United States of America

Confidence Building Measure Return covering 2020

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, 2021

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, 2021

State Party to the Convention: United States of America

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

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

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

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Confidence Building Measure A, Part 2

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List of the Biological Select Agents and Toxins, and NIAID Category A, B and C Priority Pathogens page 167

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Form A, Part 1

BWC - Confidence Building Measure

Exchange of data on research centres and laboratories

United States of America

April 15, 2021

Exchange of data on research centres and laboratories: Overview

The United States has a layered approach to laboratory biorisk management for maximum containment laboratories. To promote transparency about biorisk management, as recommended by the 2020 G7 Experts' Meeting on Strengthening Laboratory Biorisk Management, the United States is providing the following information. All research centers are required to comply with relevant laws and regulations, which depend on the nature of the laboratory's research activities and hazardous agents under study. Laws pertaining to biorisk management can be found here: https://www.phe.gov/s3/law/pages/laws.aspx.

Federal, State, and municipal guidelines and regulations shape biorisk management systems at individual research institutions to provide a layered, redundant approach to minimize potential risks from work with hazardous biological materials. These policies, regulations, and guidelines are designed to protect laboratory personnel, public health, agriculture, and the environment from accidental or deliberate exposure to hazardous biological agents and toxins. This framework includes regulations and programs designed to respond to the threat of bioterrorism and other crimes involving biological agents and toxins. The regulations and guidelines cover a wide scope of topics from handling of pathogens to transport of biological materials. Examples of key Federal regulations include:

- Applicable Occupational Safety and Health Administration regulations (which include, among others, the *General Duty Clause, Personal Protective Equipment Standard,* and *Bloodborne Pathogens Standard*) to ensure occupational safety and health of workers in the workplace (https://www.osha.gov/healthcare/standards);
- *Select Agent Regulations* to ensure appropriate safety and security measures for handling of select biological agents and toxins (https://selectagents.gov/);
- Permitting regulations for biological agents that are hazardous to agriculture and the environment (https://www.aphis.usda.gov/aphis/ourfocus/importexport), and regulations for infectious biological agents and toxins known or suspected to cause disease in humans (https://www.cdc.gov/cpr/ipp/).

While Federal regulations provide the foundation for biorisk management, implementation is by individual institutions, beginning with the Principal Investigators who are responsible for the safety and security of activities in their laboratories. Institutional Biosafety Committees, Biosafety Officers, and Select Agents Responsible Officials, among others, play a key role in institutional management and ensuring compliance with Federal regulations. Several guidelines and policies cover biosafety and biosecurity research concerns that may arise in maximum containment facilities, which include the examples below and others listed on this website: https://www.phe.gov/s3/law/Pages/Guidance.aspx.

- Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition, a guidance document to protect workers from exposure to infectious biological agents and toxins;
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, applicable to any entity funded by NIH for recombinant or synthetic nucleic research;
- U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern; and additional guidelines, policies, and recommendations related to gain-of-function research, pathogens of pandemic potential, and screening of synthesized DNA, among others.

More information on regulations and guidelines can be found in the Federal Experts Security Advisory Panel report (https://www.phe.gov/s3/Documents/FESAP-guiding-principles.pdf), which also includes transportation, export, and disposal of hazardous and/or infectious materials; response to biological incidents; and security risk assessments for individuals working with select agents and toxins.

Exchange of data on research centres and laboratories

1. Name(s) of facility.
National Biodefense Analysis and Countermeasures Center (NBACC)

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 Health and Human Services (HHS)
U.S. Department of Defense (DOD) - Partly

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.

Exchange of data on research centres and laboratories

1. Name(s) of facility.
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

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 (HHS)
U.S. Department of Agriculture (USDA)
U.S. Department of Energy (DOE)
U.S. Food and Drug Administration (FDA)
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)

2. Responsible public or private organization or company.
Centers for Disease Control and Prevention (CDC), U.S. 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[3] 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: https://www.cdc.gov/ddid/.

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

Exchange of data on research centres and laboratories

1. Name(s) of facility
Integrated Research Facility at Fort Detrick (IRF – Frederick)

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

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
U.S. 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 biodefense research with pathogens and emerging infectious diseases to develop medical 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/research/frederick-integrated-research-facility.

Exchange of data on research centres and laboratories

1. Name(s) of facility
Integrated Research Facility at Rocky Mountain Laboratories (IRF-RML)

2. Responsible public or private organization or company
National Institutes of Health (NIH), U.S. 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
U.S. 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
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) - Partly
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/.

Form A, Part 1 (i)

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
U.S. Department of Health and Human Services (HHS)
U.S. Department of Defense (DOD) - Partly
U.S. 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/research/high-containment/.

Exchange of data on research centres and laboratories

1. Name(s) of facility
Georgia State University - High Containment Core (HCC)

2. Responsible public or private organization or company
Georgia State University - High Containment Core (HCC)

3. Location and postal address
P.O. Box 4010, Atlanta, Georgia 30302-4118

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence
National Institutes of Health
U.S. Department of Defense - Partly
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
Georgia Research Alliance
Elizabeth R. Griffin Research Foundation

This facility resumed operation October 2019; agents are currently being stored in the facility, but active experimentation will not begin until July 2021 as activity in the BSL-4 for calendar year 2020 was delayed due to the Coronavirus pandemic. The funds listed above will be utilized at that time.

5. Number of maximum containment units within the research centre and/or laboratory, with an indication of their respective size (m^2)
BSL-4 60 m^2

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate
In 2017, the high containment facilities at Georgia State University were organized into the High Containment Core (HCC), for more information visit: https://research.gsu.edu/high-containment-labs/. The National B Virus Resource Laboratory now operates as part of the core. The core comprises two BSL-3 laboratories with animal facilities and one BSL-4 Class III Cabinet Line Laboratory. Research in the BSL-4 is focused on existing and emerging infectious diseases caused by Risk Group 4 viruses. The laboratory has not been used for experimental work involving Risk Group 4 viruses since decommission in 2016. The facility was recommissioned in 2019 and was approved for storage of Tier 1 Select Agents and Toxins by the Centers for Disease Control and Prevention, Federal Select Agent Program. Experimental work with Risk Group 4 agents is planned to begin in 2021 pending successful completion of CDC registration renewal. Below is a general description of those activities.

Project 1 (New):
The proposed studies will expand understanding of the mechanisms that regulate filovirus growth and pathogenesis. The goal is to characterize the impact of host proteins and genes on filovirus growth, and to mechanistically understand how different host factors affect virus replication, it will be necessary to measure levels of viral genomic RNA, viral mRNA, and viral protein produced in cells.

Project 2 (Continued):
The National B Virus Resource Laboratory provides a global resource to assist in the identification of zoonotic disease transmissions and to develop enhanced strategies to detect viral infections in macaques. In 2016, the last year of reportable operations at this facility, projects at this laboratory were focused on the molecular biology of human and non-human primate alphaherpesviruses and the diseases they cause. Studies focused on the mechanisms by which virus kills the host and how that process can be circumvented with:

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

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 Allergy and Infectious Disease (NIAID), National Institute of Health (NIH)
Boston University
U.S. Department of Health and Human Services (HHS)
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	2,566 m^2
BSL-3 Laboratory	(5 suites + 8 animal rooms) 998 m^2
BSL-4 Laboratory	(All ABSL-4 spaces are integrated with 6 suites + 7 animal rooms) 1,202 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 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 ofscientists 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, 2021

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, 2021

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.federalregister.gov/documents/2018/10/18/2018-22742/posting-of-the-national-security-presidential-memorandum-14-support-for-national-biodefense). 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: Department of Defense

Description

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 toxins.

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.
$491,055,000 U.S. Department of Defense (DOD)

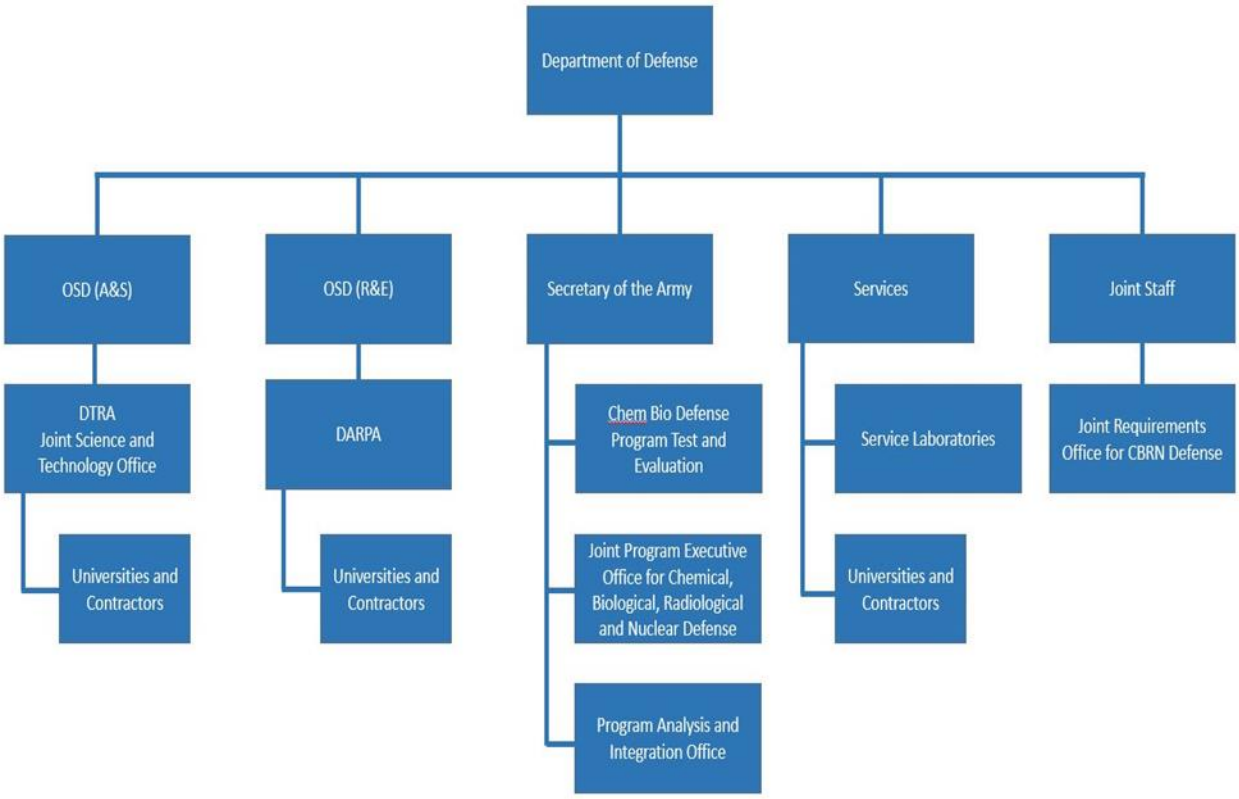
3. Are aspects of these programmes conducted under contract with industry, academic institutions, or in other non-defence facilities?
Yes.

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?
64.4%

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.

- Lothar Salomon Life Sciences Test Facility (LSTF) – Page 47
- Naval Medical Research Center (NMRC) – Page 49
- Naval Research Laboratory (NRL) – Page 52
- Naval Surface Warfare Center (NSWC) - Dahlgren Division Chemical, Biological, Radiological (CBR) Defense Laboratory – Page 54
- U.S. Army Combat Capabilities Development Command Chemical Biological Center (CCDC CBC), formerly named U.S. Army Edgewood Chemical and Biological Center – Page 56
- U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) – Page 59
- U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) – Page 61
- Air Force Research Laboratory (AFRL), 711 HPW – Page 68

The U.S. Army Combat Capabilities Development Command Soldier Center (CCDC SC), formerly named U.S. Army Natick Soldier Research Development and Engineering, did not receive funding for biodefense work in 2020 and is not included in the U.S. Confidence Building Measures covering 2020.

National biological defense research and development programmes: Environmental Protection Agency

Description

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

The U.S. Environmental Protection Agency (EPA)'s mission is to protect public health and the environment. The Homeland Security Research Program (HSRP), 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 HSRP 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.

As part of the biological decontamination mission space, the research programme supports EPA’s responsibilities related to the Federal Insecticide, Fungicide, and Rodenticide Act. Antimicrobial products, such as products used for decontamination, must be used in accordance with EPA approved registration claims. This includes disinfectants for use in support of the COVID-19 public health emergency; the research program supported the response to the emergency through testing of disinfection products and devices and the development of efficacy test methods.

2. State the total funding for the programme and its source.
$7,900,000 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 contracted or other facilities?
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, HSRP, 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, HSRP 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: National Institutes of Health

Description

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 U.S. 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 and U.S. Department of Defense (DOD). 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.

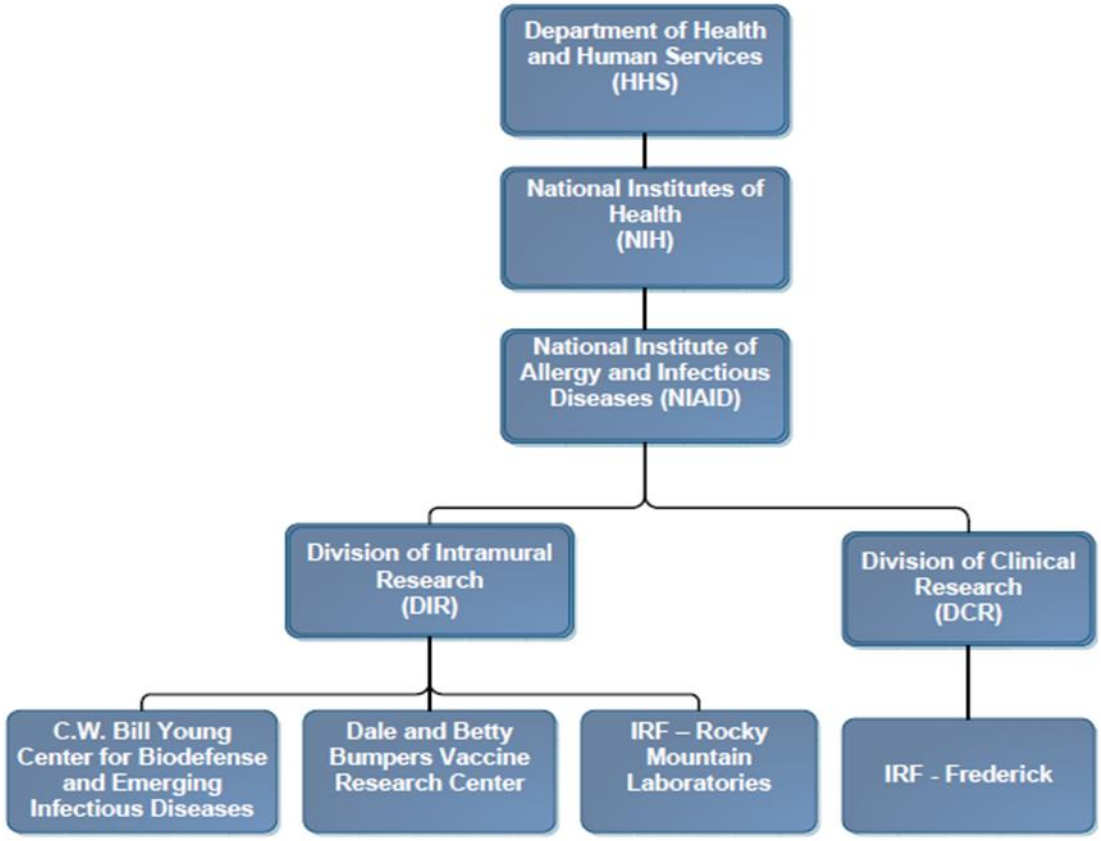
2. State the total funding for each programme and its source.
$92,248,056 U.S. Department of Health and Human Services (HHS)
$365,702 U.S. Department of Defense (DOD)

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?
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 and Laulima Government Solutions facilitate 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 95
- Integrated Research Facility at Fort Detrick (IRF-Frederick) – Page 104
- C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases – Page 108
- Dale and Betty Bumpers Vaccine Research Center – Page 117

National biological defence research and development programmes: Centers for Disease Prevention and Control

Description

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.

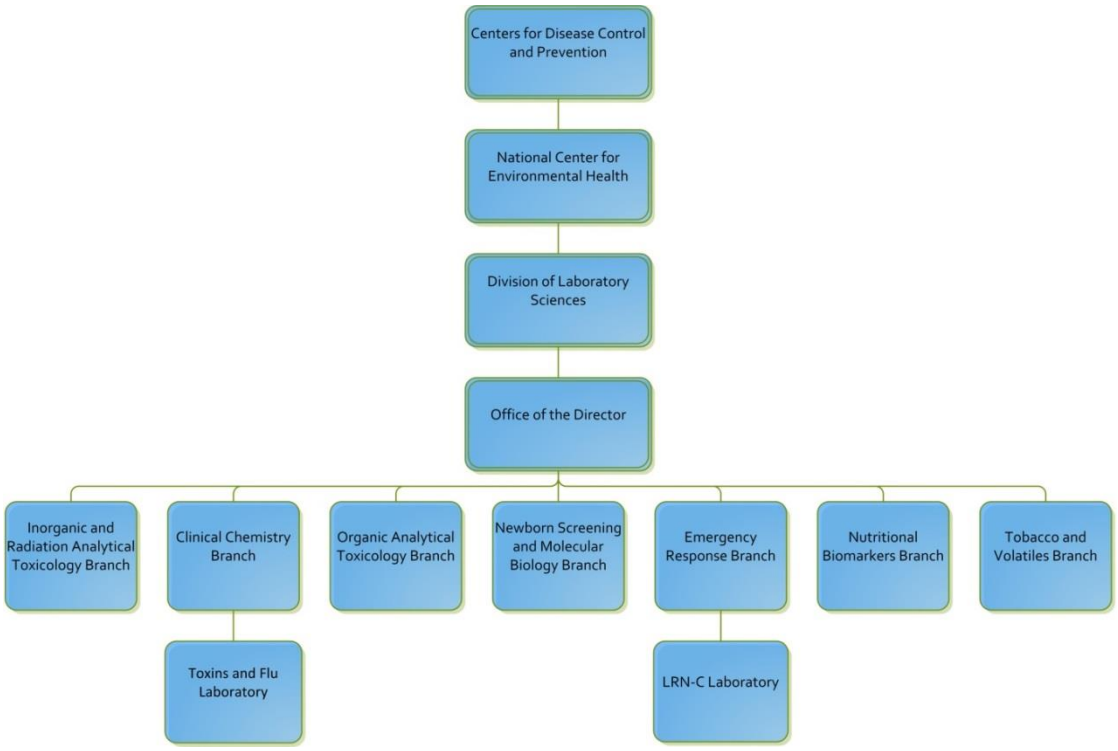
2. State the total funding for each programme and its source.
$4,717,438 U.S. Department of Health and Human Services (HHS)

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

4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?
Not Applicable.

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.
Not Applicable.

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 85

National biological defence research and development programmes: Centers for Disease Prevention and Control

Description

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 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.

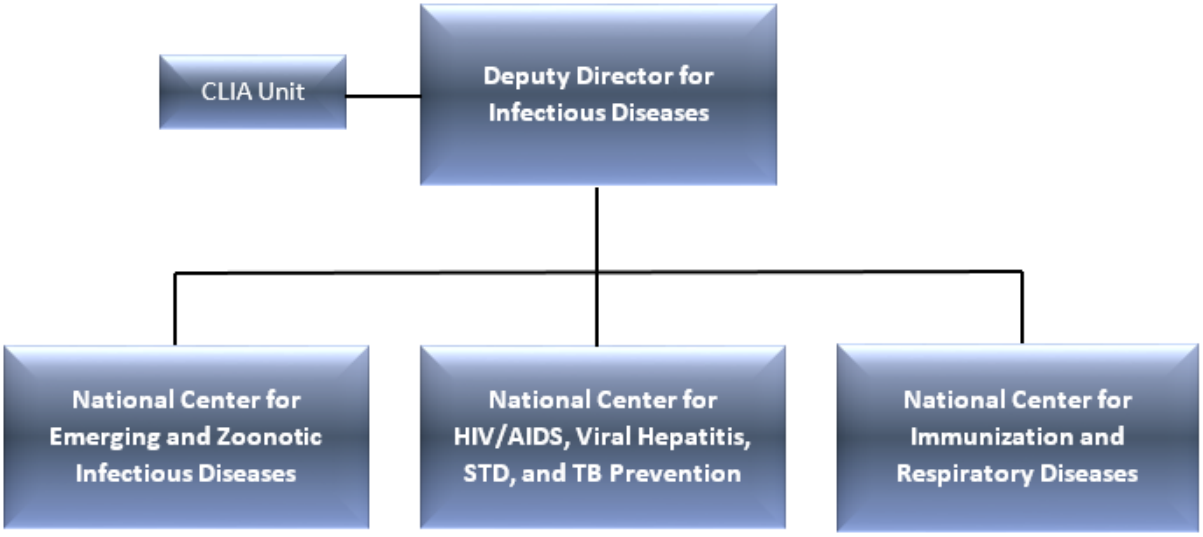
2. State the total funding for each programme and its source.
$23,451,958 Centers for Disease Control and Prevention (CDC)

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 87
- 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 93

National biological defence research and development programmes: Department of Agriculture – Agricultural Research Service

Description

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

Background

The U.S. Department of Agriculture's Agricultural Research Service (USDA-ARS) biodefense research program addresses 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 to the country's agricultural systems but also toa 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 an important infectious disease of crops, livestock or poultry believed to be absent from the U.S. and its territories that has a potentially significant health or economic impact. 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 the United 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; Beltsville, Maryland, and Frederick, Maryland.

