4 in liver microsomes of human, monkey, rat, and mouse using ultra-performance liquid chromatography-high-resolution mass spectrometry. Army Edgewood Chemical Biological Center, Aberdeen Proving Ground, United States. 2018; ECBC-TR-1496. https://apps.dtic.mil/dtic/tr/fulltext/u2/1056077.pdf
6. Kragl FJ, Broomall SM, Kim MH. Surface and air sampling validation for milling of bsl-2 bacillus anthracis simulant spores. Army Edgewood Chemical Biological Center, Aberdeen Proving Ground, United States. 2018; ECBC-TR-1543. https://apps.dtic.mil/dtic/tr/fulltext/u2/1063613.pdf
7. Metcalf KJ, Lee MFS, Jakobson CM, Tullman-Ercek D. An estimate is worth about a thousand experiments: using order-of-magnitude estimates to identify cellular engineering targets. Microb Cell Fact. 2018;17:135. https://microbialcellfactories.biomedcentral.com/articles/10.1186/s12934-018-0979-7
8. Mido T, Schaffer EM, Dorsey RW, Sozhamannan S, Hofmann ER. Sensitive detection of cive

escherichia coli by bacteriophage amplification-coupled immunoassay on the luminex (r) magpix instrument. J Microbiol Methods. 2018;152:143-7. https://doi.org/10.1016/j.mimet.2018.07.022
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10. Salemmilani R, Piorek BD, Mirsafavi RY, Fountain AW, Moskovits M, et al. Dielectrophoretic nanoparticle aggregation for on-demand surface enhanced raman spectroscopy analysis. Anal Chem. 2018;90(13):7930-6. https://pubs.acs.org/doi/10.1021/acs.analchem.8b00510

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

Objectives: Development of non-medical defensive material against biological agents including: research, development, and engineering for methods of rapid detection, identification, decontamination, and physical protection from biological threat agents. Additional information is available at https://www.ecbc.army.mil/research/.

Microorganisms and/or Toxins Studied: Select Agents and Toxins (HHS and Overlap Select Agents, NIAID Category A pathogens, and HHS Select Toxins) and Simulants

Outdoor Studies: None

* Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)

2. Where is it located (provide both address and geographical location)?
2900 Ricketts Point Road, Aberdeen Proving Ground, Maryland 21010

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	315 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	315 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 18

(ii) Division of personnel:

Military	1
Civilian	17

(iii) Division of personnel by category:

Scientists	3
Engineers	0
Technicians	15
Administrative and support staff	0

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Biochemistry, Molecular Biology, Pharmacology, Physiology, Neuroscience

(v) Are contractor staff working in the facility? If so, provide an approximate number:
Yes Number: 12

(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 (DoD),
U.S. National Institutes of Health (NIH)

(vii) What are the funding levels for the following program areas:

Research	$ 450,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 450,000

(viii) Briefly describe the publication policy of the facility:
It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international professional meetings. Such publication is an important part of the Army's research and development program.

Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include:
AR 70-31 "Standards for Technical Reporting"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r70_31.pdf
AR 360-1 "The Army Public Affairs Program"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/ARN6644_AR360-1_Admin_WEB_FINAL.pdf
AR 530-1 "Operations Security"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r530_1.pdf

Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission. Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/523009p.pdf) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.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.):

1. Thirunavukkarasu N, Johnson E, Pillai S, Hodge D, Stanker L, et al. Botulinum Neurotoxin Detection Methods for Public Health Response and Surveillance. Frontiers in bioengineering and biotechnology. 2018 Jun 22; 6:80. https://www.frontiersin.org/articles/10.3389/fbioe.2018.00080/full
2. Beske PH, Bradford AB, Hoffman KM, Mason SJ, McNutt PM. In vitro and ex vivo screening of candidate therapeutics to restore neurotransmission in nerve terminals intoxicated by botulinum neurotoxin serotype A1. Toxicon. 2018 Jun; 147:47-53. https://doi.org/10.1016/j.toxicon.2017.10.017
3. Bradford AB, Machamer JB, Russo TM, McNutt PM. 3,4-diaminopyridine reverses paralysis in botulinum neurotoxin-intoxicated diaphragms through two functionally distinct mechanisms. Toxicology and applied pharmacology. 2018 Feb 15; 341:77-86. https://doi.org/10.1016/j.taap.2018.01.012
4. Patel K, Cai S, Adler M, Singh BK, Parmar VS, et al. Natural compounds and their analogues as potent antidotes against the most poisonous bacterial toxin. Applied and Environmental Microbiology. 2018 Nov 2; 84 (24) e01280-18. https://doi.org/10.1128/AEM.01280-18
5. Lebeda FJ, Adler M, Dembek ZF. Yesterday and today: the impact of research conducted at Camp Detrick on botulinum toxin. Mil Med. 1 May 2018; 183:85-95. https://doi.org/10.1093/milmed/usx047
6. Lebeda FJ, Dembek, ZF, Adler M. Foodborne botulism from a systemic biology perspective. In Foodborne Diseases, Handbook of Food Bioengineering, Volume 15, pp. 275-308, Eds. Grumezescu, A. and Holban, AM, Academic Press, 2018. https://www.sciencedirect.com/science/article/pii/B9780128114445000105

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

* Including viruses and prions.

Objectives: Discover and develop medical products and knowledge solutions against toxin threats through research, education and training, and consultation. USAMRICD performs comprehensive, basic scientific research using established and emerging technologies that support the transition of products to advanced development; develops education and training capabilities for military, interagency, domestic, and international personnel in the medical management of chemical casualties; and provides a venue for mutually beneficial collaboration with external investigators and interagency partners to conduct medical chemical defense research against chemical warfare agents and toxins. See more at: http://usamricd.apgea.army.mil/

***Microorganisms and/or Toxins Studied*:** HHS Select Toxins

Outdoor Studies: None

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

2. Where is it located (provide both address and geographical location)?
1425 Porter Street, Fort Detrick, Frederick, Maryland 21702

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	26,026 m^2
BSL-3:	3,139 m^2
BSL-4:	1,186 m^2
Total laboratory floor area:	30,351 m2

4. The organizational structure of each facility:

(i) Total number of personnel 853

(ii) Division of personnel:

Military	178
Civilian	675

(iii) Division of personnel by category:

Scientists	235
Engineers	8
Technicians	329
Administrative and support staff	281

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Aerobiology, Biochemistry, Chemistry, Clinical Immunology, Entomology, Genetics, Immunology, Microbiology, Molecular Biology, Toxicology, Veterinary Medicine, Virology.

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 430

(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 (DoD) – Partly
U.S. Department of Homeland Security (DHS)
U.S. Department of Health and Human Services (DHHS)
U.S. Department of Agriculture (USDA)
Universities
Private sector companies

(vii) What are the funding levels for the following programme areas:

Research	$ 2,064,000
Development	$ 76,506,000*
Test and evaluation	$ 21,000,000
Total	$ 99,570,000**

*Includes reimbursables from Cooperative Research and Development Agreements and other Departments, which cannot be differentiated by the above categories.
**These figures are based on FY18 data (1 October 2017 to 30 September 2018)

(viii) Briefly describe the publication policy of the facility:

It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international professional meetings. Such publication is an important part of the Army's research and development program.

Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include:
AR 70-31 "Standards for Technical Reporting"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r70_31.pdf
AR 360-1 "The Army Public Affairs Program"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/ARN6644_AR360-1_Admin_WEB_FINAL.pdf
AR 530-1 "Operations Security"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r530_1.pdf

Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission. Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/523009p.pdf) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.pdf).

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

1. Abouelkhair MA, Thompson R, Riley MC, Bemis DA, Kania SA. Complete genome sequences of three staphylococcus pseudintermedius strains isolated from Botswana. Genome Announc. 2018 Mar 8;6(10):e01599-17. https://mra.asm.org/content/6/10/e01599-17
2. Amarasinghe GK, Aréchiga Ceballos NG, Banyard AC, et al. Taxonomy of the order Mononegavirales: update 2018. Arch Virol. 2018 Aug 16;163(8):2283-2294. Epub 2018 Apr 11. https://link.springer.com/article/10.1007/s00705-018-3814-x
3. Arnold CE, Guito JC, Altamura LA, et al. Transcriptomics reveal antiviral gene induction in the Egyptian rousette bat is antagonized in vitro by Marburg virus infection. Viruses. 2018 Nov;10(11):E607. https://www.mdpi.com/1999-4915/10/11/607
4. Bart SM, Cohen C, Dye JM, Shorter J, Bates P. Enhancement of Ebola virus infection by seminal amyloid fibrils. Proc Natl Acad Sci U S A. 2018 Jul 10;115(28):7410-7415. https://www.pnas.org/content/115/28/7410
5. Bazzill JD, Stronsky SM, Kalinyak LC, et al. Vaccine nanoparticles displaying recombinant Ebola virus glycoprotein for induction of potent antibody and polyfunctional T cell responses. Nanomedicine. 2018 Nov 22. [Epub ahead of print]. https://www.sciencedirect.com/science/article/pii/S1549963418305562
6. Blair PW, Keshtkar-Jahromi M, Psoter KJ, et al. Virulence of Marburg virus Angola compared to Mt. Elgon (Musoke) in macaques: a pooled survival analysis. Viruses. 2018 Nov 21;10(11):E658. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6267608/
7. Blitvich BJ, Beaty BJ, Blair CD, et al. Bunyavirus taxonomy: limitations and misconceptions associated with the current ICTV criteria used for species demarcation. Am J Trop Med Hyg.

2018 Jul;99(1):11-16. Epub 2018 Apr 19. https://www.ajtmh.org/content/journals/10.4269/ajtmh.18-0038
8. Brangel P, Sobarzo A, Parolo C, et al. A serological point-of-care test for the detection of IgG antibodies against Ebola virus in human survivors. ACS Nano. 2018 Jan 23;12(1):63-73. Epub 2018 Jan 5. https://pubs.acs.org/doi/10.1021/acsnano.7b07021
9. Brocato RL, Wahl V, Hammerbeck CD, et al. Innate immune responses elicited by Sin Nombre virus or type I IFN agonists protect hamsters from lethal Andes virus infections. J Gen Virol. 2018 Aug 1;99(10):1359-1366. Epub 2018 Aug 1. https://jgv.microbiologyresearch.org/content/journal/jgv/10.1099/jgv.0.001131
10. Brown JF, Dye JM, Tozay S, et al. Anti-Ebola virus antibody levels in convalescent plasma and viral load after plasma infusion in patients with Ebola virus disease. J Infect Dis. 2018 Jul 13;218(4):555-562. Epub 2018 Apr 11. https://academic.oup.com/jid/article/218/4/555/4967721
11. Bruhn M, Schindler D, Kemter FS, et al. Functionality of two origins of replication in vibrio cholerae strains with a single chromosome. Front Microbiol. 2018 Nov 30;9:2932. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6284228/
12. Burke CW, Froude JW, Miethe S, et al. Human-like neutralizing antibodies protect mice from aerosol exposure with Western equine encephalitis virus. Viruses. 2018 Mar 24;10(4):E147. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5923441/
13. Caì Y, Iwasaki M, Beitzel BF, et al. Recombinant Lassa virus expressing green fluorescent protein as a tool for high-throughput drug screens and neutralizing antibody assays. Viruses. 2018 Nov 20;10(11):E655. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6266387/
14. Callendret B, Vellinga J, Wunderlich K, et al. A prophylactic multivalent vaccine against different filovirus species is immunogenic and provides protection from lethal infections with Ebolavirus and Marburgvirus species in non-human primates. PLoS ONE. 2018 Feb 20;13(2):e0192312. Erratum in: PLoS ONE. 2018 Apr 28;13(4):e0196546. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5819775/
15. Cashman KA, Wilkinson ER, Zeng X, et al. Immune-mediated systemic vasculitis as the proposed cause of sudden-onset sensorineural hearing loss following Lassa virus exposure in Cynomolgus macaques. mBio. 2018 Oct 30;9(5):e01896-18. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6212830/
16. Chang AY, Encinales L, Porras A, et al. Frequency of chronic joint pain following Chikungunya virus infection: a Colombian cohort study. Arthritis Rheumatol. 2018 Apr;70(4):578-584. Epub 2018 Mar 2. https://onlinelibrary.wiley.com/doi/abs/10.1002/art.40384
17. Chang AY, Lynch R, Martins K, et al. Long-term clinical outcomes of Zika-associated Guillain-Barre syndrome. Emerg Microbes Infect. 2018 Aug 22;7(1):148. https://www.nature.com/articles/s41426-018-0151-9
18. Chang AY, Martins KA, Encinales L, et al. Chikungunya arthritis mechanisms in the Americas: a cross-sectional analysis of Chikungunya arthritis patients twenty-two months after infection demonstrating no detectable viral persistence in synovial fluid. Arthritis Rheumatol. 2018 Apr;70(4):585-593. https://onlinelibrary.wiley.com/doi/abs/10.1002/art.40383
19. Chang AY, Tritsch S, Reid SP, et al. The cytokine profile in acute Chikungunya infection is predictive of chronic arthritis 20 months post infection. Diseases. 2018 Oct 20;6(4):E95. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6313749/
20. Chateau A, Lunderberg JM, Oh SY, et al. Galactosylation of the secondary cell wall polysaccharide of Bacillus anthracis and its contribution to anthrax pathogenesis. J Bacteriol. 2018 Feb 7;200(5):e00562-17. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5809694/

21. Chen R, Mukhopadhyay S, Merits A, et al. ICTV virus taxonomy profile: Togaviridae. J Gen Virol. 2018 Jun;99(6):761-762. https://jgv.microbiologyresearch.org/content/journal/jgv/10.1099/jgv.0.001072
22. Chiang CY, Uzoma I, Moore RT, et al. Mitigating the impact of antibacterial drug resistance through host-directed therapies: current progress, outlook, and challenges. mBio. 2018 Jan 30;9(1):e01932-17. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5790911/
23. Coffin KM, Liu J, Warren TK, et al. Persistent Marburg virus Infection in the testes of nonhuman primate survivors. Cell Host Microbe. 2018 Sep 12;24(3):405-416.e3. https://www.sciencedirect.com/science/article/pii/S1931312818304311
24. Cooper TK, Huzella L, Johnson JC, et al. Histology, immunohistochemistry, and in situ hybridization reveal overlooked Ebola virus target tissues in the Ebola virus disease Guinea pig model. Sci Rep. 2018;8(1):1250. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5775334/
25. de la Fuente C, Pinkham C, Dabbagh D, et al. Phosphoproteomic analysis reveals Smad protein family activation following Rift Valley fever virus infection. PLoS ONE. 2018;13(2):e0191983. Erratum in: PLoS ONE. 2018 Mar 15;13(4): e0194633. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5800665/
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27. Dupuy LC, Richards MJ, Livingston BD, Hannaman D, Schmaljohn CS. A multiagent alphavirus DNA vaccine delivered by intramuscular electroporation elicits robust and durable virus-specific immune responses in mice and rabbits and completely protects mice against lethal Venezuelan, Western, and Eastern equine encephalitis virus aerosol challenges. J Immunol Res. 2018 Jun 3; 2018:8521060. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6008678/
28. Duy J, Honko AN, Altamura LA, et al. Virus-encoded miRNAs in Ebola virus disease. Sci Rep. 2018 Apr 24;8(1):6480. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5915558/
29. Dyall J, Nelson EA, DeWald LE, et al. Identification of combinations of approved drugs with synergistic activity against Ebola virus in cell cultures. J Infect Dis. 2018 Nov 22;218(suppl_5):S672-S678. Epub 2018 Jun 25. https://academic.oup.com/jid/article/218/suppl_5/S672/5043462
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intramuscular injection in mice. Antiviral Res. 2018;159:113-121. https://www.sciencedirect.com/science/article/pii/S0166354218303784
110. Trevino SR, Klimko CP, Reed MC, et al. Disease progression in mice exposed to low-doses of aerosolized clinical isolates of Burkholderia pseudomallei. PLoS ONE. 2018;13(11):e0208277. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6267979/
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115. Webb RP. Engineering of botulinum neurotoxins for biomedical applications. Toxins (Basel). 2018;10(6):E321. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6024800/
116. Whitmer SL, Ladner JT, Wiley MR, et al. Active Ebola virus replication and heterogeneous evolutionary rates in EVD Survivors. Cell Rep. 2018;22(5):1159-1168. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5809616/

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

Objectives: Develop medical countermeasures, including candidate vaccines, diagnostic tests and drug or immunological therapies for biological agents, and to perform exploratory studies and advanced development of protective and therapeutic countermeasures and agent identification technologies. Additional information is available at http://www.usamriid.army.mil/.

Agents Microorganisms and/or Toxins: Select Agents and Toxins (HHS and Overlap Select Agents, NIAID Category A pathogens, and HHS Select Toxins)

Outdoor Studies: None

[*] Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
US Army Natick Soldier Research Development and Engineering Center (NSRDEC)

2. Where is it located (provide both address and geographical location)?
15 General Greene Avenue, Natick, MA 01760

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	68 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	68 m^2

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:

Scientists	1
Engineers	0
Technicians	0
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:
No Number: 0

(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 – Wholly

(vii) What are the funding levels for the following program areas:

Research	$ 30,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 30,000

(viii) Briefly describe the publication policy of the facility:
It is Army policy to encourage scientific and technical personnel to publish research procedures and results in recognized professional journals as well as present their work at national and international professional meetings. Such publication is an important part of the Army's research and development program.

