United States of America

Confidence Building Measure Return covering 2022

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, 2023

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, 2023

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, 2023

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 Agent 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 research oversight, responsible conduct of research, pathogens of pandemic potential, and screening of synthesized DNA, among others.

More information on regulations and guidelines can be found in the Federal Experts Security Advisory Panel report (https://www.phe.gov/s3/Documents/FESAP-guiding-principles.pdf), which also includes

transportation, export, and disposal of hazardous and/or infectious materials; response to biological incidents; and security risk assessments for individuals working with select agents and toxins.

Exchange of data on research centres and laboratories

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

2. Responsible public or private organization or company.
U.S. Department of Homeland Security Science and Technology Directorate
Operated by Battelle National Biodefense Institute LLC

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

4. Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.
U.S. Department of Homeland Security (DHS)
U.S. Department of Justice (DOJ)
U.S. Department of Health and Human Services (HHS)
U.S. Department of Defense (DOD) - Partly

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

6. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.
NBACC conducts studies to better understand current and future biological threats; to assess vulnerabilities; and to determine potential impacts to guide the development of biological countermeasures such as detectors, drugs, vaccines, and decontamination technologies. When needed, NBACC conducts experimental programs to better characterize the benefits and risks of changes in U.S. biodefense preparedness. 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 Development Command
(Note: The responsible organization has not changed but was referred to as "U.S. Army Medical Research and Materiel Command" in previous CBM reports.)

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

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 (HHS)
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.

Form A, Part 1 (i)

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/.

Form A, Part 1 (i)

Exchange of data on research centres and laboratories

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

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

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

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

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

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

Exchange of data on research centres and laboratories

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

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

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

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

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. For more information on previous work at the High Containment Core, please see: https://research.gsu.edu/high-containment-labs/. The National B Virus Resource Laboratory now operates as part of the core. The core comprises three BSL-3 laboratories with animal facilities and one BSL-4 Class III Cabinet Line Laboratory. 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; however, experimental work with Risk Group 4 agents did not resume. In 2022, changes in personnel and funding resulted in a decrease in the scope of experimental work; Herpes B Virus is the only agent being stored in the BSL4 for future propagation of antigen for diagnostic testing.

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.
U.S. Department of Health and Human Services (HHS)
U.S. Department of Defense (DOD) – Partly
Boston University
Private sector 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:

1. Performs 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. Provides 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. Establishes 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: https://www.bu.edu/neidl/research/current-research/.

Exchange of data on research centres and laboratories

The National Bio and Agro-Defense Facility, which will house a BSL-4 laboratory, will be constructed and will be 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.

Form A, Part 2 (i)

BWC - Confidence Building Measure

National biological defence research and development programmes - Declaration

United States of America

April 15, 2023

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, 2023

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. In October of 2022, the U.S. Government released the "National Biodefense Strategy and Implementation Plan on Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security" and the "National Security Memorandum on Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security," which supersedes the 2018 National Biodefense Strategy and accompanying Presidential Memorandum on Support for National Biodefense (NSPM-14): https://www.whitehouse.gov/wp-content/uploads/2022/10/National-Biodefense-Strategy-and-Implementation-Plan-Final.pdf and https://www.whitehouse.gov/briefing-room/presidential-actions/2022/10/18/national-security-memorandum-on-countering-biological-threats-enhancing-pandemic-preparedness-and-achieving-global-health-security/. 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 Security Memorandum on Strengthening the Security and Resilience of United States Food and Agriculture (NSM-16, issued in November 2022 and supersedes 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 agents 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 and prophylaxes for biological agents, toxins, and novel threats; testing battlefield detection and identification methods, protective systems, and decontamination systems; and the development of rapid and deployable detection and diagnostic assays for troop protection and medical defenses.

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.
$711,223,090 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.

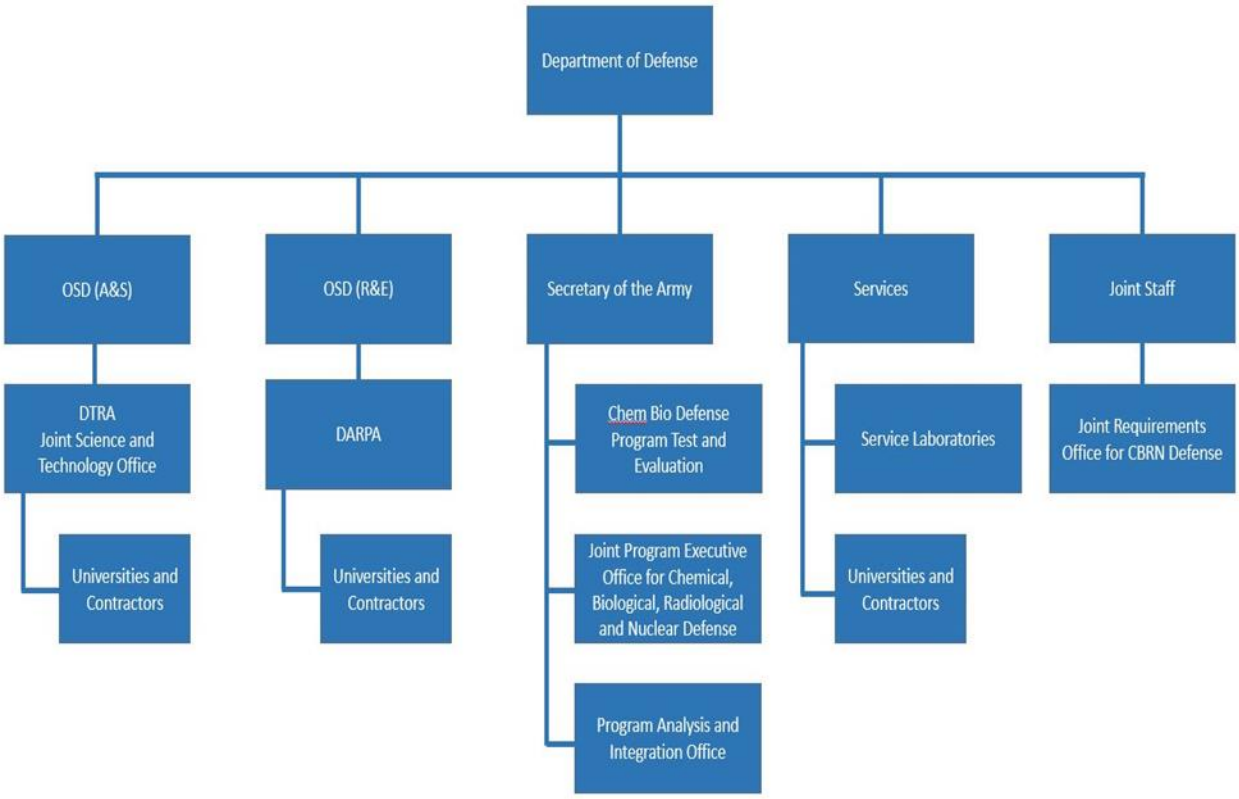
4. If yes, what proportion of the total funds for each programme is expended in these contracted or other facilities?
71.5%

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

- 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 49
- Naval Medical Research Center (NMRC) – Page 51
- Naval Research Laboratory (NRL) – Page 54
- Naval Surface Warfare Center (NSWC) - Dahlgren Division Chemical, Biological, Radiological (CBR) Defense Laboratory – Page 56
- U.S. Army Combat Capabilities Development Command Chemical Biological Center (CCDC CBC), formerly named U.S. Army Edgewood Chemical and Biological Center – Page 58
- U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) – Page 61
- U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) – Page 63
- Air Force Research Laboratory (AFRL), 711 HPW – Page 70

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

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

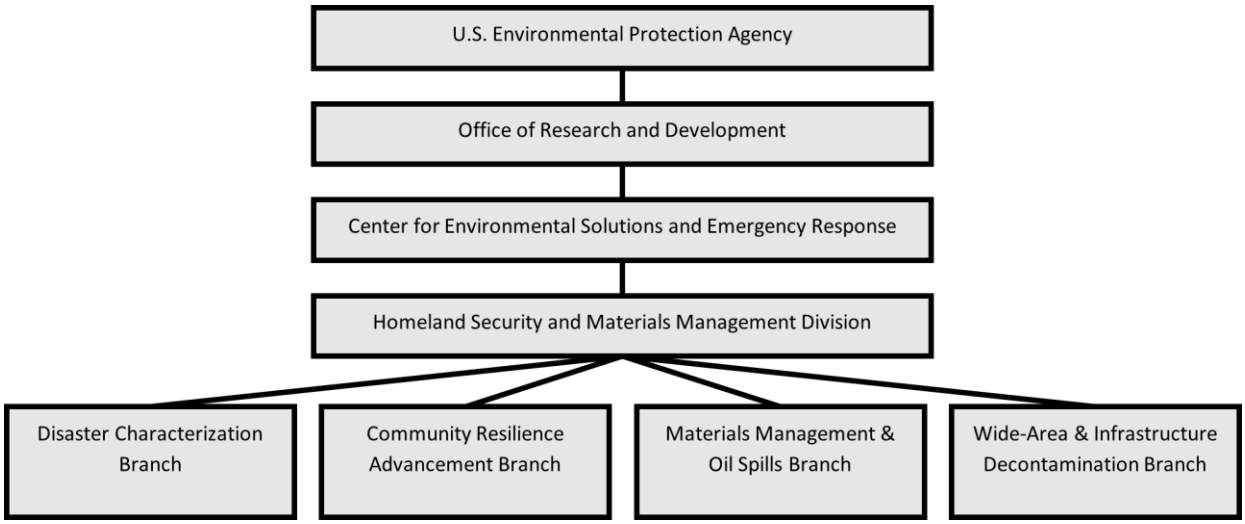
2. State the total funding for the programme and its source.
$7,800,000 U.S. Environmental Protection Agency (EPA)

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, 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 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.)



Note: EPA's Center for Environmental Solutions and Emergency Response (CESER) completed a reorganization in 2022. With CESER, the Homeland Security and Materials Management Division portion of the reorganization included 1) a name change from "System Tools & Materials Management Branch" to "Materials Management & Oil Spills Branch" and (2) a new branch called "Community Resilience Advancement Branch." More info can be found here: https://www.epa.gov/aboutepa/about-homeland-security-and-materials-management-division.

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, diagnostic assays.

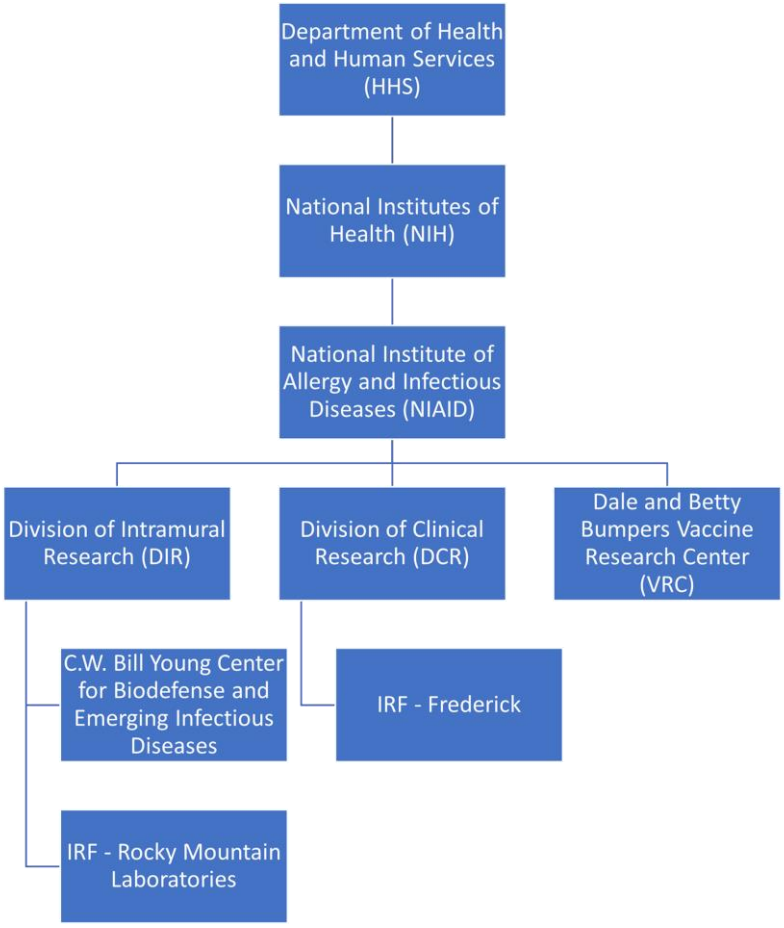
2. State the total funding for each programme and its source.
$108,699,804 U.S. Department of Health and Human Services (HHS)
$295,000 U.S. Department of Defense (DOD)

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?
12.1%

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 111
- Integrated Research Facility at Fort Detrick (IRF-Frederick) – Page 121
- C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases – Page 127
- Dale and Betty Bumpers Vaccine Research Center (VRC) – Page 135

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

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.

