United States of America

Confidence Building Measure Return covering 2021

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, 2022

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, 2022

State Party to the Convention: United States of America

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

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

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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:

Form A, Part 1

BWC - Confidence Building Measure

Exchange of data on research centres and laboratories

United States of America

April 15, 2022

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.

Form A, Part 1 (i)

Exchange of data on research centres and laboratories

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

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 Risk Group (RG)-2 toxins, RG-2 gram positive and gram negative bacterial agents, RG-2 viral agents, RG-3 gram positive and gram negative bacterial agents, RG-3 viral agents, and RG-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: https://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	118.5 m^2
BSL-4 Laboratory	308.8 m^2
BSL-4 Laboratory	118.5 m^2

Note: The changes in DDID BSL-4 laboratory space were due to a numerical calculation error, resulting in an overall increase of 12.8 m^2. In previous year's reports, some laboratory space outside of the maximum containment units were inadvertently included while accessory BSL-4-capable rooms were inadvertently not included. The laboratory space was not physically remodeled and previous reports should have included the laboratory space measurements as reported in this year's report. Additionally, one BSL-4 Laboratory space of 118.5 m^2 was operated as a BSL-3 enhanced laboratory during the reporting calendar year.

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 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)
U.S. Department of Defense (DOD) - Partly

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/.

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 has been delayed until April 2022 because of the COVID-19 pandemic, related research on SARS-CoV-2, and pending CDC registration renewal. The funding 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 is comprised of three BSL-3 laboratories with animal facilities and one BSL-4 Class III Cabinet Line Laboratory. An additional BSL3/ABSL3 was added to the core in 2021. 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. In 2021, the CDC registration was successfully renewed and experimental work with Risk Group 4 agents is planned to begin in 2022. 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 alpha-herpesviruses 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. Additional information: http://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens
2. Provide education and training in these areas of research, in order to develop the next generation of scientists in this field, and to support a national response in the event of a biodefense emergency.
3. Establish a research facility with the highest attention to community and laboratory safety and security.

Types of microorganisms currently being used are various viral and bacterial pathogens that require BSL-4, BSL-3, or BSL-2 containment. 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, 2022

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, 2022

National biological defence research and development programmes: Overview

Biological threats can impact human, animal (domestic and wildlife), plant, and environmental health. Biodefense must be broader than the threats posed by terrorist groups or those seeking to use biological weapons—it requires an integrated approach to address not only deliberate biological incidents as top national security priorities, but also naturally occurring and accidental biological threats. In today's interconnected world, biological incidents anywhere have the potential to have profound impacts domestically, in the United States, and globally on physical and mental health and wellbeing, cause significant morbidity and mortality, and disrupt livelihoods and economies including through impacts on trade and travel. Our biodefense capabilities must therefore address the range of biological threats: emerging and re-emerging infectious diseases and pests affecting humans, animals, plants, and the environment; misuse of biotechnology resulting in a biological incident; accidental release of biological agents; and threats posed by state and non-state actors seeking to develop or use biological weapons.

Health, prosperity, and security depends on our ability to stop infectious disease outbreaks at their source and to rapidly contain biological incidents, wherever they occur. On September 18, 2018, the United States issued the National Biodefense Strategy, which contains goals and objectives that 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). Integral to the strategy are research and development programs aimed at protecting against the deliberate use of biological materials and agents to cause harm. These programs focus on the swift identification of harmful pathogens and outbreaks of infectious diseases, and their containment, treatment, and elimination from the environment. Research on these pathogens, including study of molecular mechanisms and related diagnostic, vaccine and therapeutic development, not only increases U.S. biodefense preparedness, but also offers inherent benefits for broader public health. 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. While the United States takes a broad interpretation of biodefense, the programs described in the BWC confidence-building measures are those focused, at least in significant part, on the traditional interpretation of biodefense as defense against biological weapons. To promote the benefits gained by these programs beyond traditional biodefense, 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 other 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");
- Executive Order 13987 ("Organizing and Mobilizing the United States Government To Provide a Unified and Effective Response To Combat COVID-19 and To Provide United States Leadership on Global Health and Security").

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.

Department of Defense Chemical and Biological Defense Program (CBDP) develops defensive capabilities to enable the U.S. Armed Forces to deter, prevent, protect from, mitigate, respond to, and recover from the effects of chemical and biological (CB) 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 defensive 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.
$416,599,000 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.

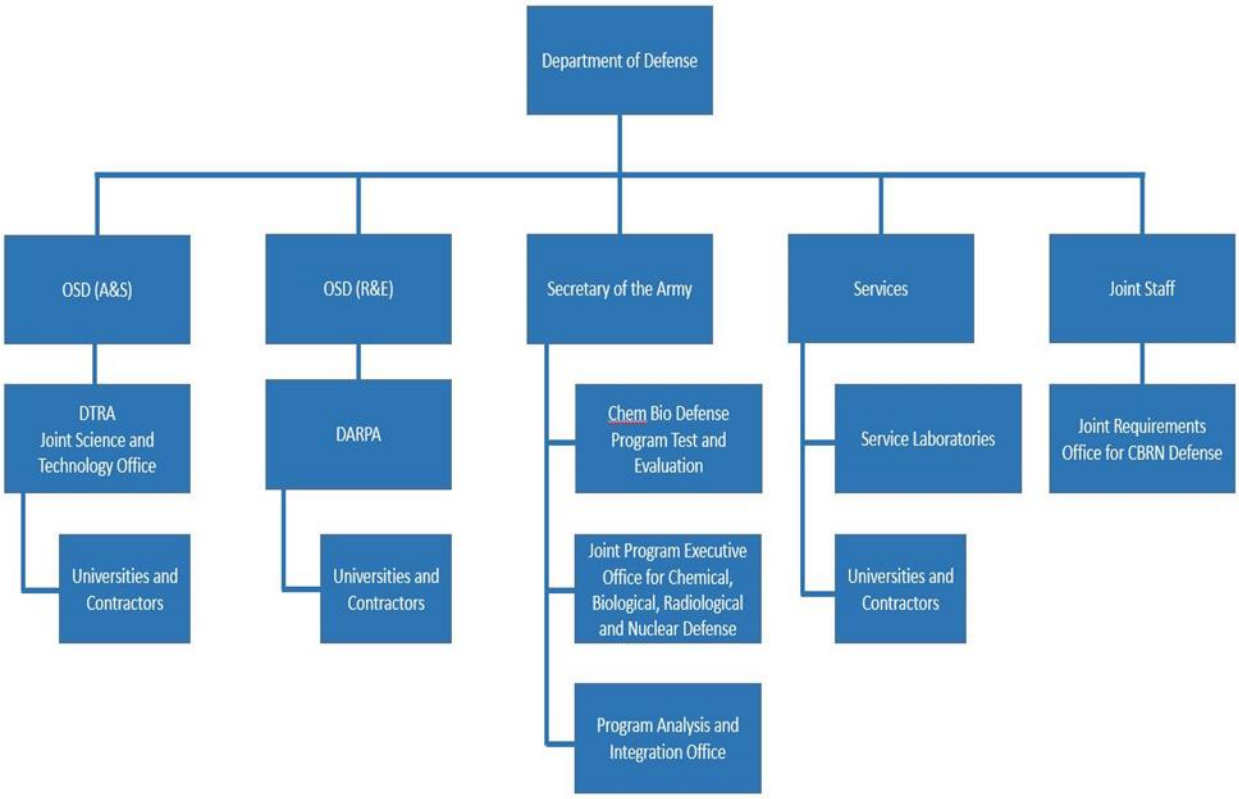
4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?
68.7%

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 58
- U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) – Page 60
- Air Force Research Laboratory (AFRL), 711 HPW – Page 70

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 2021 and is not included in the U.S. Confidence Building Measures covering 2021.

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 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.
$6,400,000 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 and water-sector 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.

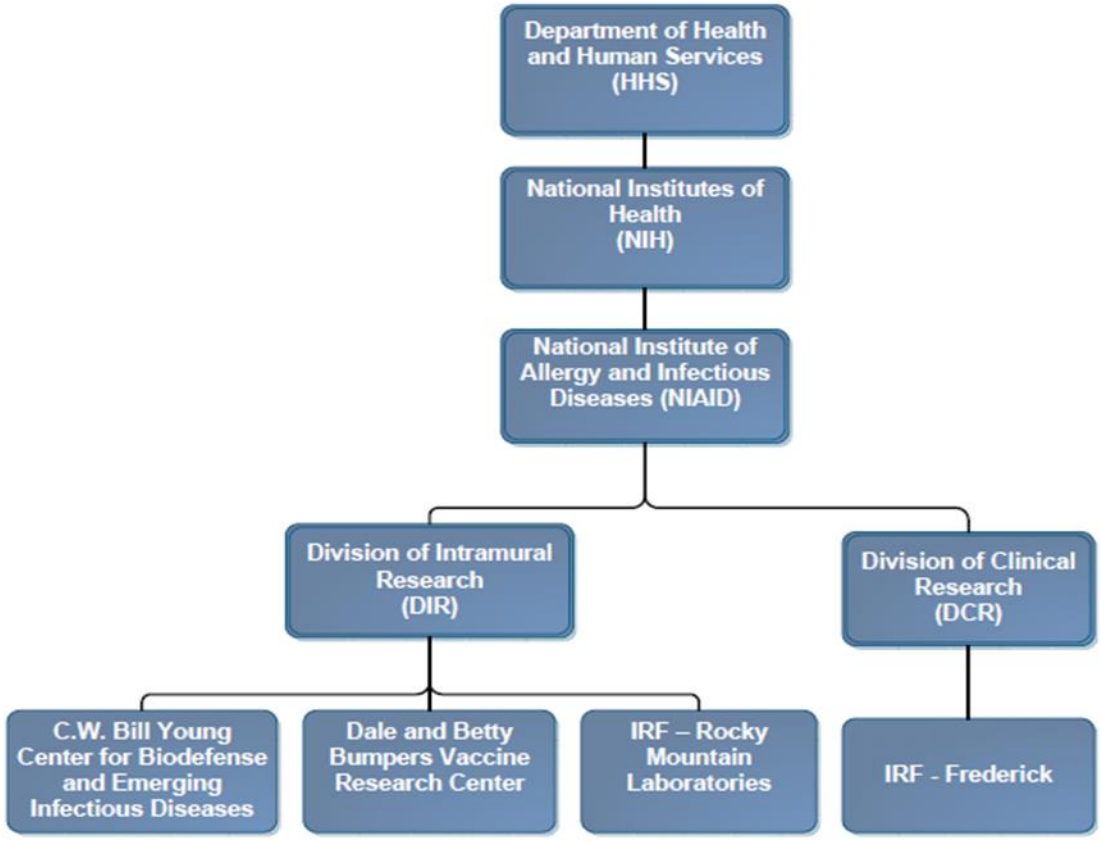
2. State the total funding for each programme and its source.
$96,070,182 U.S. Department of Health and Human Services (HHS)
$315,686 U.S. Department of Defense (DOD)

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?
14.1%

5. Summarize the objectives and research areas of each programme performed by contractors and in other facilities with the funds identified under paragraph 4.
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 104
- Integrated Research Facility at Fort Detrick (IRF-Frederick) – Page 116
- C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases – Page 121
- Dale and Betty Bumpers Vaccine Research Center (VRC) – Page 131

Form A, Part 2 (ii)

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.

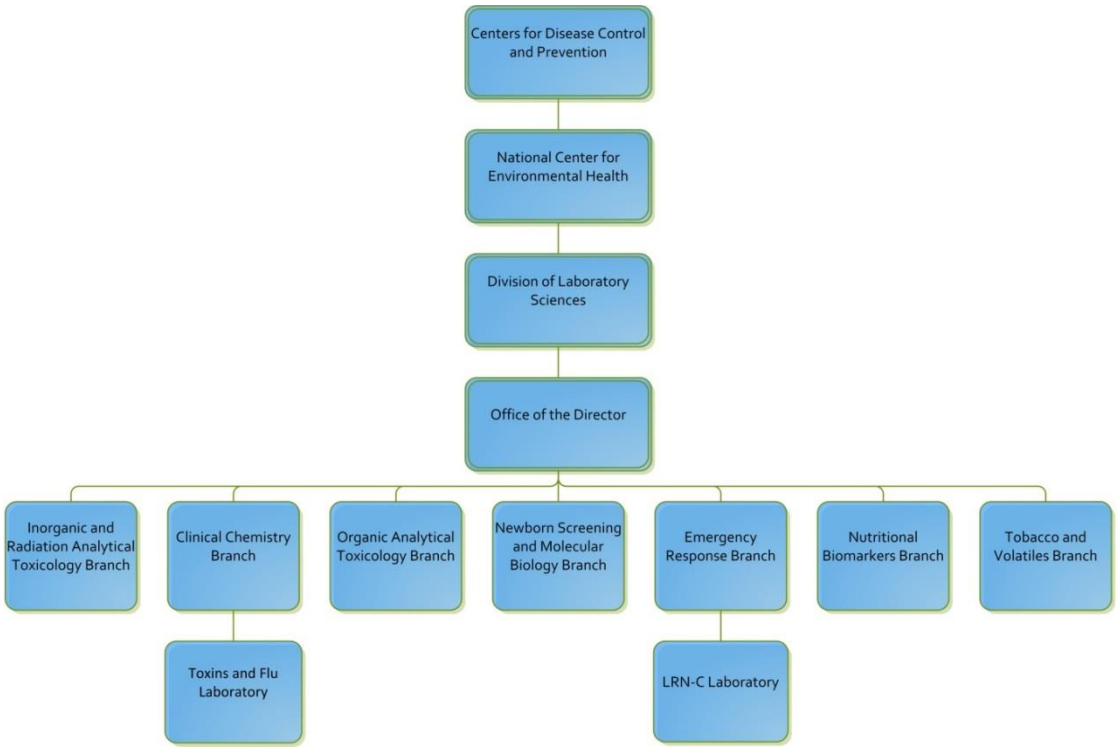
2. State the total funding for each programme and its source.
$4,785,235 U.S. Department of Health and Human Services (HHS)

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 90

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

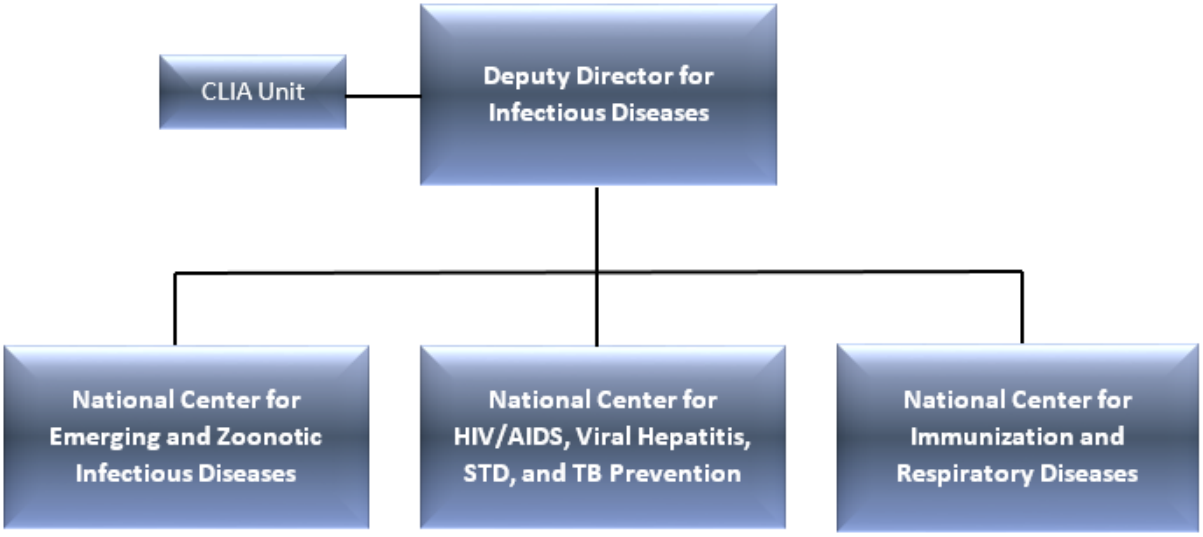
2. State the total funding for each programme and its source.
$23,574,987.70 Centers for Disease Control and Prevention (CDC)

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 92
- 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 102

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 in the country's agricultural systems but also in a wide range of economic activities. Diseases of concern include but are not limited to wheat rust, Foot-and-Mouth Disease, Avian Influenza, Classical Swine Fever, African Swine Fever, Exotic Newcastle disease, and Brucellosis.

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 potential 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.

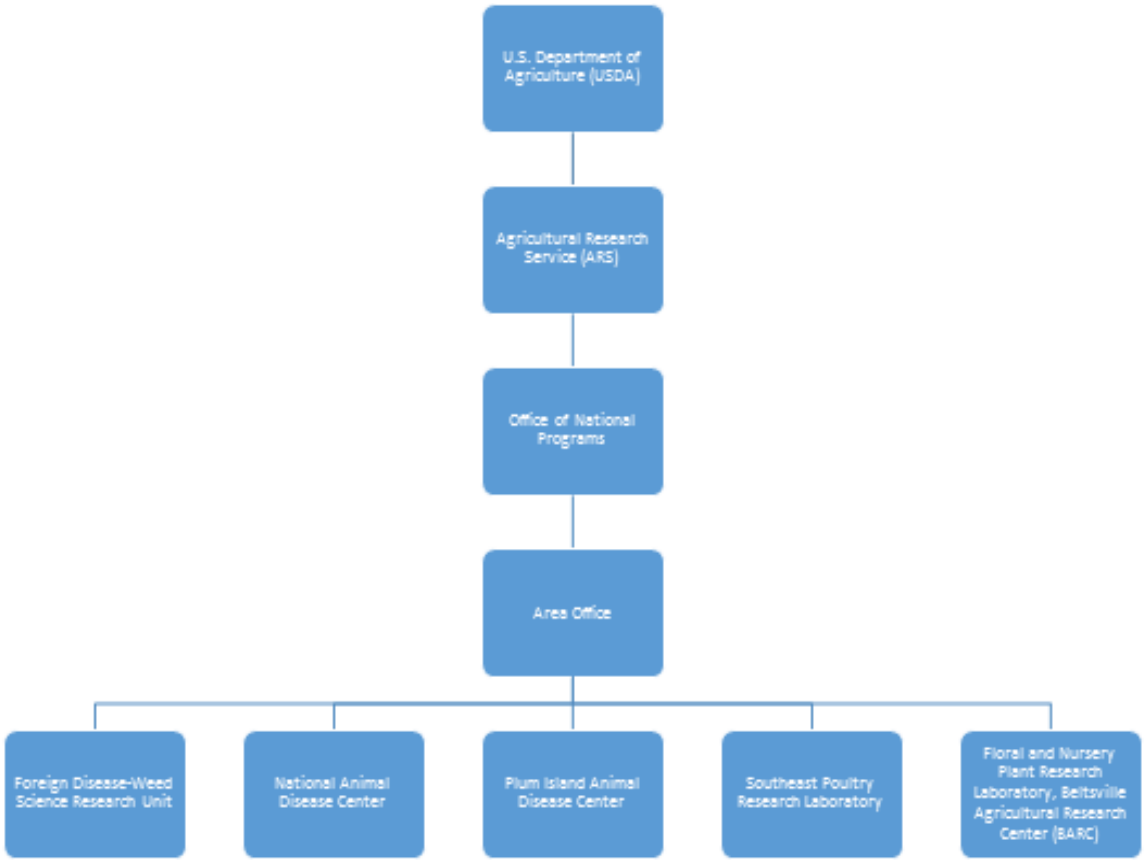
$38,203,000 U.S. Department of Agriculture (USDA)

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

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

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

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



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

- Plum Island Animal Disease Center (PIADC) – Page 42
- Foreign Disease-Weed Science Research Unit – Page 140

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 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 2021 included comprehensive threat and risk assessments to guide prioritization of the Nation's biodefense investments, biodefense knowledge management, the development of next-generation detectors for biological threat agents for critical infrastructure and urban areas, decontamination of transit systems, and bioforensics research in support of criminal investigations and attribution. Efforts at the National Biodefense Analysis and Countermeasures Center included biological threat characterization and forensic analysis for attribution, and, at the Plum Island Animal Disease Center, development of vaccines and diagnostics for foreign animal diseases.