Publications are prepared and published in accordance with Army regulations. The regulations governing the publication of research findings include:
AR 70-31 "Standards for Technical Reporting"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r70_31.pdf
AR 360-1 "The Army Public Affairs Program"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/ARN6644_AR360-1_Admin_WEB_FINAL.pdf
AR 530-1 "Operations Security"
https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/r530_1.pdf

Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission. Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/523009p.pdf) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.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.):

None

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

Objectives: NSRDEC is chartered with developing technologies in the areas of individual soldier protection, combat ration development, air drop systems, and shelters. Additional information is available at https://www.nsrdec.army.mil/#/.

Agents Microorganisms and/or Toxins: None

Outdoor Studies: None

* Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Lawrence Livermore National Laboratory (LLNL)

2. Where is it located (provide both address and geographical location)?
7000 East Avenue, Livermore, California 94550
(62 km east-southeast of San Francisco, California)

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	1,832.4 m^2
BSL-3:	59.5 m^2
BSL-4:	0 m^2
Total laboratory floor area:	1,891.9 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 49

(ii) Division of personnel:

Military:	0
Civilian:	49

(iii) Division of personnel by category:

Scientists	19
Engineers	17
Technicians	10
Administrative and support staff	3

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Aerosol Science, Analytical Biochemistry, Analytical Mass Spectrometry, Bacteriology, Biochemistry, Bioinformatics, Biomedical Engineering, Biomedical Science, Biotechnology, Computational Biology, Computer Science, Environmental Science, Epidemiology, Genomics, Immunology, Mass Spectrometry, Microbial Forensics, Microbiology, Molecular Biology, Molecular Diagnostics, Nanotechnology, Proteomics, Toxinology, 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 (DoD) – partially
U.S. Department of Energy (DOE)
U.S. Department of Homeland Security (DHS)
Internal (Laboratory Directed Research and Development)

(vii) What are the funding levels for the following program areas:

Research	$ 2,849,000
Development	$ 887,000

Test and evaluation	$ 46,000
Total	$ 3,782,000

(viii) Briefly describe the publication policy of the facility:

As a Department of Energy facility, LLNL 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. LLNL 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. LLNL 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. [US Department of Energy, Scientific and Technical Information Management: https://www.directives.doe.gov/directives/0241.1-BOrder-b/view]

(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.):

1. Franco M, D'haeseleer PM, Branda SS, et. al. Proteomic profiling of Burkholderia thalilandesis during host infection using bio-orthogonal noncanonical amino acid tagging (BONCAT). Front Cell Infect Microbiol. 2018 Oct 23; 8:1-16. https://doi.org/10.3389/fcimb.2018.00370.
2. LaBauve AE, Rinker TE, Noureddine A, et. al. Lipid-coated mesoporous silica nanoparticles for the delivery of the ML336 antiviral to inhibit encephalitic alphavirus infection. Sci Rep. 2018 Sep 18; 8:13990. https://doi.org/10.1038/s41598-018-32033-w.
3. Boone TJ, Mallozzi M, Nelson A, et. al. Coordinated assembly of the Bacillus anthracis coat and exosporium during bacterial spore outer layer formation. mBio. 2018 Nov 6; 9(6):1-16. https://mbio.asm.org/content/9/6/e01166-18.

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

***Objectives*:** The biological defense research conducted at Lawrence Livermore National Laboratory includes biological agent detection, therapeutics and prophylactics development, bioinformatics, virulence mechanism elucidation, structural characterization, agent viability testing, response planning, assay development for monitoring for biological decontamination/response as well as microbial forensic assay development to help determine geographic origin and attribution. LLNL also works to develop diagnostic platforms that use a variety of techniques, such as polymerase chain reaction (PCR), immunoassay, microarray, mass spectrometry and genomic sequencing used to gather useful information about the species present in the sampling environment. Beyond detection, response, recovery, and attribution, LLNL also has ongoing research projects to elucidate mechanisms of host-pathogen interactions. Additional information is available at https://st.llnl.gov/.

* Including viruses and prions.

***Microorganisms and/or Toxins Studied*:** Select Agents (HHS, Overlap), NIAID Category A pathogens

***Outdoor Studies*:** None.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Los Alamos National Laboratory (LANL)

2. Where is it located (provide both address and geographical location)?
Bikini Atoll Road SM-30, Los Alamos, NM 87545
(Approximately 45 miles west of Santa Fe, New Mexico)

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	354.0 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	354.0 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 25

(ii) Division of personnel:

Military	0
Civilian	25

(iii) Division of personnel by category:

Scientists	13
Engineers	0
Technicians	12
Administrative and support staff	0

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Analytical Biochemistry, Analytical Chemistry, Bacteriology, Bioinformatics, Biological Science, Biomedical Engineering, Biomedical Science, Cell Biology, Ecology, Environmental Science, Genetics, Genomics, Microbiology, Microscopy, Microbial Forensics, Molecular Biology, Molecular Diagnostics, Plant Molecular Pathology, Proteomics, Public Health, 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 (DoD) – partially
U.S. Department of Energy (DOE)
U.S. Department of Health & Human Services (HHS)
U.S. Department of Homeland Security (DHS)
Internal (Laboratory Directed Research and Development)
Other Governmental Agencies

(vii) What are the funding levels for the following program areas:

Research	$3,637,000

Development	$940,000
Test and evaluation	$1,200,000
Total	$5,777,000

(viii) Briefly describe the publication policy of the facility:

As a Department of Energy facility, 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. LANL 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. LANL 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. [US Department of Energy, Scientific and Technical Information Management: https://www.directives.doe.gov/directives/0241.1-BOrder-b/view]

(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.):

1. Dunbar J, Pillai S, Wunschel D, et al. Perspective on Improving Environmental Monitoring of Biothreats. Front Bioeng Biotechnol. 2018 Oct 23; 6:147. https://www.frontiersin.org/articles/10.3389/fbioe.2018.00147/full.
2. Micheva-Viteva SN, Ross BN, Gao J, et al. Increased mortality in mice following immunoprophylaxis therapy with high dosage of nicotinamide in Burkholderia persistent infections. Infect. Immun. 2018 Dec 19; 87(1):E00592-18. https://iai.asm.org/content/87/1/e00592-18.
3. Kumar A, Davenport KW, Vuyisich G, et al. Complete Genome Sequences of Historic Clostridioides difficile Food-Dwelling Ribotype 078 Strains in Canada Identical to That of the Historic Human Clinical Strain M120 in the United Kingdom. Microbiol. Res. Announc. 2018 Sep 27; 7(12):E00853-18. https://mra.asm.org/content/7/12/e00853-18.

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

***Objectives*:** The biological defense research and development activities at the Los Alamos National Laboratory include pathogen characterization, host-pathogen interaction studies, pathogen detection, integrative biosurveillance and analysis technology development. The main objectives for the studies are to: understand molecular mechanisms of host-pathogen interaction; study molecular, chemical, and physical characteristics of biothreat agents, including bacteria, viruses and toxins, for detection, characterization, assay design and improvement; evaluate detection assay and platform performance; assess commercial techniques for pathogen detection and biosurveillance on environmental monitoring procedures; develop DNA, RNA and protein based bioforensics assays; develop next generation high throughput microbial sequencing, finishing and analysis capabilities; perform viral and bacterial

* Including viruses and prions.

pathogen sequencing for characterization, comparative genomic analysis, and metagenomic analysis; develop high throughput assays for host-pathogen protein interactions screening; develop and validate assays to improve the ability to identify and characterize bioterrorism incident; and identify host molecular targets as potential therapeutic candidates. Additional information is available at https://www.lanl.gov/org/ddste/aldcels/bioscience/biosecurity-public-health/index.php.

***Microorganisms and/or Toxins Studied*:** HHS Select Toxin

***Outdoor Studies*:** None.

Form A, Part 2 (iii)

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Pacific Northwest National Laboratory (PNNL)

2. Where is it located (provide both address and geographical location)?
Personnel and budget were shared between two PNNL campuses in 2018:

Richland campus: 902 Battelle Boulevard, Richland, Washington 99352. The Richland campus is located 146 miles southwest from Spokane, WA and 203 miles southeast from Seattle, WA.

Sequim campus: 1529 West Sequim Bay Road, Sequim, Washington 98382. The Sequim campus is located 304 miles northwest from the PNNL Richland, WA campus and 66 miles west from Seattle, WA.

3. Floor area of laboratory areas by containment level (m^2):
Richland campus:

BSL-2:	1252 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	1252 m^2

Sequim campus:

BSL-2:	109 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	109 m^2

4. The organizational structure of each facility:

(i) Total number of personnel:

Richland campus:	85
Sequim campus:	1

(ii) Division of personnel:

Military	0
Civilian	86

(iii) Division of personnel by category:

Scientists	77
Engineers	1
Technicians	0
Admin and Support Staff	7

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Analytical Mass Spectrometry, Bacteriology, Biochemistry, Biological Science, Cell Biology, Chemistry, Computational Biology, Genetics, Genomics, Mass Spectrometry, Microbial Forensics, Microbiology, Molecular Biology, Nanotechnology, Pathology, Proteomics, Structural Biology, Systems Biology, Virology.

(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 (DoD) – partially
U.S. Department of Health & Human Services (HHS)
U.S. Department of Homeland Security (DHS)
Internal (Laboratory Directed Research and Development)
Other Government Agencies

(vii) What are the funding levels for the following program areas:

Research	$7,180,000
Development	$5,509,000
Test and evaluation	$532,000
Total	$13,221,000

(viii) Briefly describe the publication policy of the facility:
As a Department of Energy, Office of Science facility, PNNL 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. PNNL 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. PNNL also has procedures in place to manage and protect classified, 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. [US Department of Energy, Scientific and Technical Information Management: https://www.directives.doe.gov/directives/0241.1-BOrder-b/view] For this location, a searchable database of materials published since 1988 is available at http://www.pnnl.gov/publications/.

(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.):

1. Menachery V.D., Schafer A., Burnum-Johnson, K. E., et al. MERS-CoV and H5N1 influenza virus antagonize antigen presentation by altering the epigenetic landscape. Proc..Nat. Acad. Sci. 2018 Jan 30; 115(5):E1012-E1021. https://www.pnas.org/content/115/5/E1012
2. Menachery V.D., Gralinski, L., Mitchell, H.D., et al. Combination attenuation offers strategy for live-attenuated coronavirus vaccines. J. Virol. 2018 Sept 1; 92(17):e00710-18. https://www.ncbi.nlm.nih.gov/pubmed/29976657
3. Wunschel D.S., Valenzuela, B.R., Kaiser, B., Victry, K.D. and Woodruff, D.L. Method development for comprehensive extraction and analysis of marine toxins: Liquid-liquid extraction and tandem liquid chromatography separations coupled to electrospray tandem mass spectrometry. Talanta 187. 2018 May 9; https://www.ncbi.nlm.nih.gov/pubmed/29853051

4. Fredriksson S., Wunschel, D.S., Wiklund Lindstrom, I.E., et al. A Ricin Forensic Profiling Approach Based on a Complex Set of Biomarkers. Talanta 186. 2018 Aug 15; https://www.ncbi.nlm.nih.gov/pubmed/29784413
5. Jarman K.H., Heller, N.C., Jenson, S.C., et al. Proteomics Goes to Court: A Statistical Foundation for Forensic Toxin/Organism Identification Using Bottom-Up Proteomics. J. Proteome Res. 17. 2018 Sept 7; 17(9):3075-3085. https://pubs.acs.org/doi/10.1021/acs.jproteome.8b00212
6. Omberg K.M., Franklin, L., Jackson, D.R., et al. A Publicly Available Landscape Analysis Tool for Biodefense Policy. Health Sec. 2018 Nov 16; 16(1):77-78. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5815445/

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

***Objectives*:** PNNL is involved in biodefense-related activities, to include: agent characterization (e.g., knock out experiments and investigation of infectious properties of agents) and the development of detection methods (e.g., nucleic acid, toxin, and proteomic signatures), testing and evaluation of commercial off the shelf equipment for agent detection as well as investigation of next generation biodetection equipment, biological and chemical forensics, investigation of natural history of agents, pathogenesis studies, and interrogating DNA sequencing data and related analysis tools. No outdoor studies of biological aerosols were collected.

***Microorganisms and/or toxins studied*:** Simulants, HHS Select Toxins

***Outdoor Studies*:** None

* Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Sandia National Laboratories (SNL)

2. Where is it located?
Personnel and budget were shared between two SNL campuses in 2018:

New Mexico Campus: P. O. Box 5800, Albuquerque, NM 87185
(Located on Kirtland Air Force Base, in southeastern Albuquerque)

California Campus: 7011 East Avenue, Livermore, California
(Located in Livermore, CA.)

3. Floor area of laboratory areas by containment level (m^2):

New Mexico campus:

BSL-2:	1268.49 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	1268.49 m^2

California campus:

BSL-2:	230 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	230 m^2

4. Organizational structure of each facility:

(i) Total number of personnel:

New Mexico campus:	123
California campus:	82

(ii) Division of personnel:

Military	0
Civilian	205

(iii) Division of personnel by category:

Scientists	93
Engineers	67
Technicians	17
Admin and Support Staff	28

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Aerobiology, Aerosol Science, Analytical Biochemistry, Analytical Chemistry, Analytical Mass Spectrometry, Bacteriology, Biochemistry, Bioinformatics, Bioinorganic Chemistry, Biological Science, Biomedical Engineering, Biomedical Science, Biophysics, Biotechnology, Cell Biology, Chemical Engineering, Chemistry, Computational Biology, Computer Engineering, Computer Science, Electrical Engineering, Environmental Engineering, Environmental Science, Genetics,

Genomics, Immunology, Mass Spectrometry, Materials Science, Mathematics, Mechanical Engineering, Medicine, Microbial Forensics, Microbiology, Molecular Biology, Molecular Diagnostics, Nanotechnology, Neuroscience, Operations Research Analysis, Optical Spectroscopy, Pathology, Physics, Physiology, Polymer Science, Protein Engineering, Proteomics, Structural Biology, Toxicology, Virology

(v) Are Contractor staff working in the facility?

No

(vi) What is (are) the source(s) of funding for the work conducted in the facility?

U.S. Agency for International Development (USAID)
U.S. Department of Defense (DoD) - partially
U.S. Department of Health and Human Services (HHS)
U.S. Department of Homeland Security (DHS)
Internal (Laboratory Directed Research & Development)
Academia
Private sector

(vii) What are the funding levels for Research and Development and Testing and Evaluation as of the most recent calendar year?

Research	$ 11,403,000
Development	$ 3,707,000
Test and Evaluation	$ 3,718,000
Total	$ 18,828,000

(viii) Briefly describe the publication policy of the facility:

As a Department of Energy/National Nuclear Security Administration (DOE/NNSA) facility, Sandia National Laboratories 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. SNL 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. SNL 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. [Department of Energy, Scientific and Technical Information Management: https://www.directives.doe.gov/directives/0241.1-BOrder-b/view]

(ix) Provide a list of publicly available papers and reports resulting from work during the previous 12 months:

1. Dunbar J, Pillai S, Wunschel D, et al. Perspective on Improving Environmental Monitoring of Biothreats. Front Bioeng Biotechnol. 2018 Oct 23;6:147. https://www.frontiersin.org/articles/10.3389/fbioe.2018.00147/full.
2. Franco M, D'haeseleer PM, Branda SS, et al. Proteomic Profiling of Burkholderia thailandensis During Host Infection Using Bio-Orthogonal Noncanonical Amino Acid Tagging (BONCAT).

Front Cell Infect Microbiol. 2018 Oct 23;8:370. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6206043/.
3. LaBauve AE., Rinker TE, Noureddine A, et al. Lipid-Coated Mesoporous Silica Nanoparticles for the Delivery of the ML336 Antiviral to Inhibit Encephalitic Alphavirus Infection. Sci Rep. 2018 Sep 18;8(1):13990. https://www.nature.com/articles/s41598-018-32033-w.
4. Ma P, Cardenas AE, Chaudhari MI, et al. Probing Translocation in Mutants of the Anthrax Channel: Atomically Detailed Simulations with Milestoning. J Phys Chem B. 2018 Nov 15;122(45):10296-10305. https://pubs.acs.org/doi/10.1021/acs.jpcb.8b08304.
5. Seamon KJ, Light YK, Saada EA, et al Versatile High-Throughput Fluorescence Assay for Monitoring Cas9 Activity. Anal Chem. 2018 Jun 5;90(11):6913-6921. https://pubs.acs.org/doi/pdf/10.1021/acs.analchem.8b01155

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

Objectives: To improve the United States' ability to anticipate and defend against biological threats, SNL's multidisciplinary research team is applying its traditional strengths in engineering and technology development to achieve the following goals: 1) Gain basic knowledge regarding the fundamental molecular processes of pathogenesis, including the dynamic interactions between microbial pathogens and their hosts; 2) Develop assays, novel materials, and platforms to detect and diagnose traditional and unknown pathogens, as well as to discover novel therapeutic targets; and 3) Obtain an understanding of the microbiome's effects on human health in the absence or in the presence of an infectious disease.

***Microorganisms and/or toxins studied*:** NIAID Category A

***Outdoor studies*:** None

* Including viruses and prions.

Form A, Part 2 (iii)

National biological defence research and development programmes

1. What is the name of the facility?
Centers for Disease Control and Prevention (CDC), National Center for Environmental Health (NCEH), Division of Laboratory Services (DLS)

2. Where is it located (include both address and geographical location)?
4770 Buford Highway, Atlanta, Georgia 30341

3. Floor area of laboratory areas by containment level:

BL2	568 m^2
BL3	0 m^2
BL4	0m^2
Total laboratory floor area	568 m^2

4. The organizational structure of each facility.

(i) Total number of personnel	15
(ii) Division of personnel:	
Military	0
Civilian	15
(iii) Division of personnel by category:	
Scientists	15
Engineers	0
Technicians	0
Administrative and support staff	0

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Analytical Biochemistry, Analytical Chemistry, Analytical Mass Spectrometry, Biochemistry, Biology, Chemistry, Mass Spectrometry, Proteomics

(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?
Centers for Disease Control and Prevention, Department of Health and Human Services (HHS)

(vii) What are the funding levels for the following programme areas:

Research	$1,740,623
Development	$747,500
Test and evaluation	$1,433,563
Total	$3,921,686

(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. CDC also has an internal policy on "Oversight and clearance of dual use research of concern."