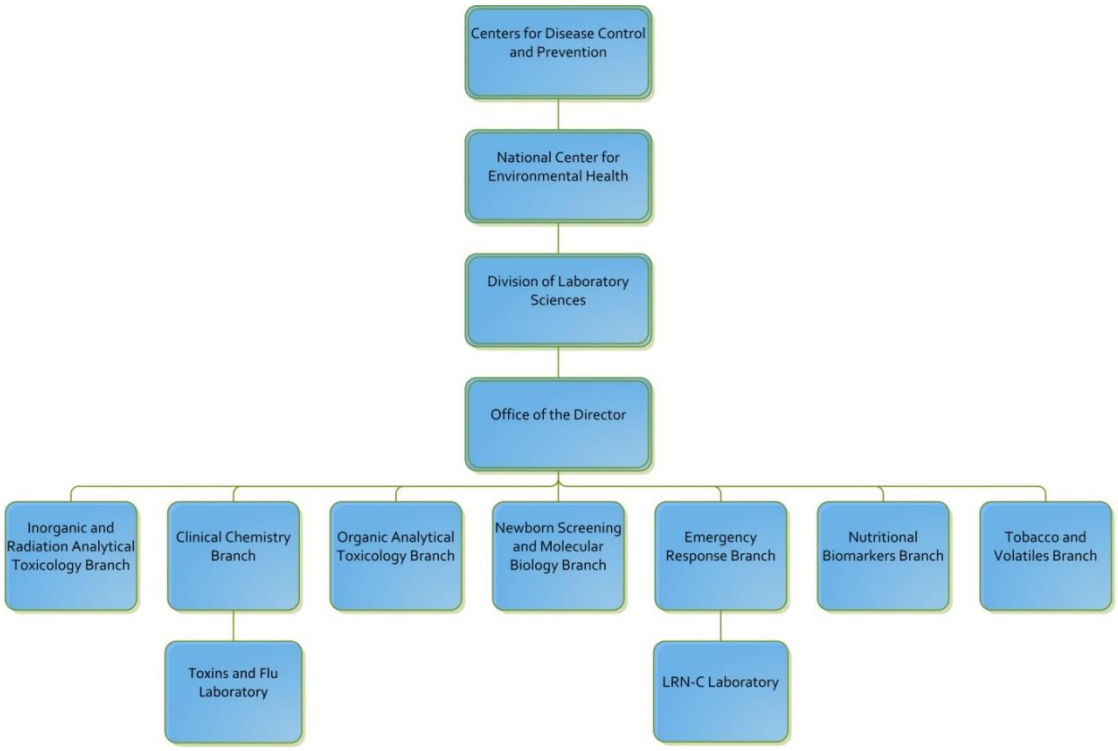
2. State the total funding for each programme and its source.
$4,817,044 U.S. Department of Health and Human Services (HHS)

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

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

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

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



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

- CDC, National Center for Environmental Health (NCEH), Division of Laboratory Sciences (DLS) – Page 85

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

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.

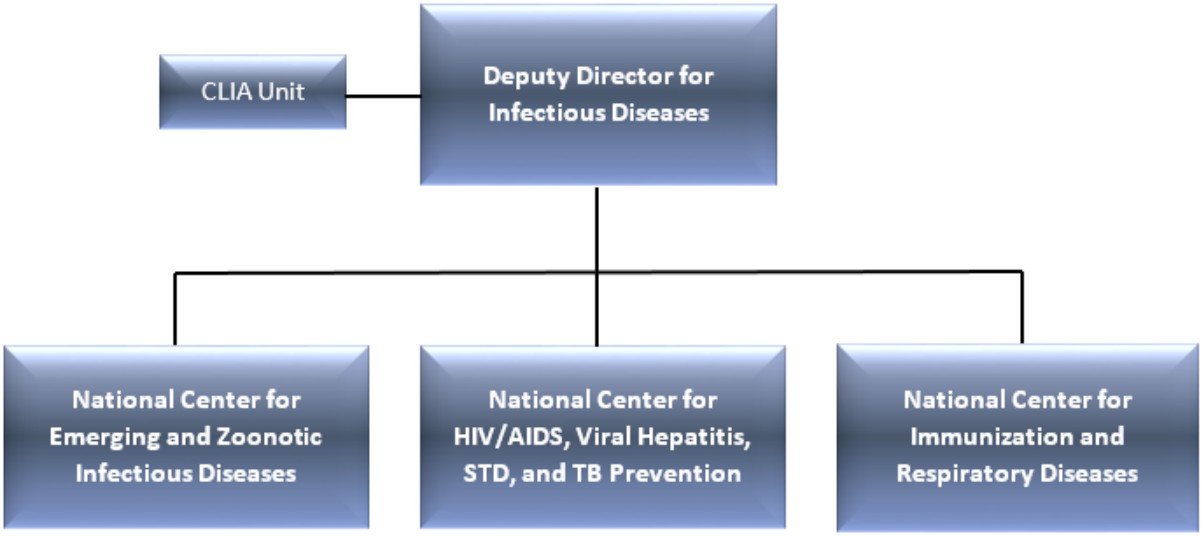
2. State the total funding for each programme and its source.
$26,134,954 Centers for Disease Control and Prevention (CDC)

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

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

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

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



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

- CDC, Deputy Director for Infectious Diseases (DDID) – Page 87
- CDC, Deputy Director for Infectious Diseases (DDID), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Vector Borne Diseases (DVBD) - Ft. Collins – Page 109

National biological defence research and development programmes: Department of Agriculture

Description

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

The U.S. 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, Vesicular Stomatitis, Highly Pathogenic Avian Influenza, Classical Swine Fever, African Swine Fever, Virulent 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 controlling 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 research 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 and microbial genomics
- 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 (WOHA) and Food and Agricultural Organization (FAO) collaborative research centers
- Establish best-in-class training centers 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: 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 of pathogen 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 pen-side diagnostic test kits and supplies present vulnerabilities in detection and response preparedness. Effective prevention and control tools need to be developed 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 consider the short amount of time available and the cost of recovery from disease outbreaks. There is a need for developing 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:
- Early detection 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 and companion diagnostic test kits that allow the 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.

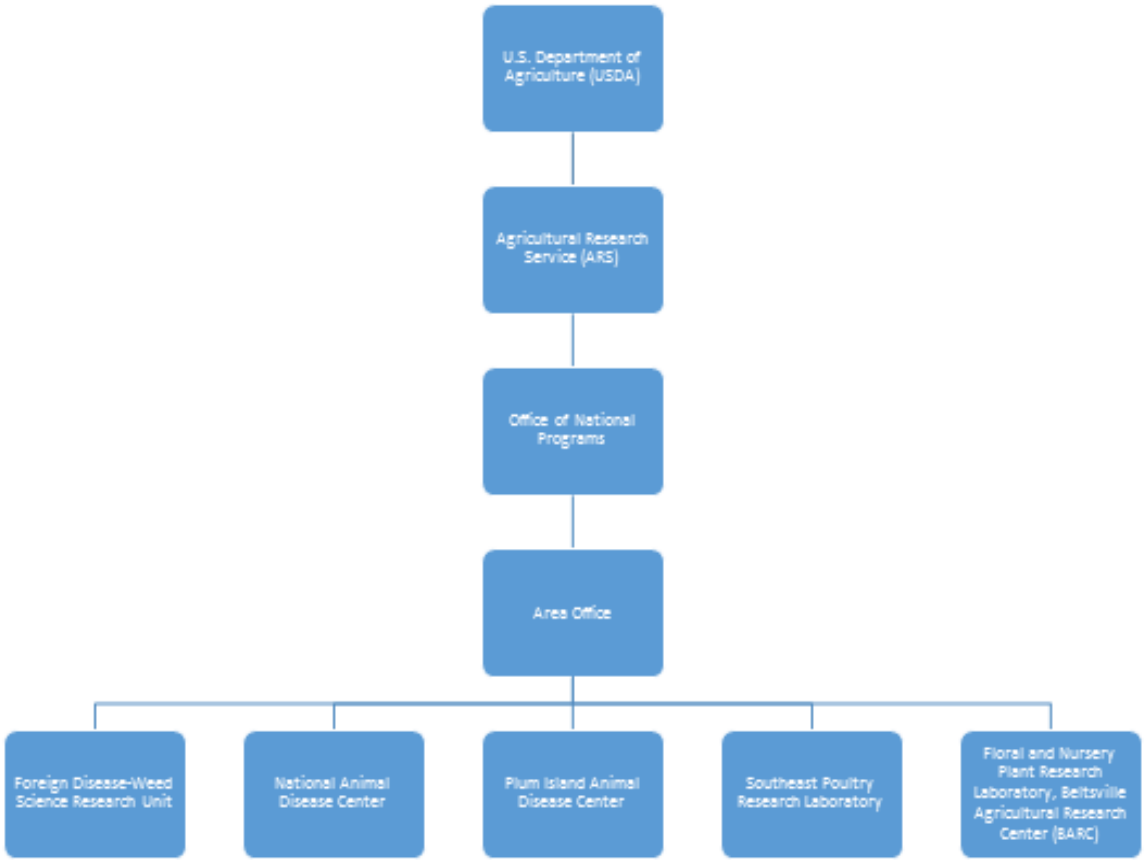
2. State the total funding for the programme and its source.
$43,819,700 U.S. Department of Agriculture (USDA)

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 43
- Foreign Disease-Weed Science Research Unit – Page 146
- National Animal Disease Center (NADC) – Page 148

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 2022 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. The DHS Compliance Review Group last met in October 2022.

2. **State the total funding for the programme and its source.**
$77,162,000 U.S. Department of Homeland Security (DHS)

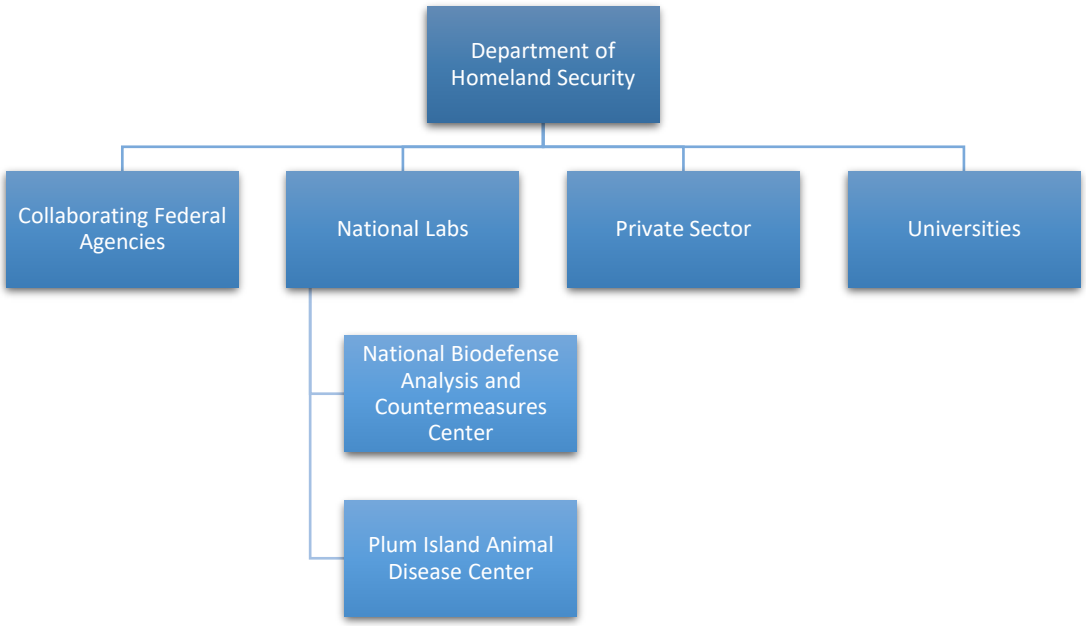
3. **Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

Yes.

4. If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?
100%

5. Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.
Identical to answer provided in question 1.

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



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

- National Biodefense Analysis and Countermeasures Center (NBACC) – Page 40
- Plum Island Animal Disease Center (PIADC) – Page 43

Form A, Part 2 (iii)

BWC - Confidence Building Measure

National biological defence research and development programmes - Facilities

United States of America

April 15, 2023

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 2022. 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. In 2022, the modified Venezuelan Equine Encephalitis Virus TC-83(A3G) strain was determined to be a select agent. 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 2022, 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.

Finally, the Argonne National Laboratory (ANL), reported in prior years, did not receive funding nor conduct biodefense work in 2022 and is therefore not included in the U.S. Confidence Building Measures covering 2022.