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

$29,265,444 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.

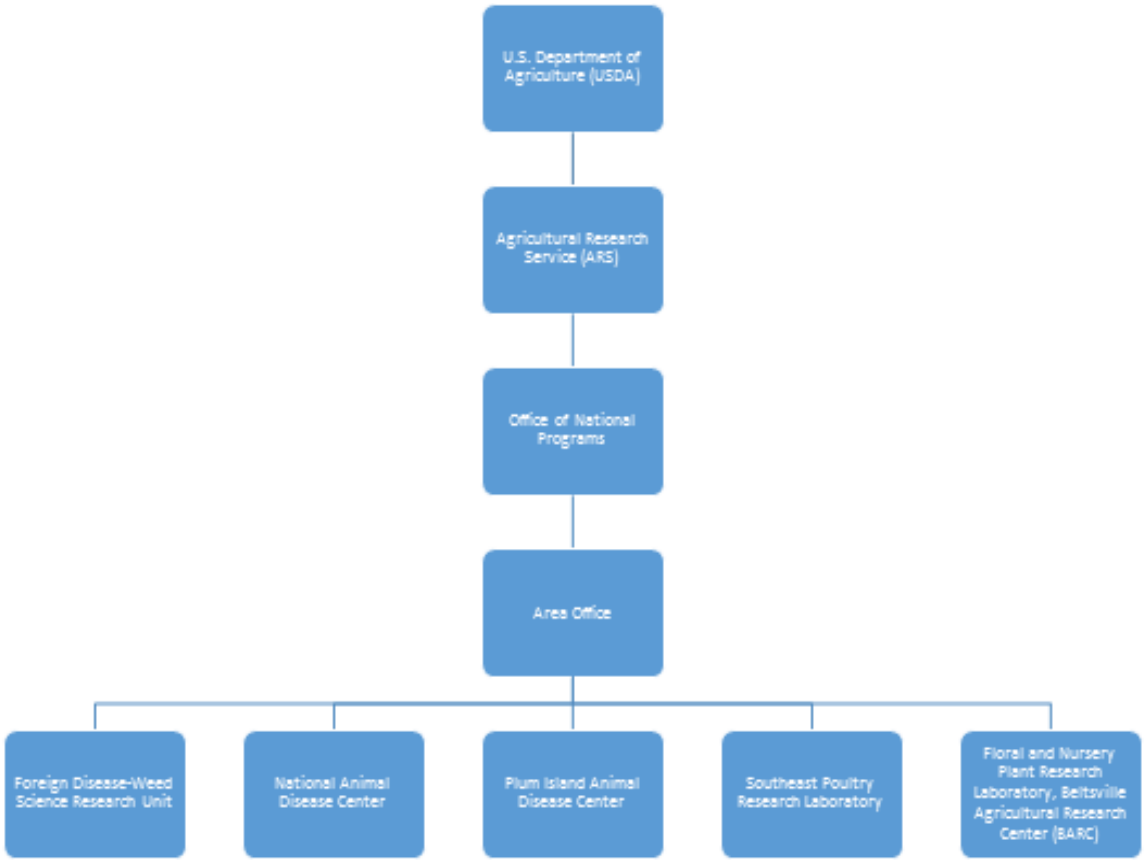
4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?

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.

- Plum Island Animal Disease Center (PIADC) – Page 42
- Foreign Disease-Weed Science Research Unit – Page 126
- National Animal Disease Center (NADC) – Page 128
- Southeast Poultry Research Laboratory – Page 131
- Floral and Nursery Plants Research, Beltsville Agricultural Research Center (BARC) – Page 134

National biological defence research and development programmes: Department of Homeland Security

Description

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

Preventing terrorism and enhancing security, including protection against biological terrorism, is one of the five key U.S. 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 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 2020 included building on comprehensive threat and risk assessments to inform CBRN 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 2020 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.

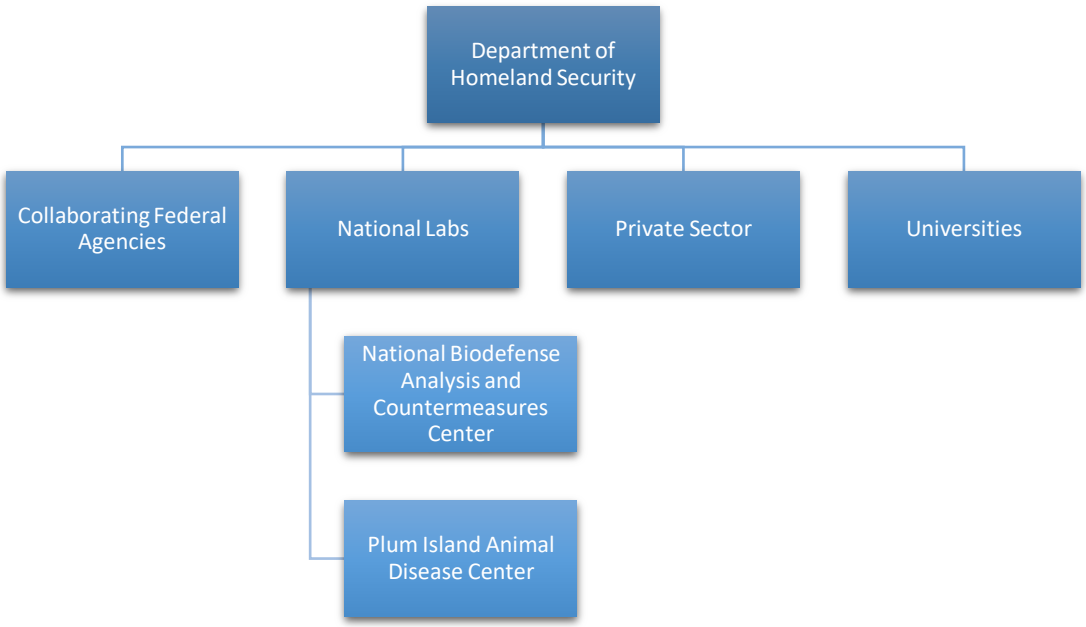
2. State the total funding for the programme and its source.
$69,280,000 U.S. Department of Homeland Security (DHS)

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 39
- Plum Island Animal Disease Center (PIADC) – Page 42

Form A, Part 2 (iii)

BWC - Confidence Building Measure

National biological defence research and development programmes - Facilities

United States of America

April 15, 2020

National biological defence research and development programme - Overview

For each facility detailed on Form A, Part 2 (iii), the entries given for question 3, "Floor area of laboratory areas by containment level (m^2)" represent lab space used for biodefense R&D purposes during calendar year 2020. Variations in laboratory space reported may be due to year-to-year variations in programming 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 Toxins" 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 health and safety, animal or plant health, or to animal or plant products, as well as the environment. Possession, use, and transfer of Select Agents and Toxins are regulated by the Select Agent Rules. Detailed information on Select Agents and Toxins and their regulations 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 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).

During 2020, several facilities detailed on Form A, Part 2 (iii) initiated emergency response research on the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) virus as part of the United States Government's response to the *Determination that a Public Health Emergency Exists Nationwide as the Result of the 2019 Novel Coronavirus* by the Department of Health and Human Services on 31 January 2020. This critical emergency response research included basic research, infection studies in animals, and research and development of SARS-CoV-2 countermeasures such as diagnostics, decontamination techniques, antivirals and vaccines in the interest of global public health. The facilities included in this form reported both print and pre-print publications resulting from SARS-CoV-2 research in response to section (ix)'s call for publicly available papers and reports, consistent with the United States' continued commitment to making its annual BWC CBM returns as complete, accurate, and transparent as possible.

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: 191

(ii) Division of personnel:

Military	0
Civilian	191

Division of personnel by category:

Scientists	38
Engineers	45
Technicians	67
Administrative and support staff	41

(iii) List the scientific disciplines represented in the scientific/engineering staff:
Aerobiology, Analytical Mass Spectrometry, Bacteriology, Biochemistry, Bioinformatics, Biological Science, Biomedical Science, Biophysics, Biotechnology, Cell Biology, Chemistry, Computer Science, Genetics, Genomics, Immunology, Microbial Forensics, Microbiology, Microscopy, Molecular Biology, Molecular Diagnostics, Toxicology, Toxinology, Veterinary Medicine, Virology.

(iv) Are contractor staff working in the facility? If so, provide an approximate number:
Yes Number: 191

(v) 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 Health and Human Services (HHS)
U.S. Department of Defense (DOD) - Partly

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

Research	$ 13,748,412
Development	$ 19,043,682
Test and evaluation	$ 0

Total	$ 32,792,094

(vii) 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/public-affairs/mgmt-dir_md-2260-1-review-of-external-publications.pdf.

(viii) 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. Arizti-Sanz J, Freije CA, Stanton AC, Petros BA, Boehm CK, Siddiqui S, et al. Streamlined inactivation, amplification, and Cas13-based detection of SARS-CoV-2. Nat Commun. 2020. 11:5921. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7680145/
2. Biryukov J, Boydston JA, Dunning RA, Yeager JJ, Wood S, Reese AL, et al. Increasing temperature and relative humidity accelerates inactivation of SARS-CoV-2 on surfaces. mSphere. 2020. 5:e00441-20. https://doi.org/10.1128/mSphere.00441-20
3. Bleka Ø, Just R, Le J, Gill P. An examination of STR nomenclatures, filters and models for MPS mixture interpretation. Forensic Sci Int Genet. 2020. 48:102319. https://www.sciencedirect.com/science/article/pii/S1872497320300922
4. Cheng K, Skillman J, Hickey S, Just R, Moreno L, Bright JA, et al. Variability and additivity of read counts for aSTRs in NGS DNA profiles. Forensic Sci Int Genet. 2020. 48:102351. https://www.sciencedirect.com/science/article/pii/S1872497320301241
5. Dabisch P, Schuit M, Herzon A, Bech K, Wood S, Krause M, et al. The Influence of Temperature, Humidity, and Simulated Sunlight on the Infectivity of SARS-CoV-2 in Aerosols. Aerosol Sci Technol. 2020. DOI: 10.1080/02786826.2020.1829536 https://www.tandfonline.com/doi/full/10.1080/02786826.2020.1829536
6. Kuhn JH, Adkins S, Alioto D, Alkhovsky SV, Amarasinghe GK, Anthony SJ, et al. 2020 Taxonomic update for phylum Negarnaviricota (Riboviria: Orthornavirae), including the large orders Bunyavirales and Mononegavirales. Arch Virol. 2020. 165:3023–3072. https://link.springer.com/article/10.1007/s00705-020-04731-2
7. Ratnesar-Shumate S, Williams G, Green B, Krause M, Holland B, Wood S, et al. Simulated Sunlight Rapidly Inactivates SARS-CoV-2 on Surfaces. J Infect Dis. 2020. 222:214–222. https://academic.oup.com/jid/article/222/2/214/5841129
8. Schuit M, Ratnesar-Shumate S, Yolitz J, Williams G, Weaver W, Green B, et al. Airborne SARS-CoV-2 is Rapidly Inactivated by Simulated Sunlight. J Infect Dis. 2020. 222:564–571. https://doi.org/10.1093/infdis/jiaa334
9. Standage DS, Mitchell RN. MicroHapDB: a portable and extensible database of all published microhaplotype marker and frequency data. Front Genet. 2020. 11:781. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7427474/

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), 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:**	454
(ii)	**Division of personnel:**	
	Military	0
	Civilian	454
(iii)	**Division of personnel by category:**	
	Scientists	97
	Engineers	4
	Technicians	18
	Administrative and support staff	335

(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: 317

(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)
U.S. Department of Homeland Security (DHS)

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

Research	$ 7,448,361
Development	$ 1,800,000
Test and evaluation	$ 8,772,595
Total	$ 18,020,956

(viii) Briefly describe the publication policy of the facility:
DHS scientific research staff are expected to publish papers in open literature. Papers are peer reviewed and approved by PIADC and DHS for security, clarity, and accuracy with regard to the description of work prior to submittal to journals or release. All USDA Agricultural Research Service (ARS) scientists

are obligated to publish scientific research data in peer-reviewed publications after review for dual use determination (not all publications by these scientists are relevant to this report). ARS scientists are encouraged to present research at scientific conferences and to publish in books and proceedings. ARS maintains a searchable online database of publications by scientists (available at https://www.ars.usda.gov/research/publications/publications-at-this-location/?modeCode=80-64-05-00).

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. Bertram MR, Palinski RM, Pauszek SJ, Hartwig EJ, Smoliga GR, Biswal JK, et al. Genome Sequences of Seven Foot-and-Mouth Disease Virus Isolates Reveal Diversity in the O/ME-SA/Ind2001 Lineage in India between 1997 and 2009. Microbiol Resour Announc. 2020. 9:e00287-20. https://mra.asm.org/content/9/16/e00287-20
2. Bertram MR, Yadav S, Stenfeldt C, Delgado A, Arzt J. Extinction Dynamics of the Foot-and-Mouth Disease Virus Carrier State Under Natural Conditions. Front Vet Sci. 2020. 7:276. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7249781/
3. Borca MV, O'Donnell V, Holinka LG, Risatti GR, Ramirez-Medina E, Vuono EA, et al. Deletion of CD2-like gene from the genome of African swine fever virus strain Georgia does not attenuate virulence in swine. Sci Rep. 2020. 10:494. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6965178/
4. Borca MV, Ramirez-Medina E, Silva E, Vuono E, Rai A, Pruitt S, et al. Development of a highly effective African swine fever virus vaccine by deletion of the I177L gene results in sterile immunity against the current epidemic Eurasia strain. J Virol. 2020. 94:e02017-19. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7081903/
5. Chitray M, Opperman PA, Rotherham L, Fehrsen J, van Wyngaardt W, Frischmuth J, et al. Diagnostic and Epitope Mapping Potential of Single-Chain Antibody Fragments Against Foot-and-Mouth Disease Virus Serotypes A, SAT1, and SAT3. Front Vet Sci. 2020. 7:475. https://doi.org/10.3389/fvets.2020.00475
6. Ehizibolo DO, Fish IH, Brito B, Bertram MR, Ardo A, Ularamu HG, et al. Characterization of transboundary foot-and-mouth disease viruses in Nigeria and Cameroon during 2016. Transbound Emerg Dis. 2020. 67:1257-1270. https://onlinelibrary.wiley.com/doi/abs/10.1111/tbed.13461
7. Eschbaumer M, Dill V, Carlson JC, Arzt J, Stenfeldt C, Krug PW, et al. Foot-and-Mouth Disease Virus Lacking the Leader Protein and Containing Two Negative DIVA Markers (FMDV LL3B3D A24) Is Highly Attenuated in Pigs. Pathogens. 2020. 9:129. https://www.mdpi.com/2076-0817/9/2/129/htm
8. Fish I, Stenfeldt C, Palinski RM, Pauszek SJ, Arzt J. Into the deep (sequence) of the FMD virus gene pool: bottlenecks and adaptation during infection in naïve and vaccinated cattle. Pathogens. 2020. 9:208. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7157448/
9. Gabbert LR, Neilan JG, Rasmussen M. Recovery and chemical disinfection of foot-and-mouth disease and African swine fever viruses from porous concrete surfaces. J Appl Microbiol. 2020. 129:1092-1101. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7687137/
10. Gladue DP, O'Donnell V, Ramirez-Medina E, Rai A, Pruitt S, Vuono EA, et al. Deletion of CD2-Like (CD2v) and C-Type Lectin-Like (EP153R) Genes from African Swine Fever Virus Georgia-delta-9GL Abrogates Its Effectiveness as an Experimental Vaccine. Viruses. 2020. 12:1185. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7590024/

11. Hardham JM, Krug P, Pacheco JM, Thompson J, Dominowski P, Moulin V, et al. Novel Foot-and-Mouth Disease Vaccine Platform: Formulations for Safe and DIVA-Compatible FMD Vaccines With Improved Potency. Front Vet Sci. 2020. 7:554305. https://doi.org/10.3389/fvets.2020.554305
12. Kloc A, Rai DK, Gladue DP, Schafer E, Kenney M, Rieder E. Residues within the Foot-and-Mouth Disease Virus 3Dpol Nuclear Localization Signal Affect Polymerase Fidelity. J Virol. 2020. 94:e00833-20. https://jvi.asm.org/content/94/17/e00833-20.long
13. Lucas J, Holder D, Dodd K, Wei J. A versatile dual-use RT-PCR control for use in assays for the detection of peste des petits ruminants virus. J Virol Methods. 2020. 277:113799. https://www.sciencedirect.com/science/article/pii/S0166093419303404?via%3Dihub
14. Medina GN, Azzinaro P, Ramirez-Medina E, Gutkoska J, Fang Y, Diaz-San Segundo F, et al. Impairment of the deISGylation activity of FMDV Lpro causes attenuation in vitro and in vivo. J Virol. 2020. 94:e00341-20. https://doi.org/10.1128/JVI.00341-20
15. Medina GN, de Los Santos T, Diaz-San Segundo F. Use of IFN-Based Biotherapeutics to Harness the Host Against Foot-And-Mouth Disease. Front Vet Sci. 2020. 7:465. https://doi.org/10.3389/fvets.2020.00465
16. O'Donnell VK, Pauszek SJ, Xu L, Moran K, Vierra D, Boston T, et al. Genome Sequences of Vesicular Stomatitis Indiana Viruses from the 2019 Outbreak in the Southwest United States. Microbiol Resour Announc. 2020. 9:e00894-20. https://doi.org/10.1128/MRA.00894-20
17. Omondi GP, Gakuya F, Arzt J, Sangula A, Hartwig E, Pauszek S, et al. The role of African buffalo in the epidemiology of foot-and-mouth disease in sympatric cattle and buffalo populations in Kenya. Transbound Emerg Dis. 2020. 67:2206-2221. https://onlinelibrary.wiley.com/doi/abs/10.1111/tbed.13573
18. Peck DE, Reeves WK, Pelzel-McCluskey AM, Derner JD, Drolet B, Cohnstaedt LW, et al. Management Strategies for Reducing the Risk of Equines Contracting Vesicular Stomatitis Virus (VSV) in the Western United States. J Equine Vet Sci. 2020. 90:103026. https://www.sciencedirect.com/science/article/pii/S0737080620301179?via%3Dihub
19. Petrovan V, Murgia MV, Wu P, Lowe AD, Jia W, Rowland RRR. Epitope mapping of African swine fever virus (ASFV) structural protein, p54. Virus Res. 2020. 279:197871. https://www.sciencedirect.com/science/article/abs/pii/S0168170218302144?via%3Dihub
20. Puckette MC, Martel E, Rutherford J, Barrera J, Hurtle W, Pisano M, et al. Generation and characterization of genetically stable heterohybridomas producing foot-and-mouth disease virus-specific porcine monoclonal antibodies. J Immunol Methods. 2020. 487:112873. https://www.sciencedirect.com/science/article/pii/S0022175920301678?via%3Dihub
21. Rai A, Pruitt S, Ramirez-Medina E, Vuono EA, Silva E, Velazquez-Salinas L, et al. Identification of a Continuously Stable and Commercially Available Cell Line for the Identification of Infectious African Swine Fever Virus in Clinical Samples. Viruses. 2020. 12:820. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7472077/
22. Ramirez-Medina E, Vuono E, Pruitt S, Rai A, Silva E, Zhu J, et al. X69R Is a Non-Essential Gene That, When Deleted from African Swine Fever, Does Not Affect Virulence in Swine. Viruses. 2020. 12:918. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7551905/
23. Ramirez-Medina E, Vuono EA, Rai A, Pruitt S, Silva E, Velazquez-Salinas L, et al. The C962R ORF of African Swine Fever Strain Georgia Is Non-Essential and Not Required for Virulence in Swine. Viruses. 2020. 12:676. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7354530/
24. Ramirez-Medina E, Vuono EA, Rai A, Pruitt S, Silva E, Velazquez-Salinas L, et al. Evaluation in Swine of a Recombinant African Swine Fever Virus Lacking the MGF-360-1L Gene. Viruses. 2020. 12:1193. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7589680/
25. Ramírez-Medina E, Vuono EA, Velazquez-Salinas L, Silva E, Rai A, Pruitt S, et al. The MGF360-16R ORF of African swine fever virus strain Georgia encodes for a nonessential gene that interacts with host proteins SERTAD3 and SDCBP. Viruses. 2020. 12:60. https://www.mdpi.com/1999-4915/12/1/60/htm