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

1. Halai U, Terashita D, Kim M, Green N, Kalb SR, Chatham-Stephens K, Balter S. Notes from the Field: Intestinal Colonization and Possible Iatrogenic Botulism Identified by Mass Spectrometry in Mouse-Bioassay-Negative Serum Specimens. MMWR Morb Mortal Wkly Rep. 2018, Nov 2;67(43):1221-1222. https://www.cdc.gov/mmwr/volumes/67/wr/mm6743a6.htm
2. Candela-Gallegos M, Boyer AE, Woolfitt AR, Brumlow J, Lins RC, Quinn CP, Hoffmaster AR, Meister G, Barr JR. Validated MALDI-TOF-MS method for anthrax lethal factor provides early diagnosis and evaluation of therapeutics. Anal. Biochem. 2018, Feb 15; 543:97-107. https://www.ncbi.nlm.nih.gov/pubmed/29224733
3. Isenberg SL, Carter MD, Miller MA, Noras AI, Mojica MA, Carlsen ST, Bulathsinghala CP, Thomas JD, Johnson RC.Quantification of Ricinine and Abrine in Human Plasma by HPLC-MS-MS: Biomarkers of Exposure to Ricin and Abrin. J Anal Toxicol. 2018 Nov 1;42(9):630-636. doi: 10.1093/jat/bky040. https://www.ncbi.nlm.nih.gov/pubmed/29931062
4. Sanford AA, Isenberg SL, Carter MD, Mojica MA, Mathews TP, Harden LA, Takeoka GR, Thomas JD, Pirkle JL, Johnson RC.Quantitative HPLC-MS/MS analysis of toxins in soapberry seeds: Methylenecyclopropylglycine and hypoglycin A. Food Chem. 2018 Oct 30;264:449-454. doi: 10.1016/j.foodchem.2018.04.093. https://www.ncbi.nlm.nih.gov/pubmed/29853400
5. Wharton RE, Ojeda-Torres G, Cunningham B, Feyereisen MC, Hill KL, Abbott NL, Seymour C, Hill D, Lang J, Hamelin EI, Johnson RC. Quantification of Microcystin-LR in Human Urine by Immunocapture Liquid Chromatography Tandem Mass Spectrometry. Chem Res Toxicol. 2018 Sep 17;31(9):898-903. doi: 10.1021/acs.chemrestox.8b00126. Epub 2018 Sep 5. https://www.ncbi.nlm.nih.gov/pubmed/30133262
6. Sanford AA, Isenberg SL, Carter MD, Mojica MA, Mathews TP, Laughlin S, Thomas JD, Pirkle JL, Johnson RC. Quantification of hypoglycin A and methylenecyclopropylglycine in human plasma by HPLC-MS/MS. J Chromatogr B Analyt Technol Biomed Life Sci. 2018 Sep 15;1095:112-118. doi: 10.1016/j.jchromb.2018.07.017. https://www.ncbi.nlm.nih.gov/pubmed/30056267
7. Abbott NL, Hill KL, Garrett A, Carter MD, Hamelin EI, Johnson RC. Detection of α-, β-, and γ-amanitin in urine by LC-MS/MS using 15N10-α-amanitin as the internal standard. Toxicon. 2018 Sep 15;152:71-77. doi: 10.1016/j.toxicon.2018.07.025. Epub 2018 Jul 30. https://www.ncbi.nlm.nih.gov/pubmed/30071219
8. Attard TJ, Carter MD, Fang M, Johnson RC, Reid GE. Structural Characterization and Absolute Quantification of Microcystin Peptides Using Collision-Induced and Ultraviolet Photo-Dissociation Tandem Mass Spectrometry. J Am Soc Mass Spectrom. 2018 Sep;29(9):1812-1825. doi: 10.1007/s13361-018-1981-3. https://www.ncbi.nlm.nih.gov/pubmed/29845563
9. Bragg WA, Garrett A, Hamelin EI, Coleman RM, Campbell K, Elliott CT, Johnson RC. Quantitation of saxitoxin in human urine using immunocapture extraction and LC-MS. Bioanalysis. 2018 Feb;10(4):229-239. doi: 10.4155/bio-2017-0156. https://www.ncbi.nlm.nih.gov/pubmed/29333869

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

Objectives: The Division of Laboratory Sciences develops methods for measuring selected toxins to help improve detection and diagnosis during a public health response to biological toxins.

Agents Microorganisms and/or toxins studied: Select Agents (HHS), Select Toxins (HHS), NIAID Category A Pathogens

Outdoor studies: Outdoor studies of biological aerosols were not conducted at the facility or off-site by facility personnel.

[*] Including viruses and prions.

Form A, Part 2 (iii)

National biological defence research and development programmes

1. What is the name of the facility?
Centers for Disease Control and Prevention (CDC), Deputy Director for Infectious Diseases (DDID)

2. Where is it located (provide both address and geographical location)?
1600 Clifton Road N.E., Atlanta, Georgia 30329

3. Floor area of laboratory areas by containment level:

BL2	423 m^2
BL3	1220 m^2
BL4	533 m^2
Total laboratory floor area	2176 m^2

4. The organizational structure of each facility.

(i) Total number of personnel 205

(ii) Division of personnel:

Military	7
Civilian	198

(iii) Division of personnel by category:

Scientists	182
Engineers	0
Technicians	14
Administrative and support staff	9

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Animal Science, Biochemistry, Bioinformatics, Biology, Biological Science, Cell Biology. Chemistry, Clinical Immunology, Ecology, Entomology, Epidemiology, Genetics, Genomics, Immunology, Medicine, Microbiology, Molecular Biology, Molecular Diagnostics, Public Health, Statistics, Veterinary Medicine, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 46

(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. Agency for International Development (USAID)
- Department of Health and Human Services (HHS)
- Department of Homeland Security (DHS)

(vii) What are the funding levels for the following program areas:

Research	$ 12,716,950
Development	$ 4,580,787
Test and evaluation	$ 8,202,768
Total	$ 25,500,505

(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. CDC also has an internal policy on "Oversight and clearance of dual use research of concern."

(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.)

NCIRD/INFLUENZA

1. Poirot E, Levine MZ, Russell K, Stewart RJ, Pompey JM, Chiu S, Fry AM, Gross L, Havers FP, Li ZN, Liu F, Crossa A, Lee CT, Boshuizen V, Rakeman JL, Slavinski S, Harper S, Gould LH. Detection of Avian Influenza A(H7N2) Virus Infection Among Animal Shelter Workers Using a Novel Serological Approach-New York City, 2016-2017. J Infect Dis. 2018. doi:10.1093/infdis/jiy595. PubMed Central: 30395249. https://www.ncbi.nlm.nih.gov/pubmed/?term=30395249
2. Sun X, Belser JA, Pappas C, Pulit-Penaloza JA, Brock N, Zeng H, Creager HM, Le S, Wilson M, Lewis A, Stark TJ, Shieh WJ, Barnes J, Tumpey TM, Maines TR. Risk assessment of fifth-wave H7N9 influenza A viruses in mammalian models. J Virol. 2018. doi:10.1128/JVI.01740-18. PubMed Central: 30305359. https://www.ncbi.nlm.nih.gov/pubmed/?term=30305359%5Buid%5D
3. Belser JA, Maines TR, Tumpey TM. Importance of 1918 virus reconstruction to current assessments of pandemic risk. Virology. 2018;524:45-55. PubMed Central: 30142572. https://www.ncbi.nlm.nih.gov/pubmed/?term=30142572
4. Dharmayanti N, Thor SW, Zanders N, Hartawan R, Ratnawati A, Jang Y, Rodriguez M, Suarez DL, Samaan G, Pudjiatmoko, Davis CT. Attenuation of highly pathogenic avian influenza A(H5N1) viruses in Indonesia following the reassortment and acquisition of genes from low pathogenicity avian influenza A virus progenitors. Emerg Microbes Infect. 2018;7:147. PubMed Central: 30131494. https://www.ncbi.nlm.nih.gov/pubmed/?term=30131494
5. Sayedahmed EE, Hassan AO, Kumari R, Cao W, Gangappa S, York I, Sambhara S, Mittal SK. A Bovine Adenoviral Vector-Based H5N1 Influenza -Vaccine Provides Enhanced Immunogenicity and Protection at a Significantly Low Dose. Mol Ther Methods Clin Dev. 2018;10:210-222. PubMed Central: 30101154. https://www.ncbi.nlm.nih.gov/pubmed/?term=30101154
6. Wang X, Wu P, Pei Y, Tsang TK, Gu D, Wang W, Zhang J, Horby PW, Uyeki TM, Cowling BJ, Yu H. Assessment of human-to-human transmissibility of avian influenza A(H7N9) virus across five waves by analyzing clusters of case-patients in mainland China, 2013-2017. Clin Infect Dis. 2018. doi:10.1093/cid/ciy541. PubMed Central: 29961834. https://www.ncbi.nlm.nih.gov/pubmed/?term=29961834
7. Nachbagauer R, Shore D, Yang H, Johnson SK, Gabbard JD, Tompkins SM, Wrammert J, Wilson PC, Stevens J, Ahmed R, Krammer F, Ellebedy AH. Broadly Reactive Human Monoclonal Antibodies Elicited following Pandemic H1N1 Influenza Virus Exposure Protect Mice against Highly Pathogenic H5N1 Challenge. J Virol. 2018;92(16). PubMed Central: 29899095. https://www.ncbi.nlm.nih.gov/pubmed/?term=29899095
8. Pushko P, Tretyakova I, Hidajat R, Sun X, Belser JA, Tumpey TM. Multi-clade H5N1 virus-like particles: Immunogenicity and protection against H5N1 virus and effects of beta-propiolactone. Vaccine. 2018;36:4346-4353. PubMed Central: 29885769. https://www.ncbi.nlm.nih.gov/pubmed/?term=29885769
9. Thi Nguyen D, Shepard SS, Burke DF, Jones J, Thor S, Nguyen LV, Nguyen TD, Balish A, Hoang DN, To TL, Iqbal M, Wentworth DE, Spackman E, van Doorn HR, Davis CT, Bryant JE. Antigenic characterization of highly pathogenic avian influenza A(H5N1) viruses with chicken

and ferret antisera reveals clade-dependent variation in hemagglutination inhibition profiles. Emerg Microbes Infect. 2018;7:100. PubMed Central: 29855467. https://www.ncbi.nlm.nih.gov/pubmed/?term=29855467
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NCEZID/DVBD

- Miller HK, Binder AM, Peterson A, Theel ES, Volpe JM, Couturier MR, Cherry CC, Kersh GJ. Trends in Q fever serologic testing by immunofluorescence from fourlarge reference laboratories in the United States, 2012-2016. Sci Rep. 2018 Nov12;8(1):16670. doi: 10.1038/s41598-018-34702-2. https://www.ncbi.nlm.nih.gov/pubmed/30420599

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

***Objectives*:** Activities at this facility include developing diagnostic assays for public health, developing and validating methods to differentiate and characterize organisms and the toxins that they produce, testing environmental samples for the presence of microorganisms and toxins, and developing environmental sampling methods for recovery of agents from porous and nonporous surfaces for public health, routine reference antimicrobial susceptibility testing of clinical isolates, conducting molecular and antigenic characterization of organisms, determining pathogenicity and virulence of infectious agents, development of culture-independent point of care diagnostics, maintaining emergency response laboratory expertise and capacity, vaccine evaluation, medical countermeasure evaluation, determining the natural history of infectious organisms and assessing immune correlates of protection, and conducting epidemiologic studies and surveillance for diseases.

Much of our research work on B. anthracis has been discontinued, which is why our staffing and funding levels have decreased substantially. Although we maintain capacity to work with live organism in the event this becomes necessary, our lab is currently doing no work with live select agent organisms and is only working with Anthrax toxin (not a select agent). Current laboratory activities are focused on the development and evaluation of diagnostic assays for B. anthracis.

Microorganisms and/or toxins studied: Select Agents (HHS, USDA, Overlap), Select Toxins (HHS), NIAID Category A pathogens

***Outdoor Studies*:** Outdoor studies of biological aerosols were NOT conducted at the facility or off-site by facility personnel.

* Including viruses and prions

Form A, Part 2 (iii)

1. What is the name of the facility?
Centers for Disease Control and Prevention (CDC), Deputy Director for Infectious Diseases (DDID), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Vector Borne Diseases (DVBD) - Ft. Collins

2. Where is it located (include both address and geographical location)?
3156 Rampart Road, Fort Collins, Colorado 80521

3. Floor area of laboratory areas by containment level:

BL2	0 m^2
BL3	421 m^2
BL4	0 m^2
Total laboratory floor area	421 m^2

4. The organizational structure of each facility.

(i) Total number of personnel 33

(ii) Division of personnel:

Military	0
Civilian	33

(iii) Division of personnel by category:

Scientists	5
Engineers	0
Technicians	9
Administrative and support staff	19

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Animal Science, Bacteriology, Bioinformatics, Biological Science, Cell Biology, Ecology, Entomology, Environmental Science, Epidemiology, Genomics, Immunology, Medicine, Microbiology, Molecular Biology, Molecular Diagnostics, Pathology, Public Health, Structural Biology, Veterinary Medicine, Virology

(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 Health & Human Services

(vii) What are the funding levels for the following programme areas:

Research	$639,471
Development	$0
Test and evaluation	$0
Total	$639,471

(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. CDC also has an internal policy on "Oversight and clearance of dual use research of concern."

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

1. Eisen RJ, Atiku LA, Boegler KA, Mpanga JT, Enscore RE, MacMillan K, Gage KL. An Evaluation of Removal Trapping to Control Rodents Inside Homes in a Plague-Endemic Region of Rural Northwestern Uganda. Vector Borne Zoonotic Dis. 2018 Sep;18(9):458-463. doi: 10.1089/vbz.2018.2276. https://www.ncbi.nlm.nih.gov/pubmed/29768127
2. Kading RC, Kityo RM, Mossel EC, Borland EM, Nakayiki T, Nalikka B, Nyakarahuka L, Ledermann JP, Panella NA, Gilbert AT, Crabtree MB, Peterhans JK, Towner JS, Amman BR, Sealy TK, Nichol ST, Powers AM, Lutwama JJ, Miller BR. Neutralizing antibodies against flaviviruses, Babanki virus, and Rift Valley fever virus in Ugandan bats. Infect Ecol Epidemiol. 2018 Feb 21;8(1):1439215. doi: 10.1080/20008686.2018.1439215. eCollection 2018. https://www.ncbi.nlm.nih.gov/pubmed/29511459

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

***Objectives*:** CDC's Division of Vector Borne Diseases (DVBD) possesses many of the select agents that are on the Department of Health and Human Services (HHS) and HHS/U.S. Department of Agriculture overlap lists. Within CDC, DVBD has the primary responsibility for research on tularemia, plague and alphaviruses. This research involves development of assays for surveillance and detection of each agent and molecular and antigenic characterization.

Microorganisms and/or toxins studied: Select Agents (HHS, Overlap), NIAID Category A pathogens

***Outdoor Studies*:** No outdoor studies of biological aerosols were conducted at the facility or off-site by facility personnel.

* Including viruses and prions.

National biological defence research and development programmes

1. What is the name of the facility?
Integrated Research Facility at Rocky Mountain Laboratories (IRF-RML)

2. Where is it located (include both address and geographical location)?
903 South 4th Street, Hamilton, Montana 59840

3. Floor area of laboratory areas by containment level:

BL2	1361 m^2
BL3	407 m^2
BL4	1145 m^2
Total laboratory floor area	2913 m^2

4. The organizational structure of each facility.

(i) Total number of personnel = 125

(ii) Division of personnel:

Military = 0
Civilian = 125

(iii) Division of personnel by category:

Scientists = 68
Engineers = 0
Technicians = 51
Administrative and support staff = 6

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Aerobiology, Animal Science, Bacteriology, Biochemistry, Biological Science, Cell Biology, Entomology, Genetics, Genomics, Immunology, Mass Spectrometry, Microbiology, Microscopy, Molecular Biology, Pathology, Proteomics, Veterinary Medicine, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 9

(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 Health and Human Services (HHS)

(vii) What are the funding levels for the following programme areas:

Research	$25,511,424
Development	$0
Test and evaluation	$0
Total	$25,511,424

(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/) 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 form NIH funds to the National Library of Medicine's PubMed Central digital archive 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 published during the previous 12 months. (To include authors, titles and full references.)