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: 194

(ii) Division of personnel:

Military	0
Civilian	194

Division of personnel by category:

Scientists	35
Engineers	44
Technicians	64
Administrative and support staff	51

(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: 194

(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	$ 10,039,157
Development	$ 15,968,551
Test and evaluation	$ 0

Total	$ 26,0007,708

(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. Bleka Ø, Just R, Agudo MM, Gill P. MPSproto: An extension of EuroForMix to evaluate MPS-STR mixtures. Forensic Sci Int Genet. 2022; 61:102781. https://www.fsigenetics.com/article/S1872-4973(22)00122-3/fulltext
2. Dabisch PA, Sanjak JS, Boydston JA, Yeager J, Herzog A, Biryukov J, et al. Comparison of Dose–Response Relationships for Two Isolates of SARS-CoV-2 in a Nonhuman Primate Model of Inhalational COVID-19. J Aerosol Med Pulm Drug Deliv. 2022; 35:296-306. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9807281/
3. Dabisch PA, Wood SP, Holland BP, Boydston JA, Beck KE, Green B, et al. Comparison of the survival of different isolates of SARS-CoV-2 in evaporating aerosols. Aerosol Sci Technol. 2022; 56:1146-1155. https://www.tandfonline.com/doi/full/10.1080/02786826.2022.2128712
4. Larason T, Grantham S, Zarobila C, Zong Y, Schuit M, Holland B, et al. Traveling Tunable Laser Projector (TTLP) for UV-Blue Disinfection Dose Determinations. Appl Opt. 2022; 61:5559-5566. https://opg.optica.org/ao/viewmedia.cfm?uri=ao-61-19-5559&seq=0&html=true
5. Schuit MA, Larason TC, Krause ML, Green BM, Holland BP, Wood SP, et al. SARS-CoV-2 inactivation by ultraviolet radiation and visible light is dependent on wavelength and sample matrix. J Photochem Photobiol B. 2022; 233:112503. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9221687/

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.

[*] Including viruses and prions.

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

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

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
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:**	413
(ii)	**Division of personnel:**	
	Military	0
	Civilian	413
(iii)	**Division of personnel by category:**	
	Scientists	88
	Engineers	20
	Technicians	84
	Administrative and support staff	221

(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: 315

(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	$ 8,166,483
Development	$ 1,500,000
Test and evaluation	**$** 9,129,491
Total	$ 18,795,491

(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. Ahmed Z, Velazquez-Salinas L, Mwiine FN, Vander Waal K, Rieder E. Complete Coding Genome Sequences of Five Foot-and-Mouth Disease Viruses Belonging to Serotype O, Isolated from Cattle in Uganda in 2015 to 2016. Microbiol Resour Announc. 2022; 11: e0044522. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9387231/
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4. Bertram M, Stenfeldt C, Holinka-Patterson L, Fish I, Farooq U, Ahmed Z, et al. Multiple Genome Sequences of Foot-and-Mouth Disease Virus Asia-1 Lineage Sindh-08 from Outbreaks in Pakistan, 2011 to 2012. Microbiol Resour Announc. 2022; 11: e0031222. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9202380/
5. Bohórquez JA, Wang M, Díaz I, Alberch M, Pérez-Simó M, Rosell R, et al. The FlagT4G Vaccine Confers a Strong and Regulated Immunity and Early Virological Protection against Classical Swine Fever. Viruses. 2022; 14:1954. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9502879/
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8. Faburay B. Genome Plasticity of African Swine Fever Virus: Implications for Diagnostics and Live-Attenuated Vaccines. Pathogens. 2022; 11:145. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8875878/
9. Fish I, Stenfeldt C, Spinard E, Medina GN, Azzinaro PA, Bertram MR, et al. Foot-and-Mouth Disease Virus Interserotypic Recombination in Superinfected Carrier Cattle. Pathogens. 2022; 11:644. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9231328/
10. Gladue DP, Borca MV. Recombinant ASF Live Attenuated Virus Strains as Experimental Vaccine Candidates. Viruses. 2022; 14:878. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9146452/

11. Gubbins S, Paton DJ, Dekker A, Ludi AB, Wilsden G, Browning CFJ, et al. Predicting cross-protection against foot-and-mouth disease virus strains by serology after vaccination. Front Vet Sci. 2022; 9:1027006. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9751447/
12. Gunasekera U, Biswal JK, Machado G, Ranjan R, Subramaniam S, Rout M, et al. Impact of mass vaccination on the spatiotemporal dynamics of FMD outbreaks in India, 2008-2016. Transbound Emerg Dis. 2022; 69: e1936-e1950. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9790522/
13. Hole K, Nfon C, Rodriguez LL, Velazquez-Salinas L. A Multiplex Real-Time Reverse Transcription Polymerase Chain Reaction Assay with Enhanced Capacity to Detect Vesicular Stomatitis Viral Lineages of Central American Origin. Front Vet Sci. 2021; 8:783198. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8720762/
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16. Mason J, Primavera V, Martignette L, Clark B, Barrera J, Simmons J, et al. Comparative Evaluation of the Foot-and-Mouth Disease Virus Permissive LF-BK Cell Line for Senecavirus A Research. Viruses. 2022; 14:1875. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9503874/
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21. Munsey A, Mwiine FN, Ochwo S, Velazquez-Salinas L, Ahmed Z, Rodriguez LL, et al. Ecological and Anthropogenic Spatial Gradients Shape Patterns of Dispersal of Foot-and-Mouth Disease Virus in Uganda. Pathogens. 2022; 11:524. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9143568/
22. Naqvi SS, Bostan N, Fukai K, Ali Q, Morioka K, Nishi T, et al. Evolutionary Dynamics of Foot and Mouth Disease Virus Serotype A and Its Endemic Sub-Lineage A/ASIA/Iran-05/SIS-13 in Pakistan. Viruses. 2022; 14:1634. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9331208/
23. Navarro-Lopez R, Xu W, Gomez-Romero N, Velazquez-Salinas L, Berhane Y. Phylogenetic Inference of the 2022 Highly Pathogenic H7N3 Avian Influenza Outbreak in Northern Mexico. Pathogens. 2022; 11:1284. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9692817/
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25. Palinski RM, Brito B, Jaya FR, Sangula A, Gakuya F, Bertram MR, et al. Viral Population Diversity during Co-Infection of Foot-And-Mouth Disease Virus Serotypes SAT1 and SAT2 in African Buffalo in Kenya. Viruses. 2022; 14:897. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9145140/
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41. Silva EB, Krug PW, Ramirez-Medina E, Valladares A, Rai A, Espinoza N, et al. The Presence of Virus Neutralizing Antibodies Is Highly Associated with Protection against Virulent Challenge in Domestic Pigs Immunized with ASFV live Attenuated Vaccine Candidates. Pathogens. 2022; 11:1311. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9694691/
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44. Stenfeldt C, Bertram M, Holinka-Patterson L, Fish I, Farooq U, Ahmed Z, et al. Genome Sequences of Foot-and-Mouth Disease Virus Serotype A and O Strains Obtained from Subclinically Infected Asian Buffalo (Bubalus bubalis) in Pakistan. Microbiol Resour Announc. 2022; 11: e0057522. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9387223/
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46. Tran XH, Phuong LTT, Huy NQ, Thuy DT, Nguyen VD, Quang PH, et al. Evaluation of the Safety Profile of the ASFV Vaccine Candidate ASFV-G-I177L. Viruses. 2022; 14:896. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9147362/
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49. Vuono E, Ramirez-Medina E, Silva E, Rai A, Pruitt S, Espinoza N, et al. Deletion of the H108R Gene Reduces Virulence of the Pandemic Eurasia Strain of African Swine Fever Virus with Surviving Animals Being Protected against Virulent Challenge. J Virol. 2022; 96: e0054522. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9327699/
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51. Zhu JJ. African Swine Fever Vaccinology: The Biological Challenges from Immunological Perspectives. Viruses. 2022; 14:2021. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9505361/
52. Zhu JJ, Stenfeldt C, Bishop EA, Canter JA, Eschbaumer M, Rodriguez LL, et al. Inferred Causal Mechanisms of Persistent FMDV Infection in Cattle from Differential Gene Expression in the Nasopharyngeal Mucosa. Pathogens. 2022; 11:822. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9329776/

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: 36

(ii) Division of personnel:

Military	0
Civilian	36

(iii) Division of personnel by category:

Scientists	19
Engineers	0
Technicians	9
Administrative and support staff	8

(iv) List the scientific disciplines represented in the scientific/engineering staff:
Aerobiology, Bacteriology, Biochemistry, Immunology, Microbiology, Molecular Biology, Toxicology, and Virology.

(v) Are contractor staff working in the facility? If so, provide an approximate number:
Yes. Number: 6

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

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

Research	$ 0
Development	$ 0
Test and evaluation	$ 2,089,805
Total	$ 2,089,805

(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/dodd/523009p.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/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.cbc.devcom.army.mil/.

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

Outdoor Studies: Yes. Outdoor studies were conducted with non-hazardous biological material; 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

4. The organizational structure of each facility:

(i) Total number of personnel: 66

(ii) Division of personnel:

Military	12
Civilian	54

(iii) Division of personnel by category:

Scientists	6
Engineers	0
Technicians	50
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: 41

(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	$ 15,648,543
Development	$ 0
Test and evaluation	$ 0
Total	$ 15,648,543

(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/dodd/523009p.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/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. Coggins S'AA, Laing ED, Olsen CH, Goguet E, Moser M, Jackson-Thompson BM et al. Adverse Effects and Antibody Titers in Response to the BNT162b2 mRNA COVID-19 Vaccine in a Prospective Study of Healthcare Workers. Open Forum Infect Dis. 2021 Nov 20; 9(1): ofab575. eCollection 2022 Jan https://www.medrxiv.org/content/10.1101/2021.06.25.21259544v1
2. Smith DR, Singh C, Green J, Lueder MR, ArnoldCE, Voegtly LJ, et al. Genomic and virological characterization of SARS-CoV-2 variants in a subset of unvaccinated and vaccinated U.S. Military personnel. Front Med. 2022 Jan 27; 8:836658. https://www.frontiersin.org/articles/10.3389/fmed.2021.836658/full
3. Goguet E, Powers 3rd, JH, Olsen CH, Tribble DR, Davies J, Illinik L, et al. Prospective Assessment of Symptoms to Evaluate Asymptomatic SARS-CoV-2 Infections in a Cohort of Health Care Workers. Open Forum Infect Dis. 2022 Feb 14;9(3): ofac030. eCollection 2022 Mar. https://academic.oup.com/ofid/article/9/3/ofac030/6528391?login=false
4. Servies T, Larsen E, Lindsay R, Jones JS, Cer RZ, Voegtly LJ, et al. Notes from the field: Outbreak of COVID-19 among a highly vaccinated population aboard a U.S. Navy ship after a port visit - Reykjavik, Iceland, July 2021. MMWR Morb Mortal Wkly Rep. 2022 Feb 18; 71(7):279-281. https://www.cdc.gov/mmwr/volumes/71/wr/mm7107a5.htm?s_cid=mm7107a5_w
5. Oduro G, Robberts FJL, Dartey PKA, Owusu-Ofori A, Oppong C, Gyampomah TK, et al. On the environmental presence of Burkholderia pseudomallei in South-Central Ghana. Appl Environ Microbiol. 2022 Jun 28;88(12): e0060022. Epub 2022 Jun 2. https://journals.asm.org/doi/10.1128/aem.00600-22
6. Liu M, Hernandez-Morales A, Clark J, Le T, Biswas B, Bishop-Lilly KA, et al. Comparative genomics of Acinetobacter baumannii and therapeutic bacteriophages from a patient undergoing phage therapy. Nat Commun. 2022 Jun 30; 13(1):3776. https://www.nature.com/articles/s41467-022-31455-5
7. Lizewski RA, Sealfon RSG, Park SW, Smith GR, Porter CK, Gonzalez-Reiche AS, et al. SARS-CoV-2 Outbreak Dynamics in an Isolated US Military Recruit Training Center with Rigorous Prevention Measures. Epidemiology. 2022 Nov 1; 33(6):797-807. Epub 2022 Aug 5. https://journals.lww.com/epidem/Fulltext/2022/11000/SARS_CoV_2_Outbreak_Dynamics_in_an_Isolated_US.5.aspx
8. Brandsma J, Chenoweth JG, Gregory MK, Krishnan S, Blair PW, Striegel DA, et al. Assessing the use of a micro-sampling device for measuring blood protein levels in healthy subjects and COVID-19 patients. PLoS One. 2022 Aug 10; 17(8): e0272572. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0272572
9. Cer RZ, Voegtly LJ, Adhikari BN, Pike BL, Lueder MR, Glang LA, et al. Genomic and Virologic Characterization of Samples from a Shipboard Outbreak of COVID-19 Reveals Distinct Variants within Limited Temporospatial Parameters. Front Microbiol. 2022 Aug 10; 13:960932. https://www.frontiersin.org/articles/10.3389/fmicb.2022.960932/full
10. Arnold CE, Voegtly LJ, Stefanov EK, Lueder MR, Luquette AE, Miller RH, et al. SARS-CoV-2 infections in vaccinated and unvaccinated populations in Camp Lemonnier, Djibouti from April 2020 to January 2022. Viruses. 2022 Aug 30; 14(9):1918. https://www.mdpi.com/1999-4915/14/9/1918
11. Kunz Coyne AJ, Stamper K, Kebriaei R, Holger D, El Ghali A, Morrisette T, et al. Phage Cocktails with Daptomycin and Ampicillin Eradicates Biofilm-Embedded Multidrug-Resistant Enterococcus

faecium with Preserved Phage Susceptibility. Antibiotics. 2022 Aug 30; 11(9):1175. https://www.mdpi.com/2079-6382/11/9/1175
12. Watts DM, Westover JLB, Palermo PM, Bailey KW, Morrill JC, Bettinger GE, et al. Estimation of the Minimal Rift Valley Fever Virus Protective Neutralizing Antibody Titer in Human Volunteers Immunized with MP-12 Vaccine Based on Protection in a Mouse Model of Disease. Am J Trop Med Hyg. 2022 Sep 19; 107(5):1091-1098. https://www.ajtmh.org/view/journals/tpmd/107/5/article-p1091.xml
13. Robberts FJL, Owusu-Ofori A, Oduro G, Gyampomah TK, Puntambekar N, Fox A, et al. Rapid, Low-Complexity, Simultaneous Bacterial Group Identification and Antimicrobial Susceptibility Testing Performed Directly on Positive Blood Culture Bottles Using Chromogenic Agar. Am J Trop Med Hyg. 2022 Nov 14; 107(6); 1302-1307. Print 2022 Dec 14. https://www.ajtmh.org/view/journals/tpmd/107/6/article-p1302.xml
14. Blair PW, Brandsma J, Chenoweth J, Richard SA, Epsi NJ, Mehta R, et al. EPICC COVID-19 Cohort Study Group. Distinct blood inflammatory biomarker clusters stratify host phenotypes during the middle phase of COVID-19. Sci Rep. 2022 Dec 28; 12(1):22471. https://www.nature.com/articles/s41598-022-26965-7