26. Rhyan J, McCollum M, Gidlewski T, Shalev M, Ward G, Donahue B, et al. Foot-and-Mouth disease in experimentally infected mule deer (ODOCOILEUS HEMIONUS). J Wildl Dis. 2020. 56:93-104. https://pubmed.ncbi.nlm.nih.gov/31329525/
27. Stenfeldt C, Arzt J. The Carrier Conundrum; A Review of Recent Advances and Persistent Gaps Regarding the Carrier State of Foot-and-Mouth Disease Virus. Pathogens. 2020. 9:167. https://www.mdpi.com/2076-0817/9/3/167/htm
28. Stenfeldt C, Bertram MR, Smoliga GR, Hartwig EJ, Delgado AH, Arzt J. Duration of Contagion of Foot-And-Mouth Disease Virus in Infected Live Pigs and Carcasses. Front Vet Sci. 2020. 7:334. https://www.frontiersin.org/articles/10.3389/fvets.2020.00334/full
29. Sorvillo TE, Rodriguez SE, Hudson P, Carey M, Rodriguez LL, Spiropoulou CF, et al. Towards a Sustainable One Health Approach to Crimean-Congo Hemorrhagic Fever Prevention. Trop Med Infect Dis. 2020. 5:113. https://www.mdpi.com/2414-6366/5/3/113/htm
30. Velazquez-Salinas L, Mwiine FN, Ahmed Z, Ochwo S, Munsey A, Lutwama JJ, et al. Genetic Diversity of Circulating Foot and Mouth Disease Virus in Uganda Cross-Sectional Study During 2014-2017. Front Vet Sci. 2020. 7:162. https://doi.org/10.3389/fvets.2020.00162
31. Velazquez-Salinas L, Pauszek SJ, Holinka LG, Gladue DP, Rekant SI, Bishop EA, et al. A Single Amino Acid Substitution in the Matrix Protein (M51R) of Vesicular Stomatitis New Jersey Virus Impairs Replication in Cultured Porcine Macrophages and Results in Significant Attenuation in Pigs. Front Microbiol. 2020. 11:1123. https://www.frontiersin.org/articles/10.3389/fmicb.2020.01123/full
32. Velazquez-Salinas L, Zarate S, Eberl S, Gladue DP, Novella I, Borca MV. Positive Selection of ORF1ab, ORF3a, and ORF8 Genes Drives the Early Evolutionary Trends of SARS-CoV-2 During the 2020 COVID-19 Pandemic. Front Microbiol. 2020. 11:550674. https://www.frontiersin.org/articles/10.3389/fmicb.2020.550674/full
33. Vierra D, Bertram MR, Palinski RM, Pauszek SJ, Hartwig EJ, Smoliga GR, et al. Foot-and-mouth disease virus serotype O/cathay genome sequences from five outbreaks in Vietnam, 2017 to 2019. Microbiol Resour Announc. 2020. 9:e01315-19. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6992863/
34. Visser LJ, Aloise C, Swatek KN, Medina GN, Olek KM, Rabouw HH, et al. Dissecting distinct proteolytic activities of FMDV Lpro implicates cleavage and degradation of RLR signaling proteins, not its deISGylase/DUB activity, in type I interferon suppression. PLoS Pathog. 2020. 16:e1008702. https://doi.org/10.1371/journal.ppat.1008702
35. Vuono EA, Ramirez-Medina E, Azzinaro P, Berggren KA, Rai A, Pruitt S, et al. SERTA Domain Containing Protein 1 (SERTAD1) Interacts with Classical Swine Fever Virus Structural Glycoprotein E2, Which Is Involved in Virus Virulence in Swine. Viruses. 2020. 12:421. https://www.mdpi.com/1999-4915/12/4/421/htm
36. Vuono EA, Ramirez-Medina E, Berggren K, Rai A, Pruitt S, Silva E, et al. Swine Host Protein Coiled-Coil Domain-Containing 115 (CCDC115) Interacts with Classical Swine Fever Virus Structural Glycoprotein E2 during Virus Replication. Viruses. 2020. 12:388. https://www.mdpi.com/1999-4915/12/4/388/htm
37. Wang L, Mi S, Madera R, Ganges L, Borca MV, Ren J, et al. A neutralizing monoclonal antibody-based competitive ELISA for classical swine fever C-strain post-vaccination monitoring. BMC Vet Res. 2020. 16:14. https://bmcvetres.biomedcentral.com/articles/10.1186/s12917-020-2237-6
38. Wang Y, Xu L, Noll L, Stoy C, Porter E, Fu J, et al. Development of a real-time PCR assay for detection of African swine fever virus with an endogenous internal control. Transbound Emerg Dis. 2020. 67:2446-2454. https://onlinelibrary.wiley.com/doi/10.1111/tbed.13582
39. Wu P, Lowe AD, Rodríguez YY, Murgia MV, Dodd KA, Rowland RR, et al. Antigenic Regions of African Swine Fever Virus Phosphoprotein P30. Transbound Emerg Dis. 2020. 67:1942-1953. https://onlinelibrary.wiley.com/doi/abs/10.1111/tbed.13533
40. Zhu JJ, Stenfeldt C, Bishop EA, Canter JA, Eschbaumer M, Rodriguez LL, et al. Mechanisms of Maintenance of Foot-and-Mouth Disease Virus Persistence Inferred From Genes Differentially

Expressed in Nasopharyngeal Epithelia of Virus Carriers and Non-carriers. Front Vet Sci. 2020. 7:340. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7318773/

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:	1,111 m^2
BSL-3:	1,174 m^2
BSL-4:	0 m^2
Total laboratory floor area:	2,285 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 30

(ii) Division of personnel:

Military	0
Civilian	30

(iii) Division of personnel by category:

Scientists	19
Engineers	0
Technicians	4
Administrative and support staff	7

(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: 8

(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	$ 1,164,000
Total	$ 1,164,000

(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/ARN4633_AR70-31_WEB_Final.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 (https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.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: No U.S. Select Agents, NIAID Category A pathogens or applicable simulants were used.

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?
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

Studies conducted at BSL-3 were carried out at the United States Army Medical Research Institute for Infectious Diseases (USAMRIID).

4. The organizational structure of each facility:

(i) Total number of personnel: 87

(ii) Division of personnel:

Military	15
Civilian	72

(iii) Division of personnel by category:

Scientists	19
Engineers	0
Technicians	60
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: 62

(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	$ 23,100,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 23,100,000

(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 clearance before submission. Release of DOD publications is guided by DOD Directive 5230.09, Clearance of DOD Information for Public Release (https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523009p_1.pdf?ver=2019-06-26-120334-963) and DOD Instruction 5320.29, Security and Policy Review of DOD Information for Public Release (https://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. Larson DT, Schully KL, Spall A, Lawler JV, Maves RC. Indirect Detection of Burkholderia pseudomallei Infection in a US Marine After Training in Australia. Open Forum Infect Dis. 2020 Mar 23;7(5) https://pubmed.ncbi.nlm.nih.gov/32391401/
2. Monath TP, Kortekaas J, Watts DM, Christofferson RC, Desiree LaBeaud A, Gowen B, et al. Theoretical risk of genetic reassortment should not impede development of live, attenuated Rift Valley Fever (RVF) vaccines: Commentary on the draft WHO target product profile. Vaccine X. 2020 Apr 9;5 https://doi.org/10.1016/j.jvacx.2020.100060
3. Malagon F, Estrella LA, Stockelman MG, Hamilton T, Teneza-Mora N, Biswas B. Phage-Mediated Molecular Detection (PMMD): A novel rapid method for phage-specific bacterial detection. Viruses. 2020 Apr 11;12(4):435. https://www.mdpi.com/1999-4915/12/4/435
4. Doub JB, Ng VY, Johnson AJ, Slomka M, Fackler J, Horne B'A, et al. Salvage bacteriophage therapy for a chronic MRSA prosthetic joint infection. Antibiotics (Basel). 2020 May 9;9(5):241 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7277870/
5. Rozo M, Schully KL, Philipson C, Fitkariwala A, Nhim D, Som T, et al. An Observational Study of Sepsis in Takeo Province Cambodia: An in-depth examination of pathogens causing severe infections. PLoS Negl Trop Dis. 2020 Aug 17;14(8) https://pubmed.ncbi.nlm.nih.gov/32804954/
6. Larson DT, Brodniak S, Voegtly LJ, Cer RZ, Glang LA, Malagon FJ, et al. A case of early re-infection with SARS-CoV-2. Clin Infect Dis. 2020 Sep 19. Online ahead of print. https://pubmed.ncbi.nlm.nih.gov/32949240/
7. Maljkovic Berry I, Rutvisuttinunt W, Voegtly LJ, Prieto K, Pollett S, Cer RZ, et al. A Department of Defense Laboratory Consortium Approach to Next Generation Sequencing and Bioinformatics Training for Infectious Disease Surveillance in Kenya. Front Genet. 2020 Sep 25;11:577563. https://pubmed.ncbi.nlm.nih.gov/33101395/
8. Maljkovic Berry I, Melendrez MC, Bishop-Lilly KA, Rutvisuttinunt W, Pollett S, Talundzic E, et al. Next Generation Sequencing and Bioinformatics Methodologies for Infectious Disease Research and Public Health: Approaches, Applications, and Considerations for Development of Laboratory Capacity J Infect Dis. 2020 Mar 28;221(Suppl 3):S292-S307. https://academic.oup.com/jid/article/221/Supplement_3/S292/5586940
9. Paskey AC, Ng JHJ, Rice GK, Chia WN, Philipson CW, Foo RJH, et al. Detection of Recombinant Rousettus Bat Coronavirus GCCDC1 in Lesser Dawn Bats (Eonycteris spelaea) in Singapore Viruses. 2020 May 14;12(5):539. https://pubmed.ncbi.nlm.nih.gov/32422932

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: The goals of the program are the development of rapid and deployable detection assays to protect deployed troops. During 2020, 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. In addition, other efforts include continued development of diagnostics for bacteria using phage combined with other technologies, and a program aimed at developing and testing a virus enrichment sequencing assay for viruses of biosurveillance and biodefense concern. We continued to develop and produce antibodies and immunoassays to detect select agents and toxins. Furthermore, we started a new project to identify biomarkers of neurological injury for encephalitic arboviruses. 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 HHS Select Toxins, NIAID Category A pathogens.

Outdoor Studies: No outdoor studies performed.

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-1:	317 m^2
BSL-2:	300 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	617 m^2

During the reported calendar year, the Naval Research Laboratory BSL-1 and BLS-2 laboratory spaces used for biodefense research and development was reapportioned, resulting in a total decrease of 135 m^2. The BSL-1 and BSL-2 laboratory spaces were not physically remodeled.

4. The organizational structure of each facility:

(i) Total number of personnel: 34

(ii) Division of personnel:

Military	1
Civilian	33

(iii) Division of personnel by category:

Scientists	25
Engineers	1
Technicians	8
Administrative and support staff	0

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

(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) – Wholly

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

Research	$ 3,085,000
Development	$ 2,150,000
Test and evaluation	$ 730,000
Total	$ 5,965,000

(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, https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.pdf) and DOD Instruction 5320.29 (Security and Policy Review of DOD Information for Public Release, https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523009p_1.pdf?ver=2019-06-26-120334-963) for publishing information related to biological defense efforts.

(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, G.P., Liu, J.L., Shriver-Lake, L.S., Goldman, E.R. Selection and Characterization of Single-Domain Antibodies for Detection of Lassa Nucleoprotein. Antibodies. 2020; 9(4), 71. doi:10.3390/antib9040071. https://www.mdpi.com/2073-4468/9/4/71/htm
2. Hart, M.B., Scotto, C.S., Tucker, J.E., Mcpherson, D.C., Minter, Z.A., Kesavan, J., Silcott, D., Lin, H-B., Eversole, J.D. Toward Biological Aerosol Reference Standards. Aerosol Science and Technology. 2020; 54 (5), pp. 601-610. doi: 10.1080/02786826.2019.1708860. https://doi.org/10.1080/02786826.2019.1708860
3. Mulvaney, S.P., Kidwell, D.A., Lanese, J.N., Lopez, R.P., Sumera, M.E., and Wei, E. Catalytic Lateral Flow Immunoassays (cLFIA): Amplified Signal in a Self-Contained Assay Format. Sens. Bio-Sens. Res. 2020; 30, 100390. https://doi.org/10.1016/j.sbsr.2020.100390
4. Shriver-Lake, L.S., Goldman, E.R., Dean, S.N., Liu, J.L., Davis, T.M., Anderson, G.P. Lipid-Tagged Single Domain Antibodies for Improved Enzyme-Linked Immunosorbent Assays. Journal of Immunological Methods. 2020; 481, 112790. doi: 10.1016/j.jim.2020.112790. https://www.sciencedirect.com/science/article/pii/S0022175920300697?dgcid=rss_sd_all
5. Taitt CR, Leski TA, Chen A, Berk KL, Dorsey RW, Gregory MH, Sozhamannan S, Frey K, Dutt DL, Vora GV. A survey of antimicrobial resistance determinants in Category A Select Agents, exempt strains, and near-neighbor species. Int J Mol Sci. 2020; 21(5) 1669. DOI: 10.3390/ijms21051669. https://www.mdpi.com/1422-0067/21/5/1669/htm

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 biodefense 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 of Select Agents and Toxins (HHS, Overlap), 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?
Naval Surface Warfare Center (NSWC) - 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: 32

(ii) Division of personnel:

Military	0
Civilian	32

(iii) Division of personnel by category:

Scientists	25
Engineers	2
Technicians	1
Administrative and support staff	4

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Chemical Engineering, Chemistry, Microbiology, Molecular Biology, Physics, Toxicology.

(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) – Partly
Internal (Laboratory Directed Research and Development)
Other Governmental Agencies

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

Research	$ 2,327,141
Development	$ 4,212,131
Test and evaluation	$ 172,000
Total	$ 6,711,272

(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 (https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.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. Buhr TL, Young AA, Borgers-Klonkowski E, Kennihan NL, Barnette HK, Minter ZA, et al. Hot, humid air decontamination of aircraft confirmed that high temperature and high humidity are critical for inactivation of infectious, enveloped ribonucleic acid (RNA) virus. 2020 Oct 23. Front. Bioeng. Biotechnol. 8:592621. https://www.frontiersin.org/articles/10.3389/fbioe.2020.592621/full#h1
2. Cote CC, Weidner JM, Klimko C, Piper AE, Miller JA, Hunter M, et al. Biological Validation of a Chemical Effluent Decontamination System. Appl Biosaf. 2020 Jul 9; https://journals.sagepub.com/doi/10.1177/1535676020937967
3. Buhr TL, Minter ZA, Kennihan NL, Young AA, Borgers-Klonkowski EL, Osborn EB, et al. Combining Spore Germination and Heat Inactivation to Decontaminate Materials Contaminated with Bacillus anthracis Spores. J Appl Microbiol. 2020 Jan;128(1):124-137. https://pubmed.ncbi.nlm.nih.gov/31573710/

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 hazard mitigation technologies, risk assessment tools, and consequence management planning.

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

Outdoor Studies: No outdoor studies performed.

Note: In 2018, The NSWC Dahlgren Chemical and Biological Defense Division began to move to NSWC Indian Head and this process is ongoing. The only remaining portion of the division at NSWC Dahlgren is the technical, laboratory-focused aspect. All of the collective protection programs and support programs were moved to Indian Head. Therefore, a significant number of programs, personnel and funding were terminated, or re-allocated during the year. This accounts for the decrease in personnel, specifically non-technical personnel, as well as the decrease in funding for the division.

* Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
U.S. Army Combat Capabilities Development Command Chemical and Biological Center (CCDC CBC)

2. Where is it located (provide both address and geographical location)?
8198 Blackhawk Road Bldg E5183, Aberdeen Proving Ground, Maryland 21010-5424 (Note: The postal address has changed from 5183 to 8198 Blackhawk Road, but the physical location remains the same)

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

BSL-2:	327 m^2
BSL-3:	177 m^2
BSL-4:	0 m^2
Total laboratory floor area:	504 m^2

During the reported calendar year, the CCDC CBC BSL-2 laboratory space used for biodefense research and development was reapportioned, resulting in a decrease of 76 m^2. The BSL- 2 laboratory space was not physically remodeled.

4. The organizational structure of each facility:

(i)	**Total number of personnel**	68
(ii)	**Division of personnel:**	
	Military	0
	Civilian	68
(iii)	**Division of personnel by category:**	
	Scientists	50
	Engineers	3
	Technicians	15
	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: 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 (DOD) – Wholly

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

Research	$ 14,792,000
Development	$ 6,715,000

Test and evaluation	$ 0
Total	$ 21,507,000

(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/ARN4633_AR70-31_WEB_Final.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 (https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.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. Calm AM, Kim M, Kragl JF, Savage A, Beyer FL, Walck S, et al. Biologically derived magnetite nanoparticles (mnps) for use in electromagnetic pulse shielding. Combat Capabilities Development Command Chemical Biological Center. May 2020, CCDC CBC-TR-1631. https://apps.dtic.mil/sti/pdfs/AD1098074.pdf
2. Cole SD, Miklos AE, Chiao AC, Sun ZZ, Lux MW. Methodologies for preparation of prokaryotic extracts for cell-free expression systems. Synth Syst Biotechnol. 2020 Jul 30; 5(4):252-67. https://www.sciencedirect.com/science/article/pii/S2405805X2030051X
3. Dunn MR, McCloskey CM, Buckley P, Rhea K, Chaput JC. Generating biologically stable tna aptamers that function with high affinity and thermal stability. J Am Chem Soc. 2020 Apr 16; 142(17):7721-4. https://pubs.acs.org/doi/10.1021/jacs.0c00641
4. Lee MS, Raig RM, Gupta MK, Lux MW. Lyophilized cell-free systems display tolerance to organic solvent exposure. ACS Synth Biol. 2020 Jul 9; 9(8):1951-7. https://pubs.acs.org/doi/10.1021/acssynbio.0c00267
5. Rastogi VK, Smith LS, Burton LL, Rastogi PR, Harris JV, Hurst S, et al. Investigations into enhancing yersinia pestis cells viability following environmental sampling for forensic analysis. J Forensic Sci. 2020 Feb 03; 65(4):1315-23. https://onlinelibrary.wiley.com/doi/10.1111/1556-4029.14293
6. Sozhamannan S, Hofmann ER. The state of the art in biodefense related bacterial pathogen detection using bacteriophages: how it started and how it's going. Viruses; 2020 Dec 04; 12(12): 1393. https://www.mdpi.com/1999-4915/12/12/1393

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

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.cbc.ccdc.army.mil/.

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

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?
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, Neurotoxicology, 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) – Partly
U.S. Department of Health and Human Services (HHS)

(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/ARN4633_AR70-31_WEB_Final.pdfAR 360-1
- "The Army Public Affairs Program" https://armypubs.army.mil/epubs/DR_pubs/DR_a/pdf/web/ARN6644_AR360-1_Admin_WEB_FINAL.pdfAR 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 (https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.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. Winner BM, Bodt SML, McNutt PM. Special Delivery: Potential Mechanisms of Botulinum Neurotoxin Uptake and Trafficking within Motor Nerve Terminals. Int J Mol Sci. 2020 Nov 18;21(22):8715. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7698961/
2. Vazquez-Cintron E, Machamer J, Ondeck C, Pagarigan K, Winner B, Bodner P, et al., Symptomatic treatment of botulism with a clinically approved small molecule. JCI Insight. 2020 Jan 30;5(2):e132891. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7098712/

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: 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 Toxin.

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?
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 m^2

4. The organizational structure of each facility:

(i) Total number of personnel 668

(ii) Division of personnel:

Military	173
Civilian	495

(iii) Division of personnel by category:

Scientists	161
Engineers	5
Technicians	280
Administrative and support staff	222

(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: 275

(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 (HHS)
U.S. Department of Agriculture (USDA)
U.S. Department of Energy (DOE)
Universities
Private sector companies

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

Research	$ 1,578,627
Development	$ 40,261,749*
Test and evaluation	$ 12,277,788

Total	$ 54,118,164

*Includes reimbursables from Cooperative Research and Development Agreements and other Departments, which cannot be differentiated by the above categories.