1. Baiardi S, Redaelli V, Ripellino P, Rossi M, Franceschini A, Moggio M, et al. Prion-related peripheral neuropathy in sporadic Creutzfeldt-Jakob disease. Journal of neurology, neurosurgery, and psychiatry. 2018. Epub 2018/10/26. doi: 10.1136/jnnp-2018-319221. PubMed PMID: 30355606. https://www.ncbi.nlm.nih.gov/pubmed/?term=30355606
2. Beare PA, Jeffrey BM, Long CM, Martens CM, Heinzen RA. Genetic mechanisms of Coxiella burnetii lipopolysaccharide phase variation. PLoS pathogens. 2018;14(3):e1006922. Epub 2018/02/27. doi: 10.1371/journal.ppat.1006922. PubMed PMID: 29481553; PubMed Central PMCID: PMCPMC5843353. https://www.ncbi.nlm.nih.gov/pubmed/?term=29481553
3. Bennett AJ, Bushmaker T, Cameron K, Ondzie A, Niama FR, Parra HJ, et al. Diverse RNA viruses of arthropod origin in the blood of fruit bats suggest a link between bat and arthropod viromes. Virology. 2018;528:64-72. Epub 2018/12/24. doi: 10.1016/j.virol.2018.12.009. PubMed PMID: 30576861. https://www.ncbi.nlm.nih.gov/pubmed/?term=30576861
4. Best SM, Feldmann H. Tip Your Cap for Ebola Virus Neutralization. Immunity. 2018;49(2):204-6. Epub 2018/08/23. doi: 10.1016/j.immuni.2018.08.001. PubMed PMID: 30134198. https://www.ncbi.nlm.nih.gov/pubmed/?term=30134198
5. Bhatia B, Hillman C, Carracoi V, Cheff BN, Tilly K, Rosa PA. Infection history of the blood-meal host dictates pathogenic potential of the Lyme disease spirochete within the feeding tick vector. PLoS pathogens. 2018;14(4):e1006959. Epub 2018/04/06. doi: 10.1371/journal.ppat.1006959. PubMed PMID: 29621350; PubMed Central PMCID: PMCPMC5886588. https://www.ncbi.nlm.nih.gov/pubmed/?term=29621350
6. Bland DM, Jarrett CO, Bosio CF, Hinnebusch BJ. Infectious blood source alters early foregut infection and regurgitative transmission of Yersinia pestis by rodent fleas. PLoS pathogens. 2018;14(1):e1006859. Epub 2018/01/23. doi: 10.1371/journal.ppat.1006859. PubMed PMID: 29357385; PubMed Central PMCID: PMCPMC5794196. https://www.ncbi.nlm.nih.gov/pubmed/?term=29357385
7. Bontemps-Gallo S, Gaviard C, Richards CL, Kentache T, Raffel SJ, Lawrence KA, et al. Global Profiling of Lysine Acetylation in Borrelia burgdorferi B31 Reveals Its Role in Central Metabolism. Frontiers in microbiology. 2018;9:2036. Epub 2018/09/21. doi: 10.3389/fmicb.2018.02036. PubMed PMID: 30233522; PubMed Central PMCID: PMCPMC6127242. https://www.ncbi.nlm.nih.gov/pubmed/?term=30233522
8. Bontemps-Gallo S, Lawrence KA, Richards CL, Gherardini FC. Borrelia burgdorferi genes, bb0639-0642, encode a putative putrescine/spermidine transport system, PotABCD, that is spermidine specific and essential for cell survival. Molecular microbiology. 2018;108(4):350-60. Epub 2018/02/25. doi: 10.1111/mmi.13940. PubMed PMID: 29476656; PubMed Central PMCID: PMCPMC5943160. https://www.ncbi.nlm.nih.gov/pubmed/?term=29476656
9. Bontemps-Gallo S, Lawrence KA, Richards CL, Gherardini FC. Genomic and phenotypic characterization of Borrelia afzelii BO23 and Borrelia garinii CIP 103362. PloS one. 2018;13(6):e0199641. Epub 2018/06/27. doi: 10.1371/journal.pone.0199641. PubMed PMID: 29944685; PubMed Central PMCID: PMCPMC6019248. https://www.ncbi.nlm.nih.gov/pubmed/?term=29944685
10. Carroll JA, Race B, Williams K, Chesebro B. Toll-like receptor 2 confers partial neuroprotection during prion disease. PloS one. 2018;13(12):e0208559. Epub

2019/01/01. doi: 10.1371/journal.pone.0208559. PubMed PMID: 30596651; PubMed Central PMCID: PMCPMC6312208. https://www.ncbi.nlm.nih.gov/pubmed/?term=30596651
11. Carroll JA, Race B, Williams K, Striebel J, Chesebro B. Microglia Are Critical in Host Defense Against Prion Disease. Journal of virology. 2018. Epub 2018/05/18. doi: 10.1128/jvi.00549-18. PubMed PMID: 29769333; PubMed Central PMCID: PMCPMC6052316. https://www.ncbi.nlm.nih.gov/pubmed/?term=29769333
12. Cross RW, Mire CE, Feldmann H, Geisbert TW. Post-exposure treatments for Ebola and Marburg virus infections. Nature reviews Drug discovery. 2018;17(6):413-34. Epub 2018/01/30. doi: 10.1038/nrd.2017.251. PubMed PMID: 29375139. https://www.ncbi.nlm.nih.gov/pubmed/?term=29375139
13. de Wit E, Feldmann F, Okumura A, Horne E, Haddock E, Saturday G, et al. Prophylactic and therapeutic efficacy of mAb treatment against MERS-CoV in common marmosets. Antiviral research. 2018;156:64-71. Epub 2018/06/10. doi: 10.1016/j.antiviral.2018.06.006. PubMed PMID: 29885377. https://www.ncbi.nlm.nih.gov/pubmed/?term=29885377
14. de Wit E, Siegers JY, Cronin JM, Weatherman S, van den Brand JM, Leijten LM, et al. 1918 H1N1 Influenza Virus Replicates and Induces Proinflammatory Cytokine Responses in Extrarespiratory Tissues of Ferrets. The Journal of infectious diseases. 2018;217(8):1237-46. Epub 2018/01/13. doi: 10.1093/infdis/jiy003. PubMed PMID: 29329410; PubMed Central PMCID: PMCPMC6018876. https://www.ncbi.nlm.nih.gov/pubmed/?term=29329410
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17. Emanuel J, Callison J, Dowd KA, Pierson TC, Feldmann H, Marzi A. A VSV-based Zika virus vaccine protects mice from lethal challenge. Scientific reports. 2018;8(1):11043. Epub 2018/07/25. doi: 10.1038/s41598-018-29401-x. PubMed PMID: 30038228; PubMed Central PMCID: PMCPMC6056530. https://www.ncbi.nlm.nih.gov/pubmed/?term=30038228
18. Emanuel J, Marzi A, Feldmann H. Filoviruses: Ecology, Molecular Biology, and Evolution. Advances in virus research. 2018;100:189-221. Epub 2018/03/20. doi: 10.1016/bs.aivir.2017.12.002. PubMed PMID: 29551136. https://www.ncbi.nlm.nih.gov/pubmed/?term=29551136
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5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms* and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: The Integrated Research Facility at Rocky Mountain Laboratories hosts research dedicated to understanding the mechanisms of pathogenesis of microbial agents associated with or likely to cause serious or lethal human diseases using molecular methods and animal model systems. Research activities include pathogenesis studies, vaccinology, and the development of therapeutic countermeasures and rapid diagnostic assays in support of the civilian biodefense program. More information is available at https://www.niaid.nih.gov/about/rocky-mountain-laboratories.

Microorganisms and/or toxins studied: Select Agents (HHS, Overlap, USDA), NIAID Category A pathogens

Outdoor studies: No outdoor studies of biological aerosols were conducted.

* Including viruses and prions.

National biological defence research and development programmes

1. What is the name of the facility?
Integrated Research Facility at Fort Detrick (IRF-Frederick)

2. Where is it located (include both address and geographical location)?
8200 Research Plaza, Frederick, Maryland 21702

3. Floor area of laboratory areas by containment level:

BL-2	878 m^2
BL-3	0 m^2
BL-4	1305 m^2
Total laboratory floor area	2183 m^2

4. The organizational structure of each facility.

(i) Total number of personnel 90

(ii) Division of personnel:

Military	0
Civilian	90

(iii) Division of personnel by category:

Scientists	21
Engineers	2
Technicians	62
Administrative and support staff	5

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Aerobiology, Aerosol Science, Analytical Biochemistry, Biochemistry, Biological Science, Cell Biology, Genomics, Immunology, Microbiology, Microscopy, Molecular Biology, Molecular Diagnostics, Pathology, Public Health, Veterinary Medicine, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 87

(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 Health and Human Services (HHS)

(vii) What are the funding levels for the following programme areas:

Research	$29,253,284
Development	$0
Test and evaluation	$0
Total	$29,253,284

(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/) 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 form NIH funds to the National Library of Medicine's PubMed Central digital archive 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 published during the previous 12 months. (To include authors, titles and full references.)

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3. Cai Y, Iwasaki M, Beitzel BF, Yu S, Postnikova EN, Cubitt B, et al. Recombinant Lassa Virus Expressing Green Fluorescent Protein as a Tool for High-Throughput Drug Screens and Neutralizing Antibody Assays. Viruses. 2018;10(11). Epub 2018/11/23. doi: 10.3390/v10110655. PubMed PMID: 30463334; PubMed Central PMCID: PMCPMC6266387. https://www.ncbi.nlm.nih.gov/pubmed/?term=30463334
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8. Davey RT, Jr., Dodd L, Proschan M, Jahrling P, Hensley L, Higgs E, et al. The Past Need Not Be Prologue: Recommendations for Testing and Positioning the Most-Promising Medical Countermeasures for the Next Outbreak of Ebola Virus Infection. The Journal of infectious diseases. 2018;218(suppl_5):S690-s7. Epub 2018/07/23. doi: 10.1093/infdis/jiy334. PubMed PMID: 30032267; PubMed Central PMCID: PMCPMC6249585. https://www.ncbi.nlm.nih.gov/pubmed/?term=30032267
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5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: The Integrated Research Facility at Fort Detrick in Frederick, Maryland manages, coordinates, and facilitates the conduct of emerging infectious disease and biodefense research to develop vaccines, countermeasures, and improved medical outcomes for patients. Battelle Memorial Institute facilitates research performed at the IRF-Frederick with direction from the IRF Scientific Steering Committee.

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap), NIAID Category A pathogens

Outdoor studies: No outdoor studies of biological aerosols were conducted.

[*] Including viruses and prions.

Form A, Part 2 (iii)

National biological defence research and development programmes

1. What is the name of the facility?
C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases

2. Where is it located (include both address and geographical location)?
9000 Rockville Pike, Bethesda, Maryland 20892

3. Floor area of laboratory areas by containment level:

BL2	2725 m^2
BL3	1356 m^2
BL4	0 m^2
Total laboratory floor area	4081 m^2

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:
Scientists = 66
Engineers = 0
Technicians = 51
Administrative and support staff = 7

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Bacteriology, Biological Science, Chemistry, Immunology, Medicine, Microbiology, Molecular Biology, Parasitology, Pathogenesis, Toxicology, Vaccine Evaluation, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 25

(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 Health and Human Services (HHS)

(vii) What are the funding levels for the following programme areas:

Research	$31,596,865
Development	$0
Test and evaluation	$0
Total	$31,596,865

(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/) 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 form NIH funds to the National Library of Medicine's PubMed Central digital archive 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 published during the previous 12 months. (To include authors, titles and full references.)

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8. Beura LK, Mitchell JS, Thompson EA, Schenkel JM, Mohammed J, Wijeyesinghe S, et al. Intravital mucosal imaging of CD8(+) resident memory T cells shows tissue-autonomous recall responses that amplify secondary memory. Nature immunology. 2018;19(2):173-82. Epub 2018/01/10. doi: 10.1038/s41590-017-0029-3. PubMed PMID: 29311694; PubMed Central PMCID: PMCPMC5896323. https://www.ncbi.nlm.nih.gov/pubmed/?term=29311694
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64. Oh S, Park Y, Engelhart CA, Wallach JB, Schnappinger D, Arora K, et al. Discovery and Structure-Activity-Relationship Study of N-Alkyl-5-hydroxypyrimidinone Carboxamides as Novel Antitubercular Agents Targeting Decaprenylphosphoryl-beta-d-ribose 2'-Oxidase. Journal of medicinal chemistry. 2018;61(22):9952-65. Epub 2018/10/24. doi: 10.1021/acs.jmedchem.8b00883. PubMed PMID: 30350998; PubMed Central PMCID: PMCPMC6257622. https://www.ncbi.nlm.nih.gov/pubmed/?term=30350998
65. Paliga D, Raudzus F, Leppla SH, Heumann R, Neumann S. Lethal Factor Domain-Mediated Delivery of Nurr1 Transcription Factor Enhances Tyrosine Hydroxylase Activity and Protects from Neurotoxin-Induced Degeneration of Dopaminergic Cells. Molecular neurobiology. 2018. Epub 2018/08/20. doi: 10.1007/s12035-018-1311-6. PubMed PMID: 30121937. https://www.ncbi.nlm.nih.gov/pubmed/?term=30121937
66. Park JK, Han A, Czajkowski L, Reed S, Athota R, Bristol T, et al. Evaluation of Preexisting Anti-Hemagglutinin Stalk Antibody as a Correlate of Protection in a Healthy Volunteer Challenge with Influenza A/H1N1pdm Virus. mBio. 2018;9(1). Epub 2018/01/25. doi: 10.1128/mBio.02284-17. PubMed PMID: 29362240; PubMed Central PMCID: PMCPMC5784259. https://www.ncbi.nlm.nih.gov/pubmed/?term=29362240
67. Pierson TC, Diamond MS. The emergence of Zika virus and its new clinical syndromes. Nature. 2018;560(7720):573-81. Epub 2018/08/31. doi: 10.1038/s41586-018-0446-y. PubMed PMID: 30158602. https://www.ncbi.nlm.nih.gov/pubmed/?term=30158602
68. Popper SJ, Strouts FR, Lindow JC, Cheng HK, Montoya M, Balmaseda A, et al. Early Transcriptional Responses After Dengue Vaccination Mirror the Response to Natural Infection and Predict Neutralizing Antibody Titers. The Journal of infectious diseases. 2018;218(12):1911-21. Epub 2018/07/17. doi: 10.1093/infdis/jiy434. PubMed PMID: 30010906; PubMed Central PMCID: PMCPMC6217718. https://www.ncbi.nlm.nih.gov/pubmed/?term=30010906
69. Powers JH, 3rd, Bacci ED, Leidy NK, Poon JL, Stringer S, Memoli MJ, et al. Performance of the inFLUenza Patient-Reported Outcome (FLU-PRO) diary in patients with influenza-like illness (ILI). PloS one. 2018;13(3):e0194180. Epub 2018/03/23. doi: 10.1371/journal.pone.0194180. PubMed PMID: 29566007; PubMed Central PMCID: PMCPMC5863969. https://www.ncbi.nlm.nih.gov/pubmed/?term=29566007
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74. Stuart CA, Zhivkoplias EK, Senkevich TG, Wyatt LS, Moss B. RNA Polymerase Mutations Selected during Experimental Evolution Enhance Replication of a Hybrid Vaccinia Virus with an Intermediate Transcription Factor Subunit Replaced by the Myxoma Virus Ortholog. Journal of virology. 2018;92(20). Epub 2018/07/27. doi: 10.1128/jvi.01089-18. PubMed PMID: 30045995; PubMed Central PMCID: PMCPMC6158416. https://www.ncbi.nlm.nih.gov/pubmed/?term=30045995
75. Tao P, Mahalingam M, Zhu J, Moayeri M, Sha J, Lawrence WS, et al. A Bacteriophage T4 Nanoparticle-Based Dual Vaccine against Anthrax and Plague. mBio. 2018;9(5). Epub 2018/10/18. doi: 10.1128/mBio.01926-18. PubMed PMID: 30327445; PubMed Central PMCID: PMCPMC6191538. https://www.ncbi.nlm.nih.gov/pubmed/?term=30327445
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77. VanBlargan LA, Himansu S, Foreman BM, Ebel GD, Pierson TC, Diamond MS. An mRNA Vaccine Protects Mice against Multiple Tick-Transmitted Flavivirus Infections. Cell reports. 2018;25(12):3382-92.e3. Epub 2018/12/20. doi: 10.1016/j.celrep.2018.11.082. PubMed PMID: 30566864. https://www.ncbi.nlm.nih.gov/pubmed/?term=30566864
78. Wei J, Yewdell JW. Flu DRiPs in MHC Class I Immunosurveillance. Virologica Sinica. 2018. Epub 2018/11/21. doi: 10.1007/s12250-018-0061-y. PubMed PMID: 30456657. https://www.ncbi.nlm.nih.gov/pubmed/?term=30456657
79. Wei J, Yewdell JW. Immunoribosomes: Where's there's fire, there's fire. Molecular immunology. 2018. Epub 2018/01/24. doi: 10.1016/j.molimm.2017.12.026. PubMed PMID: 29361306. https://www.ncbi.nlm.nih.gov/pubmed/?term=29361306
80. Wei J, Yewdell JW. Peptide secretion triggers diabetes. Nature. 2018;560(7716):33-4. Epub 2018/08/01. doi: 10.1038/d41586-018-05710-z. PubMed PMID: 30061643. https://www.ncbi.nlm.nih.gov/pubmed/?term=30061643
81. Xiao Y, Nolting JM, Sheng ZM, Bristol T, Qi L, Bowman AS, et al. Design and validation of a universal influenza virus enrichment probe set and its utility in deep sequence analysis of primary cloacal swab surveillance samples of wild birds. Virology. 2018;524:182-91. Epub 2018/09/14. doi: 10.1016/j.virol.2018.08.021. PubMed PMID: 30212665. https://www.ncbi.nlm.nih.gov/pubmed/?term=30212665
82. Xiao YL, Ren L, Zhang X, Qi L, Kash JC, Xiao Y, et al. Deep Sequencing of H7N9 Influenza A Viruses from 16 Infected Patients from 2013 to 2015 in Shanghai Reveals Genetic Diversity and Antigenic Drift. mSphere. 2018;3(5). Epub 2018/09/21. doi: 10.1128/mSphereDirect.00462-18. PubMed PMID: 30232169; PubMed Central PMCID: PMCPMC6147129. https://www.ncbi.nlm.nih.gov/pubmed/?term=30232169

83. Xie YL, Cronin WA, Proschan M, Oatis R, Cohn S, Curry SR, et al. Transmission of Mycobacterium tuberculosis From Patients Who Are Nucleic Acid Amplification Test Negative. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America. 2018;67(11):1653-9. Epub 2018/04/27. doi: 10.1093/cid/ciy365. PubMed PMID: 29697779; PubMed Central PMCID: PMCPMC6233677. https://www.ncbi.nlm.nih.gov/pubmed/?term=29697779
84. Yewdell JW. What's Fair Is Fair: Leveling the Playing Field for Young Scientists. Vaccines. 2018;6(2). Epub 2018/06/03. doi: 10.3390/vaccines6020033. PubMed PMID: 29857467; PubMed Central PMCID: PMCPMC6028907. https://www.ncbi.nlm.nih.gov/pubmed/?term=29857467
85. Zhang P, Gorman J, Geng H, Liu Q, Lin Y, Tsybovsky Y, et al. Interdomain Stabilization Impairs CD4 Binding and Improves Immunogenicity of the HIV-1 Envelope Trimer. Cell host & microbe. 2018;23(6):832-44.e6. Epub 2018/06/15. doi: 10.1016/j.chom.2018.05.002. PubMed PMID: 29902444; PubMed Central PMCID: PMCPMC6007033. https://www.ncbi.nlm.nih.gov/pubmed/?term=29902444

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

Objectives: At the C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases, the Laboratory of Infectious Diseases (LID) focuses on vaccine development, host immune response to viruses, and viral molecular biology and genetics. The Laboratory of Parasitic Diseases (LPD) conducts basic and applied research on the prevention, control, and treatment of a variety of parasitic and bacterial diseases of global importance. The Laboratory of Viral Diseases (LVD) carries out investigations on the molecular biology of viruses, the interactions of viruses with host cells, the pathogens of viral diseases, and host defense mechanisms. The Laboratory of Clinical Immunology and Microbiology (LCIM) conducts clinical and basic science, and epidemiologic research into human immunologic, inflammatory, and infectious diseases. More information can be found at http://www.nih.gov/news-events/news-releases/nih-dedicates-cw-bill-young-center-biodefense-emerging-infectious-diseases.