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 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:	208 m^2
BSL-2:	418 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	626 m^2

Note: During the reported calendar year, the NRL laboratory space used for biodefense research and development was reapportioned, resulting in an increase of 152 m^2 of BSL-1 lab space and a decrease of 22 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: 21

(ii) Division of personnel:

Military	1
Civilian	20

(iii) Division of personnel by category:

Scientists	19
Engineers	1
Technicians	1
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: 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	$ 3,682,000
Development	$ 396,000
Test and evaluation	$ 0
Total	$ 4,078,000

(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/dodd/523009p.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/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. Anderson, GP, Shriver-Lake, LS, Liu, JL, Goldman, ER. Integrated Single Domain Antibodies into Field-Deployable Rapid Assays. Antibodies 2022. 2022 Oct 17; 11, 64. https://www.mdpi.com/2073-4468/11/4/64
2. Liu, JL, Zabetakis, D, Gardner, C., Burke, CW, Glass, PJ, Webb, EM, et al. Bivalent single domain antibody constructs for effective neutralization of Venezuelan equine encephalitis. Sci Rep. 2022 Jan 13; 12:700. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8758676/
3. Matharoo K, Chua J, Park JR, Ingavale S, Jelacic TM, Jurkouich KM, et al. Engineering an Fc-Fusion of a Capsule Degrading Enzyme for the Treatment of Anthrax. ACS Infect Dis. 2022 Oct 14; 8(10):2133-2148. Epub 2022 Sep 14. https://pubs.acs.org/doi/10.1021/acsinfecdis.2c00227

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 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, Concepts and Experimentation Laboratory

Note: This facility is the same facility as described in previous CBM reports as the "Chemical, Biological, Radiological (CBR) Defense Laboratory" but the facility underwent a name change to the "Concepts and Experimentation Laboratory."

2. Where is it located (provide both address and geographical location)?
4045 Higley Road, Suite 345, Dahlgren, Virginia 22448
(Postal Address: 6149 Welsh Road, Dahlgren, Virginia 22448)

Note: The physical location of the facility has not changed, but both the postal and geographic address are provided.

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: 29

(ii) Division of personnel:

Military	0
Civilian	29

(iii) Division of personnel by category:

Scientists	22
Engineers	1
Technicians	2
Administrative and support staff	4

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

(v) Are contractor staff working in the facility? If so, provide an approximate number:
Yes Number: 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 Defense (DOD) – Partly
Internal (Laboratory Directed Research and Development)
Other Governmental Agencies

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

Research	$ 419,000
Development	$ 700,000
Test and evaluation	$ 4,540,902
Total	$ 5,659,902

(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/dodd/523009p.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/523029p.pdf).

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

1. Buhr TL, Borgers Klonkowski E, Gutting BW, Hammer EE, Hamilton SM, Huhman CM, et al. Ultraviolet dosage and decontamination efficacy was widely variable across 14 UV devices after testing a dried enveloped ribonucleic acid virus surrogate for SARS CoV-2. Front. Bioeng. Biotechnol. 2022 Oct 4; 10.3389/fbioe.2022.875817 https://www.frontiersin.org/articles/10.3389/fbioe.2022.875817/full

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. The NSWC develops standard testing materials and standardized test methods that generate high confidence data for technical assessment of detection and decontaminants.

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: Yes. Outdoor studies were conducted with non-hazardous biological material; no outdoor studies were conducted with hazardous organisms or material derived from hazardous organisms.

Note: The functions of the NSWC Dahlgren Concepts and Experimentation Laboratory were in large part moved to NSWC Indian Head between 2018 and 2021. The only remaining portion of the portfolio at NSWC Dahlgren is the microbiological laboratory-focused research. All the programs and chemical laboratories were moved to Indian Head, but the completion of the transfer remains paused (with no 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:	172 m^2
BSL-3:	177 m^2
BSL-4:	0 m^2
Total laboratory floor area:	349 m^2

Note: During the reported calendar year, the CCDC CBC BSL-2 laboratory space used for biodefense research and development was reapportioned, resulting in a decrease of 155 m2. The BSL-2 laboratory space was not physically remodeled.

4. The organizational structure of each facility:

(i) Total number of personnel 56

(ii) Division of personnel:

Military	0
Civilian	56

(iii) Division of personnel by category:

Scientists	41
Engineers	2
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	$ 16,087,000
Development	$ 4,912,000
Test and evaluation	$ 0

Total	$ 20,999,000

(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/dodd/523009p.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/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. Arévalo MT, Karavis MA, Katoski SE, Harris JV, Hill JM, Deshpande SV, et al. A Rapid, Whole Genome Sequencing Assay for Detection and Characterization of Novel Coronavirus (SARS-CoV-2) Clinical Specimens Using Nanopore Sequencing. Front Microbiol. 2022 Jun 6; 13:910955. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9207459/
2. Bernhards CB, Liem AT, Berk KL, Roth PA, Gibbons HS, Lux MW. Putative Phenotypically Neutral Genomic Insertion Points in Prokaryotes. ACS Synth Biol. 2022 Apr 15; 11(4):1681-1685. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9016761/
3. Cockell CS, Chitale R, Clement B, Davila A, Freeman KH, French KL, et al. Recommendation on Orbiting Sample Cleanliness. Astrobiology. 2022 Jun; 22(S1): S238-S241. https://www.liebertpub.com/doi/10.1089/AST.2021.0058?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed
4. Cole SD, Miklos AE. Gene Expression from Linear DNA in Cell-Free Transcription-Translation Systems. Combat Capabilities Development Command Chemical Biological Center. 2022, DEVCOM-CBC-TR-1775. https://apps.dtic.mil/sti/pdfs/AD1167580.pdf
5. Goralski TD, Angelini DJ, Horsmon JR, Glover KP. Characterization of the Emulate Liver Chip Microphysiological System. Combat Capabilities Development Command Chemical Biological Center. 2022, DEVCOM-CBC-TR-1743. https://apps.dtic.mil/sti/pdfs/AD1157828.pdf
6. Phillips DA, Miklos AE, Buckley PE, Lee JA, Smith B, Sousa D, et al. Purification and Characterization of a Membrane Sculpting Bacterial BAR Domain-Containing Protein for Engineering Tunable Scaffolds into Novel Biological Metamaterials. Combat Capabilities Development Command Chemical Biological Center. 2022, DEVCOM-CBC-TR-1782. https://apps.dtic.mil/sti/pdfs/AD1165367.pdf
7. Rastogi VK, Katoski SE, Cross O, Leija BM. Decontamination of Bacillus Anthracis Spores on Military Working Dog Skin. Combat Capabilities Development Command Chemical Biological Center. 2022, DEVCOM CBC-TR-1785. https://apps.dtic.mil/sti/pdfs/AD1175012.pdf
8. Rastogi VK, Katoski SE, Hurst S, Leija B. Sub-Scale Testing of Decontamination Technologies Against SARS-CoV-2 BSL-2 Surrogate, HuCoV229E, and BSL-1 Surrogate, Phi6. Combat Capabilities Development Command Chemical Biological Center. 2022, DEVCOM CBC-TR-1792. https://apps.dtic.mil/sti/pdfs/AD1180099.pdf
9. Tran BQ, Rizzo G, Carmany DO, Glaros TG, Mach PM, Dhummakupt ES. Proteomic Discovery of Potential Biomarkers in Zika Virus Infected Monkeys. Combat Capabilities Development Command Chemical Biological Center. 2022, CCDC-CBC-TR-1674. https://apps.dtic.mil/sti/pdfs/AD1159061.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.

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: 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:
Biochemistry, Molecular Biology, Pharmacology, Physiology, Neurotoxicology, Neuroscience

(v) Are contractor staff working in the facility? If so, provide an approximate number:
Yes Number: 0

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

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

Research	$ 236,500
Development	$ 0
Test and evaluation	$ 0
Total	$ 236,500

(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/dodd/523009p.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/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: 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.health.mil/Pages/default.aspx.

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

Outdoor Studies: No outdoor studies performed.

[*] Including viruses and prions.

National biological defence research and development programmes: Facilities

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

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

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

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

4. The organizational structure of each facility:

(i) Total number of personnel 633

(ii) Division of personnel:

Military	150
Civilian	483

(iii) Division of personnel by category:

Scientists	152
Engineers	108
Technicians	162
Administrative and support staff	211

(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: 237

(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	$ 2,562,275
Development	$ 65,348,980*
Test and evaluation	$ 19,928,119
Total	$ 87,839,374

*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:

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. Biryukov SS, Cote CK, Klimko CP, Dankmeyer JL, Rill NO, Shoe JL, et al. Evaluation of two different vaccine platforms for immunization against melioidosis and glanders. Front Microbiol. 2022 Aug 17; 13:965518. https://pubmed.ncbi.nlm.nih.gov/36060742/
2. Bixler SL, Stefan CP, Jay AN, Rossi FD, Ricks KM, Shoemaker CJ, et al. Exposure route influences disease severity in the COVID-19 Cynomolgus Macaque Model. Viruses. 2022 May 10; 14(5):1013. https://pubmed.ncbi.nlm.nih.gov/35632755/
3. Brewer MG, Monticelli SR, Ward BM. Monkeypox: Considerations as a new pandemic looms. J Invest Dermatol. 2022 Oct; 142(10):2561-2564. https://pubmed.ncbi.nlm.nih.gov/36028337/
4. Burke CW, Erwin-Cohen RA, Goodson AI, Wilhelmsen C, Edmundson JA, White CE, et al. Efficacy of Western, Eastern, and Venezuelan Equine Encephalitis (WEVEE) Virus-Replicon Particle (VRP) vaccine against WEEV in a non-human primate animal model. Viruses. 2022 Jul 8; 14(7):1502. https://pubmed.ncbi.nlm.nih.gov/35891482/
5. Caffes N, Hendricks K, Bradley JS, Twenhafel NA, Simard JM. Anthrax Meningoencephalitis and intracranial hemorrhage. Clin Infect Dis. 2022 Oct 17;75(Supplement_3): S451-S458. https://pubmed.ncbi.nlm.nih.gov/36251558/
6. Cashman KA, Wilkinson ER, Posakony J, Madu IG, Tarcha EJ, Lustig KH, et al. Lassa antiviral LHF-535 protects guinea pigs from lethal challenge. Sci Rep. 2022 Nov 19; 12(1):19911. https://pubmed.ncbi.nlm.nih.gov/36402782/
7. Chiang CY, Lane DJ, Zou Y, Hoffman T, Pan J, Hampton J, et al. A novel toll-like receptor 2 agonist protects mice in a prophylactic treatment model against challenge with Bacillus anthracis. Front Microbiol. 2022 Mar 14; 13:803041. https://pubmed.ncbi.nlm.nih.gov/35369443/
8. Chua J, Nguyenkhoa E, Mou S, Tobery SA, Friedlander AM, DeShazer D. Burkholderia pseudomallei JW270 is lethal in the Madagascar Hissing Cockroach Infection Model and can be utilized at biosafety level 2 to identify putative virulence factors. Infect Immun. 2022 Aug 18; 90(8): e0015922. https://pubmed.ncbi.nlm.nih.gov/35862734/
9. Ciencewicki JM, Herbert AS, Storm N, Josleyn NM, Huie KE, McKay LGA, et al. Characterization of an Anti-Ebola Virus Hyperimmune Globulin derived from convalescent plasma. J Infect Dis. 2022 Feb 15; 225(4):733-740. https://pubmed.ncbi.nlm.nih.gov/34448858/
10. Cline C, Bell TM, Facemire P, Zeng X, Briese T, Ian Lipkin W, et al. Detailed analysis of the pathologic hallmarks of Nipah virus (Malaysia) disease in the African green monkey infected by the intratracheal route. PLoS ONE. 2022 Feb 10; 17(2): e0263834. https://pubmed.ncbi.nlm.nih.gov/35143571/
11. Cross RW, Longini IM, Becker S, Bok K, Boucher D, Carroll MW, et al. An introduction to the Marburg virus vaccine consortium, MARVAC. PLoS Pathog. 2022 Oct 13; 18(10): e1010805. https://pubmed.ncbi.nlm.nih.gov/36227853/