(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/ARN4633_AR70-31_WEB_Final.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 (https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.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. Haddow AD, Watt TR, Bloomfield HA, Fetterer DP, Harbourt DE. Modeling the Stability of SARS-CoV-2 on Personal Protective Equipment (PPE). Am J Trop Med Hyg. 2020 Dec 22. https://doi.org/10.4269/ajtmh.20-1508
2. Salazar E, Kuchipudi SV, Christensen PA, Eagar T, Yi X, Zhao P, et al. Convalescent plasma anti-SARS-CoV-2 spike protein ectodomain and receptor-binding domain IgG correlate with virus neutralization. J Clin Invest. 2020 Dec 1;130(12):6728-6738. https://doi.org/10.1172/JCI141206
3. Welkos S, Blanco I, Okaro U, Chua J, DeShazer D. A DUF4148 family protein produced inside RAW264.7 cells is a critical Burkholderia pseudomallei virulence factor. Virulence. 2020 Aug 23;11(1):1041-1058. https://doi.org/10.1080/21505594.2020.1806675
4. Luban J, Sattler RA, Mühlberger E, Graci JD, Cao L, Weetall M, et al. The DHODH inhibitor PTC299 arrests SARS-CoV-2 replication and suppresses induction of inflammatory cytokines. Virus Res. 2020 Nov 26;292:198246. https://doi.org/10.1016/j.virusres.2020.198246
5. Grund ME, Choi SJ, McNitt DH, Barbier M, Hu G, LaSala PR, et al. Burkholderia collagen-like protein 8, Bucl8, is a unique outer membrane component of a putative tetrapartite efflux pump in Burkholderia pseudomallei and Burkholderia mallei. PLoS One. 2020 Nov 23;15(11):e0242593. https://doi.org/10.1371/journal.pone.0242593

6. Turell MJ, Dohm DJ, Fernandez R, Klein TA. Vector Competence of Peruvian Mosquitoes for Two Orthobunyaviruses Isolated From Mosquitoes Captured in Peru. J Med Entomol. 2020 Nov 19:tjaa252. https://doi.org/10.1093/jme/tjaa252
7. von Fricken ME, Voorhees MA, Koehler JW, Asbun C, Lam B, Qurollo B, et al. Molecular Characteristics of Rickettsia in Ticks Collected along the Southern Border of Mongolia. Pathogens. 2020 Nov 13;9(11):943. https://www.mdpi.com/2076-0817/9/11/943/htm
8. Keshtkar-Jahromi M, Reisler RB, Haller JM, Clizbe DP, Rivard RG, Cardile AP, et al. The Western Equine Encephalitis Lyophilized, Inactivated Vaccine: An Update on Safety and Immunogenicity. FrontImmunol. 2020 Nov 9;11:555464. https://www.frontiersin.org/articles/10.3389/fimmu.2020.555464/full
9. Harbourt DE, Haddow AD, Piper AE, Bloomfield H, Kearney BJ, Fetterer D, et al. Modeling the stability of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) on skin, currency, and clothing. PLoS Negl Trop Dis.2020 Nov 9;14(11):e0008831. https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0008831
10. DeMers HL, He S, Pandit SG, Hannah EE, Zhang Z, Yan F, et al. Development of an antigen detection assay for early point-of-care diagnosis of Zaire ebolavirus. PLoS Negl Trop Dis. 2020 Nov 3;14(11):e0008817. https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0008817
11. Haddow AD, Watt TR, Bloomfield HA, Shamblin JD, Dyer DN, Harbourt DE. Stability of SARS-CoV-2 on Produce following a Low-Dose Aerosol Exposure. Am J Trop Med Hyg. 2020 Nov;103(5):2024-2025. https://doi.org/10.4269/ajtmh.20-1033
12. Biot FV, Bachert BA, Mlynek KD, Toothman RG, Koroleva GI, Lovett SP, et al. Evolution of Antibiotic Resistance in Surrogates of Francisella tularensis (LVS and Francisella novicida): Effects on Biofilm Formation and Fitness. Front Microbiol. 2020 Oct 30;11:593542. https://doi.org/10.3389/fmicb.2020.593542
13. Guito JC, Prescott JB, Arnold CE, Amman BR, Schuh AJ, Spengler JR, et al. Asymptomatic Infection of Marburg Virus Reservoir Bats is Explained by a Strategy of Immunoprotective Disease Tolerance. Curr Biol. 2020 Oct 30:S0960-9822(20)31519-0. https://doi.org/10.1016/j.cub.2020.10.015
14. Koenig MR, Razo E, Mitzey A, Newman CM, Dudley DM, Breitbach ME, et al. Quantitative definition of neurobehavior, vision, hearingand brain volumes in macaques congenitally exposed to Zika virus. PLoS One. 2020 Oct 22;15(10):e0235877. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7580995/
15. Golden JW, Cline CR, Zeng X, Garrison AR, Carey BD, Mucker EM, et al. Human angiotensin-converting enzyme 2 transgenic mice infected with SARS-CoV-2 develop severe and fatal respiratory disease. JCI Insight. 2020 Oct 2;5(19):e142032. https://doi.org/10.1172/jci.insight.142032
16. Hewitt JA, Lutz C, Florence WC, Pitt MLM, Rao S, Rappaport J, et al. ACTIVating Resources for the COVID-19 Pandemic: In Vivo Models for Vaccines and Therapeutics. Cell Host Microbe. 2020 Oct 1;28(5):646-659. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7528903/
17. Alvarado GR, Pierson BC, Teemer ES, Gama HJ, Cole RD, Jang SS. Symptom Characterization and Outcomes of Sailors in Isolation After a COVID-19 Outbreak on a US Aircraft Carrier. JAMA Netw Open. 2020 Oct 1;3(10):e2020981. https://doi.org/10.1001/jamanetworkopen.2020.20981
18. Maljkovic Berry I, Rutvisuttinunt W, Voegtly LJ, Prieto K, Pollett S, Cer RZ, et al. A Department of Defense Laboratory Consortium Approach to Next Generation Sequencing and Bioinformatics Training for Infectious Disease Surveillance in Kenya. Front Genet. 2020 Sep 25;11:577563. https://doi.org/10.3389/fgene.2020.577563
19. Tremblay JM, Vazquez-Cintron E, Lam KH, Mukherjee J, Bedenice D, Ondeck CA, et al. Camelid VHH Antibodies that Neutralize Botulinum Neurotoxin Serotype E Intoxication or Protease Function. Toxins (Basel). 2020 Sep 24;12(10):611. https://www.mdpi.com/2072-6651/12/10/611/htm

20. Raabe V, Lai L, Xu Y, Huerta C, Wang D, Pouch SM, et al. The Immune Response to Eastern Equine Encephalitis Virus Acquired Through Organ Transplantation. Front Microbiol. 2020 Sep 24;11:561530. https://www.frontiersin.org/articles/10.3389/fmicb.2020.561530/full
21. Vial C, Whitaker A, Wilhelm J, Ovalle J, Perez R, Valdivieso F, et al. Comparison of VSV Pseudovirus and Focus Reduction Neutralization Assays for Measurement of Anti-Andes orthohantavirus Neutralizing Antibodies in Patient Samples. Front Cell Infect Microbiol. 2020 Sep 17;10:444. https://doi.org/10.3389/fcimb.2020.00444
22. Kuhn JH, Adkins S, Alioto D, Alkhovsky SV, Amarasinghe GK, Anthony SJ, et al. 2020 taxonomic update for phylum Negarnaviricota (Riboviria: Orthornavirae), including the large orders Bunyavirales and Mononegavirales. Arch Virol. 2020 Sep 4;165(12):3023-3072. https://doi.org/10.1007/s00705-020-04731-2
23. Iversen PL, Kane CD, Zeng X, Panchal RG, Warren TK, Radoshitzky SR, et al. Recent successes in therapeutics for Ebola virus disease: no time for complacency. Lancet Infect Dis. 2020 Sep;20(9):e231-e237. https://doi.org/10.1016/S1473-3099(20)30282-6
24. Alameh S, Bartolo G, O'Brien S, Henderson EA, Gonzalez LO, Hartmann S, et al. Anthraxtoxin component, Protective Antigen, protects insects from bacterial infections. PLoS Pathog. 2020 Aug 31;16(8):e1008836. https://dx.plos.org/10.1371/journal.ppat.1008836
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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: USAMRIID develops medical countermeasures, including candidate vaccines, diagnostic tests and drug or immunological therapies for biological agents, as well as performs 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 (HHS, Overlap), NIAID Category A pathogens, and simulants of HHS Select Agents and NIAID Category A pathogens.

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?
Air Force Research Laboratory (AFRL), 711 HPW

2. Where is it located (provide both address and geographical location)?
2510 Fifth Street, Wright-Patterson Air Force Base (Dayton), OH, 45433

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

BSL-1:	30 m^2
BSL-2:	30 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	60 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 6

(ii) Division of personnel:

Military	0
Civilian	6

(iii) Division of personnel by category:

Scientists	5
Engineers	0
Technicians	1
Administrative and support staff	0

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Molecular Biology, Chemical Biology, Polymer Science/Materials Science.

(v) Are contractor staff working in the facility? If so, provide an approximate number:
Yes Number: 4

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
U.S. Department of Defense (DOD) – Wholly

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

Research	$ 502,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 502,000

(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

(https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.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: Research program focuses on detection and bio-surveillance of Select Agent Toxin(s) for biodefense purposes. https://www.afrl.af.mil/711HPW/.

***Microorganisms and/or Toxins Studied*:** Simulant.

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?
Argonne National Laboratory (ANL)

2. Where is it located (provide both address and geographical location)?
9700 South Cass Ave., Lemont, IL 60439
(Located 41 km southwest of Chicago, Illinois)

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

BSL-2:	28 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	28 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 5

(ii) Division of personnel:

Military	0
Civilian	5

(iii) Division of personnel by category:

Scientists	5
Engineers	0
Technicians	0
Administrative and support staff	0

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Biotechnology.

(v) Are contractor staff working in the facility? If so, provide an approximate number:
No.

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
Internal: Laboratory Directed Research and Development (LDRD)

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

Research	$ 97,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 97,000

(viii) Briefly describe the publication policy of the facility:
As a U.S. Department of Energy facility, ANL 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. ANL 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 endeavours. ANL 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.):

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*:** The biological defense research conducted at Argonne National Laboratory includes research on printed biosensors aims to rapidly prototype highly sensitive, multiplexed, label-free biosensors that can effectively detect and persistently monitor biological agents.

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

***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?
Lawrence Livermore National Laboratory (LLNL)

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

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

BSL-2:	2,075.2 m^2
BSL-3:	59.5 m^2
BSL-4:	0 m^2
Total laboratory floor area:	2,134.7 m^2

During the reported calendar year, the LLNL BSL-2 laboratory space used for biodefense research and development underwent a physical remodel, was reapportioned, and corrected a numerical calculation error, resulting in a total increase of 252.7 m^2, of which 42.4 m^2 were due to a physical remodel.

4. The organizational structure of each facility:

(i) Total number of personnel: 66

(ii) Division of personnel:

Military:	0
Civilian:	66

(iii) Division of personnel by category:

Scientists	16
Engineers	11
Technicians	17
Administrative and support staff	22

(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) – Partly
U.S. Department of Energy (DOE)
U.S. Department of Homeland Security (DHS)
Internal (Laboratory Directed Research and Development)

U.S. Environmental Protection Agency (EPA)
Private Sector Companies
Universities

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

Research	$ 5,097,941
Development	$ 1,961,869
Test and evaluation	$ 29,512
Total	$ 7,089,322

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

As a U.S. 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 endeavours. 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. Desautels TA, Zemla A, Lau E, Franco M, Faissol D. Rapid in silico design of antibodies targeting SARS-CoV-2 using machine learning and supercomputing. BioRxiv. 2020 April 10. https://www.biorxiv.org/content/10.1101/2020.04.03.024885v1
2. He W, Evans AC, Rasley A, Bourguet F, Peters S, Kamrud KI. Cationic HDL mimetics enhance in vivo delivery of self-replicating mRNA. Nanomedicine. 2020 Feb. 24: 102154. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7487198
3. Kjærbølling I, Vesth T, Frisvad JC, Nybo JL,Theobald S, Kildgaard S, et al. A comparative genomics study of 23 Aspergillus species from section Flavi. Nat. Commun. 2020, 11(1), 1106. https://www.nature.com/articles/s41467-019-14051-y
4. Li Y, Chen C, Meshot ER, Buchsbaum SF, Herbert M, Zhu R. Autonomously Responsive Membranes for Chemical Warfare Protection. Adv. Funct. Mater. 2020, 30, 2000258. https://onlinelibrary.wiley.com/doi/full/10.1002/adfm.202000258
5. Reese KL, Rasley A, Avila JR, Jones AD, Frank M. Metabolic Profiling of Volatile Organic Compounds (VOCs) Emitted by the Pathogens Francisella tularensis and Bacillus anthracis in Liquid Culture. Sci Rep. 2020 Jun 9; 10(1):9333. https://pubmed.ncbi.nlm.nih.gov/32518249
6. Weilhammer DR, Dunkle AD, Boone T, Gilmore SF, Khemmani M, Peters, et al. Characterization of Bacillus anthracis Spore Proteins Using a Nanoscaffold Vaccine Platform. Front Immunol. 2020 Jun 23, 11, 1264. https://pubmed.ncbi.nlm.nih.gov/32714323

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, and 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/.

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

***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?
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
(Located approximately 72 km west of Santa Fe, New Mexico)

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

BSL-2:	454 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	454 m^2

During the reported calendar year, the LANL BSL-2 laboratory space used for biodefense research and development was reapportioned, resulting in a decrease of 79.2 m^2. The BSL-2 laboratory space was not physically remodeled.

4. The organizational structure of each facility:

(i) Total number of personnel: 19

(ii) Division of personnel:

Military	0
Civilian	19

(iii) Division of personnel by category:

Scientists	13
Engineers	0
Technicians	8
Administrative and support staff	0

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Analytical Biochemistry, Bacteriology, Bioinformatics, Biomedical Science, Biological Science, Biomedical Engineering, Cell Biology, Environmental Science, Genetics, Genomics, Medicine, Microbiology, Microscopy, Molecular Biology, Toxicology, Veterinary Medicine, Virology.

(v) Are contractor staff working in the facility? If so, provide an approximate number:
No.

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
U.S. Department of Defense (DOD) – Partly
U.S. Department of Energy (DOE)
Internal (Laboratory Directed Research and Development)
Other Government Agencies

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

Research	$ 1,725,000
Development	$ 950,000
Test and evaluation	$ 100,000
Total	$ 2,775,000

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

As a U.S. 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 endeavours. 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. Lillo AM, Velappan N, Kelliher J M, Watts A J, Merriman SP, Vuyisich G, et al., Development of Anti-Yersinia pestis Human Antibodies with Features Required for Diagnostic and Therapeutic Applications. ImmunoTargets and therapy. 2020, 9, 299–316. https://doi.org/10.2147/ITT.S267077
2. Micheva-Viteva S and Hong-Geller E. What can go wrong when applying immune modulation therapies to tackle persistent bacterial infections. J Cell Immunol. 2020, 2: 1-5. https://www.scientificarchives.com/article/what-can-go-wrong-when-applying-immune-modulation-therapies-to-target-persistent-bacterial-infections
3. Micheva-Viteva S, Shakya M, Adikari S, Gleasner CD, Mourant JR, Chain PS et al.. A gene cluster that encodes for histone deacetylase inhibitors contributes to bacterial persistence and antibiotic tolerance in Burkholderia thailandensis. mSystems. 2020, 5: 600609-19. https://msystems.asm.org/content/5/1/e00609-19
4. Murray AE, Avalon NE, Bishop L, Davenport KW, Delage E, Dichosa AEK, et al.. Uncovering the Core Microbiome and Distribution of Palmerolide in Synoicum adareanum Across the Anvers Island Archipelago Antarctica. Mar. Drugs. 2020, 18, 298. https://doi.org/10.3390/md18060298
5. Smith TJ, Xie G, Williamson CHD, Hill KK, Fernández RA, Sahl JW, et al.. Genomic Characterization of Newly Completed Genomes of Botulinum Neurotoxin-Producing Species from Argentina, Australia, and Africa. Genome Biology and Evolution. 2020 April 06, 12(3), 229-242. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7144720/

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*:** 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 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; study antibiotic potentials of radioisotopes; 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*:** Simulant of HHS Select Toxin.

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

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 2020:

Richland Campus: 902 Battelle Boulevard, Richland, Washington 99352.
(Located 235 km southwest from Spokane, WA and 327 km southeast from Seattle, WA.)

Sequim campus: 1529 West Sequim Bay Road, Sequim, Washington 98382.
(Located 489 km northwest from the PNNL Richland, WA campus and 106 km west from Seattle, WA.)

Seattle campus: 750 Republican Street South Lake Union Campus Seattle WA, 98109.
(Located on the South Lake Union Campus of the University of Washington in Seattle, WA.)
The Seattle campus facility is a new addition for the reported calendar year.

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

Richland campus:

BSL-2:	1,250 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	1,250 m^2

Sequim campus:

BSL-2:	29 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	29 m^2

Seattle campus:

BSL-2:	0 m^2
BSL-3:	21 m^2
BSL-4:	0 m^2
Total laboratory floor area:	21 m^2

Note: During the reported calendar year, PNNL BSL-2 laboratory space used for biodefense research and development was reapportioned, resulting in a decrease of 220 m^2 on the Richland campus and 80 m^2 on the Sequim campus. The BSL-2 laboratory space was not physically remodelled. Additionally, during the reported calendar year, PNNL began biodefense research and development work within the Seattle campus's BSL-3 laboratory space.

4. The organizational structure of each facility:

(i) Total number of personnel: 126
Richland, Sequim, & Seattle campuses (shared personnel)

(ii) Division of personnel:

Military	0
Civilian	126

(iii) Division of personnel by category:

Scientists	107
Engineers	2
Technicians	5
Admin and Support Staff	12

(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) - Partly
U.S. Department of Energy (DOE)
U.S. Department of Homeland Security (DHS)
U.S. Department of State (DOS)
U.S. Department of Health and Human Services (HHS)
Internal (Laboratory Directed Research and Development)
Other Government Agencies

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

Research	$ 9,336,734
Development	$ 2,720,054
Test and evaluation	$ 820,853
Total	$ 12,877,641

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

As a U.S. Department of Energy 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 endeavours. 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. Buchko GW, Abendroth J, Robinson JI, Phan IQ, Myler PJ, and Edwards TE. Structural diversity in the mycobacteria DUF3349 superfamily. Protein Science 29, no. 3:670-685. 2020 February 14. https://onlinelibrary.wiley.com/doi/full/10.1002/pro.3758
2. Burnet MC, Zamith-Miranda D, Heyman HM, Weitz KK, Bredeweg EL, Nosanchuk JD, et al.. Remodeling of the Histoplasma capsulatum membrane induced by monoclonal antibodies. Vaccines 8, no. 2:269. 2020 June 2. https://pubmed.ncbi.nlm.nih.gov/32498228/
3. Elnaas AR, Grice D, Han J, Feng Y, Di Capau A, Mak T, et al. Discovery of a Natural Product that Binds to the Mycobacterium tuberculosis Protein Rv1466 by Native Mass Spectrometry. Molecules 25, no. 10:2384. 2020 May 21. https://pubmed.ncbi.nlm.nih.gov/32455540/
4. Leier HC, Weinstein JB, Kyle JE, Lee JY, Bramer LM, Stratton KG, et al. A global lipid map defines a network essential for Zika virus replication. Nature Communications 11, no. 3652. 2020 July 21. https://www.nature.com/articles/s41467-020-17433-9
5. Nunn KL, Clair GC, Adkins JN, Engbrecht K, Fillmore T, Forney LJ. Amylases in the Human Vagina. mBio 5, no. 6: Article No. e00943-20. 2020 December 9. https://msphere.asm.org/content/5/6/e00943-20
6. O'Bryon I, Jenson SC, Merkley ED. Flying Blind, or Just Flying Under the Radar? The Underappreciated Power of De Novo Methods of Mass Spectrometric Peptide Identification. Protein Science 29, no. 9:1864-1878.2020 July 26. https://onlinelibrary.wiley.com/doi/full/10.1002/pro.3919
7. Ogden AJ, Bhatt JJ, Olson HM, Kintigh J, Kariuki S, Rudrabhatla SM, et al.. Phloem Exudate Protein Profiles during Drought and Recovery Reveal Abiotic Stress Responses in Tomato Vasculature. International Journal of Molecular Sciences 21, no. 12:4461. 21(12), 4461. 2020 June 23. https://www.mdpi.com/1422-0067/21/12/4461
8. Ogden AJ, Boukari W, Nava A, Lucinda N, Sunter G, Curtis WR, et al.. Characterization of Local and Systemic Impact of Whitefly (Bemisia tabaci) Feeding and Whitefly-Transmitted Tomato Mottle Virus Infection on Tomato Leaves by Comprehensive Proteomics. International Journal of Molecular Sciences 21, no. 19:7241. 21(19):7241. 2020 September 30. https://pubmed.ncbi.nlm.nih.gov/33008056/
9. Shaheen S, Barrett KF, Subramanian S, Arnold SL, Laureanti JA, Myler PJ, et al.. Solution structure for an Encephalitozoon cuniculi adrenodoxin-like protein in the oxidized state. Protein Science 29, no. 3:809-817 2020 January 8; https://onlinelibrary.wiley.com/doi/full/10.1002/pro.3818
10. Wan KH, Park S, Hess BM, Neff MJ, Booth BW and Celniker SE. Complete Genome Sequence of the Citrobacter freundii Type Strain. Microbiology Resource Announcements 9, no. 19: Article No. e00240-20. 2020 May 7. https://mra.asm.org/content/9/19/e00240-20
11. Xie Y, Feng Y, Di Capua A, Mak T, Buchko GW, Myler PJ, et al.. A Phenotarget Approach for Identifying an Alkaloid Interacting with the Tuberculosis Protein Rv1466. Marine Drugs 18, no. 3:149 2020 March 5. https://pubmed.ncbi.nlm.nih.gov/32150903/

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 including agent characterization (e.g., knock out experiments and investigation of infectious properties of agents) and the development of

[*] Including viruses and prions.

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 conducted.