Microorganisms and/or toxins studied: Select Agents (HHS, USDA), NIAID Category A pathogen

Outdoor studies: No outdoor studies of biological aerosols were conducted.

* Including viruses and prions

Form A, Part 2 (iii)

National biological defence research and development programmes

1. What is the name of the facility?
Dale and Betty Bumpers Vaccine Research Center (VRC)

2. Where is it located (include both address and geographical location)?
9000 Rockville Pike, Bethesda, Maryland 20892

3. Floor area of laboratory areas by containment level:

BL2	104m^2
BL3	0m^2
BL4	0m^2
Total laboratory floor area	104 m^2

4. The organizational structure of each facility.
(i) Total number of personnel = 13

(ii) Division of personnel:
Military = 0
Civilian = 13

(iii) Division of personnel by category:
Scientists = 13
Engineers = 0
Technicians = 0
Administrative and support staff = 0

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Biological Science

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 7

(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 Health and Human Services (HHS)

(vii) What are the funding levels for the following programme areas:

Research	$1,310,393
Development	0
Test and evaluation	0
Total	$1,310,393

(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/) 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 form

NIH funds to the National Library of Medicine's PubMed Central digital archive 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 published during the previous 12 months. (To include authors, titles and full references.)

1. Cagigi A, Misasi J, Ploquin A, Stanley DA, Ambrozak D, Tsybovsky Y, et al. Vaccine Generation of Protective Ebola Antibodies and Identification of Conserved B-Cell Signatures. The Journal of infectious diseases. 2018;218(suppl_5):S528-s36. Epub 2018/07/17. doi: 10.1093/infdis/jiy333. PubMed PMID: 30010811. https://www.ncbi.nlm.nih.gov/pubmed/?term=30010811
2. Cagigi A, Ploquin A, Niezold T, Zhou Y, Tsybovsky Y, Misasi J, et al. Vaccine-Mediated Induction of an Ebolavirus Cross-Species Antibody Binding to Conserved Epitopes on the Glycoprotein Heptad Repeat 2/Membrane-Proximal External Junction. The Journal of infectious diseases. 2018;218(suppl_5):S537-s44. Epub 2018/08/24. doi: 10.1093/infdis/jiy450. PubMed PMID: 30137549; PubMed Central PMCID: PMCPMC6249595. https://www.ncbi.nlm.nih.gov/pubmed/?term=30137549
3. Mulangu S, Alfonso VH, Hoff NA, Doshi RH, Mulembakani P, Kisalu NK, et al. Serologic Evidence of Ebolavirus Infection in a Population With No History of Outbreaks in the Democratic Republic of the Congo. The Journal of infectious diseases. 2018;217(4):529-37. Epub 2018/01/13. doi: 10.1093/infdis/jix619. PubMed PMID: 29329455; PubMed Central PMCID: PMCPMC5853806. https://www.ncbi.nlm.nih.gov/pubmed/?term=29329455
4. Ploquin A, Zhou Y, Sullivan NJ. Ebola Immunity: Gaining a Winning Position in Lightning Chess. Journal of immunology (Baltimore, Md : 1950). 2018;201(3):833-42. Epub 2018/07/25. doi: 10.4049/jimmunol.1700827. PubMed PMID: 30038036. https://www.ncbi.nlm.nih.gov/pubmed/?term=30038036
5. Wang B, DeKosky BJ, Timm MR, Lee J, Normandin E, Misasi J, et al. Functional interrogation and mining of natively paired human VH:VL antibody repertoires. Nature biotechnology. 2018;36(2):152-5. Epub 2018/01/09. doi: 10.1038/nbt.4052. PubMed PMID: 29309060; PubMed Central PMCID: PMCPMC5801115. https://www.ncbi.nlm.nih.gov/pubmed/?term=29309060

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

Objectives: The mission of the Vaccine Research Center (VRC) is to conduct research that facilitates the development of effective vaccines for human disease. The research focus of the Biodefense Research Section comprises three areas: development of vaccines and antivirals against hemorrhagic fever viruses such as Ebola, Marburg, and Lassa; studies of the mechanism of vaccine-induced immune protection and host immunity to natural infection; basic research to understand the mechanism of virus replication (entry) and neutralization.

Microorganisms and/or toxins studied: No U.S. Select Agents, NIAID Category A pathogens, or applicable simulants were used.

Outdoor studies: No outdoor studies of biological aerosols were conducted.

* Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Foreign Disease-Weed Science Research Unit

2. Where is it located (provide both address and geographical location)?
1301 Ditto Avenue, Fort Detrick, Maryland 21702

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	105 m^2
BSL-3:	950 m^2
BSL-4:	0 m^2
Total laboratory floor area:	1,055 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 34

(ii) Division of personnel:

Military	0
Civilian	34

(iii) Division of personnel by category:

Scientists	8
Engineers	0
Technicians	15
Administrative and support staff	11

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Agronomy, Biological Science, Genomics, Horticulture, Bacteriology, Microbial Forensics, Molecular Diagnostics, Plant Biochemistry, Plant Molecular Biology, Plant Pathology, Plant Physiology, Proteomics, Virology, Weed 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 Agriculture (USDA)

(vii) What are the funding levels for the following program areas:

Research	$4,000,000
Development	$0
Test and evaluation	$0
Total	$4,000,000

(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 a minimum of two peer-reviewed publications per year (not all publications by these scientists are relevant to this report). They are

encouraged to present research at scientific conferences and to publish in books and proceedings. The USDA Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at https://www.ars.usda.gov/research/publications/publications-at-this-location/?modeCode=80-44-05-00.)

(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.):

1. Davis, EW, Tabima, JF, Weisberg, AJ, et al. Evolution of the U.S. Biological Select Agent Rathayibacter toxicus. MBio. 2018; 9(4). doi: e01280-18. https://mbio.asm.org/content/mbio/9/4/e01280-18.full.pdf
2. Schroeder, BK, Schneider, WL, Luster, DG, Sechler, AJ, Murray, TD. Rathayibacter agropyri (non O'Gara 1916) comb. nov., nom. rev., isolated from western wheatgrass (Pascopyrum smithii). Int J Syst Evol Microbiol. 2018; 68:1519–1525. doi: 10.1099/ijsem.0.002708. https://doi.org/10.1099/ijsem.0.002708
3. Stone, C.L., Frederick, R.D., Tooley, P.W., et al. Annotation and analysis of the mitochondrial genome of Coniothyrium glycines, causal agent of red leaf blotch of soybean, reveals an abundance of homing endonucleases. PLoS One. 2018; 13(11):e0207062. https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0207062&type=printable or https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0207062

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

Objectives: The Foreign Disease-Weed Science Research Unit has two distinct missions united by a common relationship to plant pathology and the unit's BL-3 plant pathogen laboratory and greenhouse containment facilities. 1) The mission of the foreign disease program is to develop techniques for the rapid detection and identification of new and emerging crop pathogens, and to provide fundamental information on emerging pathogens for risk assessment and the development of practical phytosanitary regulations for the import and export of agricultural commodities and germplasm. 2) The mission of the weed biological control program is to collect foreign pathogens overseas from weeds in their native habitat, and to evaluate, characterize and release the pathogens in the U.S. for biological control of introduced weeds, leading to improved, sustainable weed control practices in agricultural systems with reduced dependence on chemical herbicides. Additional information about research projects conducted at this location is available at http://www.ars.usda.gov/research/projects_programs.htm?modecode=80-44-05-00.

Microorganisms and/or Toxins Studied: Select Agents (Plant Protection and Quarantine, PPQ).

***Outdoor Studies*:** No research work is done outdoors with infectious organisms.

* Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
National Animal Disease Center (NADC)

2. Where is it located (provide both address and geographical location)?
1920 Dayton Avenue, Ames, Iowa 50010

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	4,410 m^2
BSL-3:	2,489 m^2
BSL-4:	0 m^2
Total laboratory floor area:	6,899 m^2

In addition NADC has unique animal biocontainment facilities ranging from ABSL-2 to ABSL-3Ag (highest biocontainment level that can accommodate food producing animals and various wildlife species). Biocontainment 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; and epoxy-covered surfaces. NADC also has two large biocontainment buildings that are considered ABSL-2-enhanced.

ABSL-2:	3,467.7 m^2
ABSL-3:	160.5 m^2
ABSL-3Ag:	1,581.6 m^2
Total biocontainment facility floor area:	5209.8 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 13

(ii) Division of personnel:

Military	0
Civilian	13

(iii) Division of personnel by category:

Scientists	9
Engineers	0
Technicians	3
Administrative and support staff	1

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Agricultural Engineering, Animal Science, Biochemistry, Bioinformatics, Biology, Biotechnology, Cell Biology, Clinical Immunology, Computational Biology, Ecology, Genetics, Genomics, Immunology, Infectious Disease, Mass Spectrometry, Microbiology, Molecular Biology, Pathogenesis, Pathology, Physiology, Prionology, Proteomics, Statistics, Structural Biology, Vaccine Evaluation, Veterinarian, Veterinary Clinical Research, 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 Agriculture (USDA)
Department of Health and Human Services (HHS)

(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 a minimum of two peer-reviewed publications per year (not all publications by these scientists will be relevant to this report, e.g. non-select agent pathogens). They are encouraged to present research at scientific conferences and to publish in books and proceedings. The USDA Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at https://www.ars.usda.gov/research/publications/publications-at-this-location/?modeCode=50-30-20-00.)

(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.):

1. Boggiatto, PM, Fitzsimmons, DJ, Bayles, DO, et al. Coincidence cloning recovery of Brucella melitensis RNA from goat tissues: advancing the in vivo analysis of pathogen gene expression in brucellosis. BMC Mol Bio. 2018; 19:10. doi: 10.1186/s12867-018-0111-x. https://doi.org/10.1186/s12867-018-0111-x
- Olsen, SC, Boggiatto, PM, White, DM, McNunn, TB. Biosafety concerns related to Brucella and its potential use as a bioweapon. Appl Biosaf. 2018; 23(2)77-90. https://doi.org/10.1177/1535676018771983

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

Objectives: Support 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. Specifically, the research programs aim to produce new research knowledge and technology to: prevent, reduce or eliminate losses from impaired livestock performance, increased deaths ar condemnations; develop more sensitive, specific and rapid diagnostic tests; develop vaccines designed for the control and, when feasible, the eradication of livestock disease; improve our understanding of the ecology and epidemiology of pathogens at the domestic animal-wildlife interface; and improve our understanding of the genetic and pathophysiologic basis of disease and pathogen virulence. This research provides government regulatory agencies and the livestock industries with improved intervention strategies against priority diseases. Additional information about research projects conducted at this location is available at http://www.ars.usda.gov/research/projects_programs.htm?modecode=50-30-20-00.

* Including viruses and prions.

Microorganisms and/or Toxins Studied: Select Agents (Overlap).

Outdoor Studies: No research work is done outdoors with infectious organisms.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Southeast Poultry Research Laboratory

2. Where is it located (provide both address and geographical location)?
934 College Station Road, Athens, Georgia 30605

3. Floor area of laboratory areas by containment level (m^2):

BSL-2:	1,138 m^2
BSL-3:	624 m^2
BSL-4:	0 m^2
Total laboratory floor area:	1,762 m^2

4. The organizational structure of each facility:

(i) **Total number of personnel:** 35

(ii) **Division of personnel:**

Military	0
Civilian	35

(iii) **Division of personnel by category:**

Scientists	6
Engineers	0
Technicians	8
Administrative and support staff	21

(iv) **List the scientific disciplines represented in the scientific/engineering staff:**
Animal Science, Bioinformatics, Biological Science, Biotechnology, Cell Biology, Computational Biology, Epidemiology, Genetics, Genomics, Immunology, Microbiology, Molecular Biology, Molecular Diagnostics, Pathology, Public Health, 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 Agriculture (USDA)
Department of Health and Human Services (HHS)
Department of Defense (DoD) – partly
Non-Profit Associations
Private Sector Companies
Department of State

(vii) **What are the funding levels for the following program areas:**

Research	$4,600,000
Development	$0

Test and evaluation	$0
Total	$4,600,000

(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 a minimum of two peer-reviewed publications per year (not all publications by these scientists are relevant to this report). They are encouraged to present research at scientific conferences and to publish in books and proceedings. The USDA Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at https://www.ars.usda.gov/research/publications/publications-at-this-location/?modeCode=60-40-10-30.)

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.):

1. Balzli, CL, Bertran, K, Lee, D, et al. The efficacy of recombinant turkey herpesvirus vaccines targeting the H5 of highly pathogenic avian influenza virus from the 2014/2015 North American outbreak. Vaccine. 2018; 36:84-90. https://doi.org/10.1016/j.vaccine.2017.11.026.
2. Bertran, K, Clark, A, Swayne, DE. Mitigation strategies to reduce the generation and transmission of airborne highly pathogenic influenza virus particles during processing of infected poultry. Int J Hyg Environ Health. 2018; 221(6):893-900. https://doi.org/10.1016/j.ijheh.2018.05.013.
3. Bertran, K, Lee, D, Criado, MF, Smith, DM, Swayne, DE, Pantin Jackwood, MJ. Pathobiology of Tennessee 2017 H7N9 low and high pathogenicity avian influenza viruses in commercial broiler breeders and specific pathogen free layer chickens. BMC Vet Res. 2018; 49:82. https://doi.org/10.1186/s13567-018-0576-0.
4. Chen, L, Lee, D, Liu, Y, et al. Reassortant clade 2.3.4.4 of highly pathogenic avian influenza A (H5N6) virus, Taiwan, 2017. Emerg Infect Dis. 2018; 24(6):1147-1149. https://doi.org/10.3201/eid2406.172071.
5. He, Y, Taylor, TL, Dimitrov, KM, et al. Whole-genome sequencing of genotype VI Newcastle disease viruses from formalin-fixed paraffin-embedded tissues from wild pigeons reveals continuous evolution and previously unrecognized genetic diversity in the U.S. Virol J. 2018; 15:9. doi: 10.1186/s12985-017-0914-2. https://doi.org/10.1186/s12985-017-0914-2.
6. Igwe, AO, Afonso, CL, Ezema, WS, Brown, CC, Okoye, JO. Pathology and distribution of velogenic viscerotropic newcastle disease virus in the reproductive system of vaccinated and unvaccinated laying hens (gallus gallus domesticus) by immunohistochemical labelling. J Comp Pathol. 2018; 159:36-48. https://doi.org/10.1016/j.jcpa.2017.12.009.
7. Lee, D, Torchetti, MK, Hicks, J, et al. Transmission Dynamics of Highly Pathogenic Avian Influenza Virus A(H5Nx) Clade 2.3.4.4, North America, 2014–2015. Emerg Infect Dis. 2018; 24(10):1840-1848. https://doi.org/10.3201/eid2410.171891.
8. Liu, Y., Lee, D., Chen, L., et al. Detection of reassortant H5N6 clade 2.3.4.4 highly pathogenic avian influenza virus in a black-faced spoonbill (Platalea minor) found dead, Taiwan, 2017. Infect. Genet Evol. 2018; 62:275-278. https://doi.org/10.1016/j.meegid.2018.04.026.
9. Nguyen, D, Shepard, SS, Burke, DF, et al. Antigenic characterization of highly pathogenic avian influenza A(H5N1) viruses with chicken and ferret antisera reveals similar haemagglutination inhibition profiles. Emerg Microbes Infect. 2018; 7(1):1-15. https://doi.org/10.1038/s41426-018-0100-7.