The DHS Compliance Review Group, chaired by the DHS Deputy Secretary, meets periodically 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.

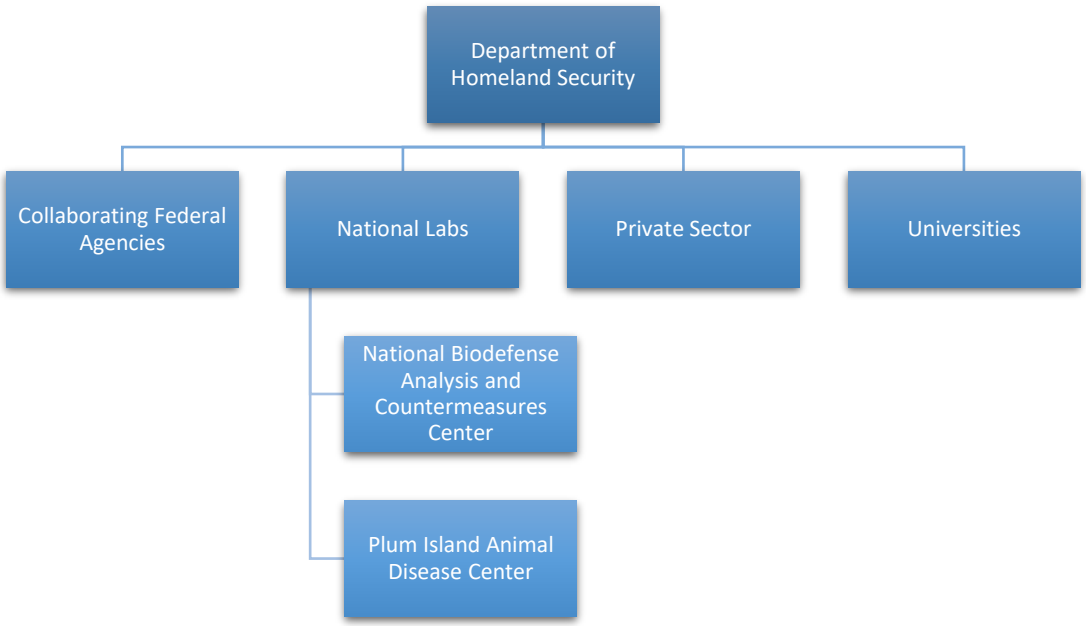
2. State the total funding for the programme and its source.
$75,037,566 U.S. Department of Homeland Security (DHS)

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, 2022

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 2021. 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 2021, several facilities detailed on Form A, Part 2 (iii) continued 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. Additionally, an Interim Final Rule issued on November 17, 2021 designated SARS-CoV/SARS-CoV-2 chimeric viruses (resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors) Select Agents, and is included in Annex B in this year's CBM report.

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: 188

(ii) Division of personnel:

Military	0
Civilian	188

Division of personnel by category:

Scientists	41
Engineers	40
Technicians	69
Administrative and support staff	38

(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, Systems Biology, Toxicology, Toxinology, Veterinary Medicine, Virology

(iv) Are contractor staff working in the facility? If so, provide an approximate number:
Yes Number: 188

(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	$ 11,240,717
Development	$ 12,797,988
Test and evaluation	$ 0

Total $ 24,038,705

(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/publication/public-affairs.

(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. Biryukov J, Boydston JA, Dunning RA, Yeager JJ, Wood S, Ferris A, et al. SARS-CoV-2 is Rapidly Inactivated at High Temperature. Environ Chem Lett. 2021; 19:1-5. https://link.springer.com/article/10.1007%2Fs10311-021-01187-x
2. Boydston JA , Yeager JJ , Taylor JR, Dabisch PA. Influence of aerodynamic particle size on botulinum neurotoxin potency in mice. Inhal Toxicol. 2021; 33:1-7. https://www.tandfonline.com/doi/abs/10.1080/08958378.2020.1851327?journalCode=iiht20
3. Cheng K, Lin MH, Moreno L, Skillman J, Hickey S, Cuenca D, et al. Modeling allelic analyte signals for aSTRs in NGS DNA profiles. J Forensic Sci. 2021; 66:1234-1245. https://onlinelibrary.wiley.com/doi/10.1111/1556-4029.14685
4. Dabisch PA, Biryukov J, Beck K, Boydston JA, Sanjak JS, Herzog A, et al. Seroconversion and fever are dose-dependent in a nonhuman primate model of inhalational COVID-19. PLoS Pathog. 2021; 17:1-19. https://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.1009865
5. DeBuysscher BL, Scott DP, Rosenke R, Wahl V, Feldmann H, Prescott J. Nipah Virus Efficiently Replicates in Human Smooth Muscle Cells without Cytopathic Effect. Cells. 2021; 10:1319. https://www.mdpi.com/2073-4409/10/6/1319
6. Kuhn JH, Adkins S, Agwanda BR, Kubrusli RA, Alkhovsky SV, Amarasinghe GK, et al. 2021 Taxonomic Update Of Phylum Negarnaviricota (Riboviria: Orthornavirae), Including the Large Orders Bunyavirales and Mononegavirales. Arch Virol. 2021;166:3513-3566. https://link.springer.com/article/10.1007%2Fs00705-021-05143-6#citeas
7. Ratnesar-Shumate S, Bohannon K, Williams G, Holland B, Krause M, Green B, et al. Comparison of the performance of aerosol sampling devices for measuring infectious SARS-CoV-2 aerosols. Aerosol Sci Technol. 2021; 55:160-175. https://www.tandfonline.com/doi/full/10.1080/02786826.2021.1910137
8. Schuit M, Biryukov J, Beck K, Yolitz J, Bohannon J, Weaver W, et al. The stability of an isolate of the SARS-CoV-2 B.1.1.7 lineage in aerosols is similar to three earlier isolates. J Infect Dis. 2021; 224:1641–1648. https://academic.oup.com/jid/article/224/10/1641/6209391
9. Schuit M, Dunning R, Freeburger D, Miller D, Hooper I, Faisca L, et al. The use of an Ebola virus reporter cell line in a semi-automated microtitration assay. J Virol Methods. 2021; 292:114116. https://www.sciencedirect.com/science/article/pii/S0166093421000550?via%3Dihub
10. Schuit M, Gardner S, Taylor J, Dabisch P. Evaluation of four sampling devices for Burkholderia pseudomallei laboratory aerosol studies. PLoS Negl Trop Dis. 2021; 15:e0009001. https://doi.org/10.1371/journal.pntd.0009001

11. Schuit MA, Taylor J, Dunning R, Miller D, Freeburger D, Faisca L, et al. Comparison of the performance of aerosol sampling devices with aerosols containing Ebola virus. Aerosol Sci Technol. 2021; 55:458-473. https://doi.org/10.1080/02786826.2020.1867310

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 United States with the scientific capabilities to understand biological threat agents to support preparedness, response, and recovery, and bioforensic analysis to support attribution and criminal investigations involving biological hazards. NBACC conducts purely defensive studies to fill in information gaps to better understand current and future biological threats to the U.S. Homeland; 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*: S**elect Agents (HHS, 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?
Plum Island Animal Disease Center (PIADC)

Note: The work performed at the Plum Island Animal Disease Center will be transitioning to the National Bio and Agro-Defense Facility and reported on in the BWC Confidence Building Measures Report once biological defense research and development work begins. More information about the National Bio and Agro-Defense Facility can be found here: https://www.usda.gov/nbaf.

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:**	419
(ii)	**Division of personnel:**	
	Military	0
	Civilian	419
(iii)	**Division of personnel by category:**	
	Scientists	72
	Engineers	3
	Technicians	4
	Administrative and support staff	340

(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: 316

(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	$ 1,833,441
Test and evaluation	**$** 9,611,606
Total	$ 18,893,408

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

DHS scientific research staffs are expected to publish papers in open literature. Papers are peer reviewed and approved by PIADC and DHS for security, clarity, and accuracy with regard to the description of work prior to submittal to journals or release. 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. Arzt J, Fish IH, Bertram MR, Smoliga GR, Hartwig EJ, Pauszek SJ, et al. Simultaneous and staggered foot-and-mouth disease virus coinfection of cattle. J Virol. 2021; 95:e0165021. https://journals.asm.org/doi/10.1128/JVI.01650-21
2. Asin J, Nyaoke AC, Moore JD, Gonzalez-Astudillo V, Clifford DL, Lantz EL, et al. Outbreak of rabbit hemorrhagic disease virus 2 in the southwestern United States: first detections in southern California. J Vet Diagn Invest. 2021; 33:728-731. https://journals.sagepub.com/doi/10.1177/10406387211006353
3. Bertram MR, Brito B, Palinski RM, Fish IH, Pauszek SJ, Hartwig EJ, et al. Novel Recombinant Foot-and-Mouth Disease Virus Circulating in Vietnam. Microbiol Resour Announc. 2021; 10:e01263-20. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8407725/
4. Bohórquez JA, Defaus S, Rosell R, Pérez-Simó M, Alberch M, Gladue DP, et al. Development of a Dendrimeric Peptide-Based Approach for the Differentiation of Animals Vaccinated with FlagT4G against Classical Swine Fever from Infected Pigs. Viruses. 2021; 13:1980. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8540558/
5. Borca MV, Rai A, Ramirez-Medina E, Silva E, Velazquez-Salinas L, Vuono E, et al. A cell culture-adapted vaccine virus against the current pandemic African swine fever virus strain. J Virol. 2021; 95:e0012321. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8315737/
6. Borca MV, Ramirez-Medina E, Silva E, Vuono E, Rai A, Pruitt S, et al. ASFV-G-DeltaI177L as an Effective Oral Nasal Vaccine against the Eurasia Strain of Africa Swine Fever. Viruses. 2021; 13:765. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8146859/
7. Coffman MS, Sanderson MW, Dodd CC, Arzt J, Renter DG. Estimation of foot-and-mouth disease windborne transmission risk from USA beef feedlots. Prev Vet Med. 2021; 195:105453. https://www.sciencedirect.com/science/article/abs/pii/S0167587721001975?via%3Dihub
8. Das A, Wang Y, Babiuk S, Bai J, Dodd K, Jia W. Development of multiplex real-time PCR assays for differential detection of capripoxvirus, parapoxvirus, and foot-and-mouth disease virus. Transbound Emerg Dis. 2021 Apr 10. doi:10.1111/tbed.14099. https://onlinelibrary.wiley.com/doi/10.1111/tbed.14099
9. Diaz-San Segundo F, Medina GN, Azzinaro P, Gutkoska J, Mogulothu A, Attreed SE, et al. Use of Protein Pegylation to Prolong the Antiviral Effect of IFN Against FMDV. Front Microbiol. 2021; 12:668890. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8131870/

10. Diaz-San Segundo F, Medina GN, Spinard E, Kloc A, Ramirez-Medina E, Azzinaro P, et al. Use of Synonymous Deoptimization to Derive Modified Live Attenuated Strains of Foot and Mouth Disease Virus. Front Microbiol. 2021; 11:610286. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7861043/
11. Drolet BS, Reeves WK, Bennett KE, Pauszek SJ, Bertram MR, Rodriguez LL. Identical Viral Genetic Sequence Found in Black Flies and the Equine Index Case of the 2006 U.S. Vesicular Stomatitis Outbreak. Pathogens. 2021; 10:929. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8398051/
12. Eschbaumer M, Vögtlin A, Paton DJ, Barnabei JL, Sanchez-Vazquez MJ, Pituco EM, et al. Non-discriminatory Exclusion Testing as a Tool for the Early Detection of Foot-and-Mouth Disease Incursions. Front Vet Sci. 2020; 7:552670. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7710516/
13. Gladue DP, Ramirez-Medina E, Vuono E, Silva E, Rai A, Pruitt S, et al. Deletion of A137R gene from the pandemic strain of African swine fever virus is attenuated and offers protection against virulent pandemic virus. J Virol. 2021; 95:e0113921. https://journals.asm.org/doi/10.1128/JVI.01139-21
14. Goonewardene K, Chung CJ, Goolia M, Blakemore L, Fabian A, Mohamed F, et al. Evaluation of oral fluid as an aggregate sample for early detection of African swine fever virus using four independent pen-based experimental studies. Transbound Emerg Dis. 2021; 68:2867-2877. https://onlinelibrary.wiley.com/doi/10.1111/tbed.14175
15. Gunasekara U, Bertram MR, Dung DH, Hoang BH, Phuong NT, Hung VV, et al. Use of Slaughterhouses as Sentinel Points for Genomic Surveillance of Foot-and-Mouth Disease Virus in Southern Vietnam. Viruses. 2021; 13:2203. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8624567/
16. Humphreys JM, Pelzel-McCluskey AM, Cohnstaedt LW, McGregor BL, Hanley KA, Hudson AR, et al. Integrating Spatiotemporal Epidemiology, Eco-Phylogenetics, and Distributional Ecology to Assess West Nile Disease Risk in Horses. Viruses. 2021; 13:1811. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8473291/
17. LaRocco M, Ahmed Z, Rodriguez-Calzada M, Azzinaro PA, Barrette R, Krug P, et al. An adventitious agent-free clonal cell line that is highly susceptible to foot -and-mouth disease virus. Biologicals. 2021; 72:33-41. https://www.sciencedirect.com/science/article/pii/S1045105621000427?via%3Dihub
18. Lopera-Madrid J, Medina-Magües LG, Gladue DP, Borca MV, Osorio JE. Optimization in the expression of ASFV proteins for the development of subunit vaccines using poxviruses as delivery vectors. Sci Rep. 2021; 11:23476. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8648923/
19. Lopez E, Bosch-Camós L, Ramirez-Medina E, Vuono E, Navas MJ, Muñoz M, et al. Deletion Mutants of the Attenuated Recombinant ASF Virus, BA71DeltaCD2, Show Decreased Vaccine Efficacy. Viruses. 2021; 13:1678. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8473413/
20. Mohamed F, Gidlewski T, Berninger ML, Petrowski HM, Bracht AJ, de Rueda CB, et al. Comparative susceptibility of eastern cottontails and New Zealand white rabbits to classical rabbit hemorrhagic disease virus (RHDV) and RHDV2. Transbound Emerg Dis. 2021 Nov 5. doi:10.1111/tbed.14381. https://onlinelibrary.wiley.com/doi/10.1111/tbed.14381
21. Munsey A, Mwiine FN, Ochwo S, Velazquez-Salinas L, Ahmed Z, Maree F, et al. Phylogeographic analysis of foot-and-mouth disease virus serotype O dispersal and associated drivers in East Africa. Mol Ecol. 2021; 30:3815-3825. https://onlinelibrary.wiley.com/doi/10.1111/mec.15991
22. O'Donnell VK, Xu L, Moran K, Mohamed F, Boston T, Pauszek SJ, et al. Coding-Complete Genome Sequences of Emerging Rabbit Hemorrhagic Disease Virus Type 2 Isolates Detected in 2020 in the United States. Microbiol Resour Announc. 2021; 10:e01064-20. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8407691/
23. Pelzel-McCluskey A, Christensen B, Humphreys J, Bertram M, Keener R, Ewing R, et al. Review of Vesicular Stomatitis in the United States with Focus on 2019 and 2020 Outbreaks. Pathogens. 2021; 10:993. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8399664/

24. Rai A, Pruitt S, Ramirez-Medina E, Vuono EA, Silva E, Velazquez-Salinas L, et al. Detection and Quantification of African Swine Fever Virus in MA-104 Cells. Bio Protoc. 2021; 11:e3955. https://bio-protocol.org/e3955
25. Ramirez-Medina E, Vuono E, Pruitt S, Rai A, Silva E, Espinoza N, et al. Development and In Vivo Evaluation of a MGF110-1L Deletion Mutant in African Swine Fever Strain Georgia. Viruses. 2021; 13:286. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7918709/
26. Ramirez-Medina E, Vuono E, Rai A, Pruitt S, Espinoza N, Velazquez-Salinas L, et al. Deletion of E184L, a putative DIVA target from the pandemic strain of African swine fever virus, produces a reduction in virulence and protection against virulent challenge. J Virol. 2021; 96:e0141921. https://journals.asm.org/doi/10.1128/JVI.01419-21
27. Stenfeldt C, Bertram MR, Meek HC, Hartwig EJ, Smoliga GR, Niederwerder MC, et al. The risk and mitigation of foot-and-mouth disease virus infection of pigs through consumption of contaminated feed. Transbound Emerg Dis. 2021 Jul 8. doi:10.1111/tbed.14230. https://onlinelibrary.wiley.com/doi/10.1111/tbed.14230
28. Tran XH, Le TTP, Nguyen QH, Do TT, Nguyen VD, Gay CG, et al. African swine fever virus vaccine candidate ASFV-G-DeltaI177L efficiently protects European and native pig breeds against circulating Vietnamese field strain. Transbound Emerg Dis. 2021 Sep 28. doi: 10.1111/tbed.14329. https://onlinelibrary.wiley.com/doi/10.1111/tbed.14329
29. Velazquez-Salinas L, Canter JA, Zhu JJ, Rodriguez LL. Molecular Pathogenesis and Immune Evasion of Vesicular Stomatitis New Jersey Virus Inferred from Genes Expression Changes in Infected Porcine Macrophages. Pathogens. 2021; 10:1134. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8469936/
30. Velazquez-Salinas L, Ramirez-Medina E, Rai A, Pruitt S, Vuono EA, Espinoza N, et al. Development Real-Time PCR Assays to Genetically Differentiate Vaccinated Pigs From Infected Pigs With the Eurasian Strain of African Swine Fever Virus. Front Vet Sci. 202; 8:768869. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8579032/
31. Vuono EA, Ramirez-Medina E, Pruitt S, Rai A, Espinoza N, Velazquez-Salinas L, et al. Evaluation of the Function of the ASFV KP177R Gene, Encoding for Structural Protein p22, in the Process of Virus Replication and in Swine Virulence. Viruses. 2021; 13:986. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8227490/
32. Vuono E, Ramirez-Medina E, Pruitt S, Rai A, Silva E, Espinoza N, et al. Evaluation in Swine of a Recombinant Georgia 2010 African Swine Fever Virus Lacking the I8L Gene. Viruses. 2021; 13:39. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7823879/
33. Vuono EA, Ramirez-Medina E, Velazquez-Salinas L, Berggren K, Rai A, Pruitt S, et al. Structural glycoprotein E2 of classical swine fever virus critically interacts with host protein Torsin-1A during the virus infectious cycle. J Virol. 2021; 95:e00314-21. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8316129/
34. Wu P, Rodríguez YY, Hershey BJ, Tadassa Y, Dodd KA, Jia W. Validation of a binary ethylenimine (BEI) inactivation procedure for biosafety treatment of foot-and-mouth disease viruses (FMDV), vesicular stomatitis viruses (VSV), and swine vesicular disease virus (SVDV). Vet Microbiol. 2021; 252:108928. https://www.sciencedirect.com/science/article/pii/S037811352031066X?via%3Dihub
35. Young KI, Valdez F, Vaquera C, Campos C, Zhou L, Vessels HK, et al. Surveillance along the Rio Grande during the 2020 Vesicular Stomatitis Outbreak Reveals Spatio-Temporal Dynamics of and Viral RNA Detection in Black Flies. Pathogens. 2021; 10:1264. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8541391/
36. Zurita M, Martignette L, Barrera J, Carrie M, Piscatelli H, Hangman A, et al. Detection of African Swine Fever virus utilizing the portable MatMaCorp ASF detection system. Transbound Emerg Dis. 2021 Dec 6. doi:10.1111/tbed.14411. https://onlinelibrary.wiley.com/doi/10.1111/tbed.14411

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: 29

(ii) Division of personnel:

Military	0
Civilian	29

(iii) Division of personnel by category:

Scientists	18
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: 9

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

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

Research	$ 0
Development	$ 0
Test and evaluation	$ 2,844,000
Total	$ 2,844,000

(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/ARN30105-AR_360-1-000-WEB-1.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/dodd/523009p.pdf) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.pdf).