12. Di Paola N, Dheilly NM, Junglen S, Paraskevopoulou S, Postler TS, Shi M, et al. Jingchuvirales: a new taxonomical framework for a rapidly expanding order of unusual Monjiviricete viruses broadly distributed among Arthropod Subphyla. Appl Environ Microbiol. 2022 Mar 22; 88(6): e0195421. https://pubmed.ncbi.nlm.nih.gov/35108077/
13. Dudley DM, Koenig MR, Stewart LM, Semler MR, Newman CM, Shepherd PM, et al. Human immune globulin treatment controls Zika viremia in pregnant rhesus macaques. PLoS One. 2022 Jul 14; 17(7): e0266664. https://pubmed.ncbi.nlm.nih.gov/35834540/
14. Dunay MA, McClain SL, Holloway RL, Norris SLW, Bendixsen Randall T, Mohr CE, et al. Pre-hospital administration of Remdesivir during a Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) outbreak in a skilled nursing facility. Clin Infect Dis. 2022 Apr 28; 74(8):1476-9. https://pubmed.ncbi.nlm.nih.gov/34410348/
15. Durie IA, Tehrani ZR, Karaaslan E, Sorvillo TE, McGuire J, Golden JW, et al. Structural characterization of protective non-neutralizing antibodies targeting Crimean-Congo hemorrhagic fever virus. Nat Commun. 2022 Nov 26; 13(1):7298. https://pubmed.ncbi.nlm.nih.gov/36435827/
16. Dyson EH, Simpson AJH, Gwyther RJ, Cuthbertson H, Patient DH, Matheson M, et al. Serological responses to Anthrax Vaccine Precipitated (AVP) increase with time interval between booster doses. Vaccine. 2022 Oct 6; 40(42):6163-6178. https://pubmed.ncbi.nlm.nih.gov/36153153/
17. Faye M, Faye O, Paola ND, Ndione MHD, Diagne MM, Diagne CT, et al. Rabies surveillance in Senegal 2001 to 2015 uncovers first infection of a honey-badger. Transbound Emerg Dis. 2022 Sep; 69(5): e1350-e1364. https://pubmed.ncbi.nlm.nih.gov/35124899/
18. Fitzpatrick CJ, Mudhasani RR, Altamura LA, Campbell CE, Tran JP, Beitzel BF, et al. Junin virus activates p38 MAPK and HSP27 upon entry. Front Cell Infect Microbiol. 2022 Apr 7; 12:798978. https://pubmed.ncbi.nlm.nih.gov/35463647/
19. Frumkin LR, Lucas M, Scribner CL, Ortega-Heinly N, Rogers J, Yin G, et al. Egg-derived anti-SARS-CoV-2 Immunoglobulin Y (IgY) with broad variant activity as intranasal prophylaxis against COVID-19. Front Immunol. 2022 Jun 1; 13:899617. https://pubmed.ncbi.nlm.nih.gov/35720389/
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5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms* and/or toxins studied, as well as outdoor studies of biological aerosols:

Objectives: USAMRIID develops medical countermeasures, including candidate vaccines, diagnostic tests and drug or immunological therapies for biological agents, as well as performs exploratory studies and advanced development of protective and therapeutic countermeasures and agent identification technologies. Additional information is available at https://usamriid.health.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.

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:	20 m^2
BSL-2:	0 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	20 m^2

Note: During the reported calendar year, the AFRL BSL-2 and BSL-3 laboratory space used for biodefense research and development was reapportioned, resulting in a decrease of 40 m2. The BSL-2 and BSL-3 laboratory space was not physically remodelled.

4. The organizational structure of each facility:

(i) Total number of personnel: 5

(ii) Division of personnel:

Military	2
Civilian	3

(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:
Biochemistry, Materials Science, Microbiology.

(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	$ 200,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 200,000

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

Professional scientists are encouraged to publish papers in peer reviewed journals. All publications must obtain the necessary command and public affairs permission before submission. Release of DoD publications is guided by DoD Directive 5230.09, Clearance of DoD Information for Public Release (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?
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:	1,953.7 m^2
BSL-3:	59.5 m^2
BSL-4:	0 m^2
Total laboratory floor area:	2,013.2 m^2

There was an overall reduction of 91.8m2 in BSL-2 lab space in 2022 due to downgrading 3 BSL-2 laboratories to BSL-1 or non-biological research laboratories (total of 127.98m2) and the addition of one new BSL-2 laboratory (36.16 m2) through re-modeling.

4. The organizational structure of each facility:

(i) Total number of personnel: 57

(ii) Division of personnel:

Military:	0
Civilian:	57

(iii) Division of personnel by category:

Scientists	30
Engineers	11
Technicians	8
Administrative and support staff	8

(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	$ 5,662,352
Development	$ 1,396,238
Test and evaluation	$ 49,067
Total	$ 7,107,657

(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-documents/200-series/0241.1-BOrder-b-chg1-adminchg.

(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. Zhu F, Bourguet FA, Bennett WF, Lau EY, Arrildt KT, Segelke BW, Zemla AT, et al. Large-scale application of free energy perturbation calculations for antibody design. Scientific Reports, 2022 Jul 21; 12(1):1-14. https://www.nature.com/articles/s41598-022-14443-z
2. Desautels TA, Arrildt KT, Zemla AT, Lau EY, Zhu F, Ricci D, et al. Computationally restoring the potency of a clinical antibody against SARS-CoV-2 Omicron subvariants. bioRxiv, 2022 Oct 24; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9628197/
3. Kimbrel J, Moon J, Avila-Herrera A, Martí JM, Thissen J, Mulakken N, et al. Multiple Mutations Associated with Emergent Variants Can Be Detected as Low-Frequency Mutations in Early SARS-CoV-2 Pandemic Clinical Samples. Viruses, 2022 Dec 13; 14(12): 2775, https://www.mdpi.com/1999-4915/14/12/2775
4. Hum NR, Bourguet FA, Sebastian A, Lam D, Phillips AM, Sanchez KR, et al., MAVS Mediates a Protective Immune Response in the Brain to Rift Valley Fever Virus. PLOS Pathogens. 2022 May 18; 18(5):e1010231 https://doi.org/10.1371/journal.ppat.1010231
5. McGowan J, Borucki M, Omairi H, Varghese M, Vellani S, Chakravatry S, et al., SARS-CoV-2 Monitoring in Wastewater Reveals Novel Variants and Biomarkers of Infection, Viruses, 2022 Sept 13; 14(9):2032, https://pubmed.ncbi.nlm.nih.gov/36146835/
6. Thissen JB, Morrison MD, Mulakken N, Nelson WC, Daum C, Messenger S, et al., Evaluation of co-circulating pathogens and microbiome from COVID-19 infections, PLOS One, 2022 Dec 01; 17(12):e0278543 https://doi.org/10.1371/journal.pone.0278543

7. Wu R, Trubl G, Tas N, Jansson JK, Permafrost as a Potential Pathogen Reservoir, One Earth, 2022 Apr 15; 5(4):351-360, https://www.cell.com/one-earth/pdf/S2590-3322(22)00143-9.pdf
8. Gilmore SF, He W, Evans AC, Tifrea DF, Pal S, Segelke B, et al., Cell-Free Scaled Production and Adjuvant Addition to a Recombinant Major Outer Membrane Protein from Chlamyida muridarum for Vaccine Development, J. Vis Exp, 2022 Mar 16; 181: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9236854/

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. LLNL also evaluates the performance of both sensor technologies and response strategies in public transportation settings. Beyond detection, response, recovery, and attribution, LLNL also has ongoing research projects to elucidate mechanisms of host-pathogen interactions. Additional information is available at https://st.llnl.gov/.

***Microorganisms and/or Toxins Studied*:** HHS Select Agents, Overlap Select Agents, NIAID Category A pathogens, HHS Select Toxins. Simulants of HHS Select Agents, Overlap Select Agents, and NIAID Category A pathogens.

***Outdoor Studies*:** Yes. Outdoor studies were conducted with non-hazardous biological material; no outdoor studies were conducted with hazardous organism 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?
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:	557 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	557 m^2

During the reported calendar year, BSL2 laboratory space at LANL previously used for biodefence R&D was reduced (by 46m2) in proportion to reduction in funding and personnel. The 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	11
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	$ 2,544,000
Development	$ 1,670,000
Test and evaluation	$ 500,000
Total	$ 4,714,000

(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-documents/200-series/0241.1-BOrder-b-chg1-adminchg.

(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. Bell TAS, Velappan N, Gleasner CD, Xie G, Starkenburg SR, Waldo G, et al., Non-classical autophagy activation pathways are essential for production of infectious Influenza A virus in vitro. Molecular Microbiology. 2022, Feb 06; 117:508‐524. https://doi.org/10.1111/mmi.14865
2. Morales D, Micheva-Viteva S, Adikari S, Werner J, Wolinsky M, Hong-Geller E, et al. Targeting bet-hedging strategy with an inhibitor of bacterial efflux capacity enhances antibiotic efficiency and ameliorates bacterial persistence in vitro. Microorganisms. 2022 Oct 5; 10(10):1966 https://doi.org/10.3390/microorganisms10101966
3. Velappan N, Nguyen HB, Micheva-Viteva S, Bedinger D, Ye C, and Lillo AM. Healthy humans can be a source of antibodies countering COVID-19. Bioengineered, 2022 May 21; 13 (5):12598-12624. https://www.tandfonline.com/doi/full/10.1080/21655979.2022.2076390
4. Kocheril PA, Lenz KD, Jacobsen DE, Kubicek-Sutherland JZ. Amplification-free nucleic acid detection with a fluorescence-based waveguide biosensor. Frontiers in Sensors. 2022 Oct 04; 3. https://www.frontiersin.org/articles/10.3389/fsens.2022.948466/full
5. Lenz KD, Klosterman KE, Mukundan H, Kubicek-Sutherland JZ. Lipoprotein capture ELISA method for the sensitive detection of amphiphilic biomarkers. Analytical Biochemistry. 2022 Sep 01; 1:14747. https://pubmed.ncbi.nlm.nih.gov/35636461/
6. Stromberg ZR, Theiler J, Foley BT, Myers y Gutiérrez A, Hollander A, Courtney SJ, et al. Fast Evaluation of Viral Emerging Risks (FEVER): A computational tool for biosurveillance, diagnostics. PLOS Glob Public Health 2022 Feb 24; 2(2): e0000207 https://journals.plos.org/globalpublichealth/article?id=10.1371/journal.pgph.0000207

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

***Objectives*:** The biological defense research and development activities at the Los Alamos National Laboratory include pathogen characterization, host-pathogen interaction studies, pathogen detection, integrative biosurveillance, and analysis technology development. The main objectives for the studies are to: understand molecular mechanisms of host-pathogen interactions; 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*:** HHS Select Toxin, simulants of HHS Select Agents, HHS Select Toxins, and Overlap Select Agents.

***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?
Pacific Northwest National Laboratory (PNNL)

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

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

Richland campus:	
BSL-2:	1,133 m^2
BSL-3:	0 m^2
BSL-4:	0 m^2
Total laboratory floor area:	1,133 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 a decrease of 970 m^2 on the Richland campus. The BSL-2 laboratory space was not physically remodeled.

4. The organizational structure of each facility:

(i) Total number of personnel: 103
Richland, Sequim, & Seattle campuses (shared personnel)

(ii) Division of personnel:

Military	0
Civilian	103

(iii) Division of personnel by category:

Scientist	91
Engineers	2
Technicians	1
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	$ 12,013,651
Development	$ 3,422,856
Test and evaluation	$ 1,804,396
Total	$ 17,240,903

(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-documents/200-series/0241.1-BOrder-b-chg1-adminchg. 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. Alfaro TD, Elmore JR, Stromberg ZR, Hutchison JR, Hess BM. Engineering citrobacter freundii using CRISPR/Cas9 system. Journal of Microbiological Methods. 2022 Sept 1; 200 (2022):106533. https://www.sciencedirect.com/science/article/pii/S0167701222001282
2. Phillips SMB, Bergstrom CJ, Walker BM, Wang GP, Alfaro TD, Stromberg ZR, et al. Engineered cell line imaging assay differentiates pathogenic from non-pathogenic bacteria. Pathogens. 2022 Feb 4; 11(2):209. https://www.mdpi.com/2076-0817/11/2/209
3. Krishnamoorthy S, Steiger AK, Nelson WC, Egbert RG, Wright AT. An activity-based probe targeting the streptococcal virulence factor C5a peptidase. Chemical Communications. 2022 July 25; 58:8113-8116. https://doi.org/10.1039/D2CC01517J
4. Keshava Murthy R, Dixon SJ, Pazdernik KT, Charles LE. Predicting infectious disease for biopreparedness and response: A systematic review of machine learning and deep learning approaches. One Health. 2022 Dec 1; 15:100439. https://www.sciencedirect.com/science/article/pii/S2352771422000714
5. Dixon SJ, R. Keshavamurthy, Farber DH, Stevens A, Pazdernik KT, Charles LE. A comparison of infectious disease forecasting methods across locations, diseases, and time. Pathogens. 2022 June 29; 11(2):185. https://www.mdpi.com/2076-0817/11/2/185
6. Mandel C, Yang H, Buchko GW, Abendroth J, Grieshaber N, Chiarelli T, et al. Expression and structure of the chlamydia trachomatis DksA ortholog. Pathogens and Disease. 2022 April 7; 80:1. https://academic.oup.com/femspd/article/80/1/ftac007/6564600
7. Abendroth J, Buchko GW, Liew FN, Nguyen JN, Kim HJ. Structural characterization of cytochrome c prime-beta MET from an ammonia-oxidizing bacterium. Biochemistry. 2022 March 22; 61:563-574. https://pubs.acs.org/doi/10.1021/acs.biochem.1c00640

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:**	355
	New Mexico campus:	285
	California campus:	70
(ii)	**Division of personnel:**	
	Military	0
	Civilian	355
(iii)	**Division of personnel by category:**	
	Scientists	126
	Engineers	72
	Technicians	113
	Admin and Support Staff	44

(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	$ 7,544,751
Development	$ 5,717,050
Test and Evaluation	$ 20,571,969
Total	$ 33,833,770

(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. The full, up-to-date directive can be found at the link below: Department of Energy, Scientific and Technical Information Management: https://www.directives.doe.gov/directives-documents/200-series/0241.1-BOrder-b-chg1-adminchg.