10. Ramey, AM, Deliberto, TJ, Berhane, Y, Swayne, DE, Stallknecht, D.E. Lessons learned from research and surveillance directed at highly pathogenic influenza A viruses in wild birds inhabiting North America. Virology. 2018; 518:55-63. https://doi.org/10.1016/j.virol.2018.02.002.
11. Susta, L, Segovia, D, Olivier, TL, et al. Newcastle disease virus infection in quail. Vet Pathol. 2018; 55(5):682-692 DOI: https://doi.org/10.1177/0300985818767996.

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

***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 of disease pathogenesis. Produce new research knowledge and technology to: prevent, reduce or eliminate losses from impaired poultry performance,increased deaths, and condemnations; develop more sensitive, specific and rapid diagnostic tests; develop vaccines designed for the control and, when feasible, the eradication of poultry 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 one research unit that conducts biological defense work: Exotic and Emerging Avian Viral Diseases Research Unit. Additional information about research projects conducted at this location is available at http://www.ars.usda.gov/main/site_main.htm?modecode=60-40-10-00.

***Microorganisms and/or Toxins Studied*:** Select Agents (USDA)

***Outdoor Studies*:** No research work is done outdoors with infectious organisms.

* Including viruses and prions.

Form A, Part 2 (iii)

National biological defence research and development programmes

1. What is the name of the facility?
Food and Drug Administration / Center for Biologics Evaluation and Research (FDA/CBER)

2. Where is it located (include both address and geographical location)?
10903 New Hampshire Avenue, Silver Spring, MD 20993

3. Floor area of laboratory areas by containment level:

BL2	186 m^2
BL3	184 m^2
BL4	0 m^2
Total laboratory floor area	370 m^2

4. The organizational structure of each facility.
(i) Total number of personnel = 50

(ii) Division of personnel:
Military = 0
Civilian = 50

(iii) Division of personnel by category:
Scientists = 30
Engineers = 0
Technicians = 0
Administrative and support staff = 20

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Bacteriology, Biological Science, Biomedical Science, Biotechnology, Cell Biology, Genetics, Immunology, Microbiology, Molecular Biology, Molecular Diagnostics, Nanotechnology, Virology

(v) Are contractor staff working in the facility? If so, provide an approximate number.
N/A

(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 Health and Human Services (HHS)

(vii) What are the funding levels for the following programme areas:

Research	$768,315
Development	0
Test and evaluation	0

(viii) Briefly describe the publication policy of the facility:
FDA and CBER staff are encouraged to publish their research results in peer-reviewed scientific journals. The FDA review and clearance policy and the CBER review and clearance policy ensures publications are of high quality and vetted by subject matter experts as well as leadership. In addition, compliance

with the public access to federally-funded scientific research (including digital data and publications) is assured by following FDA's data management plan. The policy states that publications must be uploaded to PubMed Central one year after the publication date.

- FDA review and clearance policy: (https://researchcentral.fda.gov/downloads/documents/FDA_Review_And_Clearance_of_Articles.pdf)
- CBER review and clearance policy: (http://inside.fda.gov:9003/downloads/PolicyProcedures/SOPsbyProgram/Biologics/UCM597998.pdf)

FDA Data Management Plan:
(http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM479268.pdf)

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

1. Verma A, Burns DL. Improving the stability of recombinant anthrax protective antigen. Vaccines. 2018 Oct 15; 36(43):6379-82. https://doi.org/10.1016/j.vaccine.2018.09.012
2. Verma A, Ngundi MM, Price GA, Takeda K, Yu J, Burns DL. Role of the antigen capture pathway in the induction of a neutralizing antibody response to anthrax protective antigen. MBio. 2018 Feb 27; 9(1):e00209-18. https://mbio.asm.org/content/9/1/e00209-18
3. Jesteadt E, Zhang I, Yu H, Meierovics A, Chua Yankelevich WJ, Cowley S. IL-18 is critical for MAIT cell IFN-gamma responses to Francisella species in vitro but not in vivo. Infect Immun. 2018 Apr 23;86(5):e00117-18. https://iai.asm.org/content/86/5/e00117-18
4. Kurtz SL, Voskanian-Kordi A, Simonyan V, Elkins KL. Sequence comparison of Francisella tularensis LVS, LVS-G, and LVS-R. Pathog Dis. 2018 Oct 1;76(7):fty067. https://academic.oup.com/femspd/article/76/7/fty067/5078346
5. De Pascalis R, Hahn A, Brook HM, Ryden P, Donart N, Mittereder L, Frey B, Wu TH, Elkins KL. A panel of correlates predicts vaccine-induced protection of rats against respiratory challenge with virulent *Francisella tularensis*. PLoS One 2018 May 25;13(5):e0198140. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0198140
6. Plaut RD, Staab AB, Munson MA, Gebhardt JS, Klimko CP, Quirk AV, Cote CK, Buhr TL, Rossmaier RD, Bernhards RC, Love CE, Berk KL, Abshire TG, Rozak DA, Beck LC, Stibitz S, Goodwin BG, Smith MA, Sozhamannan S. Avirulent *Bacillus anthracis* strain with molecular assay targets as surrogate for irradiation-inactivated virulent spores. Emerg Infect Dis 2018 Apr;24(4):691-9. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5875273/
7. Chen YQ, Wohlbold TJ, Zheng NY, Huang M, Huang Y, Neu KE, Lee J, Wan H, Rojas KT, Kirkpatrick E, Henry C, Palm AE, Stamper CT, Lan LY, Topham DJ, Treanor J, Wrammert J, Ahmed R, Eichelberger MC, Georgiou G, Krammer F, Wilson PC. Influenza infection in humans induces broadly cross-reactive and protective neuraminidase-reactive antibodies. Cell 2018 Apr 5;173(2):417-429.e10. https://www.cell.com/cell/fulltext/S0092-8674(18)30310-6
8. Wan H, Qi L, Gao J, Couzens LK, Jiang L, Gao Y, Sheng ZM, Fong S, Hahn M, Khurana S, Taubenberger JK, Eichelberger MC. Comparison of the efficacy of N9 neuraminidase-specific monoclonal antibodies against influenza A(H7N9) virus infection. J Virol 2018 Jan 30;92(4):e01588-17. https://jvi.asm.org/content/92/4/e01588-17

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

Objectives: The Center for Biologics Evaluation and Research (CBER) Program biodefense research program develops methods, tools, and models to evaluate biologics and product and manufacturing innovations that protect the United States from biological threats. CBER plays a critical role in ensuring the safety of the blood supply as well as the regulation of biologics, including, vaccines, certain diagnostic tests, and other medical countermeasures against CBRN agents. Our biodefense research is focused on 1) identifing correlates of protection to predict vaccine safety and effectiveness, 2) developing methods to assess vaccine potency, 3) improving approaches to enhance the availability of vaccines, and 4) developing sensitive detection assays that could be adapted for screening the blood supply or for developing diagnostic tests for detection of infectious agents.

Microorganisms and/or Toxins Studied: Select Agents (USDA)

Outdoor studies: No outdoor studies of biological aerosols were conducted.

[*] Including viruses and prions.

Form B

BWC - Confidence Building Measure

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

United States of America

April 15, 2019

Information on outbreaks of infectious diseases and similar occurrences, that seem to deviate from the normal pattern

Human Disease Events

Human Infection with influenza A(H3N2) variant virus:
On June 18, 2018, a child < 12 years old with no underlying medical conditions developed an influenza-like illness in Indiana. On June 20, the patient sought medical care from a health care provider and a respiratory specimen was collected for influenza testing which tested positive for influenza A. An additional respiratory specimen was collected at the local health department on June 22 and forwarded to the Indiana State Department of Health Public Health Laboratory on June 25. RT-PCR testing conducted at the state public health laboratory on June 27 was presumptive positive for influenza A(H3N2) variant (A(H3N2)v) virus. The specimen was forwarded to CDC on June 28; subsequent testing confirmed an influenza A(H3N2)v virus using RT-PCR. This is the first and only influenza A(H3N2)v virus infection identified in the United States during 2018. The patient was not hospitalized and fully recovered from their illness. Indirect swine exposure at an agricultural fair was reported in the week preceding illness onset. Genetic sequence analysis confirmed that this virus was closely related to influenza viruses detected in swine in 2017 and 2018 and that are known to circulate in North America. This genetic group of viruses has an hemagglutinin (HA) gene derived from a seasonal human-like H3 HA gene that was likely introduced from humans into swine in 2010.

Since reporting of novel influenza A viruses became nationally notifiable in 2005, 435 human infections with A(H3N2)v, including this one, have been reported to CDC.

This human infection case was first reported by CDC at https://www.cdc.gov/flu/weekly/weeklyarchives2017-2018/Week26.htm. General information about variant and influenza A viruses in swine are available at http://www.cdc.gov/flu/swineflu/index.htm. Additional information regarding human infections with novel influenza A viruses can be found at http://gis.cdc.gov/grasp/fluview/Novel_Influenza.html.

Human Infections with influenza A(H1N2) variant virus
In July 2018, four children < 18 years of age developed an influenza-like illness in two states (California [2] and Michigan [2]). All four children sought medical care at outpatient clinics, where a respiratory specimen was collected from each child for influenza testing. These specimens were forwarded to the respective state and local public health laboratories. Real-time RT-PCR testing conducted at each of the public health laboratories were positive for an influenza A virus but the virus subtype could not be determined. The CDC/Influenza Division received all four specimens on August 7 for additional testing. On August 8, CDC confirmed an influenza A(H1N2) variant A(H1N2)v virus using real-time RT-PCR and genome sequence analysis in all four specimens. None of the patients were hospitalized and all are recovering or have fully recovered from their illness. The patients from both California and Michigan reported direct exposure to swine at agricultural fairs within their state during the week preceding illness onset.

Influenza A viruses that normally circulate in swine are called variant influenza viruses when isolated from humans. There may be important antigenic and genetic differences between seasonal influenza viruses that circulate worldwide in the human population and influenza viruses that normally circulate in swine. Since reporting of novel influenza A viruses became nationally notifiable in 2005, 26 human infections with A(H1N2)v, including these four, have been reported to CDC.

Influenza A viruses in swine do not usually infect humans, but rare human infections have been reported, usually after direct or indirect exposure to pigs. Since 2005, a total of 469 variant virus infections have been identified in the United States. There has been some limited, non-sustained human-to-human transmission of variant influenza viruses, but no ongoing community transmission has been identified. Based on the genetic and epidemiologic data from these identifications, the development of a new A(H1N2)v candidate vaccine virus (CVV) was proposed at the WHO Southern Hemisphere vaccine consultation meeting (September 2018).

These human infection cases were first reported by CDC at https://www.cdc.gov/flu/weekly/weeklyarchives2017-2018/Week31.htm. General information about variant and influenza A viruses in swine are available at http://www.cdc.gov/flu/swineflu/index.htm. Additional information regarding human infections with novel influenza A viruses can be found at http://gis.cdc.gov/grasp/fluview/Novel_Influenza.html.

Animal Disease Events

Summary of Reports: In 2018, the United States submitted nine World Organization for Animal Health (OIE) immediate reports for animal disease events. These included four low pathogenic notifiable avian influenza reports, two rabbit hemorrhagic disease virus reports, one atypical bovine spongiform encephalopathy report, one virulent Newcastle disease virus report, and one report for *Bonamia exitiosa*.

Event summaries can be found, by country and then year of occurrence, on the OIE website: http://www.oie.int/wahis_2/public/wahid.php/Wahidhome/Home/indexcontent/newlang/en

2018 Immediate OIE reports:

Avian Influenza (Infection with Avian Influenza Viruses)
Avian influenza (AI) is caused by influenza type A viruses, which can infect poultry (such as chickens, turkeys, pheasants, quail, domestic ducks, geese, and guinea fowl) and are carried by free-flying waterfowl such as ducks, geese, and shorebirds. AI viruses are classified by a combination of two groups of proteins: hemagglutinin or "H" proteins, of which there are 16 (H1-H16), and neuraminidase or "N" proteins, of which there are 9 (N1-N9). Many different combinations of "H" and "N" proteins are possible. Each combination is considered a different subtype, and each subtype can be further sub-classified as different strains. AI viruses are identified by their pathogenicity (low or high)—the ability of a particular virus strain to produce disease in domestic chickens. Any influenza A virus (including H5 and H7 avian influenza viruses) in its high pathogenic form is reportable in birds, but only H5 and H7 low pathogenic avian influenza viral infections in poultry are notifiable as per Chapter 10.4 on avian influenza of the OIE Terrestrial Animal Health Code (2018): http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_avian_influenza_viruses.htm.

Low Pathogenic Avian Influenza (LPAI), H7N1—Missouri
OIE Immediate Report March 6, 2018 — Final Report May 23, 2018

As part of routine, pre-slaughter H5/H7 AI testing and surveillance, H7N1 LPAI was detected in a healthy commercial meat turkey flock. The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) and the Missouri Department of Agriculture completed a comprehensive epidemiological investigation of this event. All surveillance samples tested negative for avian influenza. There have been no further LPAI detections, and the following activities were accomplished: completed all mandatory surveillance in the officially established control areas with negative results for LPAI;

depopulated the infected premises and disposed of the birds and material; cleaned and disinfected the infected premises (including, but not limited to, outside areas, equipment, trucks, and other fomites).

Low Pathogenic Avian Influenza (LPAI), H7N1—Texas
OIE Immediate Report March 9, 2018 — Final Report April 12, 2018

H7N1 LPAI was detected in a commercial broiler breeder flock as part of routine, pre-slaughter testing and surveillance for H5/H7 AI. The flock exhibited a slight increase in mortality and a decrease in egg production. USDA APHIS and the Texas Animal Health Commission conducted and completed a comprehensive epidemiological investigation of this event. All surveillance samples tested negative for avian influenza. There have been no further LPAI detections, and the following activities were accomplished: completed all mandatory surveillance in the officially established control areas with negative results for LPAI; depopulated the infected premises and disposed of the birds and material; cleaned and disinfected the infected premises (including, but not limited to, outside areas, equipment, trucks, and other fomites).

Low Pathogenic Avian Influenza (LPAI), H7N3—California
OIE Immediate Report September 12, 2018 — Open at the end of 2018

As part of the pre-slaughter H5/H7 AI testing and surveillance program, H7N3 LPAI was detected in a commercial meat-type turkey flock. Additional H7N3 LPAI cases in commercial meat-type turkey flocks were detected through outbreak surveillance activities. USDA APHIS and the California Department of Food and Agriculture conducted an epidemiological investigation of the event and increased surveillance as a result of the detections. State officials quarantined the affected premises and implemented movement controls. Turkeys from all infected premises were depopulated.

Low Pathogenic Avian Influenza (LPAI), H5N2—Minnesota
OIE Immediate Report October 22, 2018 — Open at the end of 2018

Following the 2015 highly pathogenic avian influenza (HPAI) outbreak that occurred in central Minnesota, increased surveillance has been implemented during the spring and fall months. This routine surveillance detected H5N2 LPAI in a commercial meat-type turkey flock. The flock was healthy and showed no clinical signs of AI. Additional H5N2 LPAI cases in commercial meat-type turkeys were detected through the pre-slaughter testing and surveillance program for H5/H7 AI, and through outbreak surveillance activities. The Minnesota Board of Animal Health and USDA APHIS conducted an epidemiological investigation of the events and increased surveillance as a result of the detections. State officials quarantined the affected premises and implemented movement controls. Turkeys from all infected premises were depopulated through controlled marketing.

'Atypical' Bovine Spongiform Encephalopathy (BSE)—Florida
OIE Immediate Report August 28, 2018 — Final Report August 28, 2018

BSE is a transmissible spongiform encephalopathy that causes fatal neurological disease of adult cattle. Classical (C-type) BSE occurs when cattle ingest infectious BSE prions from contaminated animal-source proteins. Atypical (H- and L-type) BSE occurs spontaneously. As part of the United States' targeted surveillance program for BSE, a case of atypical BSE was identified in a 6-year-old beef-type cow. This atypical BSE case was classified as H-type. In over 20 years of surveillance, the five native cases detected in the United States have all been atypical cases. The identified animal did not enter any food supply channels and at no time presented a risk to human health. Specified risk material removal and the ruminant-to-ruminant feed bans continue to be effectively applied.

***Bonamia exitiosa*—Massachusetts**
OIE Immediate Report September 6, 2018 — Final Report September 6, 2018

Bonamia exitiosa is a Haplosporidia protozoan parasite that infects hemocytes of several oyster species and induces physiological disorders and eventually death of the animal. Testing conducted as part of routine pathogen screening for movement of oyster seed detected *B. exitiosa* in 3-month-old hatchery seed. No elevated mortality was observed in the affected stock.

Rabbit Hemorrhagic Disease (RHD)
RHD is a highly contagious and fatal disease of rabbits. It is caused by rabbit hemorrhagic disease virus (RHDV), a Calicivirus. There are three recognized pathogenic groups: RHDV (aka RHDV1), RHDVa (considered a subtype of the classic RHDV), and RHDV2.

Rabbit Hemorrhagic Disease Virus-2 (RHDV-2)—Ohio
OIE Immediate Report September 21, 2018 — Final Report November 27, 2018

RHDV-2 was identified in non-commercial pet rabbits in Ohio. The rabbits were housed in horse stalls and ran free in those stalls. The rabbits had been on the premises for 3 years and had no history of travel. The USDA APHIS and the Ohio Department of Agriculture conducted a comprehensive epidemiological investigation of this event. Surveillance samples were collected from wild cottontail rabbits in the area and all surveillance samples were negative. The premises was cleaned and disinfected. The source of the infection is unknown. This was the first detection of RHDV-2 in the United States.