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

None.

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

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

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

Outdoor Studies: Yes. All outdoor studies were conducted with non-hazardous BSL-1 bacteria; no outdoor studies were conducted with hazardous organisms or material derived from hazardous organisms.

[*] Including viruses and prions.

National biological defence research and development programmes: Facilities

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

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

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

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

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: 99

(ii) Division of personnel:

Military	14
Civilian	85

(iii) Division of personnel by category:

Scientists	23
Engineers	0
Technicians	66
Administrative and support staff	10

(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: 72

(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	$ 25,281,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 25,281,000

(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. Owens LA, Colitti B, Hirji I, Pizarro A, Jaffe JE, Moittie S, Bishop-Lilly KA, Estrella LA, et el. A Sarcina bacterium linked to lethal disease in sanctuary chimpanzees in Sierra Leone. Nat Commun. 2021 Feb 3;12(1),763. https://www.nature.com/articles/s41467-021-21012-x
2. Ramos I, Goforth C, Soares-Schanoski A, Weir DL, Samuels EC, Phogat S, et al. Antibody responses to SARS-CoV-2 following an outbreak among Marine recruits with asymptomatic or mild infection. Front Immunol. 2021 Jun 9; 12:681586. https://www.nejm.org/doi/10.1056/NEJMoa2029717
3. Pollett SD, Richard S, Fries AC, Simons M, Mende K, Lalani T, et al. The SARS-CoV-2 mRNA vaccine breakthrough infection phenotype includes significant symptoms, live virus shedding, and viral genetic diversity. Clin Infect Dis. 2021 Jun 12;ciab543. https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab543/6297424?login=true
4. Ramirez-Sanchez C, Gonzales F, Buckley M, Biswas B, Henry M, Deschenes MV, et al. Successful Treatment of Staphylococcus aureus Prosthetic Joint Infection with Bacteriophage Therapy. Viruses. 2021 Jun 21;13(6);1182. https://www.mdpi.com/1999-4915/13/6/1182/htm
5. Duplessis C, Luke TC, Watters C, Alcorta Y, Biswas B. Skin swabbing for Staphylococcus aureus - Targeting phages. Mil Med. 2021 Jun 28; usab251. https://academic.oup.com/milmed/advance-article/doi/10.1093/milmed/usab251/6310277?login=true
6. Duplessis C, Warawa JM, Lawrenz MB, Henry M, Biswas B. Successful intratracheal treatment of phage and antibiotic combination therapy of a multi-drug resistant Pseudomonas aeruginosa murine model. Antibiotics (Basel). 2021 Aug 5; 10(8):946. https://www.mdpi.com/2079-6382/10/8/946/htm
7. Sardesai AU, Tanak AS, Krishnan S, Striegel DA, Schully KL, Clark DV, et al. An approach to rapidly assess sepsis through multi-biomarker host response using machine learning algorithm. Sci Rep. 2021 Aug 19;11(1):16905. https://www.nature.com/articles/s41598-021-96081-5
8. Chan-Cuzydlo A, Harrison D, Pike B, Currie B, Mayo M, Salvador MG. Cohort Profile: A migratory cohort study of US Marines who train in Australia. BMJ Open. 2021 Sep 15;11:e050330. https://bmjopen.bmj.com/content/11/9/e050330
9. Lueder MR, Cer RZ, Patrick M, Voegtly LJ, Long KA, Rice GK, et al. Manual Annotation Studio (MAS): a collaborative platform for manual functional annotation of viral and microbial genomes. BMC Genomics. 2021 Oct 9; 22(1):733. https://bmcgenomics.biomedcentral.com/articles/10.1186/s12864-021-08029-8
10. Letizia AG, Arnold CE, Adhikari BN, Voegtly LJ, Glang L, Rice GK, et al. Immunological and genetic investigation of SARS-CoV-2 reinfection in an otherwise healthy, young Marine recruit. Pathogens. 2021 Dec 8;10(12):1589. https://www.mdpi.com/2076-0817/10/12/1589/htm
11. Nadolny RM, Kennedy AC, Rodgers JM, Vincent ZT, Cornman H, Haynes SA. et al. Bat ticks Carios kelleyi (Cooley and Kohls) (Acari: Argasidae) infected with rickettsial agents documented infesting housing in Kansas, U.S.A. J Med Ento. 2021. https://academic.oup.com/jme/article/58/6/2398/6278151.

12. Jiang J, Farris CM, Yeh KB, Richards AL. International Rickettsia Disease Surveillance: An Example of Cooperative Research to Increase Laboratory Capacity for Risk Assessment of Rickettsia Outbreaks Worldwide. Front Med. 2021. https://pubmed.ncbi.nlm.nih.gov/33738293/.
13. Orient E, Chen D, Jiang J, Maina AN, Farris CM, Luce-Fedrow A, et al. Pathogen Carriage by Peri-Domestic Fleas in Western Kenya. Vector Borne Zoonotic Dis. 2021. https://pubmed.ncbi.nlm.nih.gov/33481673/

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 goals of the program are the development of rapid and deployable detection assays to protect deployed troops and to increase understanding of infectious disease risk to deployed forces. During 2021, we continued studying clinical cases of sepsis in austere environments with the ultimate goal of understanding host-pathogen interactions, development of pathogen-agnostic diagnostic assays, and better treatment strategies against relevant infectious diseases. In addition, other efforts include continued development of diagnostics using bacteriophage combined with other technologies and expansion of 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 continued a project to identify biomarkers of neurological injury for HHS select agents. Additional information is available at https://www.med.navy.mil/Naval-Medical-Research-Center/

Microorganisms and/or Toxins Studied: Select Agents (HHS, Overlap) and HHS Select Toxins, 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?
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:	56 m^2
BSL-2:	440 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	496 m^2

During the reported calendar year, the NRL laboratory space used for biodefense research and development was reapportioned, resulting in a decrease of 261 m^2 of BSL-1 lab space and an increase of 140 m^2 of BSL-2 space. The laboratory space was not physically remodeled.

4. The organizational structure of each facility:

(i) Total number of personnel: 19

(ii) Division of personnel:

Military	1
Civilian	18

(iii) Division of personnel by category:

Scientists	16
Engineers	1
Technicians	2
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: 3

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

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

Research	$ 1,292,000
Development	$ 1,013,000
Test and evaluation	$ 0
Total	$ 2,305,000

(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 GP, Liu JL, Esparza TJ, Voelker BT, Hofmann ER, Goldman ER Single-Domain Antibodies for the Detection of SARS-CoV-2 Nucleocapsid Protein. Analytical Chemistry. 2021; 93:7283-7291. https://pubmed.ncbi.nlm.nih.gov/33955213/
2. Liu JL, Webb EM, Zabetakis D, Burke CW, Gardner CL, Glass PJ, et al. Stabilization of a Broadly Neutralizing Anti-Chikungunya Virus Single Domain Antibody. Front Med (Lausanne). 2021; Jan 28;8:626028. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7876468/
3. Reynolds N D, Aceves N M, Liu J L, Compton J R, Leary D H, Freitas BT, et al. The SARS-CoV-2 SSHHPS Recognized by the Papain-like Protease. ACS infectious diseases, 2021; 7(6), 1483–1502. https://doi.org/10.1021/acsinfecdis.0c00866
4. Stenger DA, Taitt CR, Shriver-Lake LC, Malanoski AP, Ligler FS, Kusterbeck AW, et al. Silent Guardian at NRL: October 2004-March 2005. NRL Formal Report. 2021; NRL/FR/6900—05-10,118 https://apps.dtic.mil/sti/pdfs/AD1143810.pdf

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: HHS Select Toxins and simulants of Select Agents and Toxins (Overlap, HHS), NIAID Category A

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?
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: 26

(ii) Division of personnel:

Military	0
Civilian	26

(iii) Division of personnel by category:

Scientists	21
Engineers	1
Technicians	1
Administrative and support staff	3

(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: 8

Note: The number of contractor staff working this facility during 2020 should have been 9 instead of the 6 reported.

(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	$ 1,446,097
Development	$ 1,855,650
Test and evaluation	$ 3,269,431
Total	$ 6,571,178

(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: Efforts at this defense laboratory are focused on hazard mitigation technologies, risk assessment tools, and consequence management planning.

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

Outdoor Studies: No outdoor studies performed.

Note: The NSWC Dahlgren Chemical and Biological Defense Division in large part was moved to NSWC Indian Head between 2018 and 2021. The only remaining portion of the portfolio at NSWC Dahlgren is the technical, microbiological laboratory-focused aspect. All of the programs and chemical laboratories were moved to Indian Head. This accounts for the decrease in personnel, specifically non-technical personnel, as well as the decrease in funding. The completion of biological mission transfer is on strategic pause (with transfer of lab work scheduled to take place) until no sooner than fiscal year 2026.

* 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?
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

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

4. The organizational structure of each facility:

(i) Total number of personnel 63

(ii) Division of personnel:

Military	0
Civilian	63

(iii) Division of personnel by category:

Scientists	47
Engineers	3
Technicians	13
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: 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 Defense (DOD) – Wholly

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

Research	$ 14,599,000
Development	$ 5,957,000
Test and evaluation	$ 0
Total	$ 20,556,000

(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/ARN30105-AR_360-1-000-WEB-1.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/dodd/523009p.pdf) and DOD Instruction 5320.29, Security and Policy Review of DOD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.pdf).

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

1. Amemiya K, Dankmeyer JL, Bernhards RC, Fetterer DP, Waag DM, Worsham PL, et al. Activation of Toll-Like Receptors by Live Gram-Negative Bacterial Pathogens Reveals Mitigation of TLR4 Responses and Activation of TLR5 by Flagella. Frontiers in Cellular and Infection Microbiology. 2021;11. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8650638/
2. Kennedy NW, Ikonomova SP, Lee MS, Raeder HW, Tullman-Ercek D. Self-assembling Shell Proteins PduA and PduJ have Essential and Redundant Roles in Bacterial Microcompartment Assembly. Journal of Molecular Biology. 2021;433(2). https://www.sciencedirect.com/science/article/abs/pii/S0022283620306392
3. Rastogi VK, Hurst S, Wallace, L. Quantitative efficacy of common virucidal disinfectants against viral surrogates on porous and nonporous surfaces. DEVCOM Chemical Biological Center. 2021, CCDC CBC-TR-1710. https://apps.dtic.mil/sti/pdfs/AD1140208.pdf

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.devcom.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 simulants of Select Agents (HHS, Overlap).

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: 16

(ii) Division of personnel:

Military	1
Civilian	15

(iii) Division of personnel by category:

Scientists	2
Engineers	0
Technicians	14
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: 10

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

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

Research	$ 350,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 350,000

(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/ARN30105-AR_360-1-000-WEB-1.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/dodd/523009p.pdf) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.pdf).

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

1. McNutt PM, Vazquez-Cintron EJ, Tenezaca L, Ondeck CA, Kelly KE, Mangkhalakhili M. et al. Neuronal delivery of antibodies has therapeutic effects in animal models of botulism. Sci Transl Med. 2021 Jan 6;13(575):eabd7789. doi: 10.1126/scitranslmed.abd7789. PMID: 33408188; PMCID: MC8176400. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8176400/

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: https://usamricd.amedd.army.mil/Pages/default.aspx

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

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?
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 680

(ii) Division of personnel:

Military	167
Civilian	513

(iii) Division of personnel by category:

Scientists	164
Engineers	11
Technicians	283
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: 255

(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)
Universities
Private sector companies

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

Research	$ 2,064,398
Development	$ 52,650,990*
Test and evaluation	$ 16,055,877
Total	$ 70,771,265

*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/ARN30105-AR_360-1-000-WEB-1.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/dodd/523009p.pdf) and DoD Instruction 5320.29, Security and Policy Review of DoD Information for Public Release (http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/523029p.pdf).

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

1. Alum S, Asiimwe M, Kanyomozi G, Nalikka J, Okwaro P, Migisha I, et al. Optimizing highly infectious disease isolation unit management. Experiences from the Infectious Diseases Isolation and Research Unit, Fort Portal, Uganda. Disaster Med Public Health Prep. 2021 Nov 25; 1-17. https://doi.org/10.1017/dmp.2021.339
2. Amemiya K, Dankmeyer JL, Bernhards RC, Fetterer DP, Waag DM, Worsham PL, et al. Activation of toll-like receptors by live gram-negative bacterial pathogens reveals mitigation of TLR4 responses and activation of TLR5 by flagella. Front Cell Infect Microbiol. 2021 Nov 23; 11:745325. https://doi.org/10.3389/fcimb.2021.745325
3. Arnold CE, Shoemaker CJ, Smith DR, Douglas CE, Blancett CD, Graham AS, et al. Host response transcriptomic analysis of Crimean-Congo hemorrhagic fever pathogenesis in the cynomolgus macaque model. Sci Rep. 2021 Oct 6; 11(1):19807. https://doi.org/10.1038/s41598-021-99130-1
4. Bachert BA, Richardson JB, Mlynek KD, Klimko CP, Toothman RG, Fetterer DP, et al. Development, phenotypic characterization and genomic analysis of a Francisella tularensis panel for Tularemia vaccine testing. Front Microbiol. 2021 Aug 11; 12:725776. https://doi.org/10.3389/fmicb.2021.725776
5. Beitzel BF, Radoshitzky SR, Di Paola N, Brannan JM, Kimmel D, Caviness K, et al. On-demand patient-specific phenotype-to-genotype Ebola virus characterization. Viruses. 2021 Oct 6; 13(10):2010. https://doi.org/10.3390/v13102010

6. Biryukov S, Dankmeyer JL, Shamsuddin Z, Velez I, Rill NO, Rosario-Acevedo R, et al. Impact of toll-like receptor-specific agonists on the host immune response to the Yersinia pestis plague rF1V vaccine. Front Immunol. 2021 Aug 27; 12:726416. https://doi.org/10.3389/fimmu.2021.726416
7. Blair PW, Kortepeter MG, Downey LG, Madar CS, Downs IL, Martins KA, et al. Intensive care unit-like care of nonhuman primates with Ebola virus disease. J Infect Dis. 2021 Aug 15; 224(4):632-642. https://doi.org/10.1093/infdis/jiaa781
8. Boonyalai N, Thamnurak C, Sai-Ngam P, Ta-Aksom W, Arsanok M, Uthaimongkol N, et al. Plasmodium falciparum phenotypic and genotypic resistance profile during the emergence of Piperaquine resistance in Northeastern Thailand. Sci Rep. 2021 Jun 28; 11(1):13419. https://doi.org/10.1038/s41598-021-92735-6
9. Bowling PA, Bencivenga MA, Leyva ME, Grego BE, Cornelius RN, Cornelius EM, et al. Effects of a heated anesthesia breathing circuit on body temperature in anesthetized rhesus macaques (macaca mulatta). J Am Assoc Lab Anim Sci. 2021 Nov 1; 60(6):675-680. https://doi.org/10.30802/aalas-jaalas-21-000058
10. Brocato RL, Altamura LA, Carey BD, Perley CC, Blancett CD, Minogue TD, et al. Comparison of transcriptional responses between pathogenic and nonpathogenic hantavirus infections in Syrian hamsters using NanoString. PLoS Negl Trop Dis. 2021 Aug 2; 15(8):e0009592. https://doi.org/10.1371/journal.pntd.0009592
11. Brocato RL, Kwilas SA, Josleyn MD, Long S, Zeng X, Perley CC, et al. Small animal jet injection technique results in enhanced immunogenicity of hantavirus DNA vaccines. Vaccine. 2021 Feb 12; 39(7):1101-1110. https://doi.org/10.1016/j.vaccine.2021.01.002
12. Brocato RL, Kwilas SA, Kim RK, Zeng X, Principe LM, Smith JM, et al. Protective efficacy of a SARS-CoV-2 DNA vaccine in wild-type and immunosuppressed Syrian hamsters. NPJ Vaccines. 2021 Jan 25; 6(1):16. https://doi.org/10.1038/s41541-020-00279-z
13. Cai Y, Yu S, Chi X, Radoshitzky SR, Kuhn JH, Berger EA. An immunotoxin targeting Ebola virus glycoprotein inhibits Ebola virus production from infected cells. PLoS One. 2021 Jan 7; 16(1):e0245024. https://doi.org/10.1371/journal.pone.0245024
14. Cai Y, Yu S, Fang Y, Bollinger L, Li Y, Lauck M, et al. Development and characterization of a cDNA-launch recombinant Simian hemorrhagic fever virus expressing enhanced green fluorescent protein: ORF 2b' is not required for in vitro virus replication. Viruses. 2021 Apr 7; 13(4):632. https://doi.org/10.3390/v13040632
15. Chapman NS, Zhao H, Kose N, Westover JB, Kalveram B, Bombardi R, et al. Potent neutralization of Rift Valley fever virus by human monoclonal antibodies through fusion inhibition. Proc Natl Acad Sci U S A. 2021 Apr 6; 118(14):e2025642118. https://doi.org/10.1073/pnas.2025642118
16. Chen Y, Toth EA, Ruan B, Choi EJ, Simmerman R, Chen Y, et al. Engineering subtilisin proteases that specifically degrade active RAS. Commun Biol. 2021 Mar 5; 4(1):299. https://doi.org/10.1038/s42003-021-01818-7
17. Chiang CY, Zhong Y, Ward MD, Lane DJ, Kenny T, Rosario-Acevedo R, et al. Proteomic analysis of non-human primate peripheral blood mononuclear cells during Burkholderia mallei infection reveals a role of ezrin in glanders pathogenesis. Front Microbiol. 2021 Apr 22; 12:625211. https://doi.org/10.3389/fmicb.2021.625211
18. Ciencewicki JM, Herbert AS, Storm N, Josleyn NM, Huie K, McKay LGA, et al. Characterization of an anti-Ebola virus hyperimmune globulin derived from convalescent plasma. J Infect Dis. 2021 Aug 27. https://doi.org/10.1093/infdis/jiab432
19. Clayton NP, Jain A, Halasohoris SA, Pysz LM, Lembirik S, Zumbrun SD, et al. In vitro and in vivo characterization of Tebipenem (TBP), an orally active carbapenem, against biothreat pathogens. Antimicrob Agents Chemother. 2021 Feb 16; 65(5):e02385-20. https://doi.org/10.1128/aac.02385-20
20. Cote CK, Biryukov SS, Klimko CP, Shoe JL, Hunter M, Rosario-Acevedo R, et al. Protection elicited by attenuated live Yersinia pestis vaccine strains against lethal infection with virulent Y. pestis. Vaccines (Basel). 2021 Feb 16; 9(2):161. https://doi.org/10.3390/vaccines9020161