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

1. Aiosa N, Sinha A, Jaiyesimi OA, Silva RRD, Branda SS, Garg N. Metabolomics Analysis of Bacterial Pathogen Burkholderia thailandensis and Mammalian Host Cells in Co-culture. ACS Infectious Diseases. 2022 Jun 29; 8(8):1646-62. https://pubs.acs.org/doi/10.1021/acsinfecdis.2c00233

2. Butler KS, Brinker CJ, Leong HS. Bridging the In Vitro to In Vivo gap: Using the Chick Embryo Model to Accelerate Nanoparticle Validation and Qualification for In Vivo studies. ACS Nano. 2022 Dec 01; 16:19626-19650. https://pubs.acs.org/doi/pdf/10.1021/acsnano.2c03990
3. Butler KS, Carson BD, Podlevsky JD, Mayes CM, Rowland JM, Campbell D, et al. Singleplex, multiplex and pooled sample real-time RT-PCR assays for detection of SARS-CoV-2 in an occupational medicine setting. Scientific Reports. 2022 Oct 22; 12(1):17733. https://www.nature.com/articles/s41598-022-22106-2.pdf
4. Chamblee JS, Ramsey J, Chen Y, Maddox LT, Ross C, To KH, et al. Endolysin Regulation in Phage Mu Lysis. Mbio. 2022 Jun 28; 13(3): e0081322. https://pubmed.ncbi.nlm.nih.gov/35471081/
5. Deneff JI, Butler KS, Reyes RA, Sava Gallis DF. Harnessing Particle Size-Control and DNA-Oligo Functionalization in ZIF-76 for Biological Applications. 2022 Dec O1; 2201532. http://dx.doi.org/10.1002/admi.202201532
6. Deng K, Wang X, Ing N, Opgenorth P, de Raad M, Kim J, et al. Rapid quantification of alcohol production in microorganisms based on nanostructure-initiator mass spectrometry (NIMS). Anal Biochem. 2022 Feb 01; 662:114997. https://pubmed.ncbi.nlm.nih.gov/36435200/
7. Holt A, Cahill J, Ramsey J, Martin C, O'Leary C, Moreland R, et al. Phage-Encoded Cationic Antimicrobial Peptide Required for Lysis. Journal of Bacteriology. 2022 Aug 2; 204(1): JB0021421. https://pubmed.ncbi.nlm.nih.gov/34339297/
8. Hudson CM, Pattengale ND, Iyer RK, Kalbarczyk ZT, Alli N. Genomic and Synthetic Biology Digital Biosecurity. Pac Symp Biocomput. 2022; 27:402-6. https://www.worldscientific.com/doi/abs/10.1142/9789811250477_0037
9. Iwai K, Wehrs M, Garber M, Sustarich J, Washburn L, Costello Z, et al. Scalable and automated CRISPR-based strain engineering using droplet microfluidics. Microsyst Nanoeng. 2022 Mar 15; 8:31. https://www.nature.com/articles/s41378-022-00357-3.pdf
10. Katinas C, Timlin J, Slater J, Reichardt T. Hyperspectral Signature Analysis and Characterization in Support of Remote Detection of Chemical and Biological Exposures. Proc. SPIE 12094, Algorithms, Technologies, and Applications for Multispectral and Hyperspectral Imaging XXVIII. 2022 May 31; 120940T. https://doi.org/10.1117/12.2618425
11. Mageeney CM, Trubl G, Williams KP. Improved Mobilome Delineation in Fragmented Genomes. Front Bioinform. 2022 Apr 11; 2:866850. https://www.frontiersin.org/articles/10.3389/fbinf.2022.866850/full
12. Otoupal PB, Cress BF, Doudna JA, Schoeniger JS. CRISPR-RNAa: targeted activation of translation using dCas13 fusions to translation initiation factors. Nucleic Acids Research. 2022 Aug 26; 50(15):8986-98. https://academic.oup.com/nar/article/50/15/8986/6660959
13. Permana DH, Zubaidah S, Syahrani L, Asih PBS, Syafruddin D, Rozi IE, et al. Impact of a spatial repellent product on Anopheles and non-Anopheles mosquitoes in Sumba, Indonesia. Malar J. 2022 Jun 03; 21(1):166. https://malariajournal.biomedcentral.com/counter/pdf/10.1186/s12936-022-04185-8.pdf
14. Pillai SP, Fruetel JA, Anderson K, Levinson R, Hernandez P, Heimer B, et al. Application of Multi-Criteria Decision Analysis Techniques for Informing Select Agent Designation and Decision Making. Frontiers in Bioengineering and Biotechnology. 2022 Jun 03; 10:756586. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9204104/
15. Pillai SP, West T, Levinson R, Fruetel JA, Anderson K, Edwards D, et al. The development and use of decision support framework for informing selection of select agent toxins with modelling studies to inform permissible toxin amounts. Frontiers in Bioengineering and Biotechnology. 2022 Oct 03; 10:1003127. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9573955/
16. Rozi IE, Syahrani L, Permana DH, Asih PBS, Hidayati APN, Kosasih S, et al. Human behavior determinants of exposure to Anopheles vectors of malaria in Sumba, Indonesia. PLoS One. 2022 Nov 14; 17(11): e0276783. https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0276783&type=printable

17. Santarpia JL, Collins DR, Ratnesar-Shumate SA, Glen CC, Sanchez AL, Antonietti CG, et al. Changes in the Fluorescence of Biological Particles Exposed to Environmental Conditions in the National Capitol Region. Atmosphere. 2022 Aug 25; 13(9):1358. https://www.mdpi.com/2073-4433/13/9/1358
18. Webster ER, Liu KN, Rawle RJ, Boxer SG. Modulating the Influenza A Virus-Target Membrane Fusion Interface with Synthetic DNA-Lipid Receptors. Langmuir. 2022 Feb 10; 38(7):2354-62. https://pubs.acs.org/doi/pdf/10.1021/acs.langmuir.1c03247
19. Wen PC, Rempe SL, Tajkhorshid E. Revisiting lipid II binding by teixobactin oligomers using membrane MD simulations. Biophysical Journal. 2022 Feb 11; 121(3):161A. https://www.cell.com/biophysj/pdf/S0006-3495(21)02896-4.pdf

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*:** Simulants of an Overlap Select Agent, NIAID Category A pathogens, and an HHS Select Agent.

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

* Including viruses and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
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

4. The organizational structure of each facility.

(i) Total number of personnel 18

(ii) Division of personnel:

Military	0
Civilian	18

(iii) Division of personnel by category:

Scientists	18
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	$ 1,625,251.20
Development	$ 1,389,687.20
Test and evaluation	$ 1,802,105.60
Total	$ 4,817,044.00

(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. BoyerAE, Gallegos-Candela M, Lins RC, Solano MI, Woolfitt AR, Lee JS, et al. Comprehensive characterization of toxins during progression of inhalation anthrax in a non-human primate model. 2022 Dec 19;18(12): e1010735. https://pubmed.ncbi.nlm.nih.gov/36534695/.
2. Hendricks K. Martines RB, Bielamowicz H, Boyer AE, Long S, Byers P, et al. Welder's Anthrax: A Tale of 2 Cases. Clin Infect Dis. 2022 Oct 17;75(Supplement_3): S354-S363. https://pubmed.ncbi.nlm.nih.gov/36251561/.
3. Lombarte Espinosa E, Villuendas Usón MC, Arribas García J, Jado García I, Huarte Lacunza R, Zárate Chug P, et al. Survival of Patient with Hemorrhagic Meningitis Associated with Inhalation Anthrax2022 Oct 17;75(Supplement_3): S364-S372. https://pubmed.ncbi.nlm.nih.gov/36251557/.

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

4. The organizational structure of each facility.

(ii) Total number of personnel: 232

(ii) Division of personnel:

Military	18
Civilian	214

(iii) Division of personnel by category:

Scientists	200
Engineers	0
Technicians	11
Administrative and support staff	21

(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: 47

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

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

Research	$ 12,992,500.99
Development	$ 5,390,675.00
Test and evaluation	$ 7,751,778.01
Total	$ 26,134,954.00

(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.)

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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*:** Activities include developing diagnostic assays for public health, developing and validating methods to differentiate and characterize organisms and the toxins that they produce, testing environmental samples for the presence of microorganisms and toxins, and developing environmental sampling methods, conducting molecular and antigenic characterization of organisms, determining pathogenicity and virulence of infectious agents, evaluation of antimicrobial susceptibility, research on potential therapeutics, determining the natural history of infectious organisms, and conducting epidemiologic studies and surveillance for diseases.

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

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

[*] Including viruses and prions.

National biological defence research and development programmes: Facilities

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

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

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

BSL-2	0 m^2
BSL-3	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 27

(ii) Division of personnel:

Military	0
Civilian	27

(iii) Division of personnel by category:

Scientists	14
Engineers	0
Technicians	0
Administrative and support staff	13

(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: 1

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

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

Research	$ 602,600

Development	$ 0
Test and evaluation	$ 0
Total	$ 602,600

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

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

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

1. Bai Y, Rizzo MR, Parise C, Maes S, Eisen RJ. A Novel Loop-Mediated Isothermal Amplification Assay for Rapid Detection of Yersinia pestis. Front Microbiol. 2022 Apr 7; doi: 10.3389/fmicb.2022.863142. https://pubmed.ncbi.nlm.nih.gov/35464914/
2. Calvert AE, Bennett SL, Hunt AR, Fong RH, Doranz BJ, Roehrig JT, et. al. Exposing cryptic epitopes on the Venezuelan equine encephalitis virus E1 glycoprotein prior to treatment with alphavirus cross-reactive monoclonal antibody allows blockage of replication early in infection. Virology. 2022 Jan 2; 565:13-21. https://pubmed.ncbi.nlm.nih.gov/34626907/
3. Cooley KM, Fleck-Derderian S, McCormick DW, Nelson CA. Plague Meningitis: A Systematic Review of Clinical Course, Antimicrobial Treatment, and Outcomes. Health Secur. 2022 Dec 20. doi: 10.1089/hs.2022.0081. https://pubmed.ncbi.nlm.nih.gov/36576503/
4. Eads DA, Biggins DE, Wimsatt J, Eisen RJ, Hinnebusch BJ, Matchett MR, et. al. Exploring and Mitigating Plague for One Health Purposes. Curr Trop Med Rep. 2022; 9:169-184. https://link.springer.com/article/10.1007/s40475-022-00265-6
5. Fleck-Derderian S, Cooley KM, Nelson CA. Plague in Disguise: The Discovery of Occult Buboes on Surgical Procedure or Autopsy. Vector Borne Zoonotic Dis. 2022 Apr;22(4):225-231. https://pubmed.ncbi.nlm.nih.gov/35404104/
6. Mutebi JP, Mathewson AA, Elias SP, Robinson S, Graham AC, Casey P, et. al. Use of Cervid Serosurveys to Monitor Eastern Equine Encephalitis Virus Activity in Northern New England, United States, 2009-2017. 2022 Jan 12;59(1):49-55. https://pubmed.ncbi.nlm.nih.gov/34734629/
7. Powers AM. Resurgence of Interest in Eastern Equine Encephalitis Virus Vaccine Development. J Med Entomol. 2022 Jan 12;59(1):20-26. https://pubmed.ncbi.nlm.nih.gov/34734632/

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 143

(ii) Division of personnel:

Military	0
Civilian	143

(iii) Division of personnel by category:

Scientists	84
Engineers	0
Technicians	52
Administrative and support staff	7

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Aerobiology, Animal Science, Bacteriology, Biochemistry, Biological Science, Biomedical Science, Cell Biology, Ecology, Entomology, Genetics, Genomics, Immunology, Mass Spectrometry, Microbiology, Microscopy, Molecular Biology, Pathology, Proteomics, 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	$ 40,077,628
Development	$ 0
Test and evaluation	$ 0
Total	$ 40,077,628

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

All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (http://publicaccess.nih.gov/) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise form NIH funds to the National Library of Medicine's PubMed Central digital archive upon acceptance for publication. To help advance science and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