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

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

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 (provide both address and geographical location)?
Personnel and budget were shared between two SNL campuses in 2020:

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:	1,152.45 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	1,152.45 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. The organizational structure of each facility:

(i)	**Total number of personnel:**	443
	New Mexico campus:	330
	California campus:	113
(ii)	**Division of personnel:**	
	Military	0
	Civilian	443
(iii)	**Division of personnel by category:**	
	Scientists	182
	Engineers	85
	Technicians	128
	Admin and Support Staff	48

(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, Veterinary Medicine, 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. Department of Defense (DOD) – Partly
U.S. Department of Energy (DOE)
U.S. Department of Health and Human Services (HHS)
U.S. Department of State (DOS)
U.S. Department of Veteran's Affairs (VA)
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	$ 10,206,815
Development	$ 2,000,000
Test and Evaluation	$ 9,891.848
Total	$ 22,098,663

(viii) Briefly describe the publication policy of the facility:
As a U.S. Department of Energy (DOE) facility, Sandia National Laboratories (SNL) 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 endeavours. 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. Armijo LM, Wawrzyniec SJ, Kopciuch M, Brandt YI, Rivera AC, Withers NJ, et al. Antibacterial activity of iron oxide, iron nitride, and tobramycin conjugated nanoparticles against Pseudomonas aeruginosa biofilms. J Nanobiotechnology. 2020, 18(1), 35. Epub 2020/02/20. doi: 10.1186/s12951-

020-0588-6. PubMed PMID: 32070354; PubMed Central PMCID: PMCPMC7029462. https://doi.org/10.1186/s12951-020-0588-6
2. Celina MC, Martinez E, Omana MA, Sanchez A, Wiemann D, Tezak M, et al. Extended use of face masks during the COVID-19 pandemic - Thermal conditioning and spray-on surface disinfection. Polymer Degradation and Stability. 2020, 79. doi: 10.1016/j.polymdegradstab.2020.109251. PubMed PMID: WOS:000564495800015. https://doi.org/10.1016/j.polymdegradstab.2020.109251
3. Doud DFR, Bowers RM, Schulz F, De Raad M, Deng K, Tarver A, et al. Function-driven single-cell genomics uncovers cellulose-degrading bacteria from the rare biosphere. Isme j. 2020, 14(3), 659-75. Epub 2019/11/23. doi: 10.1038/s41396-019-0557-y. PubMed PMID: 31754206; PubMed Central PMCID: PMCPMC7031533. https://doi.org/10.1038/s41396-019-0557-y
4. Fies WA, First JT, Dugger JW, Doucet M, Browning JF, Webb LJ. Quantifying the Extent of Hydration of a Surface-Bound Peptide Using Neutron Reflectometry. Langmuir. 2020, 36(2), 637-49. doi: 10.1021/acs.langmuir.9b02559. PubMed PMID: WOS:000509420200019. https://doi.org/10.1021/acs.langmuir.9b02559
5. Hirakawa MP, Krishnakumar R, Timlin JA, Carney JP, Butler KS. Gene editing and CRISPR in the clinic: current and future perspectives. Biosci Rep. 2020, 40(4). Epub 2020/03/25. doi: 10.1042/bsr20200127. PubMed PMID: 32207531; PubMed Central PMCID: PMCPMC7146048. https://doi.org/10.1042/bsr20200127
6. Liu ZL, Clausen JR, Wagner JL, Butler KS, Bolintineanu DS, Lechman JB, et al. Heterogeneous partition of cellular blood-borne nanoparticles through microvascular bifurcations. Physical Review E. 2020;102(1). doi: 10.1103/PhysRevE.102.013310. PubMed PMID: WOS:000552966100007. https://doi.org/10.1103/PhysRevE.102.013310
7. Mageeney CM, Mohammed HT, Dies M, Anbari S, Cudkevich N, Chen YY, et al. Mycobacterium Phage Butters-Encoded Proteins Contribute to Host Defense against Viral Attack. Msystems. 2020, 5(5). doi: 10.1128/mSystems.00534-20. PubMed PMID: WOS:000579368300034. https://doi.org/10.1128/mSystems.00534-20
8. Mageeney CM, Sinha A, Mosesso RA, Medlin DL, Lau BY, Rokes AB, et al. Computational Basis for On-Demand Production of Diversified Therapeutic Phage Cocktails. mSystems. 2020, 5(4). Epub 2020/08/14. doi: 10.1128/mSystems.00659-20. PubMed PMID: 32788409; PubMed Central PMCID: PMCPMC7426155. https://doi.org/10.1128/mSystems.00659-20
9. Noureddine A, Maestas-Olguin A, Saada EA, LaBauve AE, Agola JO, Baty KE, et al. Engineering of monosized lipid-coated mesoporous silica nanoparticles for CRISPR delivery. Acta Biomater. 2020, 114, 358-68. Epub 2020/07/24. doi: 10.1016/j.actbio.2020.07.027. PubMed PMID: 32702530. https://doi.org/10.1016/j.actbio.2020.07.027

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: SNL is involved in biodefense activities 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 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 Pathogen.

***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?
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 (m^2):

BSL-2	568 m^2
BSL-3	0 m^2
BSL-4	0m^2
Total laboratory floor area	568 m^2

4. The organizational structure of each facility.

(i) Total number of personnel 14

(ii) Division of personnel:

Military	0
Civilian	14

(iii) Division of personnel by category:

Scientists	14
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: 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 Health and Human Services (HHS)

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

Research	$ 1,620,244.80
Development	$ 1,209,202.00
Test and evaluation	$ 1,888,991.20
Total	$ 4,718,438.00

(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. Kalb SR, Baudys J, Kiernan K, Wang D, Becher F, and Barr JR. Proposed BoNT/A and /B Peptide Substrates Cannot Detect Multiple Subtypes in the Endopep-MS Assay. J Anal Toxicol. 2020, Mar 7; 33(2):173-179. https://pubmed.ncbi.nlm.nih.gov/31287544/
2. Drigo I, Tonon E, Pascoletti S, Anniballi F, Kalb SR, Bano L. Detection of Active BoNT/C and /D by EndoPep-MS Using MALDI Biotyper Instrument and Comparison with the Mouse Test Bioassay. Toxins. 2020, Dec 24; 13(1):E10. https://pubmed.ncbi.nlm.nih.gov/33374240/

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

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: No outdoor studies performed.

* Including viruses and prions.

National biological defence research and development programmes: Facilities

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 (include both address and geographical location)?
1600 Clifton Road N.E., Atlanta, Georgia 30329

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

BSL-2	385.75 m^2
BSL-3	1220 m^2
BSL-4	533 m^2
Total laboratory floor area	2138.75 m^2

During the reported calendar year, the DDID BSL-2 laboratory space used for biodefense research and development was reapportioned, resulting in a decrease of 37.25 m^2. The BSL-2 laboratory space was not physically remodeled.

4. The organizational structure of each facility.

(ii) Total number of personnel: 202

(ii) Division of personnel:

Military	9
Civilian	193

(iii) Division of personnel by category:

Scientists	176
Engineers	0
Technicians	17
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: 47

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
U.S. Department of Health and Human Services (HHS)
U.S. Department of Homeland Security (DHS)
U.S. Department of Defense (DOD) - Partly
U.S. Agency for International Development (USAID)

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

Research	$ 11,228,225
Development	$ 4,802,048
Test and evaluation	$ 6,897,667
Total	$ 22,927,940

(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. Aceng JR, Ario AR, Muruta AN, Makumbi I, et al. Uganda's experience in Ebola virus disease outbreak preparedness, 2018-2019. Globalization and health. 2020;16(1):24. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7081536/
2. Ackelsberg J, Liddicoat A, Burke T, Szymczak WA, et al. Brucella Exposure Risk Events in 10 Clinical Laboratories, New York City, USA, 2015 to 2017. J Clin Microbiol. 2020;58(2). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6989065/
3. Amman BR, Bird BH, Bakarr IA, Bangura J, et al. Isolation of Angola-like Marburg virus from Egyptian rousette bats from West Africa. Nat Commun. 2020;11(1):510. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6981187/
4. Belser JA, Eckert AM, Huynh T, Gary JM, Ritter JM, Tumpey TM, Maines TR. 2020. A Guide for the Use of the Ferret Model for Influenza Virus Infection. Am J Pathol 190:11-24. https://www.ncbi.nlm.nih.gov/pubmed/31654637
5. Belser JA, Pulit-Penaloza JA, Maines TR. 2020. Ferreting Out Influenza Virus Pathogenicity and Transmissibility: Past and Future Risk Assessments in the Ferret Model. Cold Spring Harb Perspect Med 10. https://www.ncbi.nlm.nih.gov/pubmed/31871233
6. Bower W, Schiffer J, Atmar R, Keitel W, Friedlander A, Liu L, Yu Y, Stephens D, Quinn C, Hendricks K. Use of Anthrax Vaccine in the United States: Recommendations of the Advisory Committee on Immunization Practices, 2019. MMWR 68(No. RR-4);1-14. DOI: http://dx.doi.org/10.15585/mmwr.rr6804a1
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8. Chen LM, Donis RO, Suarez DL, Wentworth DE, Webby R, Engelhardt OG, Swayne DE. 2020. Biosafety risk assessment for production of candidate vaccine viruses to protect humans from zoonotic highly pathogenic avian influenza viruses. Influenza Other Respir Viruses 14:215-225. https://www.ncbi.nlm.nih.gov/pubmed/31659871
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6. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

***Objectives*:** Activities 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, conducting molecular and antigenic characterization of organisms, determining pathogenicity and virulence of infectious agents, evaluation of antimicrobial susceptibility, research on potential therapeutics, determining the natural history of infectious organisms, and conducting epidemiologic studies and surveillance for diseases.

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

***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?
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 (m^2):

BSL-2	0 m^2
BSL-3	385 m^2
BSL-4	0 m^2
Total laboratory floor area	385 m^2

During the reported calendar year, the DVBD BSL-3 laboratory space used for biodefense research and development was reapportioned, resulting in a decrease of 36 m^2. The BSL-3 laboratory space was not physically remodeled.

4. The organizational structure of each facility.

(i)	**Total number of personnel**	31
(ii)	**Division of personnel**:	
	Military	0
	Civilian	31
(iii)	**Division of personnel by category**:	
	Scientists	5
	Engineers	0
	Technicians	8
	Administrative and support staff	18

(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: 2

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
U.S. Department of Health & Human Services (HHS)

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

Research	$ 524,018

Development	$ 0
Test and evaluation	$ 0
Total	$ 524,018

(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. Bai Y, Motin V, Enscore RE, Osikowicz L, Rosales Rizzo M, Hojgaard A, Kosoy M, Eisen RJ. Pentaplex real-time PCR for differential detection of Yersinia pestis and Y. pseudotuberculosis and application for testing fleas collected during plague epizootics. Microbiology open. 2020 Oct;9(10):e1105. doi: 10.1002/mbo3.1105. Epub 2020 Aug 12.PMID: 32783386. https://pubmed.ncbi.nlm.nih.gov/32783386/
2. Dietrich EA, Kingry LC, Kugeler KJ, Levy C, Yaglom H, Young JW, Mead PS, Petersen JM. Francisella opportunistica sp. nov., isolated from human blood and cerebrospinal fluid. Int J Syst Evol Microbiol. 2020 Feb;70(2):1145-1151. doi:10.1099/ijsem.0.003891.PMID: 31860434. https://pubmed.ncbi.nlm.nih.gov/31860434/
3. Eisen RJ, Atiku LA, Mpanga JT, Enscore RE, Acayo S, Kaggwa J, Yockey BM, Apangu T, Kugeler KJ, Mead PS. An Evaluation of the Flea Index as a Predictor of Plague Epizootics in the West Nile Region of Uganda. J Med Entomol. 2020 May 4;57(3):893-900. doi: 10.1093/jme/tjz248.PMID: 31891169. https://pubmed.ncbi.nlm.nih.gov/31891169/

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

***Objectives*:** CDC's Division of Vector Borne Diseases (DVBD) possesses many of the select agents that are on the U.S. Department of Health and Human Services (HHS) and Department of Agriculture (USDA) 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 performed.

* Including viruses and prions.

National biological defence research and development programmes: Facilities

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 (m^2):

BSL-2	1361 m^2
BSL-3	407 m^2
BSL-4	1145 m^2
Total laboratory floor area	2913 m^2

4. The organizational structure of each facility.

(i) Total number of personnel 127

(ii) Division of personnel:

Military	0
Civilian	127

(iii) Division of personnel by category:

Scientists	73
Engineers	0
Technicians	47
Administrative and support staff	7

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Aerobiology, Animal Science, Bacteriology, Biochemistry, Biological Science, Biomedical Science, Cell Biology, Ecology, 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: 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?
U.S. Department of Health and Human Services (HHS)
U.S. Department of Defense (DOD)

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

Research	$ 30,112,007
Development	$ 0
Test and evaluation	$ 0
Total	$ 30,112,007

(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. Adney DR, Clancy CS, Bowen RA, Munster VJ. Camelid Inoculation With Middle East Respiratory Syndrome Coronavirus: Experimental Models of Reservoir Host Infection. Viruses. 2020;12(12). Epub 2020/12/04. https://www.ncbi.nlm.nih.gov/pubmed/33266124
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3. Artikis E, Roy A, Verli H, Cordeiro Y, Caughey B. Accommodation of In-Register N-Linked Glycans on Prion Protein Amyloid Cores. ACS Chem Neurosci. 2020;11(24):4092-7. Epub 2020/11/13. https://www.ncbi.nlm.nih.gov/pubmed/33180459
4. Asher DM, Belay E, Bigio E, Brandner S, Brubaker SA, Caughey B, et al. Risk of Transmissibility From Neurodegenerative Disease-Associated Proteins: Experimental Knowns and Unknowns. J Neuropathol Exp Neurol. 2020;79(11):1141-6. Epub 2020/10/02. https://www.ncbi.nlm.nih.gov/pubmed/33000167
5. Avanzato VA, Matson MJ, Seifert SN, Pryce R, Williamson BN, Anzick SL, et al. Case Study: Prolonged Infectious SARS-CoV-2 Shedding from an Asymptomatic Immunocompromised Individual with Cancer. Cell. 2020;183(7):1901-12 e9. Epub 2020/11/30. https://www.ncbi.nlm.nih.gov/pubmed/33248470
6. Bhatia B, Feldmann H, Marzi A. Kyasanur Forest Disease and Alkhurma Hemorrhagic Fever Virus-Two Neglected Zoonotic Pathogens. Microorganisms. 2020;8(9). Epub 2020/09/17. https://www.ncbi.nlm.nih.gov/pubmed/32932653
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8. Bokelmann M, Edenborough K, Hetzelt N, Kreher P, Lander A, Nitsche A, et al. Utility of primary cells to examine NPC1 receptor expression in Mops condylurus, a potential Ebola virus reservoir. PLoS Negl Trop Dis. 2020;14(1):e0007952. Epub 2020/01/22. https://www.ncbi.nlm.nih.gov/pubmed/31961874
9. Bold D, van Doremalen N, Myagmarsuren O, Zayat B, Munster VJ, Richt JA. Middle East Respiratory Syndrome-Coronavirus Seropositive Bactrian Camels, Mongolia. Vector Borne Zoonotic Dis. 2020. Epub 2020/11/17. https://www.ncbi.nlm.nih.gov/pubmed/33197370
10. Bosio CF, Jarrett CO, Scott DP, Fintzi J, Hinnebusch BJ. Comparison of the transmission efficiency and plague progression dynamics associated with two mechanisms by which fleas transmit Yersinia pestis. PLoS Pathog. 2020;16(12):e1009092. Epub 2020/12/08. https://www.ncbi.nlm.nih.gov/pubmed/33284863
11. Boyle WK, Hall LS, Armstrong AA, Dulebohn DP, Samuels DS, Gherardini FC, et al. Establishment of an in vitro RNA polymerase transcription system: a new tool to study transcriptional activation in Borrelia burgdorferi. Sci Rep. 2020;10(1):8246. Epub 2020/05/20. https://www.ncbi.nlm.nih.gov/pubmed/32427963

12. Calvignac-Spencer S, Kouadio L, Couacy-Hymann E, Sogoba N, Rosenke K, Davison AJ, et al. Multiple DNA viruses identified in multimammate mouse (Mastomys natalensis) populations from across regions of sub-Saharan Africa. Arch Virol. 2020;165(10):2291-9. Epub 2020/08/06. https://www.ncbi.nlm.nih.gov/pubmed/32754877
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106. Williamson BN, Feldmann F, Schwarz B, Meade-White K, Porter DP, Schulz J, et al. Clinical benefit of remdesivir in rhesus macaques infected with SARS-CoV-2. Nature. 2020;585(7824):273-6. Epub 2020/06/10. https://www.ncbi.nlm.nih.gov/pubmed/32516797
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108. Yinda CK, Port JR, Bushmaker T, Owusu IO, Avanzato VA, Fischer RJ, et al. K18-hACE2 mice develop respiratory disease resembling severe COVID-19. bioRxiv. 2020. Epub 2020/08/18. https://www.ncbi.nlm.nih.gov/pubmed/32803199
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111. Zhu L, Olsen RJ, Beres SB, Saavedra MO, Kubiak SL, Cantu CC, et al. Streptococcus pyogenes genes that promote pharyngitis in primates. JCI Insight. 2020;5(11). Epub 2020/06/05. https://www.ncbi.nlm.nih.gov/pubmed/32493846

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

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 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?
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 (m^2):

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

4. The organizational structure of each facility.

(i) Total number of personnel 97

(ii) Division of personnel:

Military	0
Civilian	97

(iii) Division of personnel by category:

Scientists	27
Engineers	2
Technicians	61
Administrative and support staff	7

(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: 91

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
U.S. Department of Health and Human Services (HHS)

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

Research	$ 26,833,918
Development	$ 0
Test and evaluation	$ 0
Total	$ 26,833,918

(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. Arizti-Sanz J, Freije CA, Stanton AC, Boehm CK, Petros BA, Siddiqui S, et al. Integrated sample inactivation, amplification, and Cas13-based detection of SARS-CoV-2. bioRxiv. 2020. Epub 2020/06/09. https://www.ncbi.nlm.nih.gov/pubmed/32511415
2. Arizti-Sanz J, Freije CA, Stanton AC, Petros BA, Boehm CK, Siddiqui S, et al. Streamlined inactivation, amplification, and Cas13-based detection of SARS-CoV-2. Nat Commun. 2020;11(1):5921. Epub 2020/11/22. https://www.ncbi.nlm.nih.gov/pubmed/33219225
3. Barnes KG, Lachenauer AE, Nitido A, Siddiqui S, Gross R, Beitzel B, et al. Deployable CRISPR-Cas13a diagnostic tools to detect and report Ebola and Lassa virus cases in real-time. Nat Commun. 2020;11(1):4131. Epub 2020/08/19. https://www.ncbi.nlm.nih.gov/pubmed/32807807
4. Bedford J, Enria D, Giesecke J, Heymann DL, Ihekweazu C, Kobinger G, et al. COVID-19: towards controlling of a pandemic. Lancet. 2020;395(10229):1015-8. Epub 2020/03/21. https://www.ncbi.nlm.nih.gov/pubmed/32197103
5. Bedford J, Enria D, Giesecke J, Heymann DL, Ihekweazu C, Kobinger G, et al. Living with the COVID-19 pandemic: act now with the tools we have. Lancet. 2020. Epub 2020/10/12.. https://www.ncbi.nlm.nih.gov/pubmed/33038947
6. Beigel JH, Manosuthi W, Beeler J, Bao Y, Hoppers M, Ruxrungtham K, et al. Effect of Oral Oseltamivir on Virological Outcomes in Low-risk Adults With Influenza: A Randomized Clinical Trial. Clin Infect Dis. 2020;70(11):2317-24. Epub 2019/09/22. https://www.ncbi.nlm.nih.gov/pubmed/31541242
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9. Cai Y, Iwasaki M, Motooka D, Liu DX, Yu S, Cooper K, et al. A Lassa Virus Live-Attenuated Vaccine Candidate Based on Rearrangement of the Intergenic Region. mBio. 2020;11(2). Epub 2020/03/27. https://www.ncbi.nlm.nih.gov/pubmed/32209677
10. Cai Y, Ye C, Cheng B, Nogales A, Iwasaki M, Yu S, et al. A Lassa Fever Live-Attenuated Vaccine Based on Codon Deoptimization of the Viral Glycoprotein Gene. mBio. 2020;11(1). Epub 2020/02/27. https://www.ncbi.nlm.nih.gov/pubmed/32098811
11. Chen P, Chen H, Moussa M, Cheng J, Li T, Qin J, et al. Recombinant Human Interleukin-15 and Anti-PD-L1 Combination Therapy Expands a CXCR3+PD1-/low CD8 T-Cell Subset in Simian Immunodeficiency Virus-Infected Rhesus Macaques. J Infect Dis. 2020;221(4):523-33. Epub 2019/09/29. https://www.ncbi.nlm.nih.gov/pubmed/31562760
12. Cooper TK, Byrum RA, Cooper K, DeWald LE, Aiosa NM, Feuerstein IM, et al. Cranial Vena Cava Syndrome in Guinea Pigs with Chronic Jugular Vein Catheters. Comp Med. 2020;70(1):87-92. Epub 2020/01/18. https://www.ncbi.nlm.nih.gov/pubmed/31948513
13. Cooper TK, Logue J, Liu DX, Perry DL, Hart RJ, Hischak AMW, et al. Filoviruses Infect Rhesus Macaque Synoviocytes in Vivo and Primary Human Synoviocytes in Vitro. Am J Pathol. 2020;190(9):1867-80. Epub 2020/06/02. https://www.ncbi.nlm.nih.gov/pubmed/32479821