21. Cote CK, Weidner JM, Klimko C, Piper AE, Miller JA, Hunter M, et al. Biological validation of a chemical effluent decontamination system. Appl Biosaf. 2021 Mar 19; 26(1):23-32. https://doi.org/10.1089/apb.21.937967
22. Crooks CM, Weiler AM, Rybarczyk SL, Bliss M, Jaeger AS, Murphy ME, et al. African-lineage Zika virus replication dynamics and maternal-fetal interface infection in pregnant rhesus macaques. J Virol. 2021 Jul 26; 95(16):e0222020. https://doi.org/10.1128/jvi.02220-20
23. Davis S, Milechin L, Patel T, Hernandez M, Ciccarelli G, Samsi S, et al. Detecting pathogen exposure during the non-symptomatic incubation period using physiological data: proof of concept in non-human primates. Front Physiol. 2021 Sep 3; 12:691074. https://doi.org/10.3389/fphys.2021.691074
24. De Luca E, Álvarez-Narváez S, Maboni G, Baptista RP, Nemeth NM, Niedringhaus KD, et al. Comparative genomics analyses support the reclassification of Bisgaard Taxon 40 as Mergibacter gen. nov., with Mergibacter septicus sp. nov. as type species: novel insights into the phylogeny and virulence factors of a Pasteurellaceae family member associated with mortality events in seabirds. Front Microbiol. 2021 Nov 22; 12:667356. https://doi.org/10.3389/fmicb.2021.667356
25. Dixon BC, Culbreth MJ, Kumsher DM, Carbaugh CM, Fetterer DP, Reiter CP. Mid-tibiofibular amputation as a method of terminal blood collection in xenopus laevis. J Am Assoc Lab Anim Sci. 2021 Sep 1; 60(5):582-586. https://doi.org/10.30802/aalas-jaalas-21-000005
26. Downs I, Johnson JC, Rossi F, Dyer D, Saunders DL, Twenhafel NA, et al. Natural history of aerosol-induced Ebola virus disease in rhesus macaques. Viruses. 2021 Nov 17; 13(11):2297. https://doi.org/10.3390/v13112297
27. Dunay MA, McClain SL, Holloway RL, Norris SLW, Bendixsen Randall T, Mohr CE, et al. Pre-hospital administration of Remdesivir during a SARS-CoV-2 outbreak in a skilled nursing facility. Clin Infect Dis. 2021 Aug 19. https://doi.org/10.1093/cid/ciab715
28. Engdahl TB, Kuzmina NA, Ronk AJ, Mire CE, Hyde MA, Kose N, et al. Broad and potently neutralizing monoclonal antibodies isolated from human survivors of New World hantavirus infection. Cell Rep. 2021 May 4; 35(5):109086. https://doi.org/10.1016/j.celrep.2021.109086
29. Engdahl TB, Kusmina NA, Ronk AJ, Mire CE, Hyde MA, Kose N, et al. Erratum for "Broad and potently neutralizing monoclonal antibodies isolated from human survivors of New World hantavirus infection." Cell Rep. 2021 Jul 20; 36(3):109453. https://doi.org/10.1016/j.celrep.2021.109453
30. Evans TS, Myat TW, Hom NS, Ricks KM, Maw MT, Oo ZM, et al. Seroepidemiologic survey of Crimean-Congo hemorrhagic fever virus in logging communities, Myanmar. Emerg Infect Dis. 2021 May 6; 27(6):1709-1713. https://doi.org/10.3201/eid2706.203223
31. 31. Fall G, Diallo D, Soumaila H, Ndiaye EH, Lagare A, Sadio BD, et al. First detection of the West Nile virus Koutango lineage in sandflies in Niger. Pathogens. 2021 Feb 24; 10(3):257. https://doi.org/10.3390/pathogens10030257
32. Fels JM, Maurer DP, Herbert AS, Wirchnianski AS, Vergnolle O, Cross RW, et al. Protective neutralizing antibodies from human survivors of Crimean-Congo hemorrhagic fever. Cell. 2021 Jun 24; 184(13):3486-3501.e3421. https://doi.org/10.1016/j.cell.2021.05.001
33. 33. Franz DR, Le Duc JW. Technology advances, high-risk research, and a safe way forward. mBio. 2021 Oct 26; 12(5):e0237321. https://doi.org/10.1128/mbio.02373-21
34. Frick OM, Livingston VA, Whitehouse CA, Norris SL, Alves DA, Facemire PR, et al. The natural history of aerosolized Francisella tularensis infection in cynomolgus macaques. Pathogens. 2021 May 13; 10(5):597. https://doi.org/10.3390/pathogens10050597
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interferon-γ release assay. American journal of veterinary research. 2021 Nov 10; 83(1):15-22. https://doi.org/10.2460/ajvr.21.08.0124

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 and Overlap) and 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.

Form A, Part 2 (iii)

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	$ 400,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 400,000

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

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

None.

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

Objectives: 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:	2,045.5 m^2
BSL-3:	59.5 m^2
BSL-4:	0 m^2
Total laboratory floor area:	2,105 m^2

During the reported calendar year, the LLNL BSL-2 laboratory space used for biodefense research and development was reapportioned, resulting in a total decrease of 29.7 m^2.

4. The organizational structure of each facility:

(i) Total number of personnel: 108

(ii) Division of personnel:

Military:	0
Civilian:	108

(iii) Division of personnel by category:

Scientists	61
Engineers	9
Technicians	26
Administrative and support staff	12

(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)

National Aeronautics and Space Administration (NASA)
Private Sector Companies
Universities

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

Research	$ 5,671,020
Development	$ 1,572,294
Test and evaluation	$ 199,338
Total	$ 7,442,652

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

As a Department of Energy facility, LLNL is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. LLNL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related 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. U.S. 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. Collette N, Dhungel P, Lund SJ, Schwedler JL, Saada EA, Light YK, et al. Immunocompromised Cas9 transgenic mice for rapid in vivo assessment of host factors involved in highly pathogenic virus infection. Mol. Ther. Methods Clin. Dev. 2021. Doi: DOI: 10.1016/j.omtm.2021.09.012. https://www.cell.com/molecular-therapy-family/methods/fulltext/S2329-0501(21)00150-9
2. Constance LA, Thissen JB, Jaing CJ, McLoughlin KS, Rowland RRR, Serão NVL. et al. Gut microbiome associations with outcome following co-infection with porcine reproductive and respiratory syndrome virus (PRRSV) and porcine circovirus type 2 (PCV2) in pigs immunized with a PRRS modified live virus vaccine. Vet Microbiol. 2021 Mar;254:109018. DOI: 10.1016/j.vetmic.2021.109018. Epub 2021 Feb 16. https://pubmed.ncbi.nlm.nih.gov/33639341/
3. D'haeseleer P, Collette NM, Lao V, Segelke BW, Branda SB, Franco M. Shotgun Immunoproteomic Approach for the Discovery of Linear B-Cell Epitopes in Biothreat Agents Francisella tularensis and Burkholderia pseudomallei. Front Immunol. 2021 Sep 29;12:716676. DOI: 10.3389/fimmu.2021.716676. https://pubmed.ncbi.nlm.nih.gov/34659206/
4. Juarez JG, Garcia-Luna SM, Medeiros MCI, Dickinson KL, Borucki MB, Frank M, et al. The Eco-Bio-Social Factors That Modulate Aedes aegypti Abundance in South Texas Border Communities. Insects. 2021 Feb; 12(2): 183. DOI: 10.3390/insects12020183. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7926310/
5. Lau EY, Negrete OA, Bennett WF, Bennion BJ, Borucki M, Bourguet F, et al. Discovery of Small-Molecule Inhibitors of SARS-CoV-2 Proteins Using a Computational and Experimental Pipeline. Front Mol Biosci. 2021; 8: 678701. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8315004/

6. Massey TL, Borucki MK, Paik SY, Fuhrer KW, Bora M, Kane SR, et al. Quantitative Fit Evaluation of N95 Filtering Facepiece Respirators and Coronavirus Inactivation Following Heat Treatment. Ann. Work Expo. Health. Volume 65, Issue 8, October 2021, Pages 979–987, DOI: 10.1093/annweh/wxab020 https://academic.oup.com/annweh/article/65/8/979/6276965?login=true
7. Moehling TJ, Choi G, Dugan LC, Salit M, Meagher RJ. LAMP Diagnostics at the Point-of-Care: Emerging Trends and Perspectives for the Developer Community. Expert Rev Mol Diagn. 2021 Jan;21(1):43-61. DOI: 10.1080/14737159.2021.1873769. Epub 2021 Jan 27. https://pubmed.ncbi.nlm.nih.gov/33474990/
8. Morrison MD, Thissen JB, Karouia F, Mehta S, Urbaniak C, Venkateswaran K, et al. Investigation of Spaceflight Induced Changes to Astronaut Microbiomes. Front Microbiol. 2021; 12: 659179. DOI: 10.3389/fmicb.2021.659179. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8207296/
9. Nelson SA , Dileepan T, Rasley A, Jenkins MK, Fischer NO, Sant AJ. Intranasal Nanoparticle Vaccination Elicits a Persistent, Polyfunctional CD4 T Cell Response in the Murine Lung Specific for a Highly Conserved Influenza Virus Antigen That Is Sufficient To Mediate Protection from Influenza Virus Challenge. J Virol. 2021 Jul 26;95(16):e0084121. DOI: 10.1128/JVI.00841-21. Epub 2021 Jul 26. https://pubmed.ncbi.nlm.nih.gov/34076479/
10. Shah SR , Kane SR , Elsheikh M , Alfaro TM. Development of a rapid viability RT-PCR (RV-RT-PCR) method to detect infectious SARS-CoV-2 from swabs. J Virol Methods. 2021 Nov;297:114251. doi: 10.1016/j.jviromet.2021.114251. Epub 2021 Aug 8. https://pubmed.ncbi.nlm.nih.gov/34380012/
11. Stefan MA, Light YK, Schwedler JL. McIlroy PR, Courtney CM, Saada EA, et al. Development of potent and effective synthetic SARS-CoV-2 neutralizing nanobodies. MAbs. 2021; 13(1): 1958663. DOI: 10.1080/19420862.2021.1958663. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8344751/
12. Stevenson GA, Jones D, Kim H, Bennett WF, Bennion BJ, Borucki M, et al. High-Throughput Virtual Screening of Small Molecule Inhibitors for SARS-CoV-2 Protein Targets with Deep Fusion Models. SC-21: Proc. Int. Conf. High Perform. 2021. DOI:10.1145/3458817.3476193. https://arxiv.org/pdf/2104.04547.pdf
13. Tooker A, Moya ML, Wang DN, Freeman D, Borucki M, Wheeler E, et al. Performance of three-dimensional printed nasopharyngeal swabs for COVID-19 testing. MRS Bull. 2021 Sep 13;1-9. DOI: 10.1557/s43577-021-00170-9. https://pubmed.ncbi.nlm.nih.gov/34539055/

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/.

* Including viruses and prions.

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

***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?
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:	613 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	613 m^2

During the reported calendar year, some LANL BSL-2 laboratory space used for biodefense research and development was reapportioned, resulting in an increase of 159 m^2. The BSL-2 laboratory space was not physically remodeled.

4. The organizational structure of each facility:

(i) Total number of personnel: 34

(ii) Division of personnel:

Military	0
Civilian	34

(iii) Division of personnel by category:

Scientists	17
Engineers	0
Technicians	5
Administrative and support staff	12

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Analytical Biochemistry, Bacteriology, Biochemistry, Bioinformatics, Biological Science, Biomedical Engineering, Biomedical Science, Biophysics, Cell Biology, Environmental Science, Genetics, Genomics, Immunology, Medicine, Microbiology, Microscopy, Molecular Biology, Molecular Diagnostics, Pathology, Protein Engineering, Structural 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	$ 2,978,000
Development	$ 1,245,000
Test and evaluation	$ 500,000
Total	$ 4,723,000

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

As a Department of Energy facility, LANL is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment. LANL has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related 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. Adikari SH, Hong-Geller E, Micheva-Viteva S. Methods for Enrichment of Bacterial Persister Populations for Phenotypic Screens and Genomic Studies. Methods Mol Biol. 2021; 2357:71-82; DOI: 10.1007/978-1-0716-1621-5_5. https://pubmed.ncbi.nlm.nih.gov/34590252/
2. Courtney SJ, Stromberg ZR, Kubicek-Sutherland JZ. Nucleic Acid-Based Sensing Techniques for Diagnostics and Surveillance of Influenza. Biosensors. 2021; 11 (2): 47; DOI: 10.3390/bios11020047. https://www.mdpi.com/2079-6374/11/2/47
3. Ezeji JC, Sarikonda DK, Hopperton A, Erkkila HL, Cohen DE, Martinez SP, et al. Parabacteroides distasonis: intriguing aerotolerant gut anaerobe with emerging antimicrobial resistance and pathogenic and probiotic roles in human health. Gut Micobes. 2021; 13(1):1922241, DOI: 10.1080/19490976.2021.1922241. https://pubmed.ncbi.nlm.nih.gov/34196581/
4. Courtney SJ, Stromberg ZR, Gutierrez AMY, Jacobsen D, Stromberg LR, Lenz KD, et al. Optical Biosensor Platforms Display Varying Sensitivity for the Direct Detection of Influenza RNA. Biosensors; 2021; 11 (10): 367; DOI: 10.3390/bios11100367. https://pubmed.ncbi.nlm.nih.gov/34677323/

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

***Objectives*:** The biological defense research and development activities at the Los Alamos National Laboratory include pathogen characterization, host-pathogen interaction studies, pathogen detection,

* Including viruses and prions.

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:

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:	2,103 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	2,103 m^2

Sequim campus:	
BSL-2:	81 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	81 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

During the reported calendar year, PNNL BSL-2 laboratory space used for biodefense research and development was reapportioned, resulting in an increase of 853 m^2 on the Richland campus and an increase of 52 m^2 on the Sequim campus. The BSL-2 laboratory space was not physically remodelled. PNNL also conducts 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: 107
Richland, Sequim, & Seattle campuses (shared personnel)

(ii) Division of personnel:

Military	0
Civilian	107

(iii) Division of personnel by category:

Scientist	91
Engineers	2
Technicians	5
Admin and Support Staff	13

(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: 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 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)

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

Research	$ 8,692,506
Development	$ 4,950,536
Test and evaluation	$ 2,850,788
Total	$ 16,493,830

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

As a 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. U.S. 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. Bradley A, Melville A, Forman J, Fraga C, Addleman R, and Ozanich R. 2021. Handheld Raman Spectrometers Market Survey Report. 2021 Apr 29; https://www.dhs.gov/sites/default/files/saver_handheld_raman_spectrometers_msr_march_2021_.pdf
2. Buchko G, Zhou M, Craig J, Van Voorhis W, and Myler P. Backbone chemical shift assignments for the SARS-CoV-2 non-structural protein Nsp9: intermediate (ms – us) dynamics in the C-terminal helix at the dimer interface. Biomolecular NMR Assignments. 2021 Mar 19; 15:107-116. https://link.springer.com/article/10.1007/s12104-020-09992-1
3. Choi R, Zhou M, Shek R, Wilson J, Tillery L, Craig J, et al. High-throughput screening of the ReFRAME, Pandemic Box, and COVID Box drug repurposing libraries against SARS-CoV-2 nsp15 endoribonuclease to identify small-molecule inhibitors of viral activity. PLoS One. 2021 Apr 22; 16,(4):e0250019. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0250019
4. Detwiler R, McConn R, Grimes T, Upton S, and Engel E. Compendium of Material Composition Data for Radiation Transport Modeling. 2021 Apr 19; https://www.osti.gov/biblio/1782721
5. Handakumbura P, Rivas-Ubach A, and Battu A. Visualizing the Hidden Half: Plant-microbe Interactions in the Rhizosphere. mSystems. 2021 Oct; Volume 6, Issue 5, Article e00765-21. https://journals.asm.org/doi/epub/10.1128/mSystems.00765-21
6. Kyle J. How lipidomics can transform our understanding of virus infections. Expert Review of Proteomics. 2021 May 27; doi: 10.1080/14789450.2021.1929177. https://www.tandfonline.com/doi/full/10.1080/14789450.2021.1929177
7. Moran A, Hampton S, Dowson S, Dagdelen J, Trewartha A, Ceder G, et al. Online Interactive Platform for COVID-19 Literature Visual Analytics: Platform Development Study. J Med Internet Res. 2021 Jul 16; 23(7):e26995; https://www.jmir.org/2021/7/e26995
8. Ozanich R, Bartholomew R, Forman J, Leiser O, and Esquibel F. Standard Guide for Using Equipment and Assays for Field Detection of Fentanyl and Fentanyl-Related Compounds. 2021 Jul 5; https://www.astm.org/e3289-21.html
9. Ozanich R, Bartholomew R, Forman J, Leiser O, and Esquibel F. Standard Specification for Field Detection Equipment and Assays Used for Fentanyl and Fentanyl-Related Compounds. 2021 Jul 5; https://www.astm.org/e3243-21.html
10. Ozanich R, Bartholomew R, Forman J, Leiser O, and Esquibel F. Standard Test Method for Establishing Performance of Equipment and Assays for Field Detection of Fentanyl and Fentanyl-Related Compounds. 2021 Jul 5; https://www.astm.org/e3290-21.html
11. Ozanich R. Handheld Raman Spectrometers Focus Group Report. 2021 Mar 1; https://www.dhs.gov/sites/default/files/saver-raman-focus-group-report_26june2020-508.pdf
12. Sims A, Mitchell H, Gralinski L, Kyle J, Burnum-Johnson K, Lam M, et al. Unfolded Protein Response Inhibition Reduces Middle East Respiratory Syndrome Coronavirus-Induced Acute Lung Injury. mBio. 2021 AUG 31; 12,(4):e01572-21. https://journals.asm.org/doi/full/10.1128/mBio.01572-21
13. Tagestad J, Coleman A, Ozanich R, Murtagh C, Calhoun E, and Velasco-Lopez B. Incident Management Software for Emergency Response Focus Group Report. 2021 Jan 13; https://www.dhs.gov/sites/default/files/ims_focus_group_report_jan_2021.pdf
14. Tamano K, Takayama H, Yasokawa S, Sano M, and Baker SE. Major involvement of two laccase genes in conidial pigment biosynthesis in Aspergillus oryzae. Appl Microbiol Biotechnol. 2021 Dec 10; 106(1):287-300; https://pubmed.ncbi.nlm.nih.gov/34889980/

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 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*:** Simulant of Overlap Select Agent and NIAID Category A pathogen, HHS Select Toxins.