Rabbit Hemorrhagic Disease Virus-1 (RHDV-1)—Pennsylvania
OIE Immediate Report December 11, 2018—Open at the end of 2018

RHDV-1 was identified in non-commercial pet rabbits that died suddenly. Some of the rabbits had slight bloody discharge around the nares. The rabbits were housed in pens in a barn, and no rabbits were introduced into the colony in over 1 year. There were no known wild rabbit deaths in the area. Note: in Pennsylvania the predominant wild rabbits are eastern cottontails, which are not known to be susceptible to RHDV-1. The Pennsylvania Department of Agriculture and the USDA APHIS are conducting a comprehensive epidemiological investigation of this event.

Virulent Newcastle Disease Virus (vNDV)—California
OIE Immediate Report September 26, 2018—Open at the end of 2018

Newcastle disease (historically exotic Newcastle disease [END] in the United States) is a contagious and often fatal disease caused by infection with vNDV. Clinical signs vary and can include respiratory, neurological, reproductive, and intestinal signs. In humans, the virus causes a temporary mild conjunctivitis and influenza-like symptoms. NDV is also known as avian paramyxovirus-1 (APMV-1). APMV-1 viruses are categorized into five pathotypes according to the OIE: asymptomatic (no apparent disease), lentogenic (low virulence viruses), mesogenic (moderate virulence), and viscerotropic vs neurotropic velogenic (virulent) based upon pathogenicity experiments performed in chickens. While these definitions remain important descriptors, APMV-1 viruses are currently reported in the United States as either low virulent (e.g., lentogenic viruses) or virulent (comprising mesogenic and velogenic viruses).

As part of enhanced surveillance for Newcastle disease in exhibition birds in California, vNDV was detected in poultry at a live bird market, retail feed stores, a commercial chicken pullet (layers) flock, commercial chicken layer flocks, and a backyard non-commercial chicken layer flock. State officials quarantined all affected premises and implemented movement controls. The birds were depopulated and

the premises were cleaned and disinfected. The California Department of Food and Agriculture and USDA APHIS are conducting an epidemiological investigation of these events.

Form C

BWC - Confidence Building Measure

Encouragement of Publication of Results and Promotion of Use of Knowledge

United States of America

April 15, 2019

Department of Health and Human Services (HHS) Open Government Plan http://www.hhs.gov/open/plan	The key principles of Open Government are transparency, collaboration, and participation.
HHS Strategic Plan 2018-2022 https://www.hhs.gov/about/strategic-plan/index.html	The plan describes HHS' work to address complex, multifaceted, and ever-evolving health and human services issues.
The State of Data Sharing at HHS https://www.hhs.gov/sites/default/files/HHS_StateofDataSharing_0915.pdf	This is a comprehensive report of the data sharing environment across the twenty-nine distinct agencies of HHS.
Directory of HHS Data Resources https://aspe.hhs.gov/directory-health-and-human-services-data-resources	The directory is intended for policymakers, administrators, researchers, and the public as a reference document on data and statistical resources within HHS.
HHS Policies and Principles for Assuring Scientific Integrity https://www.hhs.gov/sites/default/files/open/pres-actions/scientifc-integrity-principles-12-19-11.pdf	The document describes policies and principles designed to assure the integrity of scientific and scholarly activities conducted and supported by HHS, and the science it uses to inform management and public policy decisions.
Guidelines for Responsible Data Management in Scientific Research https://ori.hhs.gov/images/ddblock/data.pdf	This course will educate new investigators about conducting responsible data management and includes best practice guidelines, various learning feratures, and a resources section.
2017 Annual Report of the Federal Select Agent Program https://www.selectagents.gov/annualreport2017.html	The report summarizes aggregate program data in areas such as numbers and types of registered entities; security risk assessments performed; number of inspections conducted; top registered select agents or toxins by agency; key obervations related to inspection findings and compliance with select agent regulations; identifications and transfers of select agents or toxins; and thefts, losses, and releases of select agents or toxins.
National Institutes of Health (NIH) Strategic Plan for Data Science https://datascience.nih.gov/sites/default/files/NIH_Strategic_Plan_for_Data_Science_Final_508.pdf	The plan commits to ensuring that all data-science activities and products supported by NIH ahere to the FAIR principles, meaning that data are Findable, Accessible, Interoperable, and Reusable.
NIH Data Sharing Policy and Implementation Guide http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm	This guidance provides the NIH policy statement on data sharing and additional information on the implementation of this policy.
NIH Public Access Policy http://publicaccess.nih.gov/policy.htm	The NIH Public Access Policy ensures that the public has access to the published results of NIH funded research.
Centers for Disease Control and Prevention (CDC) Policy on Releasing and Sharing Data http://www.cdc.gov/maso/Policy/ReleasingData.pdf	Public health and scientific advancement are best served when data are shared with public health agencies and academic researchers in an open, timely, and appropriate way.
2017 Division of Select Agents and Toxins (DSAT) Inspection Report Processing Annual	Inspection reports play a critical role in ensuring the safety and security of work with select agents

Summary https://www.cdc.gov/cpr/dsat/documents/DSAT-Inspection-Report-2017_508.pdf	and toxins.
The Journal *Emerging Infectious Diseases* http://wwwnc.cdc.gov/eid/	Emerging Infectious Diseases is an open access, peer-reviewed journal published by the CDC.
The Morbidity and Mortality Weekly Report (MMWR) http://www.cdc.gov/mmwr/	CDC's primary vehicle for scientific publication of reliable, authoritative, objective, and useful public health information and recommendations; open access.
The Excellence in Science Committee (EISC) at the CDC http://www.cdc.gov/od/science/excellence/	The EISC fosters, supports, and protects 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.
CDC Office of Science Quality (OSQ) http://www.cdc.gov/od/science/quality/	The OSQ is responsible for increasing the impact of CDC research and science by promoting standards and recommended practices for scientific quality, relevance, credibility, transparency, and utility within the agency and throughout the public health community (e.g., authorship, scientific clearance, peer review, and extramural research policies).
Advancing Excellence and Integrity of CDC Science http://www.cdc.gov/od/science/	The Office of the Associate Director for Science's mission is to strengthen the quality, integrity, and relevance of CDC's science and health impact
Office of Scientific Integrity (OSI) http://www.cdc.gov/od/science/integrity/	OSI ensures that CDC science and research activities comply with various federal laws, regulations, and policies; coordinates the agency's 301(d) and 308(d) confidentiality protections; ensures leadership in public health ethics; and provides trainings to promote a well-educated and ethical domestic and international workforce at CDC.
Public Health Image Library (PHIL) http://phil.cdc.gov/	The PHIL offers an organized, electronic gateway to CDC images for reference, teaching, presentation, and public health messages; open access.
U.S. Food and Drug Administration (FDA) Publications Database http://www.accessdata.fda.gov/scripts/publications/	An actively updated and searchable research publications database for all FDA publications.
FDA Office of Science and Engineering Laboratories (OSEL) Annual Report https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115989.htm	The 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.
FDA Center for Biologics Evaluation and Research (CBER) http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/default.htm	This CBER website provides links to the strategic plan for regulatory science and research, general information about research programs, as well as highlights from selected research publications.
PubMed Central (PMC) http://www.ncbi.nlm.nih.gov/pmc/	PMC is the National Library of Medicine's digital archive. Final peer-reviewed manuscripts that arise from NIH funds are accessible to the public on PMC no later than twelve months after publication; open access.

Form E

BWC - Confidence Building Measure

Declaration of legislation, regulations and other measures

United States of America

April 15, 2019

Form E

Relating to	Legislation	Regulations	Other measures[1]	Amended since last year
(a) 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[1]
(b) Exports of micro-organisms[2] and toxins	Yes	Yes	Yes	Yes [2]
(c) Imports of micro-organisms[2] and toxins	Yes	Yes	Yes	No
(d) Biosafety[3] and biosecurity[4]	Yes	Yes	Yes	Yes [3]

EXPLANATORY NOTES

[1] (a) Development, production stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I

- **National Biodefense Strategy:** A major objective (Objective 2.3) of the National Biodefense Strategy is to prevent attempts to pursue, acquire, or use biological weapons, related materials, and their means of delivery. More broadly, the Strategy enables risk awareness to inform decision-making across the biodefense enterprise; ensures biodefense enterprise capabilities to prevent bio-incidents; strives for biodefense enterprise preparedness to reduce the impacts of bio-incidents; enables rapid response to limit the impacts of bio incidents; and facilitates recovery to restore the community, the economy, and the environment after a bio-incident. Read more at: https://www.phe.gov/Preparedness/biodefense-strategy/Pages/default.aspx

- **National Security Presidential Memorandum 14 "Support for National Biodefense" (NSPM-14), 18 September 2018:** The foundation for the United States Government's role in the biodefense enterprise is the National Biodefense Strategy and its implementation plan (Strategy), which serve as the authoritative sources for the goals, objectives, and definitions for United States Government activities in support of the broader biodefense enterprise. This National Security Presidential Memorandum creates a new mechanism for coordinating the full range of biodefense activities and budget resources across the U.S. Government. Enhancing coordination will enable government to better anticipate, prevent, prepare for, respond to, and recover from biological disasters. Read more at: https://www.whitehouse.gov/presidential-actions/presidential-memorandum-support-national-biodefense/

[1] Including guidelines.
[2] Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.
[3] In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.
[4] In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

[2] (b) Exports of micro-organisms and toxins:

- **Implementation of the February 2017 Australia Group (AG) Intersessional Decisions and the June 2017 AG Plenary Understandings; Including the Addition of India to the Australia Group - Effective April 2, 2018.** This final rule amends the Export Administration Regulations (EAR) to implement the recommendations presented at the February 2017 Australia Group (AG) Intersessional Implementation Meeting and the June 2017 AG Plenary Implementation Meeting that were adopted by the AG Export Control Classification Number (ECCN) 2B352, "Equipment capable of use in handling biological materials," is amended to clarify how the capacity of certain fermenters should be measured to determine whether they are controlled. Certain nucleic acid assemblers and synthesizers are also added to this ECCN to reflect the updated to the AG common control list. The license requirements for these items have not changed.

  This rule amends ECCN 1C353, "Genetic elements and genetically modified organisms," to reflect updates to the AG controls and clarify that genetically modified organisms include organisms in which the nucleic acid sequences have been created or altered by deliberate molecular manipulation and that inactivated organisms containing recoverable nucleic acids are considered to be genetic elements. The license requirements for these items have not changed.

  Finally, this rule updates the advance notification requirements for certain exports of saxitoxin and amends the EAR to reflect the addition of India as a participating country in the AG, as of January 19, 2018.

  https://www.bis.doc.gov/index.php/documents/regulations-docs/federal-register-notices/federal-register-2018/2203-83-fr-13849/file

[3] (d) Biosafety and biosecurity:

1. Amendments to Select Agent and Toxin Regulations:

- **Regulatory Technical Revision:** On September 24, 2018, the United States Department of Agriculture (USDA) published technical amendments to its select agent regulations to (1) remove bovine spongiform encephalopathy agent, which had already been removed from the list of select agents or toxins, from the list of those select agents or toxins whose seizure must be reported within 24 hours; (2) update the name of another select agent to reflect its most current scientific classification (*Phoma glycinicola* [formerly *Pyrenochaeta glycines]* is now *Coniothyrium glycines)* based on recent molecular and phylogenetic studies; (3) correct a typographical error; and (4) update the name of a guidance document referenced in the regulations. The full technical amendment is available at https://www.federalregister.gov/d/2018-20694.

2. Policy Statements and regulatory interpretations concerning Select Agent and Toxin Regulations:

- **Amendment to policies associated with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agricultural Bioterrorism Protection Act of 2002 (the Federal Select Agent Program):** During 2018, the Departments of Health and Human Services (HHS) and Agriculture (USDA) generated the following policies:

- Policy statement regarding live bird lethality testing requirements for pathogenicity testing of reverse genetically derived viruses for avian influenza virus
- Policy statement on biosafety level requirements for virulent Newcastle Disease virus
- Policy Statement on chemical inactivation of whole tissue or homogenized tissue
- Policy statement regarding entity annual internal inspections
- Policy statement for registration and inspection of Effluent Decontamination Systems
- Policy statement regarding a select agent contained in formalin-fixed, paraffin-embedded tissue
- Policy statement on inactivation certificate
- Policy statement regarding validated inactivation procedure

- **Federal Select Agent Program Joint *Strategic Plan:*** On 27 November 2018, the Federal Select Agent Program (FSAP) published a joint *FSAP Strategic Plan*, which will guide FSAP program efforts from fiscal year (FY) 2018 through FY2021. The content reflects FSAP's intent to prioritize activities, placing emphasis on the strategies that effectively and efficiently support achievement of FSAP goals and objectives. The document outlines FSAP's mission, vision, and four key goals, which encompass the following priority areas: 1) Ensure the recruitment, development, and retention of a knowledgeable and professional FSAP workforce; 2) Harmonize FSAP organizational processes and inspections; 3) Leverage data-driven, risk-based approaches to guide FSAP operations; and 4) Engage, increase transparency, and highlight program benefits with FSAP's diverse stakeholders. Read more at: https://www.selectagents.gov/resources/FSAP-Strategic-Plan-2017_508.pdf

- **Clarifying Regulatory Requirements related to Agent Inactivation**: Throughout 2018, USDA and U.S. Department of Health and Human Services, through the Federal Select Agent Program (FSAP), issued policy statements to clarify regulatory requirements related to the inactivation of select agents and toxins, including: the process for validating the inactivation of whole or homogenized tissue, available at https://www.selectagents.gov/policystatement_tissueinactivation.html; guidance on inactivation certification, available at https://www.selectagents.gov/policystatement_certificate.html; updated guidance on inactivation procedure validation, available at https://www.selectagents.gov/policystatement_inactivation.html; and clarification of acceptable methods of inactivating select agents in formalin-fixed paraffin-embedded tissues, available at https://www.selectagents.gov/policystatement_formalintissue.html. On September 9, 2018, FSAP notified the regulated community of updates to the Guidance on the Inactivation or Removal of Select Agents and Toxins for Future Use; the update is available at https://www.selectagents.gov/irg-intro.html.

- **Regulatory Oversight of Effluent Decontamination Systems (EDS)**: After identifying concerns related to aging effluent decontamination systems (EDS) in older facilities, on August 6, 2018, FSAP issued a policy statement on EDS registration and inspection. The statement is available at https://www.selectagents.gov/policystatement_effluent.html. EDS sterilize biohazardous liquid waste generated from a biocontainment laboratory or other facility prior to discharge. Though the rooms that contain the EDS do not have to be registered with FSAP, the EDS are an extension of registered space, subject to FSAP inspection and incorporation in the entity's biosafety and biocontainment plans to prevent the theft, loss, or release of select agents or toxins.

3. **Federal Select Agent Program Security and Biosafety Guidance Documents for the Regulated Community:**

- **Providing Biosafety and Biocontainment Guidance Documents to the Regulated Community:** On August 9, 2018, FSAP finalized a new policy statement and guidance document to assist entities in meeting the annual internal inspection requirement of the select agent regulations. The policy statement is available at https://www.selectagents.gov/policystatement_annualinspection.html, and the guidance document is available at https://www.selectagents.gov/aig-intro.html. Throughout the year, FSAP also reviewed and updated existing guidance, as needed. In February, USDA updated guidance for safely working with avian influenza viruses, including categorization, biocontainment, and the transfer of highly pathogenic and low pathogenic avian influenza viruses. The guidance is available at https://www.selectagents.gov/guidance-avian.html. In March, FSAP updated its Incident Response Plan Guidance and the associated template to assist entities in developing a site-specific incident response plan to ensure the security and safeguarding of select agents and toxins from natural and manmade disasters. The plan and template are available at https://www.selectagents.gov/irp-intro.html.

- **Federal Select Agent Program Annual Internal Inspection Guidance (August 2018):** This document is intended to provide guidance and assist entities regarding the regulatory requirement that the Responsible Official (RO) ensure that an annual inspection is conducted for each registered space where select agents or toxins are stored or used. Establishing an internal annual inspection program provides a means for the RO to monitor compliance with the select agent regulations and identify deviations from acceptable laboratory safety, containment, or security practices. This action can be separate from an overall periodic reconciliation of the entire select agent and toxin inventory. The document is available at: https://www.selectagents.gov/resources/Annual_Inspection_Guidance.pdf

4. Other Measures to Advance Biosafety and Biosecurity in the United States:

- **FBI Enforcement of BWC Article I:** To implement Article I of the BWC, the United States established the Biological Weapons Antiterrorism (BWAT) Act, which establishes BWC violations as a federal crime. The BWAT Act was codified in the U.S. federal criminal code (Title 18 of the United States Code, Section 175(a) and (b); also referred to as 18 USC 175). As a result, individual(s) in the United States can be charged with a federal crime if they use a biological agent, toxin, or delivery system as a weapon, or are in possession of any biological agent without a justifiable research or peaceful purpose. It is also a crime to knowingly possess a Select Agent or toxin, regardless of intent, if the individual does not have legitimate access (registered with the U.S. Federal Select Agent Program) and purpose. In 2018, the FBI responded to several incidents that involved biological material and led investigations that resulted in the prosecutions for the violation of 18 USC 175.

- **FBI Security Risk Assessments (SRAs) –3,751 SRAs Completed in 2018:** The FBI conducts Security Risk Assessments (SRAs), a requirement of the U.S. Federal Select Agent Program (FSAP), on all entities and personnel in the United States requesting possession, use, or transfer of biological select agents and toxins (BSAT). Using various biographical and biometric databases, the FBI determines if a candidate meets the criteria of a "restricted person" based upon a list of prohibitors found under 18 U.S. Code 175b (derived from the USA PATRIOT Act and the Public Health Security and Bioterrorism Preparedness and Response Act). In 2018, 3,751 SRAs were processed by the FBI (Criminal Justice Information Services Division, Bioterrorism Risk Assessment Group). Of the 3,751 individual SRAs processed, 23 BSAT access candidates

were determined to meet the criteria of a "restricted person." The FBI's adjudication is provided to the Department of Health and Human Services or the Department of Agriculture, who decides whether to grant or deny the requesting entity or individual access to BSAT.