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21. Imamichi H, Smith M, Adelsberger JW, Izumi T, Scrimieri F, Sherman BT, et al. Defective HIV-1 proviruses produce viral proteins. Proc Natl Acad Sci U S A. 2020;117(7):3704-10. Epub 2020/02/08.. https://www.ncbi.nlm.nih.gov/pubmed/32029589
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24. Lane HC, Fauci AS. Research in the Context of a Pandemic. N Engl J Med. 2020. Epub 2020/07/18. https://www.ncbi.nlm.nih.gov/pubmed/32678528
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26. Lee JH, Hammoud DA, Cong Y, Huzella LM, Castro MA, Solomon J, et al. The Use of Large-Particle Aerosol Exposure to Nipah Virus to Mimic Human Neurological Disease Manifestations in the African Green Monkey. J Infect Dis. 2020;221(Supplement_4):S419-S30. Epub 2019/11/07.https://www.ncbi.nlm.nih.gov/pubmed/31687756
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Guidelines Panel. Ann Intern Med. 2020. Epub 2020/09/26. https://www.ncbi.nlm.nih.gov/pubmed/32976026
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33. Solomon J, Aiosa N, Bradley D, Castro MA, Reza S, Bartos C, et al. Atlas-based liver segmentation for nonhuman primate research. Int J Comput Assist Radiol Surg. 2020;15(10):1631-8. Epub 2020/07/11. https://www.ncbi.nlm.nih.gov/pubmed/32648161
34. Speranza E, Caballero I, Honko AN, Johnson JC, Bohannon JK, Evans DeWald L, et al. Previremic Identification of Ebola or Marburg Virus Infection Using Integrated Host-Transcriptome and Viral Genome Detection. mBio. 2020;11(3). Epub 2020/06/18. https://www.ncbi.nlm.nih.gov/pubmed/32546624
35. Weston S, Baracco L, Keller C, Matthews K, McGrath ME, Logue J, et al. The SKI complex is a broad-spectrum, host-directed antiviral drug target for coronaviruses, influenza, and filoviruses. Proc Natl Acad Sci U S A. 2020;117(48):30687-98. Epub 2020/11/14. https://www.ncbi.nlm.nih.gov/pubmed/33184176
36. Winchester NE, Maldarelli F, Mejia Y, Dee N, Dewar R, Laidlaw E, et al. Eight-day Inpatient Directly Observed Therapy for Antiretroviral Therapy (ART) Failure: A Tool For Preventing Unnecessary ART Changes and Optimizing Adherence Support. Clin Infect Dis. 2020;70(6):1222-5. Epub 2019/07/13. https://www.ncbi.nlm.nih.gov/pubmed/31298273

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

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

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap) and Toxin (HHS), 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?
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 (m^2):

BSL-2	2725 m^2
BSL-3	1356 m^2
BSL-4	0 m^2
Total laboratory floor area	4081 m^2

4. The organizational structure of each facility.

(i) Total number of personnel 120

(ii) Division of personnel:

Military	0
Civilian	120

(iii) Division of personnel by category:

Scientists	72
Engineers	0
Technicians	42
Administrative and support staff	6

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Animal Science, Bacteriology, Biological Science, Biomedical Science, Cell Biology, Chemistry, Genetics, Immunology, Medicine, Microbiology, Molecular Biology, Parasitology, Pathology, Toxicology, Veterinary Medicine, Virology.

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 32

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
U.S. Department of Health and Human Services (HHS)

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

Research	$ 32,789,733
Development	$ 0
Test and evaluation	$ 0
Total	$ 32,789,733

(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 from

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. Akkina R, Barber DL, Bility MT, Bissig KD, Burwitz BJ, Eichelberg K, et al. Small Animal Models for Human Immunodeficiency Virus (HIV), Hepatitis B, and Tuberculosis: Proceedings of an NIAID Workshop. Curr HIV Res. 2020;18(1):19-28. Epub 2019/12/25. https://www.ncbi.nlm.nih.gov/pubmed/31870268
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5. Chakraborty S, Edwards K, Buzzanco AS, Memoli MJ, Sherwood R, Mallajosyula V, et al. Symptomatic SARS-CoV-2 infections display specific IgG Fc structures. medRxiv. 2020. Epub 2020/06/09. https://www.ncbi.nlm.nih.gov/pubmed/32511463
6. Chakraborty S, Gonzalez J, Edwards K, Mallajosyula V, Buzzanco AS, Sherwood R, et al. Proinflammatory IgG Fc structures in patients with severe COVID-19. Nat Immunol. 2021;22(1):67-73. Epub 2020/11/11. https://www.ncbi.nlm.nih.gov/pubmed/33169014
7. Chen GL, Coates EE, Plummer SH, Carter CA, Berkowitz N, Conan-Cibotti M, et al. Effect of a Chikungunya Virus-Like Particle Vaccine on Safety and Tolerability Outcomes: A Randomized Clinical Trial. JAMA. 2020;323(14):1369-77. Epub 2020/04/15. https://www.ncbi.nlm.nih.gov/pubmed/32286643
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9. Clemens E, Angeletti D, Holbrook BC, Kanekiyo M, Jorgensen MJ, Graham BS, et al. Influenza-infected newborn and adult monkeys exhibit a strong primary antibody response to hemagglutinin stem. JCI Insight. 2020;5(5). Epub 2020/02/23. https://www.ncbi.nlm.nih.gov/pubmed/32078584
10. Clemens EA, Holbrook BC, Kanekiyo M, Yewdell JW, Graham BS, Alexander-Miller MA. An R848 conjugated influenza virus vaccine elicits robust IgG to hemagglutinin stem in a newborn nonhuman primate model. J Infect Dis. 2020. Epub 2020/11/28. https://www.ncbi.nlm.nih.gov/pubmed/33245745
11. Costa DL, Amaral EP, Andrade BB, Sher A. Modulation of Inflammation and Immune Responses by Heme Oxygenase-1: Implications for Infection with Intracellular Pathogens. Antioxidants (Basel). 2020;9(12). Epub 2020/12/04. https://www.ncbi.nlm.nih.gov/pubmed/33266044
12. Costa DL, Amaral EP, Namasivayam S, Mittereder LR, Fisher L, Bonfim CC, et al. Heme oxygenase-1 inhibition promotes IFNgamma- and NOS2-mediated control of Mycobacterium tuberculosis infection. Mucosal Immunol. 2021;14(1):253-66. Epub 2020/08/31. https://www.ncbi.nlm.nih.gov/pubmed/32862202
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18. Dersh D, Phelan JD, Gumina ME, Wang B, Arbuckle JH, Holly J, et al. Genome-wide Screens Identify Lineage- and Tumor-Specific Genes Modulating MHC-I- and MHC-II-Restricted Immunosurveillance of Human Lymphomas. Immunity. 2021;54(1):116-31 e10. Epub 2020/12/04. https://www.ncbi.nlm.nih.gov/pubmed/33271120
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21. Duggan S, Laabei M, Alnahari AA, O'Brien EC, Lacey KA, Bacon L, et al. A Small Membrane Stabilizing Protein Critical to the Pathogenicity of Staphylococcus aureus. Infect Immun. 2020;88(9). Epub 2020/06/24. https://www.ncbi.nlm.nih.gov/pubmed/32571989
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24. Fox D, Mathur A, Xue Y, Liu Y, Tan WH, Feng S, et al. Bacillus cereus non-haemolytic enterotoxin activates the NLRP3 inflammasome. Nat Commun. 2020;11(1):760. Epub 2020/02/08. https://www.ncbi.nlm.nih.gov/pubmed/32029733
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5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

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) and Toxin (HHS), NIAID Category A pathogen.

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?
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 (m^2):

BSL-2	104 m^2
BSL-3	0 m^2
BSL-4	0 m^2
Total laboratory floor area	104 m^2

4. The organizational structure of each facility.

(i) Total number of personnel 19

(ii) Division of personnel:

Military	0
Civilian	19

(iii) Division of personnel by category:

Scientists	18
Engineers	0
Technicians	0
Administrative and support staff	1

(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?
U.S. Department of Health and Human Services (HHS)

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

Research	$ 2,878,100
Development	$ 0
Test and evaluation	$ 0
Total	$ 2,878,100

(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. Corbett KS, Flynn B, Foulds KE, Francica JR, Boyoglu-Barnum S, Werner AP, et al. Evaluation of the mRNA-1273 Vaccine against SARS-CoV-2 in Nonhuman Primates. N Engl J Med. 2020;383(16):1544-55. Epub 2020/07/30. https://www.ncbi.nlm.nih.gov/pubmed/32722908
2. Stringer LD, Sullivan NJ, White R, Jimenez-Perez A, Furlong J, Kean JM, et al. Mazes to Study the Effects of Spatial Complexity, Predation and Population Density on Mate Finding. Insects. 2020;11(4). Epub 2020/04/25. https://www.ncbi.nlm.nih.gov/pubmed/32326018
3. Zhang B, Chao CW, Tsybovsky Y, Abiona OM, Hutchinson GB, Moliva JI, et al. A Versatile Platform to Incorporate Viral Trimeric Antigens into Self-Assembling Nanoparticle Immunogens. bioRxiv. 2020. Epub 2020/07/18. https://www.ncbi.nlm.nih.gov/pubmed/32676596
4. Zhang B, Chao CW, Tsybovsky Y, Abiona OM, Hutchinson GB, Moliva JI, et al. A platform incorporating trimeric antigens into self-assembling nanoparticles reveals SARS-CoV-2-spike nanoparticles to elicit substantially higher neutralizing responses than spike alone. Sci Rep. 2020;10(1):18149. Epub 2020/10/25. https://www.ncbi.nlm.nih.gov/pubmed/33097791
5. Zhou T, Teng IT, Olia AS, Cerutti G, Gorman J, Nazzari A, et al. Structure-Based Design with Tag-Based Purification and In-Process Biotinylation Enable Streamlined Development of SARS-CoV-2 Spike Molecular Probes. SSRN. 2020:3639618. Epub 2020/08/04. https://www.ncbi.nlm.nih.gov/pubmed/32742241
6. Zhou T, Teng IT, Olia AS, Cerutti G, Gorman J, Nazzari A, et al. Structure-Based Design with Tag-Based Purification and In-Process Biotinylation Enable Streamlined Development of SARS-CoV-2 Spike Molecular Probes. bioRxiv. 2020. Epub 2020/07/01. https://www.ncbi.nlm.nih.gov/pubmed/32596696
7. Zhou T, Teng IT, Olia AS, Cerutti G, Gorman J, Nazzari A, et al. Structure-Based Design with Tag-Based Purification and In-Process Biotinylation Enable Streamlined Development of SARS-CoV-2 Spike Molecular Probes. Cell Rep. 2020;33(4):108322. Epub 2020/10/23. https://www.ncbi.nlm.nih.gov/pubmed/33091382

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

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 performed.

[*] Including viruse and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Food and Drug Administration (FDA) White Oak Campus

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 (m^2):

BSL-2	1072 m^2
BSL-3	184 m^2
BSL-4	0 m^2
Total laboratory floor area	1256 m^2

4. The organizational structure of each facility.

(i) Total number of personnel 57

(ii) Division of personnel:

Military	0
Civilian	57

(iii) Division of personnel by category:

Scientists	48
Engineers	0
Technicians	0
Administrative and support staff	9

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

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 16

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
U.S. Department of Health and Human Services (HHS)

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

Research	$ 1,158,539.50
Development	$ 0.00
Test and evaluation	$ 0.00
Total	$ 1,158,539.50

(viii) Briefly describe the publication policy of the facility:
FDA staff are encouraged to publish their research results in peer-reviewed scientific journals. The FDA 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. Each medical product Center may also have an additional review and clearance policy.

- FDA review and clearance policy: https://www.fda.gov/media/80061/download
- CDER review and clearance policy: https://www.fda.gov/media/72538/download
- 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. Bradford MK, Elkins KL. Immune lymphocytes halt replication of Francisella tularensis LVS within the cytoplasm of infected macrophages. Sci Rep 2020 Jul 21;10(1):12023. https://pubmed.ncbi.nlm.nih.gov/32694562/
2. Buszko M, Park JH, Verthelyi D, Sen R, Young HA, Rosenberg AS. The dynamic changes in cytokine responses in COVID-19: a snapshot of the current state of knowledge. Nat Immunol. 2020;21(10):1146-51. https://www.nature.com/articles/s41590-020-0779-1
3. De Pascalis R, Rossi AP, Mittereder L, Takeda K, Akue A, Kurtz SL, Elkins KL. Production of IFN-gamma by splenic dendritic cells during innate immune responses against Francisella tularensis LVS depends on MyD88, but not TLR2, TLR4, or TLR9. PLoS One 2020 Aug 3;15(8):e0237034. https://pubmed.ncbi.nlm.nih.gov/32745117/
4. Ireland DDC, Manangeeswaran M, Lewkowicz AP, Engel K, Clark SM, Laniyan A, et al. Long-term persistence of infectious Zika virus: Inflammation and behavioral sequela in mice. PLOS Pathogens. 2020;16(12):e1008689. https://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.1008689
5. Manangeeswaran M, Lewkowicz AP, Israely T, Ireland DDC, Verthelyi D. CpG Oligonucleotides Protect Mice From Alphavirus Encephalitis: Role of NK Cells, Interferons, and TNF. Frontiers in Immunology. 2020;11:237. https://www.frontiersin.org/articles/10.3389/fimmu.2020.00237/full
6. Rice HM, Rossi AP, Bradford MK, Elkins KL, De Pascalis R. rM-CSF efficiently replaces L929 in generating mouse and rat bone marrow-derived macrophages for in vitro functional studies of immunity to intracellular bacteria. J Immunol Methods 2020 Feb;477:112693. https://pubmed.ncbi.nlm.nih.gov/31689421/
7. Yu H, Yang A, Derrick S, Mak JYW, Liu L, Fairlie DP, Cowley S. Artificially induced MAIT cells inhibit M. bovis BCG but not M. tuberculosis during in vivo pulmonary infection. Sci Rep 2020 Aug 12;10(1):13579. https://www.nature.com/articles/s41598-020-70615-9

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

Objectives: This facility includes the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). 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. Biodefense research is focused on 1) identifying correlates of protection to predict vaccine safety and

[*] Including viruse and prions.

effectiveness, 2) developing methods to assess vaccine potency, and 3) improving approaches to enhance the availability of vaccines.

The Center for Drug Evaluation and Research (CDER) activities include the development of animal models of viral infections including Dengue virus for the purpose of understanding host-pathogen interactions and testing of safety and efficacy of immunomodulatory and other therapeutics.

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

Outdoor studies: No outdoor studies performed.

Form A, Part 2 (iii)

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Food and Drug Administration (FDA) College Park Campus

2. Where is it located (include both address and geographical location)?
5001 Campus Drive, College Park, MD 20740

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

BSL-2	304 m^2
BSL-3	0 m^2
BSL-4	0 m^2
Total laboratory floor area	304 m^2

4. The organizational structure of each facility.

(i) Total number of personnel 5

(ii) Division of personnel:

Military	0
Civilian	5

(iii) Division of personnel by category:

Scientists	5
Engineers	0
Technicians	0
Administrative and support staff	0

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Chemistry, Biochemistry, Microbiology, Molecular Biology.

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 2

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
U.S. Department of Health and Human Services (HHS)
U.S. Department of Homeland Security (DHS)

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

Research	$ 600,000
Development	$ 0
Test and evaluation	$ 50,000
Total	$ 650,000

(viii) Briefly describe the publication policy of the facility:
FDA staff are encouraged to publish their research results in peer-reviewed scientific journals. The FDA 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://www.fda.gov/media/80061/download
- 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. DePalma L, Prentice KW, Ramage JG, Chapman C, Pillai SP, Prentice KW et al. Comprehensive Laboratory Evaluation of a Specific Lateral Flow Assay for the Presumptive Identification of Francisella tularensis in Suspicious White Powders and Aerosol Samples. Health Security, 2020, Vol.18(2),p.83-95. https://www.liebertpub.com/doi/10.1089/hs.2019.0151
2. Sharma SK, Gonzalez-Escalona N. Closing Clostridium botulinum Group I Genomes Using a Combination of Short- and Long-Reads. Frontiers in Microbiology, 2020, Vol.11, https://doi.org/10.3389/fmicb.2020.00239. https://www.frontiersin.org/articles/10.3389/fmicb.2020.00239/full

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

Objectives: This facility includes work undertaken by the FDA's Center for Food Safety and Applied Nutrition (CFSAN), a national leader in protecting and promoting public health. Biodefense work at CFSAN is aimed at developing diagnostic assays for public health and food safety. The microbial genomics and analytical chemical and food technology processing techniques developed at CFSAN are available to other Federal agencies charged with forensic investigations.

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

Outdoor studies: No outdoor studies performed.

* Including viruse and prions.

Form A, Part 2 (iii)

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Food and Drug Administration (FDA) Moffett Campus

2. Where is it located (include both address and geographical location)?
6502 South Archer Road, Bedford Park, IL 60501-1957

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

BSL-2	167 m^2
BSL-3	0 m^2
BSL-4	0 m^2
Total laboratory floor area	167 m^2

4. The organizational structure of each facility.

(i) Total number of personnel 5

(ii) Division of personnel:

Military	0
Civilian	5

(iii) Division of personnel by category:

Scientists	3
Engineers	1
Technicians	0
Administrative and support staff	1

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Chemistry, Chemical Engineering, Biological Science, Microbiology, Genomics.

(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 Health and Human Services (HHS)

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

Research	$ 50,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 50,000

(viii) Briefly describe the publication policy of the facility:
FDA staff are encouraged to publish their research results in peer-reviewed scientific journals. The FDA 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://www.fda.gov/media/80061/download
- 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.)

None.

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

Objectives: This facility includes work undertaken by the FDA's Center for Food Safety and Applied Nutrition (CFSAN), a national leader in protecting and promoting public health. Biodefense work at CFSAN is aimed at developing tools essential for testing a broad array of food products for biological threats. The microbial genomics and analytical chemical and food technology processing techniques developed at CFSAN are available to other Federal agencies charged with forensic investigations.

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

Outdoor studies: No outdoor studies performed.

* Including viruse 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: 31

(ii) Division of personnel:

Military	0
Civilian	31

(iii) Division of personnel by category:

Scientists	10
Engineers	0
Technicians	12
Administrative and support staff	9

(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	$ 4,090,994
Development	$ 0
Test and evaluation	$ 0
Total	$ 4,090,994

(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. Luster DG, McMahon MB, Carter ML, Sechler AJ, Rogers EE, Schroeder BK, et al. Immunoreagents for development of a diagnostic assay specific for Rathayibacter toxicus. Food Agric Immunol. 2020; 31(1):231-242. https://doi.org/10.1080/09540105.2020.1714554
2. Tancos, MA, Sechler, AJ, Davis, EW, Chang, JH, Schroeder, BK, Murray, TD, et al. The identification and conservation of tunicaminyluracil-related biosynthetic gene clusters in several Rathayibacter species collected from Australia, Africa, Eurasia and North America. Front Microbiol. 2020; 10:2914. https://doi.org/10.3389/fmicb.2019.02914

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 outdoor studies performed.

* 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-1 to ABSL-3 and BSL-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-inactivated 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:	160.6 m^2
ABSL-3AG:	1,581.6 m^2
Total biocontainment facility floor area:	5,209.8 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 5

(ii) Division of personnel:

Military	0
Civilian	5

(iii) Division of personnel by category:

Scientists	2
Engineers	0
Technicians	2
Administrative and support staff	1

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Immunology, Infectious Disease, Molecular Biology, Pathology, Vaccinology and Veterinary Medicine.

(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	$ 6,016,309
Development	$ 0
Test and evaluation	$ 0
Total	$ 6,016,309

(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=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. Olsen SC, Boggiatto P, Kanipe C. Immune responses and clinical effects of experimental challenge of elk with Brucella abortus strain 2308. Vet Immunol Immunopathol. 2020. 227:11086. https://doi.org/10.1016/j.vetimm.2020.110086
2. Olsen SC, Crawford LS, Fuentes A, Kostovic M, Boggiatto PM. Influence of species of negative control sera on results of a brucellosis fluorescence polarization assay. J Vet Diagn Invest. 2020. 33:67-72. https://doi.org/10.1177%2F1040638720970888
3. Pierce CF, Brown VR, Olsen SC, Boggiatto PM, Pedersen K, et al. Loci associated with antibody response in feral swine (Sus scrofa) infected with Brucella suis. Front Vet Sci. 2020. 7:554674. https://dx.doi.org/10.3389%2Ffvets.2020.554674
4. Sang, ER, Tian, Y, Gong, Y, Miller, LC, Sang, Y. Integrate structural analysis, isoform diversity, and interferon-inductive propensity of ACE2 to predict SARS-CoV2 susceptibility in vertebrates. Heliyon. 2020; 6(9):e04818. https://doi.org/10.1016/j.heliyon.2020.e04818

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, or condemnations; develop more sensitive, specific and rapid diagnostic tests; develop vaccines designed for the control and, when feasible, the eradication of disease; improve our understanding of the ecology and epidemiology of pathogens at the domestic 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

* Including viruses and prions.

projects conducted at this location is available at http://www.ars.usda.gov/research/projects_programs.htm?modecode=50-30-20-00.