***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?
Sandia National Laboratories (SNL)

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

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:**	404
	New Mexico campus:	324
	California campus:	80
(ii)	**Division of personnel:**	
	Military	0
	Civilian	404
(iii)	**Division of personnel by category:**	
	Scientists	150
	Engineers	90
	Technicians	117
	Admin and Support Staff	47

(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)
Internal (Laboratory Directed Research & Development)
Academia
Private sector

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

Research	$ 11,468,115
Development	$ 5,795,248
Test and Evaluation	$ 20,629,442
Total	$ 37,892,805

(viii) Briefly describe the publication policy of the facility:
As a 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. Borras E, McCartney MM, Thompson CH, Meagher RJ, Kenyon NJ, Schivo M, et al. Exhaled breath biomarkers of influenza infection and influenza vaccination. J Breath Res. 2021;15(4). Epub 2021/08/04. DOI: 10.1088/1752-7163/ac1a61. PubMed PMID: 34343985; https://iopscience.iop.org/article/10.1088/1752-7163/ac1a61/meta
2. Collette N, Dhungel P, Lund SJ, Schwedler JL, Saada EA, Light YK, et al. Immunocompromised

Cas9 transgenic mice for rapid in vivo assessment of host factors involved in highly pathogenic virus infection. Mol Ther Methods Clin Dev. 2021;23:286-95. Epub 2021/11/04. DOI: 10.1016/j.omtm.2021.09.012. PubMed PMID: 34729376; PubMed Central PMCID: PMCPMC8526419 https://pubmed.ncbi.nlm.nih.gov/34729376/

3. DeAngelis HE, Grillet AM, Nemer MB, Wasiolek MA, Hanson DJ, Omana MA, et al. Gamma radiation sterilization of N95 respirators leads to decreased respirator performance. PLoS One. 2021;16(4):e0248859. Epub 2021/04/09. DOI: 10.1371/journal.pone.0248859. PubMed PMID: 33831014; PubMed Central PMCID: PMCPMC8031388 https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0248859
4. Deneff JI, Butler KS, Kotula PG, Rue BE, Sava Gallis DF. Expanding the ZIFs Repertoire for Biological Applications with the Targeted Synthesis of ZIF-20 Nanoparticles. ACS Applied Materials and Interfaces. 2021;13(23):27295-304. DOI: 10.1021/acsami.1c05657. http://dx.doi.org/10.1021/acsami.1c05657
5. D'Haeseleer P, Collette NM, Lao V, Segelke BW, Branda SS, Franco M. Shotgun Immunoproteomic Approach for the Discovery of Linear B-Cell Epitopes in Biothreat Agents Francisella tularensis and Burkholderia pseudomallei. Front Immunol. 2021;12:716676. Epub 2021/10/19. DOI: 10.3389/fimmu.2021.716676. PubMed PMID: 34659206; PubMed Central PMCID: PMCPMC8513525. https://doi.org/10.3389/fimmu.2021.716676
6. Domino SP. A Case Study on Pathogen Transport, Deposition, Evaporation and Transmission: Linking High-Fidelity Computational Fluid Dynamics Simulations to Probability of Infection. Int J Comput Fluid Dyn.15. 2021 Apr 01. DOI: 10.1080/10618562.2021.1905801. PubMed PMID: WOS:000635815200001. https://www.tandfonline.com/doi/abs/10.1080/10618562.2021.1905801?journalCode=gcfd20
7. Grillet AM, Nemer MB, Storch S, Sanchez AL, Piekos ES, Leonard J, et al. COVID-19 global pandemic planning: Performance and electret charge of N95 respirators after recommended decontamination methods. Exp Biol Med (Maywood). 2021;246(6):740-8. Epub 2020/12/17. DOI: 10.1177/1535370220976386. PubMed PMID: 33325749; PubMed Central PMCID: PMCPMC7961645. https://pubmed.ncbi.nlm.nih.gov/33325749/
8. Haxton T, Klise KA, Laky D, Murray R, Laird CD, Burkhardt JB. Evaluating Manual Sampling Locations for Regulatory and Emergency Response. J Water Resour Plan Manage-ASCE. 2021;147(12). DOI: 10.1061/(ASCE)WR.1943-5452.0001473. http://dx.doi.org/10.1061/(ASCE)WR.1943-5452.0001473
9. Hirakawa M, Tjahjono N, Light YK, Chintalapudi P, Butler K, Branda S, et al. Augmentation of Antibacterial Activity in Mesenchymal Stromal cells Through Systems-level Analysis and CRISPR-mediated Activation of CD14. Cytotherapy. 2021;23(5):S46-S7. PubMed PMID: WOS:000650965900051 https://www.biorxiv.org/content/10.1101/2020.10.14.338020v1
10. Ho CK, Binns R. Modeling and mitigating airborne pathogen risk factors in school buses. Int Commun Heat Mass Transf. 2021;129:10. DOI: 10.1016/j.icheatmasstransfer.2021.105663. PubMed PMID: WOS:000716169400010. https://www.sciencedirect.com/science/article/pii/S073519332100556X
11. Ho CK. Modeling airborne pathogen transport and transmission risks of SARS-CoV-2. Appl Math Model. 2021;95:297-319. Epub 2021/03/02. DOI: 10.1016/j.apm.2021.02.018. PubMed PMID: 33642664; PubMed Central PMCID: PMCPMC7902220. https://www.sciencedirect.com/science/article/pii/S0307904X21000950?via%3Dihub
12. Ho CK. Modelling Airborne Transmission and Ventilation Impacts of a COVID-19 Outbreak in a Restaurant in Guangzhou, China. Int J Comput Fluid Dyn.19. DOI: 10.1080/10618562.2021.1910678. PubMed PMID: WOS:000637616500001. https://www.tandfonline.com/doi/abs/10.1080/10618562.2021.1910678?journalCode=gcfd20
13. Kent MS, Stefan M, Sale K, Hudson C, Martinez D, Juarros M, et al. Combining Computational Modeling with Library Screening to Adapt SARS-CoV-Neutralizing Antibody 80R to SARS-CoV-2.

Biophys J. 2021;120(3):21A-A. PubMed PMID: WOS:000629601400101. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7879741/
14. Klise K, Beyeler W, Finley P, Makvandi M. Analysis of mobility data to build contact networks for COVID-19. PLoS One. 2021;16(4):e0249726. Epub 2021/04/16. DOI: 10.1371/journal.pone.0249726. PubMed PMID: 33857208; PubMed Central PMCID: PMCPMC8049304. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0249726
15. Kuo T-T, Bath T, Ma S, Pattengale N, Yang M, Cao Y, et al. Benchmarking blockchain-based gene-drug interaction data sharing methods: A case study from the iDASH 2019 secure genome analysis competition blockchain track. Int J Med Inform. 2021;154. DOI: 10.1016/j.ijmedinf.2021.104559. http://dx.doi.org/10.1016/j.ijmedinf.2021.104559
16. Lau EY, Negrete OA, Bennett WFD, Bennion BJ, Borucki M, Bourguet F, et al. Discovery of Small-Molecule Inhibitors of SARS-CoV-2 Proteins Using a Computational and Experimental Pipeline. Front Mol Biosci. 2021;8:678701. Epub 2021/07/31. DOI: 10.3389/fmolb.2021.678701. PubMed PMID: 34327214; PubMed Central PMCID: PMCPMC8315004. https://doi.org/10.3389/fmolb.2021.678701
17. Lenz KD, Jakhar S, Chen JW, Anderson AS, Purcell DC, Ishak MO, et al. A centrifugal microfluidic cross-flow filtration platform to separate serum from whole blood for the detection of amphiphilic biomarkers. Sci Rep. 2021;11(1):5287. Epub 2021/03/07. DOI: 10.1038/s41598-021-84353-z. PubMed PMID: 33674653; PubMed Central PMCID: PMCPMC7935985. https://www.nature.com/articles/s41598-021-84353-z
18. Li W, Li M, Anthony SM, Yu Y. Spatial organization of Fc-gamma-R and TLR2/1 on phagosome membranes differentially regulates their synergistic and inhibitory receptor crosstalk. Sci Rep. 2021;11(1):13430. Epub 2021/06/30. DOI: 10.1038/s41598-021-92910-9. PubMed PMID: 34183758; PubMed Central PMCID: PMCPMC8238967. https://www.nature.com/articles/s41598-021-92910-9
19. Lin YT, Neumann J, Miller EF, Posner RG, Mallela A, Safta C, et al. Daily Forecasting of Regional Epidemics of Coronavirus Disease with Bayesian Uncertainty Quantification, United States. Emerg Infect Dis. 2021;27(3):767-78. DOI: 10.3201/eid2703.203364. PubMed PMID: WOS:000634463000011. https://wwwnc.cdc.gov/eid/article/27/3/20-3364_article
20. Moehling TJ, Choi G, Dugan LC, Salit M, Meagher RJ. LAMP Diagnostics at the Point-of-Care: Emerging Trends and Perspectives for the Developer Community. Expert Rev Mol Diagn. 2021;21(1):43-61. Epub 2021/01/22. DOI: 10.1080/14737159.2021.1873769. PubMed PMID: 33474990; https://pubmed.ncbi.nlm.nih.gov/33474990/
21. O'Callahan B, Qafoku O, Balema V, Negrete OA, Passian A, Engelhard MH, et al. Atomic Force Microscopy and Infrared Nanospectroscopy of COVID-19 Spike Protein for the Quantification of Adhesion to Common Surfaces. Langmuir. 2021;37(41):12089-97. DOI: 10.1021/acs.langmuir.1c01910. http://dx.doi.org/10.1021/acs.langmuir.1c01910
22. Otoupal PB, Eller KA, Erickson KE, Campos J, Aunins TR, Chatterjee A. Potentiating antibiotic efficacy via perturbation of non-essential gene expression. Commun Biol. 2021;4(1):1267. Epub 2021/11/07. DOI: 10.1038/s42003-021-02783-x. PubMed PMID: 34741116; PubMed Central PMCID: PMCPMC8571399. https://www.nature.com/articles/s42003-021-02783-x
23. Stefan MA, Light YK, Schwedler JL, McIlroy PR, Courtney CM, Saada EA, et al. Development of potent and effective synthetic SARS-CoV-2 neutralizing nanobodies. MAbs. 2021;13(1):1958663. Epub 2021/08/05. DOI: 10.1080/19420862.2021.1958663. PubMed PMID: 34348076; PubMed Central PMCID: PMCPMC8344751. https://www.biorxiv.org/content/10.1101/2021.05.06.442911v1.abstract
24. Stevenson GA, Jones D, Kim H, Bennett WFD, Bennion BJ, Borucki M, et al., editors. High-Throughput virtual screening of small molecule inhibitors for sars-cov-2 protein targets with deep fusion models. 33rd International Conference for High Performance Computing, Networking, Storage and Analysis: Science and Beyond, SC 2021, November 14, 2021 - November 19, 2021; 2021; Virtual, Online, United states: IEEE Computer Society.

https://dl.acm.org/doi/10.1145/3458817.3476193
25. Thomson GJ, Kakade P, Hirakawa MP, Ene IV, Bennett RJ. Adaptation to the dietary sugar D-tagatose via genome instability in polyploid Candida albicans cells. G3 (Bethesda). 2021;11(7). Epub 2021/04/10. DOI: 10.1093/g3journal/jkab110. PubMed PMID: 33836061; PubMed Central PMCID: PMCPMC8495922. https://doi.org/10.1093/g3journal/jkab110
26. Yang B, Huang AT, Garcia-Carreras B, Hart WE, Staid A, Hitchings MDT, et al. Effect of specific non-pharmaceutical intervention policies on SARS-CoV-2 transmission in the counties of the United States. Nat Commun. 2021;12(1):3560. Epub 2021/06/13. doi: 10.1038/s41467-021-23865-8. PubMed PMID: 34117244; PubMed Central PMCID: PMCPMC8195990 https://www.nature.com/articles/s41467-021-23865-8#:~:text=Transmission%20was%20consistently%20higher%20in,consistently%20lower%20in%20counties%20with

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*:** None.

***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?
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	379 m^2
BSL-3	0 m^2
BSL-4	0m^2
Total laboratory floor area	379 m^2

The changes in NCEH/DLS laboratory space from 568 m^2 to 379 m^2 were due to a numerical calculation error, resulting in a decrease of 189 m^2. Since at least 2012, laboratory space unrelated to biological defense research and development was inadvertently included; the laboratory space was not physically remodeled.

4. The organizational structure of each facility.

(i) Total number of personnel 16

(ii) Division of personnel:

Military	0
Civilian	16

(iii) Division of personnel by category:

Scientists	16
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: 5

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

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

Research	$ 1,620,244.80
Development	$ 1,267,802.00

Test and evaluation	$ 1,897,188.20
Total	$ 4,785,235.00

(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. Alhatali B, Al Lawatia S, Khamis F, Kantur S, Al-Abri S, Kapil V, et al. A cluster of tetrodotoxin poisoning in Oman. Clin Toxicol. 2021 Apr 29;1-5 DOI:10.1080/15563650.2021.1917595 https://pubmed.ncbi.nlm.nih.gov/33913398/
2. Cunningham BR, Coleman RM, Schaefer AM, Hamelin EI, Johnson RC. Detection of Brevetoxin in Human Plasma by ELISA. J Anal Toxicol. 2021 Jan 30;bkab010. DOI: 10.1093/jat/bkab010 https://pubmed.ncbi.nlm.nih.gov/33515246/
3. Hoyt K, Barr JR, Kalb SR. Detection of ricin activity and structure by using novel galactose-terminated magnetic bead extraction coupled with mass spectrometric detection. Anal Biochem. 2021 Oct 15; 631:114364. DOI: 10.1016/j.ab.2021.114364 https://www.sciencedirect.com/science/article/pii/S0003269721002657?via%3Dihub

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 Toxins (HHS)

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	413 m^2
BSL-3	999.8 m^2
BSL-4	545.9 m^2
Total laboratory floor area	1958.7 m^2

Note: The changes in DDID laboratory spaces were due to a numerical calculation error, resulting in an increase of 27.3 m^2 of BSL-2 laboratory space, a decrease of 220.2 m^2 of BSL-3 laboratory space, an increase of 12.8 m^2 BSL-4 laboratory space, and a total decrease of 180.1 m^2 in laboratory space. In previous year's reports, some accessory rooms outside of the laboratories were inadvertently included while some laboratory space conducting biological defense research was inadvertently not included. The laboratory space was not physically remodeled and previous reports should have included the laboratory space measurements as reported in this year's report. Additionally, one BSL-4 Laboratory space of 118.5 m^2 was operated as a BSL-3 enhanced laboratory during the reporting calendar year.

4. The organizational structure of each facility.

(ii)	**Total number of personnel:**	156
(ii)	**Division of personnel:**	
	Military	10
	Civilian	146
(iii)	**Division of personnel by category:**	
	Scientists	145
	Engineers	0
	Technicians	7
	Administrative and support staff	4

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

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 30

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
U.S. Department of Health and Human Services (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	$ 11,855,933.25
Development	$ 4,381,736.10
Test and evaluation	$ 7,337,318.66
Total	$ 23,574,988.01

(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. Abayneh T, Getachew B, Gelaye E, Traxler R, Vieira AR. Viability evaluation of freeze dried and suspension Anthrax spore vaccine formulations stored at different temperatures. Vaccine, October 8, 2021; 39(42), 6245-6249. https://www.sciencedirect.com/science/article/pii/S0264410X21012020?via%3Dihub
2. Agnihotri S, Alpren C, Bangura B, Bennett S, Gorina Y, Harding JD, et al. Building the Sierra Leone Ebola Database: organization and characteristics of data systematically collected during 2014-2015 Ebola epidemic. Ann Epidemiol. 2021 Aug;60:35-44. doi: 10.1016/j.annepidem.2021.04.01. https://pubmed.ncbi.nlm.nih.gov/33965545/
3. Alam M, Jahan MI, Jahan S, Blau DM, Rahman A, Rahman MZ, et al. Coding-Complete Sequence of a SARS-CoV-2 B.1.1.25 Lineage Obtained from an 8-Day-Old Deceased Neonate. Microbiol Resour Announc. 2021;10(35):e0075621. Epub 2021/09/03. doi: 10.1128/mra.00756-21. PubMed PMID: 34472974; PubMed Central PMCID: PMC8411918. https://pubmed.ncbi.nlm.nih.gov/34472974/
4. Amman BR, Schuh AJ, Albarino CG, Towner JS (2021) Marburg virus persistence on fruit as a plausible route of bat to primate filovirus transmission, *Viruses* 2021, *13*(12), 2394; https://doi.org/10.3390/v13122394
5. Balinandi S, Whitmer S, Mulei S, Nyakarahuka L, Tumusiime A, Kyondo J, et al. Clinical and Molecular Epidemiology of Crimean-Congo Hemorrhagic Fever in Humans in Uganda, 2013-2019. Am J Trop Med Hyg. 2021 Oct 18;106(1):88-98. doi: 10.4269/ajtmh.21-0685.Am J Trop Med Hyg. 2021. PMID: 34662872. https://pubmed.ncbi.nlm.nih.gov/34662872/
6. Barbeau DJ, Cartwright HN, Harmon JR, Spengler JR, Spiropoulou CF, Sidney J, et al. Identification and Characterization of Rift Valley Fever Virus-Specific T Cells Reveals a Dependence on CD40/CD40L Interactions for Prevention of Encephalitis. J Virol. 2021 Nov 9;95(23):e0150621. doi: 10.1128/JVI.01506-21. Epub 2021 Sep 8. PMID: 34495703; PMCID: PMC8577384. https://pubmed.ncbi.nlm.nih.gov/34495703/
7. Barbosa C G, Silva de Oliveira J, Townsend MB, Carson WC, Borges IA, McCollum AM, et al..Educational Approach to Prevent the Burden of Vaccinia Virus Infections in a Bovine Vaccinia Endemic Area in Brazil. Pathogens. 2021 Apr 23;10(5):511 https://www.mdpi.com/2076-0817/10/5/511
8. Belay ED, Godfred CS, Rao AK, Abrams J, Wilson WW, Lim S, et al.Multisystem Inflammatory Syndrome in Adults after SARS-CoV-2 infection and COVID-19 vaccination. Clin Infect Dis. 2021 Nov 28:ciab936. https://wwwnc.cdc.gov/eid/article/27/7/21-0594_article

9. Bessières M, Plebanek E, Chatterjee P, Shrivastava-Ranjan P, Flint M, Spiropoulou CF, et al. Design, synthesis and biological evaluation of 2-substituted-6-[(4-substituted-1-piperidyl)methyl]-1H-benzimidazoles as inhibitors of ebola virus infection. Eur J Med Chem. 2021 Mar 15;214:113211. doi: 0.1016/j.ejmech.2021.113211. Epub 2021 Jan 27. PMID: 33548632. https://pubmed.ncbi.nlm.nih.gov/33548632/
10. Blackburn JK, Kenu E, Asiedu-Bekoe F, Sarkodie B, Kracalik IT, Bower WA, et al. High Case-Fatality Rate for Human Anthrax, Northern Ghana, 2005-2016. Emerg Infect Dis. 2021; Apr;27(4):1216-1219. doi: 10.3201/eid2704.204496. PMID: 33754993; PMCID: PMC8007318. https://wwwnc.cdc.gov/eid/article/27/4/20-4496_article
11. Bonaparte SC, Adams L, Bakamutumaho B, Barbosa CG, Cleaton JM, Gilbert AT, et al.Rabies post-exposure healthcare-seeking behaviors and perceptions: Results from a knowledge, attitudes, and practices survey, Uganda, 2013. PLoS One. 2021 Jun 2;16(6):e0251702. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0251702
12. Bonwitt J, Deya RW, Currie DW, Lipton B, Huntington-Frazier M, Sanford SJ, et al. COVID-19 Surveillance and Investigations in Workplaces - Seattle & King County, Washington, June 15-November 15, 2020. Public Health — Seattle & King County COVID-19 Community Investigation Team; Public Health — Seattle & King County Analytics and Informatics Team. MMWR Morb Mortal Wkly Rep. 2021 Jun 25;70(25):916-921. https://www.cdc.gov/mmwr/volumes/70/wr/mm7025a3.htm
13. Bugrysheva JV, Lascols C, McLaughlin HP, Gee JE, Elrod MG, Sue D. Antimicrobial Susceptibility of Western Hemisphere Isolates of *Burkholderia pseudomallei*: Phenotypic and Genomic Analyses. Microb Drug Resist. 2021 Sep;27(9):1176-1185. doi: 10.1089/mdr.2020.0362. Epub 2021 Feb 10. PMID: 33570476. https://www.liebertpub.com/doi/10.1089/mdr.2020.0362?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub++0pubmed&
14. Bullock HA, Goldsmith CS, Zaki SR, Martines RB, Miller SE. Difficulties in differentiating coronaviruses from subcellular structures in human tissues by electron microscopy. Emerg Infect Dis. 2021;27(4):1023-31. Epub 2021/02/19. doi: 10.3201/eid2704.204337. PubMed PMID: 33600302; PubMed Central PMCID: PMC8007326. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8007326/pdf/20-4337.pdf.
15. Camerini D, Randall AZ, Trappl-Kimmons K, Oberai A, Hung C, Edgar J, et al. (2021). Mapping SARS-CoV-2 Antibody Epitopes in COVID-19 Patients with a Multi-Coronavirus Protein Microarray. Microbiol Spectr. 9, e0141621. https://journals.asm.org/doi/10.1128/Spectrum.01416-21
16. Carpenter A, Ghai RR, Gary J, Ritter JM, Carvallo FR, Diel DG, et al. Determining the role of natural SARS-CoV-2 infection in the death of domestic pets: 10 cases (2020-2021). J Am Vet Med Assoc. 2021 Nov 1;259(9):1032-1039. https://avmajournals.avma.org/view/journals/javma/259/9/javma.259.9.1032.xml
17. Chapman AP, Tang X, Lee JR, Chida A, Mercer K, Wharton RE, et al. Rapid development of neutralizing and diagnostic SARS-COV-2 mouse monoclonal antibodies. Sci Rep. 2021 May 6;11(1):9682. http://doi.org/10.1038/s41598-021-88809-0
18. Cherry CC, Nichols Heitman K, Bestul NC, Kersh GJ. Acute and chronic Q fever national surveillance - United States, 2008-2017. Zoonoses Public Health. 2021 Oct 8. PMID: 34626097. https://pubmed.ncbi.nlm.nih.gov/34626097/
19. Choi MJ, Cossaboom CM, Whitesell AN, Dyal JW, Joyce A, Morgan RL, Campos-Outcalt D, et al. 2021. Use of Ebola vaccine: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020. MMWR Recomm Rep. 2021 Jan 8;70(1), 1-2. doi: 10.15585/mmwr.rr7001a1. https://pubmed.ncbi.nlm.nih.gov/33417593/
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1. 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.