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

1. Adney DR, Lovaglio J, Schulz JE, Yinda CK, Avanzato VA, Haddock E, et al. Severe acute respiratory disease in American mink experimentally infected with SARS-CoV-2. JCI Insight. 2022; 7(22). https://pubmed.ncbi.nlm.nih.gov/36509288/
2. Artikis E, Kraus A, Caughey B. Structural biology of ex vivo mammalian prions. J Biol Chem. 2022; 298(8):102181. https://pubmed.ncbi.nlm.nih.gov/35752366/
3. Binette P, Tesfamariam M, Cockrell D, Heinzen RA, Richards C, Shaia C, et al. Murine Q Fever Vaccination Model Reveals Sex Dimorphism in Early Phase Delayed-Type Hypersensitivity Responses. Front Immunol. 2022; 13:894536. https://pubmed.ncbi.nlm.nih.gov/35784317/
4. Bohrer AC, Castro E, Tocheny CE, Assmann M, Schwarz B, Bohrnsen E, et al. Rapid GPR183-mediated recruitment of eosinophils to the lung after Mycobacterium tuberculosis infection. Cell Rep. 2022; 40(4):111144. https://pubmed.ncbi.nlm.nih.gov/35905725/
5. Boon ACM, Darling TL, Halfmann PJ, Franks J, Webby RJ, Barouch DH, et al. Reduced airborne transmission of SARS-CoV-2 BA.1 Omicron virus in Syrian hamsters. PLoS Pathog. 2022; 18(12): e1010970. https://pubmed.ncbi.nlm.nih.gov/36459536/
6. Bushmaker T, Yinda CK, Morris DH, Holbrook MG, Gamble A, Adney D, et al. Comparative aerosol and surface stability of SARS-CoV-2 Variants of Concern. bioRxiv. 2022. https://pubmed.ncbi.nlm.nih.gov/36451892/
7. Cable J, Fauci A, Dowling WE, Günther S, Bente DA, Yadav PD, et al. Lessons from the pandemic: Responding to emerging zoonotic viral diseases-a Keystone Symposia report. Ann N Y Acad Sci. 2022 Dec;1518(1):209-225. https://pubmed.ncbi.nlm.nih.gov/36183296/
8. Carroll T, Fox D, van Doremalen N, Ball E, Morris MK, Sotomayor-Gonzalez A, et al. The B.1.427/1.429 (epsilon) SARS-CoV-2 variants are more virulent than ancestral B.1 (614G) in Syrian hamsters. PLoS Pathog. 2022;18(2): e1009914. https://pubmed.ncbi.nlm.nih.gov/35143587/
9. Caughey B, Standke HG, Artikis E, Hoyt F, Kraus A. Pathogenic prion structures at high resolution. PLoS Pathog. 2022;18(6): e1010594. https://pubmed.ncbi.nlm.nih.gov/35771767/
10. Chamberlain NB, Dimond Z, Hackstadt T. Chlamydia trachomatis suppresses host cell store-operated Ca(2+) entry and inhibits NFAT/calcineurin signaling. Sci Rep. 2022;12(1):21406. https://pubmed.ncbi.nlm.nih.gov/36496532/
11. Cheng E, Dorjsuren D, Lehman S, Larson CL, Titus SA, Sun H, et al. A Comprehensive Phenotypic Screening Strategy to Identify Modulators of Cargo Translocation by the Bacterial Type IVB Secretion System. mBio. 2022;13(2): e0024022. https://pubmed.ncbi.nlm.nih.gov/35258332/
12. Clancy CS, Shaia C, Munster V, de Wit E, Hawman D, Okumura A, et al. Histologic pulmonary lesions of SARS-CoV-2 in 4 nonhuman primate species: An institutional comparative review. Vet Pathol. 2022;59(4):673-80. https://pubmed.ncbi.nlm.nih.gov/34963391/
13. Clemente TM, Ratnayake R, Samanta D, Augusto L, Beare PA, Heinzen RA, et al. Coxiella burnetii Sterol-Modifying Protein Stmp1 Regulates Cholesterol in the Intracellular Niche. mBio. 2022;13(1): e0307321. https://pubmed.ncbi.nlm.nih.gov/35073737/
14. Cohen AA, van Doremalen N, Greaney AJ, Andersen H, Sharma A, Starr TN, et al. Mosaic RBD nanoparticles protect against challenge by diverse sarbecoviruses in animal models. Science. 2022;377(6606): eabq0839. https://pubmed.ncbi.nlm.nih.gov/35857620/

15. Cohen AA, van Doremalen N, Greaney AJ, Andersen H, Sharma A, Starr TN, et al. Mosaic RBD nanoparticles protect against multiple sarbecovirus challenges in animal models. bioRxiv. 2022. https://pubmed.ncbi.nlm.nih.gov/35378752/
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18. DeGrace MM, Ghedin E, Frieman MB, Krammer F, Grifoni A, Alisoltani A, et al. Defining the risk of SARS-CoV-2 variants on immune protection. Nature. 2022;605(7911):640-52. https://pubmed.ncbi.nlm.nih.gov/35361968/
19. Dimond Z, Bauler LD, Zhang Y, Carmody A, Hackstadt T. Chlamydia trachomatis Alters Mitochondrial Protein Composition and Secretes Effector Proteins That Target Mitochondria. mSphere. 2022;7(6): e0042322. https://pubmed.ncbi.nlm.nih.gov/36286535/
20. Drecktrah D, Hall LS, Crouse B, Schwarz B, Richards C, Bohrnsen E, et al. The glycerol-3-phosphate dehydrogenases GpsA and GlpD constitute the oxidoreductive metabolic linchpin for Lyme disease spirochete host infectivity and persistence in the tick. PLoS Pathog. 2022;18(3): e1010385. https://pubmed.ncbi.nlm.nih.gov/35255112/
21. Evans AB, Winkler CW, Peterson KE. Differences in neuroinvasion and protective innate immune pathways between encephalitic California Serogroup orthobunyaviruses. PLoS Pathog. 2022;18(3): e1010384. https://pubmed.ncbi.nlm.nih.gov/35245345/
22. Files MA, Naqvi KF, Saito TB, Clover TM, Rudra JS, Endsley JJ. Self-adjuvanting nanovaccines boost lung-resident CD4(+) T cell immune responses in BCG-primed mice. NPJ Vaccines. 2022;7(1):48. https://pubmed.ncbi.nlm.nih.gov/35474079/
23. Fischer RJ, Gallogly S, Schulz JE, van Doremalen N, Munster V, Das S. Evaluation of Five Buffers for Inactivation of Monkeypox Virus and Feasibility of Virus Detection Using the Panther Fusion (®) Open Access System. Viruses. 2022;14(10). https://pubmed.ncbi.nlm.nih.gov/36298782/
24. Fischer RJ, Port JR, Holbrook MG, Yinda KC, Creusen M, Ter Stege J, et al. UV-C Light Completely Blocks Aerosol Transmission of Highly Contagious SARS-CoV-2 Variants WA1 and Delta in Hamsters. Environ Sci Technol. 2022;56(17):12424-30. https://pubmed.ncbi.nlm.nih.gov/36001075/
25. Furuyama W, Shifflett K, Pinski AN, Griffin AJ, Feldmann F, Okumura A, et al. Rapid Protection from COVID-19 in Nonhuman Primates Vaccinated Intramuscularly but Not Intranasally with a Single Dose of a Vesicular Stomatitis Virus-Based Vaccine. mBio. 2022;13(1): e0337921. https://pubmed.ncbi.nlm.nih.gov/35012339/
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27. Griffin AJ, O'Donnell KL, Shifflett K, Lavik JP, Russell PM, Zimmerman MK, et al. Serum from COVID-19 patients early in the pandemic shows limited evidence of cross-neutralization against variants of concern. Sci Rep. 2022;12(1):3954. https://pubmed.ncbi.nlm.nih.gov/35273264/
28. Guarnieri JW, Dybas JM, Fazelinia H, Kim MS, Frere J, Zhang Y, et al. Targeted Down Regulation of Core Mitochondrial Genes During SARS-CoV-2 Infection. bioRxiv. 2022. https://pubmed.ncbi.nlm.nih.gov/35233572/
29. Guizzo MG, Tirloni L, Gonzalez SA, Farber MD, Braz G, Parizi LF, et al. Coxiella Endosymbiont of Rhipicephalus microplus Modulates Tick Physiology with a Major Impact in Blood Feeding Capacity. Front Microbiol. 2022; 13:868575. https://pubmed.ncbi.nlm.nih.gov/35591999/

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31. Hall S, Orrù CD, Serrano GE, Galasko D, Hughson AG, Groveman BR, et al. Performance of alpha-Synuclein RT-QuIC in relation to neuropathological staging of Lewy body disease. Acta Neuropathol Commun. 2022;10(1):90. https://pubmed.ncbi.nlm.nih.gov/35733234/
32. Hansen F, Meade-White K, Clancy C, Rosenke R, Okumura A, Hawman DW, et al. SARS-CoV-2 reinfection prevents acute respiratory disease in Syrian hamsters but not replication in the upper respiratory tract. Cell Rep. 2022;38(11):110515. https://pubmed.ncbi.nlm.nih.gov/35263638/
33. Hawman DW, Meade-White K, Archer J, Leventhal SS, Wilson D, Shaia C, et al. SARS-CoV2 variant-specific replicating RNA vaccines protect from disease following challenge with heterologous variants of concern. Elife. 2022;11: e75537. https://pubmed.ncbi.nlm.nih.gov/35191378/
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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.

* Including viruses and prions.

Microorganisms and/or toxins studied: Select Agents (HHS, Overlap, USDA) and Toxins (HHS), 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?
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 113

(ii) Division of personnel:

Military	1
Civilian	112

(iii) Division of personnel by category:

Scientists	43
Engineers	3
Technicians	52
Administrative and support staff	15

(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: 109

(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	$ 27,071,401
Development	$ 0
Test and evaluation	$ 0
Total	$ 27,071,401

(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. 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. 2022;22(5):622-35. https://pubmed.ncbi.nlm.nih.gov/34953520/
2. ITAC (INSIGHT 013) Study Group. Hyperimmune immunoglobulin for hospitalised patients with COVID-19 (ITAC): a double-blind, placebo-controlled, phase 3, randomised trial. Lancet. 2022;399(10324):530-40. https://pubmed.ncbi.nlm.nih.gov/35093205/
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13. Dacon C, Tucker C, Peng L, Lee CD, Lin TH, Yuan M, et al. Broadly neutralizing antibodies target the coronavirus fusion peptide. Science. 2022;377(6607):728-35. https://pubmed.ncbi.nlm.nih.gov/35857439/
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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 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.

[*] Including viruses and prions.

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?
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 110

(ii) Division of personnel:

Military	0
Civilian	110

(iii) Division of personnel by category:

Scientists	70
Engineers	0
Technicians	34
Administrative and support staff	6

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

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

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

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

Research	$ 37,752,221
Development	$ 0
Test and evaluation	$ 0
Total	$ 37,752,221

(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. Aisenberg LK, Rousseau KE, Cascino K, Massaccesi G, Aisenberg WH, Luo W, et al. Cross-reactive antibodies facilitate innate sensing of dengue and Zika viruses. JCI Insight. 2022;7(12): e151782. https://pubmed.ncbi.nlm.nih.gov/35588060/
2. Almeida GG, Rimkute I, do Vale I, Liechti T, Henriques PM, Roffe E, et al. Chagasic cardiomyopathy is marked by a unique signature of activated CD4(+) T cells. J Transl Med. 2022;20(1):551. https://pubmed.ncbi.nlm.nih.gov/36447264/
3. Amaral EP, Foreman TW, Namasivayam S, Hilligan KL, Kauffman KD, Barbosa Bomfim CC, et al. GPX4 regulates cellular necrosis and host resistance in Mycobacterium tuberculosis infection. J Exp Med. 2022;219(11). https://pubmed.ncbi.nlm.nih.gov/36069923/
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5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

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

Microorganisms and/or toxins studied: Select Agents (HHS) 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

4. The organizational structure of each facility.

(i) Total number of personnel 37

(ii) Division of personnel:

Military	0
Civilian	37

(iii) Division of personnel by category:

Scientists	36
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: 15

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

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

Research	$ 3,798,554
Development	$ 0
Test and evaluation	$ 0
Total	$ 3,798,554

(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. Finch CL, King TH, Alfson KJ, Albanese KA, Smith JNP, Smock P, et al. Single-Shot ChAd3-MARV Vaccine in Modified Formulation Buffer Shows 100% Protection of NHPs. Vaccines (Basel). 2022;10(11). https://pubmed.ncbi.nlm.nih.gov/36423030/
2. Hunegnaw R, Honko AN, Wang L, Carr D, Murray T, Shi W, et al. A single-shot ChAd3-MARV vaccine confers rapid and durable protection against Marburg virus in nonhuman primates. Sci Transl Med. 2022;14(675): eabq6364. https://pubmed.ncbi.nlm.nih.gov/36516269/
3. Tiemessen MM, Solforosi L, Dekking L, Czapska-Casey D, Serroyen J, Sullivan NJ, et al. Protection against Marburg Virus and Sudan Virus in NHP by an Adenovector-Based Trivalent Vaccine Regimen Is Correlated to Humoral Immune Response Levels. Vaccines (Basel). 2022;10(8). https://pubmed.ncbi.nlm.nih.gov/36016151/

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	252.5 m^2
BSL-3	184 m^2
BSL-4	0 m^2
Total laboratory floor area	436.5 m^2

The changes in the Food and Drug Administration (FDA) White Oak Campus BSL-2 laboratory space were due to a reporting error, resulting in a decrease of 350.64 m^2. The laboratory space was not physically remodelled.