***Microorganisms and/or Toxins Studied*:** Overlap Select Agents.

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

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: 29

(ii) Division of personnel:

Military	0
Civilian	29

(iii) Division of personnel by category:

Scientists	7
Engineers	0
Technicians	4
Administrative and support staff	18

(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, Vaccinology, 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)
U.S. Department of Health and Human Services (HHS)
Non-Profit Associations
Private Sector Companies
Universities

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

Research	$ 4,576,711
Development	$ 0
Test and evaluation	$ 0

Total $ 4,576,711

(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).

(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. Chaudhry, M, Webby, R, Swayne, DE, Rashid, H, Debeauchamp, J, Killmaster, L., et al. Avian influenza at animal-human interface: One-health challenge in live poultry retail stalls of Chakwal, Pakistan. Influenza Other Respir Viruses. 2020; 14(3):257-265. https://doi.org/10.1111/irv.12718
2. Chen, L, Donis, RO, Suarez, DL, Wentworth, DE, Webby, R, Engelhardt, OG., et al. Biosafety risk assessment for production of candidate vaccine viruses to protect humans from zoonotic highly pathogenic avian influenza viruses. Influenza Other Respir Viruses. 2020; 14(2):215-225. https://doi.org/10.1111/irv.12698
3. Ferreira, H., Reilley, AM, Goldenberg, D, Ortiz, IR, Gallardo, RA, Suarez, DL. Protection conferred by commercial NDV live attenuated and double recombinant HVT vaccines against virulent California 2018 Newcastle disease virus (NDV) in chickens. Vaccine. 2020; 38(34):5507-5515. https://doi.org/10.1016/j.vaccine.2020.06.004
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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*:** 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 livestock performance, increased deaths, or condemnations; develop more sensitive, specific and rapid diagnostic tests; develop vaccines designed for the control and, when feasible, the eradication of disease; improve our understanding of the ecology and epidemiology of viruses at the wild bird-domestic poultry interface; and improve our understanding of the genetic and pathobiological basis of virulence. This research provides government regulatory agencies and the poultry industries with improved intervention strategies against poultry viral diseases. The Laboratory has 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 outdoor studies performed.

* Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Floral and Nursery Plants Research, Beltsville Agricultural Research Center (BARC)

The Floral and Nursery Plants Research, Beltsville Agricultural Research Center is a new addition for the 2020 CBM report.

2. Where is it located (provide both address and geographical location)?
10300 Baltimore Avenue, Beltsville, MD 20705

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

BSL-2:	98.8 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	98.8 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 3

(ii) Division of personnel:

Military	0
Civilian	3

(iii) Division of personnel by category:

Scientists	2
Engineers	0
Technicians	1
Administrative and support staff	0

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Bacteriology, Bioinformatics, Genomics, Horticulture, Molecular Diagnostics, Plant Pathology.

(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	$ 552,503
Development	$ 0
Test and evaluation	$ 0
Total	$ 552,503

(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).

(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*:** The specific research objectives in this project include studies on detection, host range, epidemiology and control of bacterial wilt and are included in the ARS Research Project entitled "Detection, Identification, and Characterization of New and Emerging Viral and Bacterial Diseases of Ornamental Plants". Specifically, these research objectives include studies on detection, host range, disease mechanisms, and control of bacterial wilt. The overall approach is to develop knowledge and tools that will aid U.S. regulatory agencies to establish effective pathogen testing protocols, and U.S. floriculture companies to improve clean stock production for new vegetatively propagated annuals and perennials. The goals of the current research project include 1) identification and characterization of genes and/or regulatory elements, in order to facilitate the accurate definition, detection, and control; and, 2) isolation and biological and molecular characterization of bacteriophages to better understand their involvement in competitive fitness and virulence. Additional information about this research project is available at https://www.ars.usda.gov/research/project/?accnNo=432744; https://www.ars.usda.gov/research/project/?accnNo=431988; and, https://www.ars.usda.gov/research/project/?accnNo=430955.

***Microorganisms and/or Toxins Studied*:** PPQ Select Agent.

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

* 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, 2021

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

Human Disease Events

SARS-CoV-2 in the United States:

On January 21, 2020, the International Health Regulations (IHR) National Focal Point (NFP) for the United States of America reported the first confirmed case of novel coronavirus (SARS-CoV-2) in the United States. The case is a 35-year-old resident of Snohomish County, Washington State, who travelled from the United States to Wuhan, Hubei Province, China, on November 26, 2019. He returned to Snohomish County, Washington State, United States, on January 15, 2020, and had onset of symptoms on January 16, 2020. The case was seen at a clinic in Snohomish County and was later transported to Providence Regional Medical Center in Everett, Washington. The case had normal chest x-rays and tested negative for influenza virus. The case did not report exposure to ill persons, livestock, or seafood/animal markets while in the People's Republic of China. Because of a travel history to Wuhan city, the case was tested for SARS-CoV-2. Patient samples were collected on January 19, 2020, which were sent to the U.S. Centers for Disease Control and Prevention (U.S. CDC); on January 20, 2020, the samples tested positive for SARS-CoV-2 through real-time Reverse Transcription-Polymerase Chain Reaction (rRT-PCR). Between January 24-26, 2020, U.S. CDC announced 4 additional confirmed cases of SARS-CoV-2, all imported from Wuhan, China, in Arizona (1 case in Maricopa County), California (1 case in Orange County and 1 case in Los Angeles County), and Illinois (1 case in the city of Chicago).

On January 30, 2020, U.S. CDC reported the first confirmed case due to human-to-human transmission in the United States, in a male in his 60s and is the spouse of the imported confirmed case identified in Illinois. This newly identified case had no travel history to Wuhan, China, and had close contact with his wife after she developed symptoms. Public health officials identified this case through contact tracing; both of these epidemiologically-linked cases were hospitalized but in stable condition. At the time this brought the total number of confirmed cases of SARS-CoV-2 to 6 in the United States.

CDC Press Release from January 21, 2020: https://www.cdc.gov/media/releases/2020/p0121-novel-coronavirus-travel-case.html.

COVID-19 Data Tracker for cases, deaths, and trends in the United States: https://covid.cdc.gov/covid-data-tracker/#datatracker-home.

Human Infection with Influenza A (H3N2) in the United States:

On 25 July 2020, the IHR NFP informed the Pan American Health Organization (PAHO) and the World Health Organization (WHO) of a human infection with influenza A (H3N2) variant virus (A[H3N2]v). According to the report, on June 30, 2020, a child < 18 years old, with no underlying medical conditions, developed an influenza-like illness in Hawaii. On July 1, the patient sought medical care at an outpatient clinic and a respiratory specimen was collected for influenza testing. The patient was not hospitalized. The specimen was then forwarded to the public health laboratory at the Hawaii State Department of Health as part of routine surveillance activities. Real-time RT-PCR testing conducted at the public health laboratory indicated a presumptive influenza A(H3N2)v virus. The specimen was forwarded to the CDC Influenza Division on July 21 according to national specimen submission guidelines and was received on July 23. On July 24, CDC confirmed an influenza A(H3N2)v virus using RT-PCR and genome sequence

analysis. Further genetic and antigenic characterization of the virus was conducted to understand the relatedness of the virus to other influenza A(H3N2)v viruses circulating in swine, and to existing candidate vaccine viruses.

This is the first influenza A(H3N2)v virus infection identified in the United States since 2018. The investigation is ongoing into the source of the patient's infection. No human-to-human transmission has been identified and no exposure to swine has been reported to date. The most up-to-date information about H3N2v cases, hospitalizations, and deaths reported to CDC can be accessed by visiting: https://www.cdc.gov/flu/swineflu/variant/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fflu%2Fswineflu%2Fh3n2v-case-count.htm.

Animal Disease Events

Summary of Reports: In 2020, the United States submitted six World Organization for Animal Health (OIE) immediate reports for animal disease events. These included one low pathogenic notifiable avian influenza report, one highly pathogenic avian influenza report, one severe acute respiratory syndrome-coronavirus disease report, two rabbit hemorrhagic disease virus type 2 reports, and one Ostreid herpesvirus 1 microvariant disease report.

Event summaries can be found on the OIE website: https://www.oie.int/en/animal-health-in-the-world/the-world-animal-health-information-system/the-world-animal-health-information-system/.

2020 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 (2019): http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_avian_influenza_viruses.htm.

Low Pathogenic Avian Influenza (LPAI), H7N3---North Carolina and South Carolina
OIE Immediate Report March 16, 2020—Final Report July 24, 2020

As part of routine surveillance for H5/H7 avian influenza, H7 LPAI was detected in a commercial turkey breeder and two turkey meat flocks. The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS), South Carolina State Veterinarian's Office (part of Clemson University Livestock Poultry Health (CULPH)), and the North Carolina Department of Agriculture and Consumer Services (NCDA&CS) conducted a comprehensive epidemiological investigation and implemented enhanced surveillance and testing related to this event. Sequencing determined subtype/pathotype of H7N3 on all premises. Clinical signs noted: slight drop in egg production in turkey breeder flock. All affected premises were depopulated, with appropriate disposal of birds and material.

All affected premises completed cleaning and disinfection/virus elimination. By July 24, 2020, all environmental sampling and testing for avian influenza virus post-cleaning and disinfection completion were negative for avian influenza virus and the State Veterinarians of South Carolina and North Carolina had released quarantines on all affected premises.

High Pathogenic Avian Influenza (HPAI), H7N3—South Carolina
OIE Immediate Report April 8, 2020 — Final Report August 5, 2020

HPAI H7N2 was confirmed on one commercial meat-type turkey premises in South Carolina. USDA APHIS and the South Carolina State Veterinarian's Office, part of Clemson University Livestock Poultry Health (CULPH), conducted a comprehensive epidemiological investigation and enhanced surveillance related to this event. The affected premises had an epidemiological link to another South Carolina premises where recent low pathogenic avian influenza (LPAI) H7N3 detections were found. Clinical signs included respiratory signs, snicking, and increased mortality. Depopulation of the infected premises and appropriate disposal was completed. The affected premises were cleaned and disinfected (including, but not limited to, outside areas, equipment, trucks, and other fomites). By May 28, 2020, all environmental sampling and testing for avian influenza virus post-cleaning and disinfection completion were negative for avian influenza virus at the affected premises and the State Veterinarian of South Carolina released the premises for quarantine. After no HPAI was detected in over 3 months, the event was closed on August 5, 2020.

Severe Acute Respiratory Syndrome-Coronavirus Disease (SARS-CoV-2)—United States
OIE Immediate Report April 5, 2020 — Open at the end of 2020

SARS-CoV-2 detections were confirmed and reported, beginning on April 4, 2020, in 135 individual animals from six species groups and from 20 states throughout the United States. The majority of cases occurred in companion animals (dogs (41) and cats (56)) from residential households. Noteworthy other cases included lions (3), tigers (7), and snow leopards (3) from zoos. If clinical signs were present, respiratory clinical signs were most often seen, followed by lethargy and gastrointestinal signs. Approximately 96% of cases have had associations with a confirmed or suspected COVID-19 positive human. Multisector One Health partners, including state officials and/or Federal agencies (USDA APHIS, U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) and Food and Drug Administration) worked together to complete epidemiological investigations and case follow-up. Additionally, there were confirmed detections of SARS-CoV-2 on 16 mink farms in Utah, Michigan, Wisconsin, and Oregon with high mortality rates. Clinical signs included respiratory signs, inappetence, epistaxis and sudden death. The affected premises reported positive or suspect cases of COVID-19 in people that were in contact with the mink. State officials and Federal One Health partners (USDA APHIS, CDC) are conducting comprehensive epidemiological investigation and implemented enhanced surveillance and testing related to these outbreaks. All affected premises have been quarantined and mink mortality rates have since decreased, returning to normal levels.

Rabbit Hemorrhagic Disease Virus-2 (RHDV2)—Washington, New York, New Mexico, Arizona, Texas, Colorado, Nevada, California, and Utah
OIE Immediate Report July 19, 2019—Final Report July 2, 2020

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

RHDV2 was detected in domestic rabbits, feral domestic rabbits, and wild lagomorphs with high mortality rates in disease events in Washington, New York, and the southwestern United States. General clinical signs seen in confirmed cases from all the affected states included lethargy, seizures, and sudden death. State animal health officials (SAHOs) from affected states and USDA APHIS conducted epidemiological investigations into these events. The SAHOs in each of the affected States determined the response for their State. For most States this included quarantine, cleaning and disinfection, and fallow periods before restocking. Some States utilized depopulation of positive premises in the response, and one State without regulatory or quarantine authority over rabbits worked with affected premises owners to voluntarily limit risk of further spread. Full genome sequencing and analysis was completed on RHDV2 isolates detected in the United States from 2018 through 2020, including from the outbreaks in the southwestern United States. Phylogenetic analysis indicated isolates clustered by geographical region. Recent 2020 isolates from New Mexico, Texas, Arizona, and Colorado formed a single genetic cluster suggesting the outbreaks of RHDV2 in these states were caused by introduction of a single genetic isolate into the region; this virus was responsible for RHDV2 in both wild rabbits and domestic rabbits. Virus circulating in the southwestern United States was distinct from RHDV2 isolates collected from domestic rabbits in Ohio, Washington State, and New York as well as British Columbia, Canada.

All affected states received or pursued import of European Union-licensed RHDV2 vaccine for emergency use by special approval of the USDA. In all states, SAHOs directed the use of the vaccine including record and identification requirements. SAHOs in states where feral or wild lagomorph detections of RHDV2 occurred were given permission by the USDA to begin designating laboratories that could perform RHDV2 testing for their state following standard operating procedures and a testing algorithm provided by the National Veterinary Services Laboratories. Laboratories were designated in Colorado, California, and New Mexico. The event was declared stable on July 2, 2020 for the existing positive states at that time, and updates for these states continue in 6-month interval reports to the OIE.

Washington—RHDV2 was detected on five domestic rabbit (Oryctolagus cuniculus) premises as well as in feral domestic rabbits. Following cleaning, disinfection, and a fallow period when no additional cases of RHDV2 were detected, State officials released quarantines on all premises.

New York—RHDV3 was detected on one domestic rabbit (Oryctolagus cuniculus) premise. No further RHDV2 rabbit deaths associated with the premise were reported after March 6, 2020. Cleaning, disinfection, and a fallow period were completed. Sentinel rabbits present in the facility for 2 weeks showed no signs of disease, and State officials released the premises from quarantine on April 18, 2020.

New Mexico— RHDV2 was detected on 42 domestic rabbit (Oryctolagus cuniculus) premises. Additionally, there were nine RHDV2 detections in wild lagomorphs. Affected species included black-tailed jackrabbits (Lepus californicus), desert cottontail rabbits (Sylvilagus audobonii), and cottontail rabbits (Sylvilagus sp.).

Arizona—RHDV2 was detected on 38 domestic rabbit (Oryctolagus cuniculus) premises. Additionally, there were 26 RHDV2 detections in wild lagomorphs. Affected species included black-tailed jackrabbits (Lepus californicus), antelope jackrabbits (Lepus alleni), desert cottontail rabbits (Sylvilagus audobonii) and mountain cottontail rabbits (Sylvilagus nuttallii).

Texas—RHDV2 was detected on nine domestic rabbit (Oryctolagus cuniculus) premises. Additionally, there were 19 RHDV2 detections in wild lagomorphs. Affected species included black-tailed jackrabbits (Lepus californicus), desert cottontail rabbits (Sylvilagus audobonii), and cottontail rabbits (Sylivilagus sp.).

Colorado—RHDV2 was detected on 11 domestic rabbit (Oryctolagus cuniculus) premises. Additionally, there was one RHDV2 detection in feral domestic rabbits (Oryctolagus cuniculus) and 14 detections in wild lagomorphs. Affected species included black-tailed jackrabbits (Lepus californicus), cottontail rabbits (Sylivilagus sp.), and jackrabbits (Lepus sp.)

Nevada—RHDV2 was detected on two domestic rabbit (Oryctolagus cuniculus) premises, as well as in a feral domestic rabbit (Oryctolagus cuniculus). Additionally, there were two detections in wild lagomorphs. Affected species included wild desert cottontail rabbits (Sylvilagus audubonii).

California— RHDV2 was detected on 10 domestic rabbit (Oryctolagus cuniculus) premises. Additionally, there were 15 detections of RHDV2 in wild lagomorphs. Affected species included black-tailed jackrabbits (Lepus californicus) and desert cottontail rabbits (Sylvilagus audobonii).

Utah—RHDV2 was detected on one domestic rabbit (Oryctolagus cuniculus) premise as well as in feral domestic rabbits (Oryctolagus cuniculus). Additionally, there were eight detections in wild lagomorphs. Affected species included black-tailed jackrabbits (Lepus californicus), jackrabbits (Lepus sp.) and cottontail rabbits (Sylivilagus sp.)

RHDV2—Wyoming
OIE Immediate Report December 18, 2020 — Open at the end of 2020

In mid-December 2020, RHDV2 was detected in wild lagomorphs. Affected species included eastern cottontail rabbits (Sylvilagus floridanus). An immediate report was made December 18, 2020. The event was open at the end of 2020.

Ostreid Herpesvirus 1 microvariant Disease (OsHV-1 microvariant)—California
OIE Immediate Report November 19, 2020—Final Report December 22, 2020

OsHV-1 microvariant was detected in sentinel juvenile Pacific oysters (C. gigas) in California. The sentinel animals were sourced from an OsHV-1 tested negative population and deployed at this site as part of a research effort. The affected sentinel population was depopulated. No commercially farm-raised animals, at any facilities in the United States, were exposed or affected. The identical OsHV-1 microvariant was first detected in oysters at the same site in San Diego Bay in October 2018.

Form C

BWC - Confidence Building Measure

<u>Encouragement of Publication of Results and Promotion of Use of Knowledge</u>

United States of America

April 15, 2021

US Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR), Technical Resources, Assistance Center, and Information Exchange (TRACIE) https://asprtracie.hhs.gov/	The TRACIE portal provides a collection of disaster medical, healthcare, and public health preparedness materials, searchable by keywords and functional areas, which include: • The Communications Systems Topic Collection • The Cybersecurity Topic Collection • Emergency Public Information and Warning/Risk Communications
CDC National Center for Health Statistics, Data Release Policy https://www.cdc.gov/nchs/about/policy/data_release.htm	The CDC National Center for Health Statistics released a new Data Release Policy, titled "Timing Considerations in the Release of Data to Collaborators, Co-sponsors, and the Public Policy Statement Adopted April 24, 2000."
U.S. Department of Health and Human Services, Office for Human Research Protections, Research Guidance on Coronavirus https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html	U.S. HHS released guidance regarding the regulatory requirements at 45 Code of Federal Regulations part 46 applying to actions taken by research institutions and investigators in response to the COVID-19.
U.S. Department of Health and Human Services, Office of Research Integrity (ORI), Research Misconduct Case Summaries https://ori.hhs.gov/case_summary	The Research Misconduct Case Summaries contain cases in which administrative actions were imposed due to findings of research misconduct. The list includes those who currently have an imposed administrative action against them and each case is categorized according to the year in which ORI closed the case.
National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI), NHLBI Policy for Data Sharing from Clinical Trials and Epidemiological Studies https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2007152932-zb-nhlbi_policyfordatasharingfromclinicaltrialsandepidemiologicalstudies.pdf	The NIH NHLBI released a policy to describe the requirements for data sharing in applicable NHLBI-funded studies.
NIH Policy for Data Management and Sharing https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html	NIH issued the NIH Policy for Data Management and Sharing (DMS Policy) to promote good management and sharing of scientific data generated from NIH funded or conducted research, including the submission of Data Management and Sharing Plans.
NIH Data Sharing Policies https://www.nlm.nih.gov/NIHbmic/nih_data_sharing_policies.html	The NIH created a repository of data sharing policies in effect at the NIH, IC, division, and program levels which apply to broad sets of investigators and data.

CDC, Federal Select Agent Program, The *2019 Annual Report of the Federal Select Agent Program*, released in September 2020 https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2019_508.pdf	The *2019 Annual Report of the Federal Select Agent Program*, released in September 2020, summarizes 2019 program data for the Federal Select Agent Program (FSAP), which regulates the possession, use and transfer of biological select agents and toxins so that important work with potentially dangerous and deadly pathogens can be conducted as safely and securely as possible. FSAP is a partnership between HHS's Centers for Disease Control and Prevention and USDA's Animal and Plant Health Inspection Service.
CDC, Federal Select Agent Program, 2019 Federal Select Agent Program (FSAP) Inspection Report Processing Annual Summary released 6/30/2020 https://www.selectagents.gov/resources/publications/docs/2019_FSAP_Inspection_Report_Processing_508.pdf	The FSAP Inspection Report summarizes timeliness data related to FSAP-issued inspection reports for the Federal Select Agent Program January 1, 2019 – December 31, 2019.
2019 Biodefense Public Report https://www.phe.gov/Preparedness/biodefense-strategy/2019-report/Documents/2019-Biodefense-Public-Report-508.pdf	The United States released the "2019 Biodefense Public Report: Implementation of the National Biodefense Strategy," which includes an overview of U.S. activities to implement the National Biodefense Strategy.