Form A, Part 2 (iii)

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	175 m^2
BSL-4	0 m^2
Total laboratory floor area	175 m^2

During the reported calendar year, the CDC/NCEZID/DVBD BSL-3 laboratory space used for biodefense research and development was reapportioned, resulting in a decrease of 210 m^2. The BSL-3 laboratory space was not physically remodeled.

4. The organizational structure of each facility.

(i) Total number of personnel 28

(ii) Division of personnel:

Military	0
Civilian	28

(iii) Division of personnel by category:

Scientists	3
Engineers	0
Technicians	11
Administrative and support staff	14

(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	$ 513,615

Development	$ 0
Test and evaluation	$ 97,374
Total	$ 610,989

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

Publication is encouraged and managed by editorial and clearance policies conducted at all levels of the Agency. The clearance policy for information products disseminated outside CDC for public use is available online at: http://www.cdc.gov/od/science/policies. CDC also has an internal policy on "Oversight and clearance of dual use research of concern."

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

1. Eisen RJ, Atiku LA, Enscore RE, Mpanga JT, Acayo S, Mead PS, et al. Epidemiology, Ecology and Prevention of Plague in the West Nile Region of Uganda: The Value of Long-Term Field Studies. Am J Trop Med Hyg. 2021 May 3;105(1):18-23. doi:10.4269/ajtmh.20-1381. https://pubmed.ncbi.nlm.nih.gov/33939638/
2. Hughes HR, Velez JO, Davis EH, Laven J, Gould CV, Panella AJ, et al. Fatal Human Infection with Evidence of Intrahost Variation of Eastern Equine Encephalitis Virus, Alabama, USA, 2019. Emerg Infect Dis. 2021;27(7):1886-1892. https://doi.org/10.3201/eid2707.210315. https://pubmed.ncbi.nlm.nih.gov/34152960/
3. Nelson CA, Meaney-Delman D, Fleck-Derderian S, Cooley KM, Yu PA, Mead PS. Antimicrobial Treatment and Prophylaxis of Plague: Recommendations for Naturally Acquired Infections and Bioterrorism Response. MMWR Recomm Rep . 2021 Jul 16;70(3):1-27. doi: 10.15585/mmwr.rr7003a1. https://pubmed.ncbi.nlm.nih.gov/34264565/
4. Öhrman C, Uneklint I, Karlsson L, Respicio-Kingry L, Forsman M, Petersen JM, et al. Complete Genome Sequence of Francisella sp. Strain LA11-2445 (FDC406), a Novel Francisella Species Isolated from a Human Skin Lesion. Microbiol Resour Announc. 2021 Jan 14;10(2):e01233-20. doi: 10.1128/MRA.01233-20. https://pubmed.ncbi.nlm.nih.gov/33446589/

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 144

(ii) Division of personnel:

Military	0
Civilian	144

(iii) Division of personnel by category:

Scientists	85
Engineers	0
Technicians	53
Administrative and support staff	6

(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, Structural Biology, 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	$ 32,642,370
Development	$ 0
Test and evaluation	$ 0
Total	$ 32,642,370

(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. Bakkour S, Saá P, Groves JA, Montalvo L, Di Germanio C, Best SM, et al. Minipool testing for SARS-CoV-2 RNA in United States blood donors. Transfusion. 2021;61(8):2384-91. https://onlinelibrary.wiley.com/doi/10.1111/trf.16511
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6. Bhatia B, Haddock E, Shaia C, Rosenke R, Meade-White K, Griffin AJ, et al. Alkhurma haemorrhagic fever virus causes lethal disease in IFNAR(-/-) mice. Emerg Microbes Infect. 2021;10(1):1077-87. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8183530/
7. Bhatia B, Hillman C, Stewart PE, Rosa P. Probing the Role of bba30, a Highly Conserved Gene of the Lyme Disease Spirochete, Throughout the Mouse-Tick Infectious Cycle. Infect Immun. 2021;89(12):e0033321. https://journals.asm.org/doi/10.1128/IAI.00333-21?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed
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10. Bland DM, Miarinjara A, Bosio CF, Calarco J, Hinnebusch BJ. Acquisition of yersinia murine toxin enabled Yersinia pestis to expand the range of mammalian hosts that sustain flea-borne plague. PLoS Pathog. 2021;17(10):e1009995. https://pubmed.ncbi.nlm.nih.gov/34648607/
11. 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. 2021;21(2):128-31. https://www.liebertpub.com/doi/10.1089/vbz.2020.2669?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub++0pubmed&
12. Boyle WK, Richards CL, Dulebohn DP, Zalud AK, Shaw JA, Lovas S, et al. DksA-dependent regulation of RpoS contributes to Borrelia burgdorferi tick-borne transmission and mammalian infectivity. PLoS Pathog. 2021;17(2):e1009072. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7924775/
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27. Figueroa DM, Kuisma E, Matson MJ, Ondzie AU, Bushmaker T, Seifert SN, et al. Development and validation of portable, field-deployable Ebola virus point-of-encounter diagnostic assay for wildlife surveillance. One Health Outlook. 2021;3(1):9. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8142476/
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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: 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) and 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?
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 105

(ii) Division of personnel:

Military	0
Civilian	105

(iii) Division of personnel by category:

Scientists	44
Engineers	3
Technicians	44
Administrative and support staff	14

(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: 99

(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	$ 26,110,108
Development	$ 0
Test and evaluation	$ 0
Total	$ 26,110,108

(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. ACTIV-3/Therapeutics for Inpatients with COVID-19 (TICO) Study Group. Efficacy and safety of two neutralising monoclonal antibody therapies, sotrovimab and BRII-196 plus BRII-198, for adults hospitalised with COVID-19 (TICO): a randomised controlled trial. Lancet Infect Dis. 2021. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8700279/
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11. Connors M, Graham BS, Lane HC, Fauci AS. SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn. Ann Intern Med. 2021;174(5):687-90. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7839932/

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Analysis during COVID-19 Case Surge, Liberia, 2021. Emerg Infect Dis. 2021;27(12):3185-8. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8632187/
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42. Uruena A, Cassetti I, Kashyap N, Deleage C, Estes JD, Trindade C, et al. Prolonged Posttreatment Virologic Control and Complete Seroreversion After Advanced Human Immunodeficiency Virus-1 Infection. Open Forum Infect Dis. 2021;8(1):ofaa613. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7824876/

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. Laulima Government Solutions facilitates 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 125

(ii) Division of personnel:

Military	0
Civilian	125

(iii) Division of personnel by category:

Scientists	68
Engineers	0
Technicians	52
Administrative and support staff	5

(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: 31

(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	$ 33,843,749
Development	$ 0
Test and evaluation	$ 0
Total	$ 33,843,749

(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. Adeleke OA, Fisher L, Moore IN, Nardone GA, Sher A. A Long-Acting Thermoresponsive Injectable Formulation of Tin Protoporphyrin Sustains Antitubercular Efficacy in a Murine Infection Model. ACS Pharmacol Transl Sci. 2021;4(1):276-87. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7887855/
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3. Bae JS, Da F, Liu R, He L, Lv H, Fisher EL, et al. Contribution of Staphylococcal Enterotoxin B to Staphylococcus aureus Systemic Infection. J Infect Dis. 2021;223(10):1766-75. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8161638/
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111. Xie YL, de Jager VR, Chen RY, Dodd LE, Paripati P, Via LE, et al. Fourteen-day PET/CT imaging to monitor drug combination activity in treated individuals with tuberculosis. Sci Transl Med. 2021;13(579. https://www.science.org/doi/10.1126/scitranslmed.abd7618?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed
112. Yamini G, Kanchi S, Kalu N, Momben Abolfath S, Leppla SH, Ayappa KG, et al. Hydrophobic Gating and 1/f Noise of the Anthrax Toxin Channel. J Phys Chem B. 2021;125(21):5466-78. https://pubs.acs.org/doi/10.1021/acs.jpcb.0c10490
113. Yang HJ, Wang D, Wen X, Weiner DM, Via LE. One Size Fits All? Not in In Vivo Modeling of Tuberculosis Chemotherapeutics. Front Cell Infect Microbiol. 2021;11:613149. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8008060/
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116. Yewdell JW. Individuals cannot rely on COVID-19 herd immunity: Durable immunity to viral disease is limited to viruses with obligate viremic spread. PLoS Pathog. 2021;17(4):e1009509. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8075217/
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119. Yewdell WT, Smolkin RM, Belcheva KT, Mendoza A, Michaels AJ, Cols M, et al. Temporal dynamics of persistent germinal centers and memory B cell differentiation following respiratory virus infection. Cell Rep. 2021;37(6):109961. https://www.sciencedirect.com/science/article/pii/S2211124721014388?via%3Dihub
120. Zarkoob H, Allué-Guardia A, Chen YC, Jung O, Garcia-Vilanova A, Song MJ, et al. Modeling SARS-CoV-2 and Influenza Infections and Antiviral Treatments in Human Lung Epithelial Tissue Equivalents. bioRxiv. 2021. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8132232/
121. Zou B, Goodwin M, Saleem D, Jiang W, Tang J, Chu Y, et al. A highly conserved host lipase deacylates oxidized phospholipids and ameliorates acute lung injury in mice. Elife. 2021;10. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8594946/

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) 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	204 m^2
BSL-3	0 m^2
BSL-4	0 m^2
Total laboratory floor area	204 m^2

During the reported calendar year, the VRC BSL-2 laboratory space used for biodefense research and development was reapportioned, resulting in an increase of 100 m^2. The laboratory space was not physically remodeled.

4. The organizational structure of each facility.

(i) Total number of personnel 24

(ii) Division of personnel:

Military	0
Civilian	24

(iii) Division of personnel by category:

Scientists	23
Engineers	0
Technicians	0
Administrative and support staff	1

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Biological Science, Biotechnology, Genomics, Immunology, Molecular Biology, Protein Engineering, Structural Biology, 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 Health and Human Services (HHS)

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

Research	$ 3,789,641
Development	$ 0
Test and evaluation	$ 0
Total	$ 3,789,641

(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. Loomis RJ, DiPiazza AT, Falcone S, Ruckwardt TJ, Morabito KM, Abiona OM, et al. Chimeric Fusion (F) and Attachment (G) Glycoprotein Antigen Delivery by mRNA as a Candidate Nipah Vaccine. Front Immunol. 2021;12:772864. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8692728/
2. Marcus H, Thompson E, Zhou Y, Bailey M, Donaldson MM, Stanley DA, et al. Ebola-GP DNA Prime rAd5-GP Boost: Influence of Prime Frequency and Prime/Boost Time Interval on the Immune Response in Non-human Primates. Front Immunol. 2021;12:627688. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8006325/
3. Mbala-Kingebeni P, Pratt C, Mutafali-Ruffin M, Pauthner MG, Bile F, Nkuba-Ndaye A, et al. Ebola Virus Transmission Initiated by Relapse of Systemic Ebola Virus Disease. N Engl J Med. 2021;384(13):1240-7. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7888312/
4. Misasi J, Sullivan NJ. Immunotherapeutic strategies to target vulnerabilities in the Ebolavirus glycoprotein. Immunity. 2021;54(3):412-36. https://www.sciencedirect.com/science/article/pii/S1074761321000388?via%3Dihub

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. The ImmunoTechnology Section is dedicated to understanding the roles and interactions of the individual components of the mature central immune system, including research on immunological correlates of protection and correlates of pathogenesis. The Structural Biology Section seeks to apply structural biology to the development of effective vaccines and monoclonal antibody development.

Microorganisms and/or toxins studied: HHS Select Toxin

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) 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	603.14 m^2
BSL-3	184 m^2
BSL-4	0 m^2
Total laboratory floor area	787.14 m^2

During the reported calendar year, the White Oak Campus BSL-2 laboratory space used for biodefense research and development was reapportioned, resulting in an increase of 75.4 m^2, and the remaining differences were due to a numerical calculation error. The laboratory space was not physically remodeled.

4. The organizational structure of each facility.

(i) Total number of personnel 46

(ii) Division of personnel:

Military	0
Civilian	46

(iii) Division of personnel by category:

Scientists	38
Engineers	0
Technicians	0
Administrative and support staff	8

(iv) List the scientific disciplines represented in the scientific/engineering staff.
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: 13

(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	$ 878,609.30
Development	$ 0.00
Test and evaluation	$ 0.00
Total	$ 878,609.30

(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. Buskzko M, Nita-Lazar A, Park JH, Schwartzberg PI, Verthelhi D, Young HA et. Al. Lessons learned: new insights on the role of cytokines in COVID-19.Buszko et al. Nat Immunol (2021). 22: 404-411 https://pubmed.ncbi.nlm.nih.gov/33723418
2. Lee HN, McWilliams IL, Lewkowica AP, Engel K, Ireland DDC, Kelley-Baker L et. al. Characterization of the therapeutic effect of antibodies targeting the Ebola glycoprotein using a novel BSL2-compliant rVSV-delta-G-EBOV-GP infection model. Emerg Microbes Infect. (2021) Dec;10(1):2076-2089. https://pubmed.ncbi.nlm.nih.gov/34674613/
3. Lo CY, Misplon JA, Li X, Price GE, Ye Z, Epstein SL. Vaccine 2021 Jul 30;39(33):4628-40. Universal influenza vaccine based on conserved antigens provides long-term durability of immune responses and durable broad protection against diverse challenge virus strains in mice. https://pubmed.ncbi.nlm.nih.gov/34226103/
4. Ouyang Q and Frucht DM. Erk 1/2 Inactivation-Induced c-Jun Degradation is Regulated by Protein Phosphatases, UBE2d3, and the C-terminus of c-Jun. Int J Mol Sci (2021) 9:3889. https://pubmed.ncbi.nlm.nih.gov/33918729/
5. Radvak P, Kosikova M, Kuo YC, Li X, Garner R, Schmeisser F, et. al. NPJ Vaccines 2021 Feb 26;6(1):30. Highly pathogenic avian influenza A/Guangdong/17SF003/2016 is immunogenic and induces cross-protection against antigenically divergent H7N9 viruses. https://www.nature.com/articles/s41541-021-00295-7

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 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 determining the natural history

* Including viruse and prions.

of infectious organisms, determining pathogenicity and virulence of infectious agents, developing animal models for human infectious diseases, and developing bioassays to assess the potency, safety, and efficacy of medical countermeasures.

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 4

(ii) Division of personnel:

Military	0
Civilian	4

(iii) Division of personnel by category:

Scientists	4
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	$ 550,000
Development	$ 0
Test and evaluation	$ 50,000
Total	$ 600,000

(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. Christine A. Pillai, Gowri Manickam, Nagarajan Thirunavukkarasu, Segaran P. Pillai, Stephen A. Morse, Julie R. Avila, et. al. Evaluation of an Electrochemiluminescence Assay for the Rapid Detection of Abrin Toxin. Health Security 2021 19:4, 431-441 https://pubmed.ncbi.nlm.nih.gov/34227874/
2. Javkar K, Rand H, Hoffmann M, Luo Y, Sarria S, Thirunavukkarasu N, et. al. Whole-Genome Assessment of Clinical Acinetobacter baumannii Isolates Uncovers Potentially Novel Factors Influencing Carbapenem Resistance. Front Microbiol. 2021 Oct 1;12:714284. doi: 10.3389/fmicb.2021.714284. PMID: 34659144; PMCID: PMC8518998. https://doi.org/10.3389/fmicb.2021.714284

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. Activities include developing diagnostic assays for public health and food safety as well as conducting molecular characterization of organisms

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

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 10

(ii) Division of personnel:

Military	0
Civilian	10

(iii) Division of personnel by category:

Scientists	4
Engineers	0
Technicians	0
Administrative and support staff	6

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

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 3

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

1. Reddy, NR, Morrissey, TM, Aguilar, VL, Schill, KM, Skinner, GE. Evidence of Bacillus cereus spores as the target pathogen in thermally processed extended shelf life refrigertaed foods. J Food Prot. 2021:84(3):442-448. https://doi.org/10.4315/JFP-20-267

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: 33

(ii) Division of personnel:

Military	0
Civilian	33

(iii) Division of personnel by category:

Scientists	11
Engineers	0
Technicians	12
Administrative and support staff	10

(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	$ 4,169,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 4,169,000

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

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have a minimum of two peer-reviewed publications per year (not all publications by these scientists are relevant to this report). They are encouraged to present research at scientific conferences and to publish in books and proceedings. The USDA Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at https://www.ars.usda.gov/research/publications/publications-at-this-location/?modeCode=80-44-05-00).

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

1. Tancos MA, McMahon MB, Garrett WM, Luster, DG, Rogers EE. Comparative secretome analyses of toxigenic and atoxigenic Rathayibacter species. Phytopathology. 2021; 111(9):1530-1540. https://doi.org/10.1094/PHYTO-11-20-0495-R.

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: 10

(ii) Division of personnel:

Military	0
Civilian	10

(iii) Division of personnel by category:

Scientists	6
Engineers	0
Technicians	2
Administrative and support staff	2

(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	$ 6,054,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 6,054,000

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

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have a minimum of two peer-reviewed publications per year (not all publications by these scientists are relevant to this report). They are encouraged to present research at scientific conferences and to publish in books and proceedings. The USDA Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at https://www.ars.usda.gov/research/publications/publications-at-this-location/?modeCode=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. Buckley A, Falkenberg S, Martins M, Laverack M, Palmer MV, Lager K, et al. Intravenous, intratracheal, and intranasal inoculation of swine with SARS-CoV-2. Viruses. 2021; 13(8):1506. https://doi.org/10.3390/v13081506.
2. Falkenberg S, Buckley A, Laverack, M, Martins, M., Palmer MV, Lager K, et al. Experimental inoculation of young calves with SARS-CoV-2. Viruses. 2021; 13(3):441. https://doi.org/10.3390/v13030441.
3. Fiebig A, Vrentas CE, Le T, Huebner M, Boggiatto PM, Olsen SC, et al. Quantification of Brucella abortus population structure in a natural host. Proc Natl Acad Sci. 2021; 118(11):e2023500118. https://doi.org/10.1073/pnas.2023500118.
4. Khwatenge CN, Pate M, Miller LC, Sang Y. Immunometabolic dysregulation at the intersection of obesity and COVID-19. Front Immunol. 2021; 12:732913. https://doi.org/10.3389/fimmu.2021.732913.
5. Olsen SC, Boggiatto PM, Nol P, McCollum MP, Rhyan JC. Immune responses and efficacy of Brucella abortus Strain RB51 in bison after delivery in a dry dart formulation or by parenteral inoculation. Front Vet Sci. 2021; 8:706160. https://doi.org/10.3389/fvets.2021.706160.
6. Palmer MV, Martins M, Falkenberg S, Buckley, A, Caserta LC, Mitchell PK. et al. Susceptibility of white-tailed deer (Odocoileus virginianus) to SARS-CoV-2. J Virol. 2021; 95(11):e0008321. https://doi.org/10.1128/JVI.00083-21.
7. Sang ER, Tian Y, Miller LC, Sang Y. Epigenetic evolution of ACE2 and IL-6 genes: non-canonical interferon-stimulated genes correlate to COVID-19 susceptibility in vertebrates. Genes. 2021; 12(2):154. https://doi.org/10.3390/genes12020154.

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,

* Including viruses and prions.

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 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:	1,100 m^2
BSL-3:	624 m^2
BSL-4:	0 m^2
Total laboratory floor area:	1,724 m^2

During the reported calendar year, the Southeast Poultry Research BSL-2 laboratory space used for biodefense research and development underwent a physical remodel, resulting in a decrease of 38 m^2.