- **FBI Biosecurity Outreach:** During 2018, the FBI conducted fifteen biosecurity outreach events to research institutions across the United States. These outreach events provided an environment where law enforcement and the academic science communities (research students, professors/researchers, biosafety officers, etc.) could engage in mutually beneficial dialogue. During these events, the FBI aimed to: 1) improve situational awareness of biosecurity threats, and 2) foster a mechanism for academia to report suspicious activities. The FBI works to enhance the science community's awareness of threats and vulnerabilities, both internal and external, as scientists could be exploited because of their expertise and access to biological material/technologies. The FBI also educates the science community of the FBI's roles and responsibilities in the biosecurity arena and provides resources that can be used to mitigate suspicious activities.

  In addition, the FBI conducted biosecurity engagements with both the international synthetic biology sector and the amateur biology community in the United States. Engagements include attendance at conferences and regional meetings, FBI-sponsored national and international workshops, assistance in the development of safety and security framework, and dissemination of education materials. For example, during 2018, the FBI participated in security discussions with domestic and international synthetic biology stakeholders, as well as sponsored and conducted biosecurity outreach at the 2018 International Genetically Engineered Machine Competition, the largest, annual synthetic biology meeting of undergraduate students worldwide. The FBI also provided training on Food Defense and on multi-sectoral approaches to determine if disease outbreaks in human, plant, and animal populations could be other than natural occurrences. These trainings include courses within the United States, elements of which were included in international governmental engagement efforts.

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, 2019

Form F

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**
   26 March 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, 2019

Form G

Declaration of vaccine production facilities

The U.S. Food and Drug Administration publishes a current list of human vaccines licensed in the United States, including associated production facilities. This list is available at: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm.

Data provided on CBM Form G are excerpted from the publicly available website listed above (as accessed on February 3, 2018). Trade names are included when provided by the manufacturer. Specific and current information about a vaccine, and contact information for the manufacturer, are available by following the hyperlinks provided on the above website.

Form G

Declaration of vaccine production facilities

1. Name of facility
Barr Laboratories, Inc.

2. Location (Mailing Address)
1235 Mays Mill Road,
Forrest, Virgina 24551

3. General description of the types of diseases covered:
Acute respiratory disease caused by Adenovirus Type 4 and Type 7

Vaccines:
• Adenovirus Type 4 and Type 7 Vaccine, Live, Oral

Form G

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*

   Vaccines:
   • Anthrax Vaccine Adsorbed - [BioThrax]

   Smallpox disease

   Vaccines:
   • Smallpox (Vaccinia) Vaccine, Live - [ACAM2000]

Form G

Declaration of vaccine production facilities

1. **Name of facility**
   MassBiologics

2. **Location (Mailing Address)**
   University of Massachusetts Medical School
   Boston, Massachusetts 02130

3. **General description of the types of diseases covered:**
   Diphtheria and tetanus caused by *Corynebacterium diphtheriae* and *Clostridium tetani*.

   Vaccines:
   - Tetanus and Diphtheria Toxoids Adsorbed

Form G

Declaration of vaccine production facilities

1. **Name of facility**
   MCM Vaccine Company/Sanofi Pasteur, Inc.

2. **Location (Mailing Address)**
   Discovery Drive
   Swiftwater, PA 18370

3. **General description of the types of diseases covered:**
   Diphtheria, tetanus, pertussis, poliomyletis, hepatitis B and invasive disease due to *Haemophilus influenzae* type b.

   Vaccines:
   - VAXELIS, Diptheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (recombinant) Vaccine

Form G

Declaration of vaccine production facilities

1. **Name of facility**
   Merck Sharp & Dohme Corp.

2. **Location (Mailing Address)**
   PO Box 1000, UG2D-68
   North Wales, Pennsylvania 19454

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; cervical, vulvar and vaginal cancer and certain other diseases caused by Human Papillomavirus (HPV); Measles; Mumps; diseases 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 Vaccine (Meningococcal Protein Conjugate) - [PedvaxHIB]
   - Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) & 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]
   - Human Papillomavirus 9-valent Vaccine, Recombinant - [GARDASIL 9]
   - Measles, Mumps, and Rubella Virus Vaccine, Live - [M-M-R II]
   - Measles, Mumps, Rubella and Varicella Virus Vaccine Live - [ProQuad]
   - Pneumococcal Vaccine, Polyvalent - [Pneumovax 23]
   - Rotavirus Vaccine, Live, Oral, Pentavalent - [RotaTeq]
   - Varicella Virus Vaccine Live - [Varivax]
   - Zoster Vaccine, Live, (Oka/Merck) - [Zostavax]

Form G

Declaration of vaccine production facilities

1. **Name of facility**
   Organon Teknika Corporation, LLC

2. **Location (Mailing Address)**
   100 Rodolphe Street
   Building 1300
   Durham, North Carolina 27712

3. **General description of the types of diseases covered:**

   For the prevention of tuberculosis

   Vaccines:
   • BCG Live [BCG Vaccine]

Form G

Declaration of vaccine production facilities

1. **Name of facility**
   Protein Sciences Corporation

2. **Location (Mailing Address)**
   1000 Research Parkway
   Meriden, Connecticut 06450-7159

3. **General description of the types of diseases covered:**

   Disease caused by influenza virus subtypes A and B

   Vaccines:
   • Influenza vaccine for subtypes A and B, (Flublok)

Form G

Declaration of vaccine production facilities

1. **Name of facility**
   Sanofi Pasteur, Inc

2. **Location (Mailing Address)**
   Discovery Drive
   Swiftwater, Pennsylvania 18370

3. **General description of the types of diseases covered:**

   Diphtheria caused by *Corynebacterium diphtheria*; tetanus caused by *Clostridium tetani*; pertussis (whooping cough) caused by *Bordetella pertussis*; influenza disease caused by pandemic (H1N1) 2009 virus; influenza disease caused by H5N1 subtype; influenza disease caused by influenza virus subtypes A and B; invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135; meningitis and meningococcemia caused by *N. meningitidis*; and Yellow fever acute viral illness caused by a mosquito-borne flavivirus.

   Vaccines:
   • Diphtheria & Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed - [Tripedia; Daptacel]
   • Diphtheria and Tetanus Toxoids Adsorbed USP (For Pediatric Use) (DT)
   • Influenza Virus Vaccine (Fluzone, Fluzone High-Dose, Fluzone Intradermal and Fluzone Quadrivalent)
   • Influenza Virus Vaccine, H5N1
   • Meningococcal Polysaccharide (Serogroups A, C, Y and W-135) Diphtheria Toxoid Conjugate Vaccine - [Menactra]
   • Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined - [Menomune®-A/C/Y/W-135]
   • Tetanus and Diphtheria Toxoids Adsorbed for Adult Use - [DECAVAC]
   • Tetanus Toxoid for Booster Use Only
   • Yellow Fever Vaccine - [YF-VAX®]

Form G

Declaration of vaccine production facilities

1. **Name of facility**
   Wyeth Pharmaceuticals, Inc

2. **Location (Mailing Address)**
   Pfizer, Inc.,
   401 N. Middletown Road
   Pearl River, New York 10965

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; and invasive disease caused by *Neisseria meningitides* serogroup B.

   Vaccines:
   • Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein) - [Prevnar 13]
   • Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM197 Protein)

Appendix A

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
Bacillus cereus Biovar *anthracis*
Botulinum neurotoxins
Botulinum neurotoxin-producing species of *Clostridium*
Conotoxins (alpha)
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus
Ebola virus
Francisella tularensis
Lassa fever virus
Lujo 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 (Reconstructed1918 Influenza virus)
Ricin
Rickettsia prowazekii
SARS-associated coronavirus (SARS-CoV)
Saxitoxin
South American Haemorrhagic Fever viruses: Chapare, Guanarito, Junin, Machupo, Sabia
Staphylococcal enterotoxins (A, B, C, D, E subtypes)
T-2 toxin
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses: Far Eastern Tick-borne encephalitis, Siberian subtype, Kyasanur Forest disease, Omsk Hemorrhagic Fever
Variola major virus (Smallpox virus)
Variola minor virus (Alastrim)
Yersinia pestis

OVERLAP Select Agents and Toxins

Bacillus anthracis
Bacillus anthracis Pasteur strain
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
Avian influenza virus (highly pathogenic)
Classical swine fever virus
Foot-and-mouth disease virus
Goat pox virus
Lumpy skin disease virus
Mycoplasma capricolum subspecies *capripneumoniae* (contagious caprine pleuropneumonia)
Mycoplasma mycoides subspecies mycoides small colony (*Mmm* SC) (contagious bovine pleuropneumonia)
Newcastle disease virus (virulent virus serotype1)
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus

USDA PLANT PROTECTION AND QUARANTINE (PPQ) Select Agents and Toxins
Coniothyrium glycines (formerly Phoma glycinicola and Pyrenochaeta glycines)
Peronosclerospora philippinensis (Peronosclerospora sacchari)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae
Synchytrium endobioticum
Xanthomonas oryzae

Appendix A

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 is available at: https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens

Category A pathogens are those organisms/biological agents that pose the highest risk to national security and public health because they

- Can be easily disseminated or transmitted from person to person
- Result in high mortality rates and have the potential for major public health impact
- Might cause public panic and social disruption
- Require special action for public health preparedness

Category A Priority Pathogens

Bacillus anthracis (anthrax)
Clostridium botulinum toxin (botulism)
Yersinia pestis (plague)
Variola major (smallpox) and other related pox viruses
Francisella tularensis (tularemia)
Viral hemorrhagic fevers
Arenaviruses (Junin virus, Machupo virus, Guanarito virus, Chapare virus, Lassa virus, and Lujo virus)
Bunyaviruses (Hantaviruses, Rift Valley Fever virus, Crimean Congo Hemorrhagic Fever virus)
Flaviruses (Dengue virus)
Filoviruses (Ebola, Marburg viruses)

Category B pathogens are the second highest priority organisms/biological agents. They

- Are moderately easy to disseminate
- Result in moderate morbidity rates and low mortality rates
- Require specific enhancements for diagnostic capacity and enhanced disease surveillance

Category B Priority Pathogens

Burkholderia pseudomallei (melioidosis)
Coxiella burnetii (Q fever)
Brucella species (brucellosis)
Burkholderia mallei (glanders)
Chlamydia psittaci (Psittacosis)
Ricin toxin (*Ricinus communis*)
Epsilon toxin (*Clostridium perfringens*)
Staphylococcus enterotoxin B (SEB)
Typhus fever (*Rickettsia prowazekii*)
Food- and Waterborne Pathogens

- Bacteria: Diarrheagenic *E.coli*, Pathogenic Vibrios, *Shigella* species, *Salmonella*, *Listeria monocytogenes*, *Campylobacter jejuni*, *Yersinia enterocolitica*
- Viruses: Caliciviruses, Hepatitis A virus
- Protozoa: *Cryptosporidium parvum*, *Cyclospora cayatanensis*, *Giardia lamblia*, *Entamoeba histolytica*, *Toxoplasma gondii*, *Naegleria fowleri*, *Balamuthia mandrillaris*
- Fungi: Microsporidia

Mosquito-born viruses: West Nile Virus, LaCrosse virus, California encephalitis virus, Venezuelan equine encephalitis virus, Eastern equine encephalitis virus, Western equine encephalitis virus, Japanese Encephalitis Virus, St. Louis encephalitis virus, Yellow fever virus, chikungunya virus, Zika virus

Category C pathogens are the third highest priority and include emerging pathogens that could be engineered for mass dissemination in the future because of

- Availability
- Ease of production and dissemination
- Potential for high morbidity and mortality rates and major health impact

Category C Priority Pathogens

Emerging infectious disease threats such as Nipah virus, Hendra virus, and additional hantaviruses
Tickborne hemorrhagic fever viruses such as Bunya viruses (Severe Fever with Thrombocytopenia Syndrome virus, Heartland virus) and Flaviviruses (Omsk Hemorrhagic Fever virus, Alkhurma virus, Kyasanur Forest virus)
Tickborne encephalitis viruses (Tickborn encephalitis virus, European subtype, Far Eastern subtype, Siberian subtype, Powassan/Deer Tick virus)
Tuberculosis, including drug-resistant TB
Influenza virus
Other Rickettsias
Rabies virus
Prions
Coccidioides spp.
Severe acute respiratory syndrome associated coronavirus (SARS-CoV), MERS-CoV, and other highly pathogenic human corona viruses
Antimicrobial resistance, excluding research on sexually transmitted organisms, unless the the resistance is newly emerging[1]

[1] 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, *Treponema pallidum*, *Trichomonas vaginalis*

- 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

Immunology studies that advance our understanding of host defenses applicable to the biodefense effort, for example: Adjuvants, Innate Immunity, Adaptive Immunity, Mucosal Immunity

Additional Emerging Infectious Diseases/Pathogens: Acanthamebiasis, Anaplasmosis, Australian bat lyssavirus, *Babesia*, atypical, *Bartonella henselae*, BK virus, *Bordetella pertussis*, *Borrelia mayonii*, *Borrelia miyamotoi*, Ehrlichiosis, Enterovirus 68, Enterovirus 71, Hepatitis C, Hepatitis E, Human herpesvirus 6, Human herpesvirus 8, JC virus, Leptospirosis, Mucormycosis, Poliovirus, Rubeola (measles), *Streptococcus* Group A

Appendix B

Compiled list of microorganisms and toxins used for biodefense research

MICROORGANISM	CATEGORY
African horse sickness virus	USDA Select Agent
African swine fever virus	USDA Select Agent
Avian influenza virus (highly pathogenic)	USDA Select Agent
Bacillus anthracis	Overlap Select Agent + NIAID Category A
Bacillus anthracis (non-viable)	Simulant
Bacillus anthracis Pasteur strain	Overlap Select Agent
Bacillus anthracis Sterne	Simulant
Bacillus cereus Biovar anthracis	HHS Select Agent
Bacillus thuringensis (non-viable)	Simulant
Brucella abortus	Overlap Select Agent
Brucella melitensis	Overlap Select Agent
Brucella suis	Overlap Select Agent
Burkholderia mallei	Overlap Select Agent
Burkholderia mallei (killed)	Simulant
Burkholderia pseudomallei	Overlap Select Agent
*Burkholderia pseudomallei (*non-viable protein*)*	Simulant
Chapare virus	HHS Select Agent
Classical swine fever virus	USDA Select Agent
Clostridium species producing botulinum neurotoxin	HHS Select Agent + NIAID Category A
Coniothyrium glycines	PPQ Select Agent
Coxiella burnetti	HHS Select Agent
Coxiella burnetti (killed)	Simulant
Crimean-Congo hemorrhagic fever virus	HHS Select Agent
Dengue virus	NIAID Category A
Dengue virus (inactivated)	Simulant
Eastern equine encephalitis virus	HHS Select Agent
Eastern equine encephalitis virus (non-viable protein)	Simulant
Ebola virus	HHS Select Agent + NIAID Category A
Ebola virus (inactivated)	Simulant
Foot-and-mouth disease virus	USDA Select Agent
Francisella tularensis	HHS Select Agent + NIAID Category A
Francisella tularensis (killed)	Simulant
Goatpox	USDA Select Agent
Guanarito virus	HHS Select Agent + NIAID Category A
Hantaviruses	NIAID Category A
Hendra virus	Overlap Select Agent
Influenza A virus, reconstructed replication-competent pandemic 1918 strains	HHS Select Agent
Junin virus	HHS Select Agent + NIAID Category A
Kyasanur Forest disease virus	HHS Select Agent
Lassa virus	HHS Select Agent + NIAID Category A

Lujo virus	HHS Select Agent
Lumpy skin disease virus	USDA Select Agent
Lymphocytic choriomeningitis virus	NIAID Category A
Machupo virus	HHS Select Agent + NIAID Category A
Marburg virus	HHS Select Agent + NIAID Category A
Marburg virus (non-viable protein)	Simulant
Monkeypox virus	HHS Select Agent
Mycoplasma mycoides	USDA Select Agent
Newcastle disease virus	USDA Select Agent
Nipah virus	Overlap Select Agent
Omsk hemorrhagic fever virus	HHS Select Agent
Rathayibacter toxicus	PPQ Select Agent
Rickettsia prowazekii	HHS Select Agent
Rift Valley fever virus	Overlap Select Agent + NIAID Category A
Sabia virus	HHS Select Agent
Severe acute respiratory syndrome-related coronavirus	HHS Select Agent
Tick-borne encephalitis complex flavivirus, Far Eastern subtype	HHS Select Agent
Tick-borne encephalitis complex flavivirus, Siberian subtype	HHS Select Agent
Variola major virus	HHS Select Agent + NIAID Category A
Variola minor virus	HHS Select Agent
Venezuelan equine encephalitis virus	Overlap Select Agent
Venezuelan equine encephalitis virus (non-viable protein)	Simulant
Yersinia pestis	HHS Select Agent + NIAID Category A
Yersinia pestis (killed)	Simulant
TOXINS	**CATEGORY**
Abrin	HHS Select Toxin
Alpha conotoxins	HHS Select Toxin
Botulinum neurotoxins	HHS Select Toxin
Diacetoxyscirpenol	HHS Select Toxin
Ricin	HHS Select Toxin
Saxitoxin	HHS Select Toxin
Staphylococcal enterotoxins A, B, C, D, E subtypes	HHS Select Toxin
T-2 toxin	HHS Select Toxin
Tetrodotoxin	HHS Select Toxin