Form E

BWC - Confidence Building Measure

Declaration of legislation, regulations and other measures

United States of America

April 15, 2021

Relating to	Legislation	Regulations	Other measures*	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	No
(b) Exports of micro-organisms† and toxins	Yes	Yes	Yes	Yes[1]
(c) Imports of micro-organisms† and toxins	Yes	Yes	Yes	Yes[2]
(d) Biosafety‡ and biosecurity§	Yes	Yes	Yes	Yes[3]

EXPLANATORY NOTES

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

- **Amendments to Country Groups for Russia and Yemen under the Export Administration Regulations.** (Effective date February 24, 2020) In this final rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) to revise the Country Group designations for the Russian Federation and Yemen based on national security and foreign policy concerns, including proliferation-related concerns. As part of this rule, BIS revises the licensing policy for items to Russia to a policy of presumption of denial when the items are controlled for reasons described under § 742.2 (Proliferation of chemical and biological weapons) of the EAR. These items include human pathogens, genetically modified microorganisms, and plant pathogens identified in Export Control Classification Numbers (ECCNs) 1C351, 1C353 and 1C354, and equipment and materials identified in ECCN 2B352 that can be used in the production of biological agents, as well as related technologies. This rule also removes Yemen from Country Group B in Supplement No. 1 to part 740 of the EAR. This eliminates the eligibility to use License Exception "Shipments to Country Group B Countries" (GBS) for shipments to Yemen of protective and detection equipment for biological agents listed in ECCN 1A004. These changes are being made to address concerns about diversion of U.S.-origin items in Yemen for unauthorized purposes, including prohibited proliferation activities, end uses, and end users.
  https://www.bis.doc.gov/index.php/documents/regulations-docs/federal-register-notices/federal-register-2020/2534-85-fr-10274/file

- **Implementation of the February 2020 Australia Group Intersessional Decisions: Addition of Certain Rigid-Walled, Single-Use Cultivation Chambers and Precursor Chemicals to the Commerce Control List.** (Effective Date June 17, 2020) This final rule amends the EAR to implement decisions made by the Australia Group (AG) in 2020 and amends the Commerce Control List (CCL) and ECCN 1C351 by adding the Middle East respiratory syndrome-related coronavirus (MERS-related coronavirus) as ECCN 1C351.a.30. The viruses in ECCN 1C351 are renumbered to reflect this addition. Additionally, equipment capable of use in handling biological materials in

* Including guidelines.
† Micro-organisms pathogenic to man, animals and plants in accordance with the Convention.
‡ In accordance with the latest version of the WHO Laboratory Biosafety Manual or equivalent national or international guidance.
§ In accordance with the latest version of the WHO Laboratory Biosecurity Guidance or equivalent national or international guidance.

ECCN 2B352, is amended by adding a Technical Note to indicate that cultivation chamber holding devices include single-use cultivation chambers with rigid walls. https://www.bis.doc.gov/index.php/documents/regulations-docs/federal-register-notices/federal-register-2020/2564-85-fr-36483/file

- **Expansion of Export, Reexport, and Transfer (in-Country) Controls for Military End Use or Military End Users in the People's Republic of China, Russia, or Venezuela.** (Effective date June 29, 2020) In this final rule, BIS amends section 744.21 of the EAR to add a license requirement for exports of items intended for a "military end user" in China and broadens the existing definition of ''military end use'' to include any item that supports or contributes to the operation, installation, maintenance, repair, overhaul, refurbishing, "development," or "production," of military items. License applications for items destined to China, Russia, or Venezuela for a 'military end use' or 'military end user' will be reviewed under a presumption of denial. If the end use may involve certain proliferation activities, it may also be reviewed under the chemical and biological weapons control policy in section 742.2 to determine whether the export or reexport would make a material contribution to the design development, production, stockpiling or use of chemical or biological weapons. https://www.bis.doc.gov/index.php/documents/regulations-docs/federal-register-notices/federal-register-2020/2545-85-fr-23459/file

- **Wassenaar Arrangement 2018 Plenary Decisions Implementation; and other Revisions Related to National Security Controls.** (Effective Date September 11, 2020) This final rule revises the CCL and other corresponding parts of the EAR to implement changes made to the Wassenaar Arrangement List of Dual-Use Goods and Technologies and Munitions List (WA Lists) at the December 2018 WA Plenary meeting. This rule adds the eligibility to use License Exception "Shipments to Country Group B Countries" (GBS) to ECCNs 1A004.a, b, and c.2. Two of those ECCNs, 1004.a and 1004.b, include full face masks, filter canisters, decontamination equipment and their components designed or modified for defense against 'biological agents,' and protective suits, gloves and shoes, ''specially designed'' or modified for defense against 'biological agents,' respectively. While the U.S. export controls on these items do not change, the eligibility to use this license exception may make it easier for countries listed in Country Group B (Supplement No. 1 to part 740 of the EAR) to receive these items from the U.S. without undergoing the BIS license application and review process. https://www.bis.doc.gov/index.php/documents/regulations-docs/federal-register-notices/federal-register-2020/2624-85-fr-56294/file

- **Addition of 'Military End User' (MEU) List to the Export Administration Regulations and Addition of Entities to the MEU List.** (Effective Date December 23, 2020) In this final rule, the BIS amends the EAR to add one hundred and two 'military end users' to the MEU List in Supplement No. 7 to part 744; consisting of 57 in China and 45 in Russia. The U.S. Government has determined that these entities are subject to the 'military end user' controls in 744.21 of the EAR with a license application presumption of denial. If the end use may involve certain proliferation activities, license applications to these end users may be reviewed under the chemical and biological weapons control policy in 742.2 of the EAR to determine whether the export or reexport would make a material contribution to the design development, production, stockpiling or use of chemical or biological weapons. https://www.bis.doc.gov/index.php/documents/regulations-docs/federal-register-notices/federal-register-2020/2684-85-fr-83793/file

[2] (c) Imports of micro-organisms and toxins:

- **2020 Updates for the CDC Import Permit Program (IPP):** The IPP regulates infectious biological materials coming into the U.S. in order to prevent the introduction and spread of disease in humans.

This helps to protect the health of laboratory workers and those in the surrounding communities. In 2020, CDC published a Federal Register Notice seeking public comment on the request for continued approval by the Office of Budget and Management to collect information through use of the CDC's Import Permit Program's key reporting forms. Additionally, the CDC Import Permit Program included an COVID-19 update on importing SARS-CoV-2: https://www.cdc.gov/cpr/ipp/index.htm. Read more at: https://www.cdc.gov/cpr/ipp/about.htm

[3] (d) Biosafety and biosecurity:

- **Amendments to Select Agent and Toxin Regulations:**
  - Biennial review: As required by the Bioterrorism Response Act, the Federal Select Agent Program (FSAP) reviews the list of select agents and toxins on at least a biennial basis. FSAP last republished the list of select agents and toxins in the Federal Register on January 19, 2017 (82 FR 6278 and 82 FR 6197). In 2019, FSAP initiated the review of the list of select agents and toxins. In 2020, FSAP published in the Federal Register an Advance Notice of Proposed Rulemaking and Request for Comments for Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List: https://www.federalregister.gov/documents/2020/03/17/2020-05477/possession-use-and-transfer-of-select-agents-and-toxins-biennial-review and https://www.federalregister.gov/documents/2020/03/17/2020-05499/agricultural-bioterrorism-protection-act-of-2002-biennial-review-and-republication-of-the-select

- **Policy statements and regulatory interpretations concerning Select Agent and Toxin Regulations (Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agricultural Bioterrorism Protection Act of 2002 concerning the Federal Select Agent Program):**

  - During 2020, FSAP generated the following policies:
    - Regulatory interpretation/policy statement regarding: Laboratory Work with Regulated Genomes (https://www.selectagents.gov/regulations/policy/labwork.htm)
    - Revised policy statement regarding regulated genomes and guidance regarding the regulation of select agent and toxin nucleic acids. https://www.hhs.gov/guidance/document/fsap-guidance-regulations-select-agent-and-toxin-nucleic-acids

  - Draft FSAP Policy Statement: In October 2020, the FSAP posted to its website a preview of the Draft FSAP Policy Statement, Biosafety for Large Animal Study-Related Activities with B. abortus and B. suis Using Outdoor Containment Spaces (https://www.selectagents.gov/regulations/policy/animalstudy.htm). FSAP received approval to share with the public the draft policy statement prior to publishing it in the Federal Register. In January 2021, the draft policy was posted in the Federal Register for public comment. (https://www.federalregister.gov/documents/2021/01/15/2021-00774/notice-of-availability-of-a-draft-federal-select-agent-program-policy-statement-for-biosafety-for and https://www.selectagents.gov/regulations/policy/animalstudy.htm)

  - FSAP Select Agent Forms for Public Comment: Federal Register Notice was published to seek public comment on the Federal Select Agent Program's request for continued approval by the Office of Management and Budget to collect select agent and toxin information through the use of specific forms. https://www.federalregister.gov/documents/2020/04/03/2020-06948/proposed-data-collection-submitted-for-public-comment-and-recommendations

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

  - Federal Select Agent Program Updated Security Plan Guidance Document (February 2020): provides guidance for developing and implementing a security plan in compliance with section 11 of the select agent regulations, including information regarding site-specific risk assessments, planning requirements, access, inventory and audits, and barriers. The document is available at: https://www.selectagents.gov/compliance/guidance/security-plan/index.htm.

  - Federal Select Agent Program Updated Transfer of Select Agents and Toxins (June 2020): provides guidance on how to safely transfer select agents and toxins in compliance with federal select agent regulations. The document is available at: https://www.selectagents.gov/compliance/guidance/transfer/index.htm.

  - Federal Select Agent Program, Guidance Revisions: Several Guidance documents were revised to correct editorial errors, improve clarity and update the information related to relevant policy updates.
    - Guidance on the Regulation of Select Agent and Toxin Nucleic Acids (revised February 2020): https://www.selectagents.gov/compliance/guidance/nucleic/index.htm
    - Guidance on the Inventory of Select Agents and Toxins (revised December 2020): https://www.selectagents.gov/compliance/guidance/inventory/index.htm
    - Responsible Official Resource Manual (revised December 2020): https://www.selectagents.gov/compliance/guidance/ro/index.htm

- **Other Measures to Advance Biosafety and Biosecurity in the United States:**

  - FBI Enforcement Actions: The Biological Weapons Anti-terrorism (BWAT) Act (codified in the U.S. federal criminal code, Title 18 of the United States Code, Section 175(a), 175(b), and 175b; also referred to as 18 USC 175) implements provisions of the BWC, consistent with Article IV of the Convention. 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, are in possession of any biological agent without a justifiable research or peaceful purpose, or knowingly possess a Biological Select Agent or Toxin, regardless of intent, if the individual does not have legitimate access under the Federal Select Agent Program. In 2020, the FBI responded to several incidents that involved biological material and led investigations that resulted in prosecutions for violations of 18 USC 175.

  - FBI Security Risk Assessments (SRAs): 2,792 SRAs Completed in 2020: 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 2020, 2,792 SRAs were processed by the FBI (Criminal Justice Information Services Division, Bioterrorism Risk Assessment Group). Due to operational constraints in adherence to COVID 19 pandemic prevention recommendations, production capacity was slightly diminished. Of the 2,792 individual SRAs processed, 12 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, which decides whether to grant or deny the requesting entity or individual access to BSAT.

- FBI Biosecurity Outreach: During 2020, the FBI conducted 36 biosecurity outreach events at public and private research institutions across the United States. These engagements provided an environment where law enforcement (the FBI and State and local law enforcement agencies) and the research 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 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.

  The FBI also conducted biosecurity engagements with the international synthetic biology sector, the citizen biology community in the United States, and international engagements to increase university student access to biosecurity training and mentoring opportunities. Despite challenges introduced by the pandemic, the FBI reconfigured long-standing programs to be virtual, developed initiatives to address newly identified training needs, sponsored national and international workshops, provided assistance in the development of safety and security frameworks, and disseminated education materials. The following are examples of FBI outreach activities in 2020: 1) security discussions with domestic and international synthetic biology stakeholders, as well as sponsored and conducted biosecurity outreach at the 2020 International Genetically Engineered Machine Competition, the largest, annual synthetic biology meeting of undergraduate students worldwide; 2) worked with the United Nations to address disinformation campaigns against the life sciences, with particular emphasis on the COVID-19 pandemic) presented best practices to domestic and international industry stakeholders on the use of synthetic DNA for secure, long-term storage solutions of large data; and 3) formulated and implemented animal-plant health workshops to provide agricultural biosecurity vulnerabilities, threats and mitigation strategies to veterinary professionals, customs/border control officials, academia, first responders to determine if disease outbreaks in humans, plants, and/or animals could be from other than natural occurrences.

- USDA Biorisk Management Policy: On September 3, 2020, the U.S. Department of Agriculture (USDA) issued Departmental Regulation 4400-007, USDA Biorisk Management Policy, which establishes the policy, requirements, and responsibilities for administering a comprehensive biorisk management policy across the Department. This updated policy will help to ensure that work performed at USDA biocontainment laboratories is done safely and in a contained manner. The regulation applies to all USDA Mission Areas, agencies, staff offices, employees, contractors, and others who work for, or on behalf of USDA. The regulation is available at: https://www.ocio.usda.gov/document/departmental-regulation-4400-007.

- CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition: was released in November 2020 and serves as the cornerstone of biosafety practice in the United States. The BMBL is a guidance document recommending best practices for the safe conduct of work in biomedical and clinical laboratories and this edition includes revised sections, agent summary statements, and appendices. Specifically, this edition includes new appendices on the following topics: inactivation and verification; laboratory sustainability; large-scale biosafety; and clinical laboratory biosafety. https://www.cdc.gov/labs/BMBL.html

- Interim Laboratory Biosafety Guidance relevant to SARS-CoV-2: The United States issued interim guidance and guidelines for work with SARS-CoV-2 to ensure safe and secure handling.
    - CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html
    - Interim Laboratory Biosafety Guidance for Research with SARS-CoV-2 and IBC Requirements under the *NIH Guidelines:* https://osp.od.nih.gov/biotechnology/interim-lab-biosafety-guidance-for-research-with-sars-cov-2/

- National Strategy for Planetary Protection: The National Strategy for Planetary Protection Planetary aims to prevent potentially harmful biological contamination in the exploration of other planetary bodies. https://aerospace.org/sites/default/files/2021-01/Planetary%20Protection%20Strategy%2030Dec20.pdf

- Review and Revision of the Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA: The U.S. Department of Health and Human Services issued a Request for Information in August of 2020 regarding the review and revision of this Guidance, which seeks to reduce the risk that individuals with ill intent may exploit the application of nucleic acid synthesis technology. https://www.phe.gov/Preparedness/legal/guidance/syndna/Pages/update2020.aspx

- Guidance on Elimination of Institutional review Board Review of Research Applications and Proposals: The U.S. Department of Health and Human Services issued clarifying guidance regarding requirements that research proposals undergo institutional review board evaluation, https://www.hhs.gov/ohrp/regulations-and-policy/guidance/elimination-of-irb-review-of-research-applications-and-proposals/index.html

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, 2021

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, 2021

Form G

Declaration of vaccine production facilities - Overview

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 14, 2021). 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.

In response to the extraordinary public health emergency caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) virus, the U.S. Food and Drug Administration has approved an Emergency Use Authorization (EUA) for human vaccines to prevent the Coronavirus Disease 2019 (COVID-19). An EUA may be appropriate once clinical studies have demonstrated the safety and effectiveness of the vaccine, but before the manufacturer has submitted, and/or the U.S. Food and Drug Administration has completed, its formal review of the biologics license application. The COVID-19 vaccines that have received an EUA from the U.S. Food and Drug Administration include the Pfizer-BioNTech COVID-19 Vaccine, Moderna COVID-19 Vaccine, and the Janssen COVID-19 Vaccine. More information is available at: https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained.

Form G

Declaration of vaccine production facilities

1. Name of facility
Barr Laboratories, Inc.

2. Location (Mailing Address)
1235 Mays Mill Road,
Forrest, Virginia 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 Biosolutions

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* and smallpox disease

Vaccines:
- Anthrax Vaccine Adsorbed - [Biothrax]
- 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 - [TDVAX]

Form G

Declaration of vaccine production facilities

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

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

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

Vaccines:

- Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine - [VAXELIS]

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:
Ebola virus disease, 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:

- Ebola Zaire Vaccine, Live - [ERVEBO]
- Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) - [PedvaxHIB]
- 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 - [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 in persons not previously infected with M. tuberculosis who are at high risk for exposure and the treatment and prophylaxis of carcinoma in situ (CIS) of the urinary bladder, and the prophylaxis of primary or recurrent state Ta and/or T1 papillary tumors following transurethral resection (TUR).

Vaccines:
- BCG Live, attenuated - [BCG Vaccine], [TICE BCG]

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 (Trivalent) - [Flubok]
- Influenza Vaccine (Quadrivalent) - [Flubok Quadrivalent]

Form G

Declaration of vaccine production facilities

1. Name of facility
Sanofi Pasteur, Inc.

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

3. General description of the types of diseases covered:
Dengue disease caused by dengue virus serotypes 1, 2, 3 and 4; influenza disease caused by pandemic (H1N1) 2009 virus; influenza disease caused by H5N1 subtype; influenza disease caused by influenza virus subtype A and type B; invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y and W-135; invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y, and W-135; yellow fever acute viral illness caused by a mosquito-borne flavivirus; and invasive disease caused by H influenzae type b

Vaccines:

- Dengue Tetravalent Vaccine, Live - [DENGVAXIA]
- Influenza A (H1N1) 2009 Monovalent Vaccine
- Influenza Virus Vaccine, H5N1
- Influenza Virus Vaccine (Trivalent, Types A and B) - [Fluzone, Fluzone High-Dose, and Fluzone Intradermal]
- Influenza Virus Vaccine (Quadrivalent, Types A and Types B) - [Fluzone Quadrivalent]
- Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine - [Menactra]
- Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined - [Menomune-A/C/Y/W-135]
- Yellow Fever Vaccine - [YF-Vax]
- Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) - [ActHIB]

Form G

Declaration of vaccine production facilities

1. Name of facility
Seqirus Inc.

2. Location (Mailing Address)
475 Green Oaks Parkway
Holly Springs, NC 27540

3. General description of the types of diseases covered:
Influenza A subtype viruses and type B viruses

Vaccines:

- Influenza Virus vaccine, Influenza A (H5N1) Monovalent Vaccine, Adjuvanted - [AUDENZ]
- Influenza Virus Vaccine, Adjuvanted - [FLUAD], [FLUAD QUADRIVALENT]
- Influenza Virus Vaccine (Trivalent) - [Flucelvax]
- Influenza Virus Vaccine (Quadrivalent) - [FLUCELVAX Quadrivalent]

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 S. pneumoniae serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F, and invasive disease caused by *Neisseria meningitides* serogroup B.

Vaccines:
- Meningococcal Group B Vaccine - [TRUMENBA]
- Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein) - [Prevnar 13]

Form G

Declaration of vaccine production facilities

1. Name of facility
Emergent Travel Health, Inc.

This facility is a new entry for 2020 and was approved in December 23, 2020 for the manufacturing of VAXCHORA

2. Location (Mailing Address)
300 Professional Drive,
Gaithersburg, MD 20879

3. General description of the types of diseases covered:
VAXCHORA is a vaccine indicated for active immunization against disease caused by Vibrio cholerae serogroup O1. VAXCHORA is approved for use in persons 2 through 64 years of age traveling to cholera-affected areas.

Vaccines:
- Cholera Vaccine Live Oral - [VAXCHORA]

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 (Reconstructed 1918 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

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 encephalitis 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 Bunyaviruses (Severe Fever with Thrombocytopenia Syndrome virus, Heartland virus) and Flaviviruses (Omsk Hemorrhagic Fever virus, Alkhurma virus, Kyasanur Forest virus)

Tickborne encephalitis complex flaviviruses (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[*]

- 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

[*] 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*

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 Pasteur strain	Overlap Select Agent
Bacillus anthracis Sterne Strain	Simulant
Bacillus cereus Biovar anthracis	HHS Select Agent
Brucella abortus	Overlap Select Agent
Brucella melitensis	Overlap Select Agent
Brucella suis	Overlap Select Agent
Burkholderia mallei	Overlap Select Agent
Burkholderia pseudomallei	Overlap Select Agent
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
Crimean-Congo hemorrhagic fever virus	HHS Select Agent
Dengue virus	NIAID Category A
Eastern equine encephalitis virus	HHS Select Agent
Ebola virus	HHS Select Agent + NIAID Category A
Foot-and-mouth disease virus	USDA Select Agent
Francisella tularensis	HHS Select Agent + NIAID Category A
Goatpox virus	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
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

Ralstonia solanacearum	PPQ 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
Yersinia pestis	HHS Select Agent + NIAID Category A
TOXINS	**CATEGORY**
Abrin	HHS Select Toxin
Alpha conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7)	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