4. The organizational structure of each facility:

(i) Total number of personnel: 27

(ii) Division of personnel:

Military	0
Civilian	27

(iii) Division of personnel by category:

Scientists	9
Engineers	0
Technicians	4
Administrative and support staff	14

(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	$ 5,520,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 5,520,000

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

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

(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. Bertran K, Kassa A, Criado MF, Nunez IA, Lee D, Killmaster, L, et al. Efficacy of recombinant Marek's disease virus vectored vaccines with computationally optimized broadly reactive antigen (COBRA) hemagglutinin insert against genetically diverse H5 high pathogenicity avian influenza viruses. Vaccine. 2021; 39(14):1933-1942. https://doi.org/10.1016/j.vaccine.2021.02.075.
2. Bonney PJ, Malladi S, Ssematimba A, Spackman E, Torchetti MK, Culhane M, et al. Estimating epidemiological parameters using diagnostic testing data from low pathogenicity avian influenza infected turkey houses. Sci Rep. 2021; 11:1602. https://doi.org/10.1038/s41598-021-81254-z.
3. Criado MF, Leyson CM, Youk S, DeBlois S, Olivier T, Killian ML, et al. The pathobiology of H7N3 low and high pathogenicity avian influenza viruses from the United States outbreak in 2020 differs between turkeys and chickens. Viruses. 2021; 13(9):1851. https://doi.org/10.3390/v13091851.
4. Criado MF, Moresco KA, Stallknecht DE, Swayne DE. Low-pathogenicity influenza viruses replicate differently in laughing gulls and mallards. Influenza Other Respir Viruses. 2021; 15(6):701-706. https://doi.org/10.1111/irv.12878.
5. Dimitrov KM, Taylor TL, Marcano VC, Williams-Coplin D, Olivier,TL, Yu Q, et al. Novel recombinant Newcastle disease virus-based in ovo vaccines bypass maternal immunity to provide full protection from early virulent challenge. Vaccines (Basel). 2021; 9(10):1189. https://doi.org/10.3390/vaccines9101189.
6. Ferreira HL, Miller PJ, Suarez DL. Protection against different genotypes of Newcastle disease viruses (NDV) afforded by an adenovirus-vectored fusion protein and live NDV vaccines in chickens. Vaccines (Basel). 2021; 9(2):182. https://doi.org/10.3390/vaccines9020182.
7. Jerry C, Stallknecht DE, Leyson C, Berghaus R, Jordan B, Pantin-Jackwood M, et al. Age-associated changes in recombinant H5 highly pathogenic and low pathogenic avian influenza hemagglutinin tissue binding in domestic poultry species. Animals. 2021; 11(8):2223. https://doi.org/10.3390/ani11082223.
8. Karithi HM, Ferreira HL, Welch CN, Ateya LO, Apopo AA, Zoller R. et al. Surveillance and genetic characterization of virulent Newcastle disease virus subgenotype V.3 in indigenous chickens from backyard poultry farms and live bird markets in Kenya. Viruses. 2021; 13(1):103. https://doi.org/10.3390/v13010103.
9. Khalid Z, He L, Yu Q, Breedlove C, Joiner K, Toro, H. Enhanced protection by recombinant Newcastle disease virus expressing infectious bronchitis virus spike ectodomain and chicken granulocyte-macrophage colony-stimulating factor. Avian Dis. 2021; 65(3):364–372. https://doi.org/10.1637/aviandiseases-D-21-00032.

10. Kwon J, Ferreira Criado M, Killmaster L, Ali MZ, Giasuddin M, Samad MA, et al. Efficacy of two vaccines against recent emergent antigenic variants of Clade 2.3.2.1a highly pathogenic avian influenza viruses in Bangladesh. Vaccine. 2021; 39(21):2824-2832. https://doi.org/10.1016/j.vaccine.2021.04.022.
11. Lee D, Killian M, Deliberto TJ, Wan X, Lei L, Swayne DE, et al. H7N1 low pathogenicity avian influenza viruses in poultry in the United States during 2018. Avian Dis. 2021; 65(1):59-62. https://doi.org/10.1637/aviandiseases-D-20-00088.
12. Leyson CM, Youk S, Ferreira HL, Suarez DL, Pantin-Jackwood, M. Multiple gene segments are associated with enhanced virulence of clade 2.3.4.4 H5N8 highly pathogenic avian influenza virus in mallards. J Virol. 2021; 95(18):e00955-21. https://doi.org/10.1128/JVI.00955-21.
13. Mo J, Youk S, Pantin-Jackwood MJ, Suarez DL, Lee D, Killian M, et al. The pathogenicity and transmission of live bird market H2N2 avian influenza viruses in chickens, Pekin ducks, and guinea fowl. Vet Microbiol. 2021; 260:109180. https://doi.org/10.1016/j.vetmic.2021.109180.
14. Spackman E, Pantin-Jackwood MJ, Sitaras I, Stephens CB, Suarez DL. Identification of efficacious vaccines against contemporary North American H7 avian influenza viruses. Avian Dis. 2021; 65(1):113–121. https://doi.org/10.1637/aviandiseases-D-20-00109.
15. Youk S, Cho AY, Lee D, Sol J, Kim Y, Lee S, et al. Detection of newly introduced Y280-lineage H9N2 avian influenza viruses in live bird markets in Korea. Transbound Emerg Dis. 2021; 00:1-5. https://doi.org/10.1111/tbed.14014.
16. Youk S, Leyson CM, Seibert BA, Perez D, Jadhao S, Perez DR, et al. Mutations in PB1, NP, HA, and NA contribute to increased virus fitness of H5N2 highly pathogenic avian influenza virus clade 2.3.4.4 in chickens. J Virol. 2021; 95(5):e01675-20. https://doi.org/10.1128/JVI.01675-20.

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)

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	$ 556,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 556,000

(viii) Briefly describe the publication policy of the facility:
All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have a minimum of two peer-reviewed publications per year (not all publications by these scientists are relevant to this report). They are encouraged to present

research at scientific conferences and to publish in books and proceedings. The USDA Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at https://www.ars.usda.gov/research/publications/publications-at-this-location/?modeCode=60-40-10-30).

(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. Ahmad AA, Addy HS, Huang Q. Biological and molecular characterization of a jumbo bacteriophage infecting plant pathogenic Ralstonia solanacearum species complex strains. Front Microbiol. 2021; 12:741600. https://doi.org/10.3389/fmicb.2021.741600.
2. Schachterle JK, Huang Q. A high-throughput virulence screening method for the Ralstonia solanacearum species complex. J. Microbiol Methods. 2021; 187:106270. https://doi.org/10.1016/j.mimet.2021.106270.
3. Schachterle JK, Huang Q. Implication of the type III effector RipS1 in the cool-virulence of Ralstonia solanacearum strain UW551. Front Plant Sci. 2021; 12:705717. https://doi.org/10.3389/fpls.2021.705717.

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.

***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, 2022

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: The COVID-19 pandemic continued throughout 2021 and the following variants of concern as classified by WHO were detected in the U.S. during 2021: Alpha (first detected in 2020), Beta, Gamma, Delta, and Omicron. Please see the 2020 report for more details.

General information about variant and the SARS-CoV-2 virus are available at the CDC COVID Data Tracker: https://covid.cdc.gov/covid-data-tracker/#variant-proportions.

Human Infection with Influenza: Influenza A viruses that normally circulate in swine are called variant influenza viruses when isolated from humans. There may be important antigenic and genetic differences between seasonal influenza viruses that circulate worldwide in the human population and influenza viruses that normally circulate in swine. Influenza A viruses in swine do not usually infect humans, but rare human infections have been reported, usually after direct or indirect exposure to pigs. Since 2005, a total of 486 variant virus infections (of all subtypes) have been identified in the United States. There have been some instances of limited, non-sustained human-to-human transmission of variant influenza viruses, but no ongoing community transmission has been identified outside of the 2009 H1N1 pandemic.

General information about variant and influenza A viruses in swine are available at: http://www.cdc.gov/flu/swineflu/index.htm and http://gis.cdc.gov/grasp/fluview/Novel_Influenza.html

Human Infection with Influenza A(H3N2) variant virus (Wisconsin):
On January 13, 2021, a child under 18 years of age in Wisconsin developed respiratory disease. A respiratory specimen was collected on 14 January. Real-time RT-PCR testing conducted at the Wisconsin State Laboratory of Hygiene indicated a presumptive positive influenza A(H3N2) variant virus infection. The specimen was forwarded to the Influenza Division of the Centers for Disease Control and Prevention (CDC) on 21 January for further testing. On 22 January, CDC confirmed an influenza A(H3N2)v virus infection using RT-PCR and genome sequence analysis. Investigation into the source of the infection has been completed and revealed that the child lives on a farm with swine present. Five family members of the patient reported respiratory illness during the investigation and were tested for influenza; all tested negative. The patient was prescribed antiviral treatment and was not hospitalized and has made a full recovery. No human-to-human transmission has been identified associated with this investigation. Sequencing of the virus by CDC revealed it is similar to A(H3N2) viruses circulating in swine in the mid-western USA during 2019-2020. Viruses related to this A(H3N2)v virus were previously circulating as human seasonal A(H3N2) viruses until around 2010-2011 when they entered the USA swine population. Thus, past vaccination or infection with human seasonal A(H3N2) virus is likely to offer some protection in humans.

This is the first influenza A(H3N2)v virus identified in the United States in 2021. Since 2005, a total of 485 influenza variant virus human infections caused by all subtypes including 437 human infections with A(H3N2)v, including this one, have been reported in the United States.

Human Infection with Influenza A(H1N1) variant virus (North Carolina):
On 24 March 2021, the United States International Health Regulations (IHR) National Focal Point (NFP) informed PAHO/WHO of a human infection by influenza A(H1N1)v virus. According to the report, on

approximately 17 November 2020, an adult over 18 years of age old, with no underlying medical conditions that would covey increased risk for severe influenza, developed an influenza-like illness in North Carolina. On 24 November 2020, the patient sought medical care and a respiratory specimen was collected for influenza testing.

Real-time RT-PCR testing conducted at the North Carolina Department of Public Health: State Laboratory of Public Health indicated an influenza A(H1N1)pdm09 virus infection. The specimen was forwarded to the National Influenza Reference Center in New York on 23 February 2021, for inclusion in the U.S. national influenza virus strain surveillance program where genomic sequencing was performed. On 22 March 2021, sequence analysis by the Influenza Division of the Centers for Disease Control and Prevention confirmed an A(H1N1)v virus infection. The virus detected belongs to 1A.3.3.3 gamma lineage of classical swine influenza viruses, which is genetically very similar to human influenza A(H1N1)pdm09, hence initial diagnosis identified the sample as A(H1N1)pdm09 positive. Retrospective investigation into the source of the infection revealed that the patient worked with and had daily contact with swine. The patient was not hospitalized and has recovered from illness. No human-to-human transmission has been identified associated with this patient.

Since reporting of novel influenza A viruses became nationally notifiable in 2005, 111 human infections with A(H1N1)v, including this one, have been reported to CDC.

- Information regarding this A(H1N1)v case can be found at: https://www.cdc.gov/flu/weekly/weeklyarchives2020-2021/week11.htm

Human Infection with Influenza A(H1N1) variant virus (Wisconsin):
On 16 April 2021, the United States IHR National Focal Point (NFP) informed PAHO/WHO of a human infection by influenza A(H1N1)v virus. According to the report, on 31 March 2020, a child under 18-years old of age, with no underlying medical conditions associated with increased risk for severe influenza, developed an influenza-like illness in Wisconsin. On 1 April 2020, the patient sought medical care and a respiratory specimen was collected for influenza testing.

Real-time RT-PCR testing conducted at the Wisconsin State Laboratory of Hygiene indicated an unsubtypeable influenza A virus infection. The specimen was forwarded to the Influenza Division of the Centers for Disease Control and Prevention (CDC) on 8 April 2021, for further testing.
On 15 April 2021, the Influenza Division of the Centers for Disease Control and Prevention confirmed an A(H1N1)v virus infection by genome sequence analysis. Sequence analysis demonstrated close genetic similarity to swine influenza viruses currently circulating in the U.S.. Virus was isolated from the specimen and further characterization is underway. Retrospective investigation into the source of the infection revealed that the child had direct contact with swine at the child's residence. The patient was not hospitalized and has recovered from illness. No human-to-human transmission has been identified associated with this patient. This is the first human infection caused by influenza A(H1N1)v occurred in the United States in 2021. Since reporting of novel influenza A viruses became nationally notifiable in 2005, 112 human infections with A(H1N1)v, including this one, have been reported to CDC.

- Information regarding this A(H1N1)v case can be found at: https://www.cdc.gov/flu/weekly/weeklyarchives2020-2021/week14.htm

Human Infection with Influenza A(H1N2) variant virus (Ohio):
On 27 May 2021, the United States IHR National Focal Point (NFP) informed PAHO/WHO of a human infection caused by influenza A(H1N2)v virus. According to the report, on 24 March 2021, a patient <18 years of age in Ohio developed respiratory illness and sought outpatient medical care on 31 March 2021.

A respiratory sample was collected, which tested positive for influenza. The specimen was received at the Ohio Department of Health Laboratory on 14 May 2021, where RT-PCR analysis indicated it was positive for influenza A virus but lacked reactivity with tests specific for the detection of contemporary seasonal influenza viruses of A(H1)pdm09 or A(H3) subtypes. The specimen was then forwarded to the Influenza Division of the Centers for Disease Control (CDC) and Prevention for further testing; it was received at CDC on 20 May 2021. On 21 May 2021, CDC confirmed an A(H1)v virus infection using RT-PCR and genome sequence analysis. Additional diagnostic analysis on the specimen on 25 May 2021, confirmed that the virus was an A(H1N2)v virus. The patient was not hospitalized and has recovered from this illness. No human-to-human transmission of influenza A(H1N2)v virus has been identified associated with this case. This is the first influenza A(H1N2)v virus identified in the United States that occurred in 2021. Since reporting of novel influenza A viruses became nationally notifiable in 2005, 27 human infections with A(H1N2)v, including this one, have been reported to CDC.

- Information regarding this A(H1N2)v case can be found at: https://www.cdc.gov/flu/weekly/weeklyarchives2020-2021/week20.htm

Human Outbreak of Melioidosis (*Burkholderia pseudomallei)* (Georgia, Kansas, Minnesota, Texas):
In March-July 2021, CDC confirmed four linked cases (including two deaths) of melioidosis in patients from Georgia, Kansas, Minnesota, and Texas. Most cases of melioidosis in the United States are in people who traveled to areas where the disease is more common, but these patients had no recent history of international travel. Whole genome sequencing showed the strains of bacteria (*Burkholderia pseudomallei)* that sickened the patients closely matched each other, suggesting there was a common source of infection. The strain of bacteria that sickened the patients was similar to those found most often in South Asia, which led CDC to suspect that an imported product may have been involved in the patients' illnesses.

As part of the public health investigation into these illnesses, CDC tested blood samples from the patients, as well as soil, water, and consumer products from in and around their homes. In October 2021, CDC identified *B. pseudomallei,* which causes melioidosis, in an aromatherapy spray that was found in the home of the Georgia patient. Further CDC testing showed that the genetic fingerprint of the bacteria in the bottle matches those of the bacteria identified in the four patients. This finding confirms the spray was the source of the Georgia patient's infection, and that the spray or another product with the same contaminated ingredient caused illness in the three other linked cases. CDC is coordinating with the state health departments to try to determine whether the other three patients may have also used this or similar products. Working with the Consumer Product Safety Commission and Walmart, CDC is also in contact with the manufacturer in India to determine if ingredients from the implicated spray were used in any other products.

- CDC Press Release from October 26, 2021: https://www.cdc.gov/media/releases/2021/p1026-melioidosis-outbreak.html
- CDC Press Release from November 4 2021: https://www.cdc.gov/melioidosis/outbreak/2021/index.html
- CDC Health Alert Update: https://emergency.cdc.gov/han/2021/han00456.asp

Human Infection with Monkeypox (Texas):
On 17 July 2021, the United States IHR NFP notified PAHO/WHO of an imported human monkeypox case in Dallas, Texas. The case corresponds to a male, resident of the United States with a recent travel history to Nigeria from the United States.

According to the report, the case-patient flew from Dallas, Texas to Lagos, Nigeria on 25 June 2021. On 26 June, he traveled to Lagos Island by car. On 29 June, he traveled from Lagos Island to Ibadan city, Oyo state, Nigeria, where on 30 June he became ill with subjective fever, vomiting, and a mild cough. On 2 July, he attended the funeral of a woman who reportedly died of "old age" and diabetes. On 3 July, he traveled to Lagos and developed a painful rash on 7 July. He departed Nigeria on 8 July to Atlanta, Georgia, USA where he arrived on 9 July and took a connecting flight to Dallas, Texas, USA.
On 10 July, the patient reported feeling ill and experienced the appearance of a rash on his face. He sought medical attention at a hospital in Dallas on 13 July where he was immediately placed in isolation. His signs/symptoms included fever (39.6°C), cough, abdominal pain, and disseminated rash on the head, face, torso, and genitals. The preliminary result of an Orthopoxvirus infection was reported by the Dallas County Laboratory Response Network (LRN) on 14 July from testing on a lesion sample from the patient's back; this testing was done using the Orthopoxvirus generic and Non-variola Orthopoxvirus RT-PCR assays. On 15 July, patient specimens were tested positive for West African clade Monkeypox virus via rtPCR assays conducted at the U.S. CDC Poxvirus and Rabies Branch Laboratory at the Centers for Disease Control and Prevention. The patient is hospitalized in Dallas and is in stable condition. The hospital has implemented contact and airborne precautions and he is currently isolated in a negative pressure room.

At this time, the source of infection for this case is unknown. Although monkeypox is considered a zoonotic disease, the wildlife reservoir has not been determined. During a 2003 outbreak of monkeypox in the United States, infections were traced back to originate from imported African rodents from Ghana. Contact with wild animals (including live animals, meat for consumption, and other products), as well as other human monkeypox cases, are known potential risk factors in enzootic countries.

- CDC Press Release from July 16, 2021: https://www.cdc.gov/media/releases/2021/s0716-confirm-monkeypox.html

Human Infection with Monkeypox (Maryland):
On 16 November 2021, the USA International Health Regulation National Focal Point (IHR NFP) notified PAHO/WHO of an imported human monkeypox case in Maryland, USA. The case-patient is an adult resident of the USA with a recent travel history to Nigeria. This is the second imported human monkeypox case in 2021 in the United States.

According to the report, the case-patient was in Lagos, Nigeria when he presented rash on the face. On 6 November, the case-patient flew from Lagos, Nigeria to Istanbul, Turkey and, on 7 November, the case-patient flew from Istanbul, Turkey to Washington, D.C, USA. The case-patient is currently in isolation in Maryland. The case-patient had not been vaccinated against smallpox in the past. On 13 November 2021 the Maryland laboratory of the Laboratory Response Network (LRN) reported positive results with two PCR assays, Orthopoxvirus and non-variola Orthopoxvirus, on two lesion specimens. On 16 November 2021, the U.S. CDC confirmed the diagnosis by two PCR assays, monkeypox and West African monkeypox, on 2 lesion specimens. The case-patient was infected with monkeypox virus and the infection matches the strain that has been re-emerging in Nigeria since 2017. At this time, while the patient had remained in Lagos throughout the stay in Nigeria, the source of infection for this case is unknown.

- CDC Press Release from November 17, 2021: https://www.cdc.gov/media/releases/2021/s1117-monkeypox.html

Animal Disease Events

Summary of Reports: In 2021, the United States submitted two World Organization for Animal Health (OIE) immediate reports for animal disease events. These included one rabbit hemorrhagic disease virus type 2 (RHDV2) report and one rabies disease report. There were two events from 2020 that continued into 2021. These included one RHDV2 event and the severe acute respiratory syndrome coronavirus 2 event.

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/

2021 Immediate OIE Reports:

Severe Acute Respiratory Syndrome-Coronavirus Disease (SARS-CoV-2)—United States
OIE Follow-up Reports January 1, 2021 — Open at the end of 2021

SARS-CoV-2 is considered to be an emerging disease by the World Organisation for Animal Health (OIE). We are still learning about the SARS-CoV-2 virus, which causes COVID-19 in people and can spread between people and animals, mostly after close contact.

Throughout 2021, the U.S. Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS) confirmed and reported SARS-CoV-2 detections in 128 individual animals from 15 species groups and 26 states and the District of Columbia. Cases occurred in household companion animals, including 10 cats, 8 dogs, and 1 ferret; zoo animals, including 33 tigers, 29 lions, 11 gorillas, 8 otters, 8 snow leopards, 2 spotted hyenas, 1 binturong, 1 coatimundi, 1 cougar, 1 fishing cat, and 1 lynx; and in wildlife in 13 white-tailed deer.

Rabbit Hemorrhagic Disease Virus-2 (RHDV2) — Georgia, New York, Florida, Kentucky, Mississippi, South Dakota, and Minnesota
OIE Immediate Report May 5, 2021— Open at the end of 2021

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. Disease events occurred in Georgia, New York, Florida, Kentucky, Mississippi, South Dakota, and Minnesota. General clinical signs seen in confirmed cases included lethargy, seizures, and sudden death.

- Georgia – RHDV2 detected on two domestic rabbit (Oryctolagus Cuniculus) premises.
- New York – RHDV2 detected on one domestic rabbit (Oryctolagus Cuniculus) premises.
- Florida – RHDV2 detected on one domestic rabbit (Oryctolagus Cuniculus) premises.
- Kentucky – RHDV2 detected on one domestic rabbit (Oryctolagus Cuniculus) premises.
- Mississippi – RHDV2 detected on one domestic rabbit (Oryctolagus Cuniculus) premises.
- South Dakota – RHDV2 detected on one domestic rabbit (Oryctolagus Cuniculus) premises.
- Minnesota – RHDV2 detected on one domestic rabbit (Oryctolagus Cuniculus) premises.

RHDV2—Wyoming, Florida, Montana, Idaho and Oregon
OIE Immediate Report December 18, 2020 — Final Report July 19, 2021

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. This event continued into 2021.

- Wyoming – RHDV2 was detected on one domestic rabbit (*Oryctolagus cuniculus*) premises. Additionally, there were 26 detections of RHDV2 in wild lagomorphs. Affected species included black-tailed jackrabbits (*Lepus californicus*), cottontail rabbits (*Sylivilagus sp.),* desert cottontail rabbits (*Sylvilagus audubonii*), and eastern cottontail rabbits (*Sylvilagus floridanus*.)
- Florida – RHDV2 was detected on one domestic rabbit (*Oryctolagus cuniculus*) premises.
- Montana – RHDV2 was detected in two feral domestic rabbits (*Oryctolagus cuniculus*) and a wild mountain cottontail rabbit (*Sylvilagus nuttallii*).
- Idaho – RHDV2 was detected in one feral domestic rabbit (*Oryctolagus cuniculus*) and two wild black-tailed jackrabbits (*Lepus californicus*).
- Oregon – RHDV2 was detected on four domestic rabbit (*Oryctolagus cuniculus*) premises. Additionally, there were two RHDV2 detections in feral domestic rabbits (*Oryctolagus cuniculus*) and three detections in wild lagomorphs. Affected species included black-tailed jackrabbits (*Lepus californicus*).

Rabies virus – Pennsylvania
OIE Immediate Report July 15, 2021 — Final report January 19, 2022

Rabies is a disease caused by neurotropic viruses of the Genus Lyssavirus in the family Rhabdoviridae of the order Mononegavirales and is transmissible to all mammals. Populations of the orders Carnivora and Chiroptera are considered to be the main reservoir hosts. Rabies fatality rate is almost 100%.

This case was due to the importation of a dog infected with the canine rabies variant into the United States, which has been considered free from this viral variant since 2007. The imported rabid dog developed signs of rabies 3 days after importation and was euthanized by a private veterinarian before testing positive at the National Reference Laboratory. Virus characterization confirmed the dog was infected with a canine rabies virus variant that has been previously reported in Azerbaijan. Additional animals that originated from the same rescue as the rabid dog are undergoing serological screening and quarantine.

The rabid dog potentially exposed up to 36 people and 33 other animals (32 dogs and 1 cat). After assessment, post exposure prophylaxis was recommended to 15 people. The exposed animals were closely monitored under quarantine. In July 2021, results of prospective serologic monitoring (paired rabies titers at day 0 and 5 after rabies booster vaccine) were available from 30/33 (91%) exposed animals. Seven of 32 (22%) animals did not show an expected response to booster vaccination, indicating a failure of vaccination practices among these dogs. The Centers for Disease Control and Prevention (CDC) determined that the vaccine failures were the result of improper vaccination practices attributed to one veterinarian in the clinic responsible for preparing these dogs for importation.

All 33 exposed animals received a rabies booster vaccination in the United States. Of the 33 animals, 8 were required to complete a 4- to 6-month strict quarantine and 25 were required to undergo a 45-day in-home quarantine based on post-booster serum testing results. None of the 33 exposed animals died or exhibited rabies symptoms while under quarantine. All exposed animals completed their required quarantines on December 29, 2021.

Form C

BWC - Confidence Building Measure

Encouragement of Publication of Results and Promotion of Use of Knowledge

United States of America

April 15, 2022

CDC, Federal Select Agent Program, **2020 Annual Report of the Federal Select Agent Program,** released in September 2021 https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2020_508.pdf	The *2020 Annual Report of the Federal Select Agent Program,* released in September 2021, summarizes 2020 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**, 2020 Federal Select Agent Program (FSAP) Inspection Report Processing Annual Summary**, released August 2021 https://www.selectagents.gov/resources/publications/docs/2020-FSAP-Inspection-Report-Processing-Annual-Summary.pdf	The FSAP Inspection Report summarizes timeliness data related to FSAP-issued inspection reports for the Federal Select Agent Program January 1, 2020 – December 31, 2021.
CDC OneLab initiative https://www.cdc.gov/labtraining/onelab.html	In 2021, CDC conducted a training needs assessment and launched the OneLab initiative to bridge, train, and sustain a capacity-building community among public health and clinical laboratory professionals to support rapid, large-scale responses to public health emergencies.
The U.S. Office of Research Integrity FY 2020 Annual Report, released February 2021 **https://ori.hhs.gov/sites/default/files/2021-02/ORI%20FY%202020%20Annual%20Report%20%28ver%201.1%29.pdf**	This is the annual report of The Office of Research Integrity (ORI) which oversees and directs Public Health Service (PHS) research integrity activities on behalf of the Secretary of Health and Human Services with the exception of the regulatory research integrity activities of the Food and Drug Administration. This includes oversight of research misconduct inquiries and investigations, as well as of institutional compliance.

Form E

BWC - Confidence Building Measure

Declaration of legislation, regulations and other measures

United States of America

April 15, 2022

Form E

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:

- **Commerce Control List: Expansion of Controls on Certain Biological Equipment Software.** (Effective date October 5, 2021) This final rule amends the Export Administration Regulations (EAR) to implement the decision made at the Australia Group (AG) Virtual Implementation Meeting session held in May 2021, and later adopted pursuant to the AG's silence procedure, that updated the AG Common Control List for dual-use biological equipment by adding controls on nucleic acid assembler and synthesizer software that is capable of designing and building functional genetic elements from digital sequence data. Consistent with this AG decision, this final rule amends the EAR by adding new Export Control Classification Number (ECCN) 2D352 to the Commerce Control List (CCL) to control this software. In addition, this rule amends ECCN 2E001 to control, *inter alia*, technology for the development of this software. This rule also makes conforming changes to Section 742.2 of the EAR to reflect the addition of ECCN 2D352 to the CCL and to indicate that technology for the development of software controlled by new ECCN 2D352 is controlled by ECCN 2E001. https://bis.doc.gov/index.php/documents/regulations-docs/federal-register-notices/federal-register-2021/2850-86-fr-54814/file

- **Expansion of Certain End-Use and End-User Controls and Controls on Specific Activities of U.S. Persons.** (Effective date January 15, 2021, updated March 16, 2021) The Bureau of Industry and Security (BIS) issued this final rule to implement the provisions of the Export Control Reform Act of 2018 by: imposing additional license requirements under the EAR for exports, reexports, and transfers (in-country), as well as expanding the scope of specific activities of U.S. persons, in connection with certain military-intelligence end uses and end users; clarifying that license requirements under the EAR for specific activities of U.S. persons apply even when the items at issue are not subject to the EAR; establishing restrictions on transactions intended to circumvent license requirements for listed entities; and expanding the scope of activities subject to chemical and biological weapons and rocket systems and unmanned aerial vehicles end-use controls. More specifically, BIS revised § 744.6 to impose an additional license requirement on when a U.S. person

* 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.

knowingly supports an export, reexport, or transfer (in-country) of an item where that person knows that such item will be used in the design, development, production, stockpiling, or use of biological weapons in or by any country or destination, worldwide. The insertion of the language "will support," which supplements "will directly assist," an export, reexport, or transfer (in-country) of such items expands the scope of activities subject to end-use controls to include any action, including financing, transportation, and freight forwarding, by which a person facilitates an export, reexport, or transfer (in-country) of such items. https://www.bis.doc.gov/index.php/documents/regulations-docs/federal-register-notices/federal-register-2021/2708-86-fr-4862/file

- **Commerce Control List: Clarifications to the Scope of Export Control Classification Number 1C991 to Reflect Decisions Adopted at the June 2019 Australia Group Plenary Meeting** (Effective date January 7, 2021) This final rule amends the EAR to clarify the scope of the export controls that apply to certain vaccines, consistent with the vaccine release (i.e., exclusion) notes contained in the Australia Group (AG) "Human and Animal Pathogens and Toxins for Export Control" common control list. Specifically, this rule amends Export Control Classification Number (ECCN) 1C991 on the CCL to indicate that it includes vaccines containing, or designed for use against, any of the items identified in ECCN 1C351, 1C353 or 1C354. Prior to the effective date of this final rule, ECCN 1C991 indicated that it controlled vaccines "against" such items, but was not specific about whether all vaccines "containing" such items were controlled, irrespective of whether the vaccines were designed for use "against" such items. In this update to ECCN 1C991, vaccines designed for use against COVID-19 that incorporate controlled agents (e.g. Newcastle disease virus and Vesicular stomatitis virus) or their genetic elements are controlled under ECCN 1C991 for anti-terrorism reasons (AT). Therefore, a license is required to export these vaccines to certain destinations in accordance with the embargoes and other special controls described in Part 746 of the EAR. Prior to this update to the EAR, these chimeric vaccines were controlled under ECCN 1C353 for both chemical and biological weapons (CB) and anti-terrorism (AT) reasons with worldwide licensing requirements.[*] [Note: For the purpose of export controls, the U.S. Department of Commerce currently considers SARS-CoV-2 to be distinct from the SARS-CoV virus and classifies SARS-CoV-2 and its specific genetic elements as EAR99. An export license is generally not required for export of this virus or its genetic elements to most destinations. In the very few instances where an export license is required, BIS is expediting applications for the export or reexport of COVID-19 vaccines.] This rule also expands the scope of medical products controlled under ECCN 1C991 to include those containing genetically modified organisms and genetic elements described in ECCN 1C353.a.3. In addition, this rule clarifies the definition of immunotoxin that appears in ECCN 1C351 and ECCN 1C991 and removes the definition of subunit from ECCN 1C351. Finally, this rule renumbers ECCN 1C991.c and .d by listing medical products that are subject to chemical/biological (CB) controls, as well as anti-terrorism (AT) controls, under ECCN 1C991.c and listing medical products that are subject only to AT controls under ECCN 1C991.d. A conforming amendment is made to Section 742.2(a)(3) of the EAR to reflect this change in paragraph sequencing. https://www.bis.doc.gov/index.php/documents/regulations-docs/federal-register-notices/federal-register-2021/2703-86-fr-944/file

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

- **2021 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. CDC IPP also inspects entities to verify that facilities have implemented the appropriate biosafety measures for the infectious biological agent, infectious substance, or vector to be imported. This helps

[*] Chimeric virus based COVID-19 vaccines which incorporate an additional virus that is not controlled (e.g. adenovirus and measles), then the vaccine is considered to be EAR99. An export license is generally not required for export of these COVID-19 vaccines to most destinations.

to protect the health of laboratory workers and those in the surrounding communities. Read more at: https://www.cdc.gov/cpr/ipp/about.htm The IPP program:

- Updated the standardized checklists used for inspections in 2021 to reflect the changes in the 6th edition of *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*: https://www.cdc.gov/cpr/ipp/inspection/index.htm
- Published its IPP inspectors requirements on 01 November 2021: https://www.cdc.gov/cpr/ipp/ippgrams/index.htm
- Hosted a public webinar on December 2, 2021 to address import permit regulations for bringing infectious biological agents, infectious substances, and vectors of human disease into the U.S. Presentations are available for download at: https://www.cdc.gov/cpr/ipp/webcast-2021/index.htm

[3] (d) Biosafety and biosecurity:

- **Amendments to Select Agent and Toxin Regulations:**

  - Interim Final Rule (IFR) - Addition of SARS-CoV/SARS-CoV-2 Chimeric Viruses to Select Agents and Toxins List: Added SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors to the list of HHS select agents and toxins and require prior approval of this work by CDC in the *Federal Register* on November 17, 2021 (86 FR 64075). The IFR issues immediate regulatory oversight while continuing to solicit public comment on the rule. Read more at https://www.selectagents.gov/overview/whatsnew/2021.htm and https://www.federalregister.gov/documents/2021/11/17/2021-25204/possession-use-and-transfer-of-select-agents-and-toxins-addition-of-sars-covsars-cov-2-chimeric.

- **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 2021, the Departments of Health and Human Services (HHS) and Agriculture (USDA) generated the following policies:
    - Draft FSAP Policy Statement: Biosafety for Large Animal Study-Related Activities with *Brucella abortus* and *B. suis* Using Outdoor Containment Spaces (https://www.federalregister.gov/documents/2021/01/15/2021-00877/notice-of-availability-of-a-draft-policy-statement-for-the-biosafety-of-large-animal-study-related)
    - Excluded ASFV-G-DeltaI177L DeltaLVR strain of African swine fever virus from the requirements of the select agents and toxins regulations (effective March 11, 2021) (https://www.selectagents.gov/sat/exclusions/usda.htm).

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

  - Federal Select Agent Program Updated Guidance to the Select Agent Regulations Training Requirements (March 2021): This document provides guidance for meeting the training requirements of the select agent regulations. Topics include what types of training are required, training programs, frequency requirements, and training records. The document is available at: https://www.selectagents.gov/compliance/guidance/training/index.htm.

- Federal Select Agent Program Updated Occupational Health Program Guidance (April 2021): This document provides guidance for developing and implementing an Occupational Health Program for entities that possess or use Tier 1 select agents and toxins. This includes information about Tier 1 precautions, medical assessments and surveillance, post exposure management, hazard communication, and more. The document is available at: https://www.selectagents.gov/compliance/guidance/occupational-health/index.htm.

- Federal Select Agent Program Updated Incident Response Plan Guidance (August 2021): This document provides guidance for developing and implementing an incident response plan in accordance with section 14 of the select agent regulations. This includes information regarding requirements, natural disasters, and the goals of incident response planning. The document is available at: https://www.selectagents.gov/compliance/guidance/incident-response/index.htm.

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

- FBI Enforcement Actions: Signed into law in 1990, the Biological Weapons Anti-terrorism (BWAT) Act implements provisions of the BWC, consistent with Article IV of the Convention. The BWAT Act was 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). 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 U.S. Federal Select Agent Program. In 2021, the FBI responded to several incidents that involved known or suspected biological material and led investigations predicated by potential violations of 18 USC 175.

- FBI Security Risk Assessments (SRAs): 3,354 SRAs Completed in 2021: 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 2021, 3,354 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 3,354 individual SRAs processed, 23 BSAT access candidates were determined to meet the criteria of a "restricted person." The FBI's adjudication is provided to the Department of Health and Human Services or the Department of Agriculture, who decides whether to grant or deny the requesting entity or individual access to BSAT.

- FBI Biosecurity Outreach: During 2021, the FBI conducted over 20 biosecurity engagements with domestic and international scientific communities, taking a multisectoral approach wherever feasible to enable mutually beneficial dialogue across disciplines. These engagements focused on the FBI's roles and responsibilities in the biosecurity arena and provided resources to mitigate suspicious activities to improve situational awareness of biosecurity threats and foster a mechanism to report suspicious activities to mitigate risk. The scientific community (both academia and private sector) provided insights of research advances and biotechnology innovations, describing the potential benefits as well as their perspectives of potential misuse by nefarious actors. The inclusion of government, first response, as well as public, animal, and environmental health officials enabled a whole-of-community effort to further biosafety and biosecurity.

Examples of FBI outreach activities in 2021: 1) hosted security discussions with domestic and international synthetic biology stakeholders, such as biosecurity outreach at the 2021 International Genetically Engineered Machine Competition; 2) continued to work with the United Nations Interregional Crime and Justice Research Institute to develop biosecurity, biosafety, and bioethics teaching modules, including health misinformation and disinformation, that can be incorporated into academic curricula,; 3) formulated and implemented animal-plant health workshops to enhance agricultural biosecurity practices among veterinary professionals, customs/border control officials, academia, and first responders for potentially deliberate disease events; and 4) Sponsored workshops with regional biomedical research associations.

- American Pandemic Preparedness: On January 20, 2021, the President of the United States released Executive Order 13987, "Organizing and Mobilizing the United States Government To Provide a Unified and Effective Response To Combat COVID-19 and To Provide United States Leadership on Global Health and Security," which directed the United States Government to review emerging domestic and global biological risks and national biopreparedness policies, in light of COVID-19. As part of this review, the United States released *American Pandemic Preparedness: Transforming Our Capabilities*, which sets out an ambitious beneficial research agenda in an effort to curb future pandemics and to protect the United States against biological threats, including building core capabilities like biosafety and biosecurity.

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, 2022

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, 2022

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 December 15, 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 approved several Emergency Use Authorization (EUA) applications in addition to already EUA approved vaccines for humans 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 and its prescribed use, 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 Moderna COVID-19 Vaccine, and the Janssen COVID-19 Vaccine, and Pfizer-BioNTech COVID-19 Vaccine. In December 2021, the Pfizer-BioNTech vaccine received full FDA approval, as reflected below with the listing of this facility; whereas the lower-dose vaccine for children remains under EUA. 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
BioNTech Manufacturing GmbH/Pfizer Inc.

This facility is a new entry for 2021 and was approved December 16, 2021 for the manufacturing of COVID-19 Vaccine, mRNA (Comirnaty).

2. Location (Mailing Address)
Pfizer, Inc. 235 E 42nd St,
New York, New York 10017

3. General description of the types of diseases covered:
Comirnaty is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

Vaccines:

- COVID-19 Vaccine, mRNA - [Comirnaty]

Form G

Declaration of vaccine production facilities

1. Name of facility
Dynavax Technologies Corporation

This facility is a new entry for 2021 and was approved May 6, 2020 for the manufacturing of Hepatitis B Vaccine (Recombinant), Adjuvanted (HEPLIVSAV-B).

2. Location (Mailing Address)
2100 Powell Street, Suite 900,
Emeryville, California 94608

3. General description of the types of diseases covered:
For prevention of infection caused by all known subtypes of hepatitis B virus. HEPLISAV-B is approved for use in adults 18 years of age and older.

Vaccines:

- Hepatitis B Vaccine (Recombinant), Adjuvanted - [HEPLISAV-B]

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
Emergent Travel Health, Inc.

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

4. 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]

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, Pennsylvania 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; 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, W) Conjugate Vaccine – [MenQuadfi] (This vaccine is a new entry for 2021 and was approved October 27, 2021.)
- 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, North Carolina 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. Active immunization for the prevention of pneumonia and invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F,14, 15B, 18C, 19A, 19F, 22F, 23F and 33F in adults 18 years of age and older.

Vaccines:
- Meningococcal Group B Vaccine - [TRUMENBA]
- Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein) - [Prevnar 13]
- Pneumococcal 20-valent Conjugate Vaccine – [PREVNAR 20]

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)
SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors
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 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
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
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
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 (SARS-COV)	HHS Select Agent
SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors	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
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