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	20
Engineers	0
Technicians	0
Administrative and support staff	8

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

(v) Are contractor staff working in the facility? If so, provide an approximate number.
Yes Number: 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 Health and Human Services (HHS)

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

Research	$ 279,751.77
Development	$ 0.00
Test and evaluation	$ 0.00
Total	$ 279,751.77

(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. Bellusci L, Grubbs G, Srivastava P, Nemeth MJ, Griffiths EA, Golding H et al. Neutralization of SARS-CoV-2 Omicron after vaccination of myelodysplastic syndromes and acute myeloid leukemia patients. Blood 2022 May 5;139(18):2842-6. https://ashpublications.org/blood/article/139/18/2842/484507/Neutralization-of-SARS-CoV-2-Omicron-after
2. Bellusci L, Grubbs G, Zahra FT, Forgacs D, Golding H, Ross TM et al. Antibody affinity and cross-variant neutralization of SARS-CoV-2 Omicron BA.1, BA.2 and BA.3 following third mRNA vaccination. Nat Commun 2022 Aug 8;13(1):4617. https://www.nature.com/articles/s41467-022-32298-w
3. Bellusci L, Zahra FT, Hopkins DE, Salazar JC, Hyams JS, Khurana S. Durability of immunity is low against SARS-CoV-2 Omicron BA.1, BA.2 and BA.3 variants following second and third vaccination in children and young adults with inflammatory bowel disease receiving biologics. Gastroenterology 2022 Dec;163(6):1672-5. https://www.sciencedirect.com/science/article/pii/S0016508522009209?via%3Dihub
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9. Habibzadeh F, Chumakov K, Sajadi MM, Yadollahie M, Stafford K, Simi A et al. Use of oral polio vaccine and the incidence of COVID-19 in the world. PLoS One 2022 Mar 17;17(3): e0265562. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0265562

10. Hahn G, Lee S, Prokopenko D, Abraham J, Novak T, Hecker J et al. Unsupervised outlier detection applied to SARS-CoV-2 nucleotide sequences can identify sequences of common variants and other variants of interest. BMC Bioinformatics 2022 Dec 19;23(1):547. https://bmcbioinformatics.biomedcentral.com/articles/10.1186/s12859-022-05105-y
11. Hong J, Kwon HJ, Cachau R, Ho M. Dromedary camel nanobodies broadly neutralize SARS-CoV-2 variants. Proc Natl Acad Sci U S A 2022 May 3;119(18): e2201433119. https://www.pnas.org/doi/10.1073/pnas.2201433119
12. Jana S, Heaven MR, Stauft CB, Wang TT, Williams MC, D'Agnillo F et al. HIF-1alpha-dependent metabolic reprogramming, oxidative stress, and bioenergetic dysfunction in SARS-CoV-2-infected hamsters. Int J Mol Sci 2022 Dec 29;24(1):558. https://www.mdpi.com/1422-0067/24/1/558
13. Kwon HJ, Kosikova M, Tang W, Ortega-Rodriguez U, Radvak P, Xiang R et al. Enhanced virulence and waning vaccine-elicited antibodies account for breakthrough infections caused by SARS-CoV-2 Delta and beyond. iScience 2022 Dec 22;25(12):105507. https://www.sciencedirect.com/science/article/pii/S2589004222017795?via%3Dihub
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18. Liu S, Stauft CB, Selvaraj P, Chandrasekaran P, D'Agnillo F, Chou C-K et al. Intranasal delivery of a rationally attenuated SARS-CoV-2 is immunogenic and protective in Syrian hamsters. Nat Commun 2022 Nov 10;13(1):6792. https://www.nature.com/articles/s41467-022-34571-4
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20. Lusvarghi S, Pollett SD, Neerukonda SN, Wang W, Wang R, Vassell R et al. SARS-CoV-2 BA.1 variant is neutralized by vaccine booster-elicited serum, but evades most convalescent serum and therapeutic antibodies. Sci Transl Med 2022 May 18;14(645): eabn8543. https://www.science.org/doi/full/10.1126/scitranslmed.abn8543?rfr_dat=cr_pub++0pubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org
21. Lusvarghi S, Wang W, Herrup R, Neerukonda SN, Vassell R, Bentley L et al. Key substitutions in the spike protein of SARS-CoV-2 variants can predict resistance to monoclonal antibodies, but other substitutions can modify the effects. J Virol 2022 Jan;96(1): e0111021. https://journals.asm.org/doi/10.1128/JVI.01110-21
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27. Rothenberger S, Hurdiss DL, Walser M, Malvezzi F, Mayor J, Ryter S et al. The trispecific DARPin ensovibep inhibits diverse SARS-CoV-2 variants. Nat Biotechnol 2022 Dec;40(12):1845-54. https://www.nature.com/articles/s41587-022-01382-3
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29. Stauft CB, Tegenge M, Khurana S, Lee Y, Selvaraj P, Golding H et al. Pharmacokinetics and efficacy of human hyperimmune intravenous immunoglobulin treatment of SARS-CoV-2 infection in adult Syrian hamsters. Clin Infect Dis 2022 Jul 1;75(1): e459-65. https://academic.oup.com/cid/article/75/1/e459/6374486?login=true
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33. Tang J, Novak T, Hecker J, Grubbs G, Zahra FT, Bellusci L et al. Cross-reactive immunity against the SARS-CoV-2 Omicron variant is low in pediatric patients with prior COVID-19 or MIS-C. Nat Commun 2022 May 27;13(1):2979. https://www.nature.com/articles/s41467-022-30649-1
34. Tang J, Randolph AG, Novak T, Walker TC, Loftis LL, Zinter MS et al. Systemic and lower respiratory tract immunity to SARS-CoV-2 Omicron and variants in pediatric severe COVID-19 and Mis-C. Vaccines 2022 Feb 10;10(2):270. https://www.mdpi.com/2076-393X/10/2/270
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36. Yagovkina NV, Zheleznov LM, Subbotina KA, Tsaan AA, Kozlovskaya LI, Gordeychuk IV et al. Vaccination with oral polio vaccine reduces COVID-19 incidence. Front Immunol 2022 May 30; 13:907341. https://www.frontiersin.org/articles/10.3389/fimmu.2022.907341/full#:~:text=Incidence%20of%20COVID%2D19,-Analysis%20of%20the&text=79.0%20per%201000%3B%20p%3D0.036,of%20OPV%20against%20COVID%2D19

37. Zahra FT, Bellusci L, Grubbs G, Golding H, Khurana S. Neutralisation of circulating SARS-CoV-2 delta and omicron variants by convalescent plasma and SARS-CoV-2 hyperimmune intravenous human immunoglobulins for treatment of COVID-19. Ann Rheum Dis 2022 Jul;81(7):1044-5. https://ard.bmj.com/content/81/7/1044
38. Zahra FT, Grubbs G, Dummer K, Tremoulet AH, Shimizu C, Burns JC et al. Neutralization of SARS-CoV-2 Omicron and other variants in serum from children with vaccination-induced myocarditis. Clin Infect Dis 2022 Nov 1;75(9):1645-8. https://academic.oup.com/cid/article/75/9/1645/6571576?login=true
39. Zhang Q, Radvak P, Lee J, Xu Y, Cao-Dao V, Xu M et al. Mitoxantrone modulates a heparan sulfate-spike complex to inhibit SARS-CoV-2 infection. Sci Rep 2022 Apr 15;12(1):6294. https://www.nature.com/articles/s41598-022-10293-x#:~:text=The%20presence%20of%20Mitoxantrone%20in,fusion%20remains%20to%20be%20elucidated

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 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) and NIAID Category A pathogens

Outdoor studies: No outdoor studies performed.

* Including viruse and prions.

National biological defence research and development programmes: Facilities

1. What is the name of the facility?
Food and Drug Administration (FDA) 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. Bowe BK, Wentz TG, Gregg BM, Tepp WH, Schill KM, Sharma S, Pellett S. Genomic Diversity, Competition, and Toxin Production by Group I and II Clostridium botulinum Strains Used in Food Challenge Studies. Microorganisms. 2022; 10(10):1895. URL: https://doi.org/10.3390/microorganisms10101895
2. Adler M, Pellett S, Sharma SK, Lebeda FJ, Dembek ZF, Mahan MA. Preclinical Evidence for the Role of Botulinum Neurotoxin A (BoNT/A) in the Treatment of Peripheral Nerve Injury. Microorganisms. 2022; 10(5):886. URL: https://doi.org/10.3390/microorganisms10050886

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 9

(ii) Division of personnel:

Military	0
Civilian	9

(iii) Division of personnel by category:

Scientists	3
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. Redan BW, Morrissey TM, Rolfe CA, Aguilar VL, Skinner GE, Reddy NR. Rapid detection and quantitation of dipicolinic acid from Clostridium botulinum spores using mixed-mode liquid chromatography-tandem mass spectrometry. Anal Bioanal Chem. 2022; 414:2767-2774. URL: https://doi.org/10.1007/s00216-022-03926-7

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

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

Outdoor studies: No outdoor studies performed.

* Including viruse and prions.

National biological defence research and development programmes: Facilities

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

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

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

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

4. The organizational structure of each facility:

(i) Total number of personnel: 31

(ii) Division of personnel:

Military	0
Civilian	31

(iii) Division of personnel by category:

Scientists	11
Engineers	0
Technicians	12
Administrative and support staff	8

(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:
Yes Number: 1

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

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

Research	$ 4,268,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 4,268,000

(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.):

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 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: 24

(ii) Division of personnel:

Military	0
Civilian	24

(iii) Division of personnel by category:

Scientists	10
Engineers	0
Technicians	7
Administrative and support staff	7

(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:
Yes Number: 1

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

U.S. Department of Agriculture (USDA)

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

Research	$ 5,901,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 5,901,000

(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. Martins M, Boggiatto PM, Buckley A, Cassmann ED, Falkenberg SM, Caserta LC, et al. From Deer-to-Deer: SARS-CoV-2 is efficiently transmitted and presents broad tissue tropism and replication sites in highly susceptible white-tailed deer. PLoS Pathogens. 2022; 18(3): e1010197. https://doi.org/10.1371/journal.ppat.1010197.
2. Olsen SC, Boggiatto PM. Characterization of the duration of immunity of Brucella abortus strain RB51 vaccination in cattle after experimental challenge. Preventive Veterinary Medicine. 2022; 206:105705. https://doi.org/10.1016/j.prevetmed.2022.105705.
3. Palmer MV, Kanipe C, Boggiatto PM. The Bovine Tuberculoid Granuloma. Pathogens. 2022 Jan 4;11(1):61. https://doi.org/10.3390/pathogens11010061
4. Kanipe C, Boggiatto PM, Putz EJ, Palmer MV. Histopathologic differences in granulomas of Mycobacterium bovis bacille Calmette Guérin (BCG) vaccinated and non-vaccinated cattle with bovine tuberculosis. Front Microbiol. 2022 Nov 8; 13:1048648. . https://doi.org/10.3389/fmicb.2022.1048648
5. Abdelaal HFM, Thacker TC, Wadie B, Palmer MV, Talaat AM. Transcriptional Profiling of Early and Late Phases of Bovine Tuberculosis. Infect Immun. 2022 Feb 17;90(2): e0031321. https://doi.org/10.1128/IAI.00313-21
6. Hadi SA, Brenner EP, Palmer MV, Waters WR, Thacker TC, Vilchèze C, et al..: Mycobacterium bovis Strain Ravenel Is Attenuated in Cattle. Pathogens. 2022 Nov 11;11(11):1330. https://doi.org/10.3390/pathogens11111330
7. Sridhara AA, Johnathan-Lee A, Elahi R, Lambotte P, Esfandiari J, Boschiroli ML, et al. . Differential detection of IgM and IgG antibodies to chimeric antigens in bovine tuberculosis. Vet Immunol Immunopathol. Nov; 253:110499 2022 https://doi.org/10.1016/j.vetimm.2022.110499. Epub 2022 Oct 4
8. Sridhara AA, Johnathan-Lee A, Elahi R, Sikar-Gang A, Lambotte P, Esfandiari J, et al. Potential for improved detection of bovine tuberculosis by targeting combined blood biomarkers in multi-test algorithms. Vet Immunol Immunopathol. 2022 Jun; 248:110419. https://doi.org/10.1016/j.vetimm.2022.110419

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

***Objectives*:** Support the control and eradication of national and international exotic, emerging, zoonotic, and endemic infectious diseases of animals through a comprehensive research program emphasizing basic and applied research in diagnostics, prevention, and control strategies, prediction of disease outbreaks, molecular epidemiology, and understanding disease pathogenesis. Specifically, the research programs aim to produce new research knowledge and technology to: prevent, reduce or eliminate losses from impaired livestock performance, increased deaths, or condemnations; develop more sensitive, specific and rapid diagnostic tests; develop vaccines designed for the control and, when feasible, the eradication of disease; improve our understanding of the ecology and epidemiology of pathogens at the domestic animal-wildlife interface; and improve our understanding of the genetic and pathophysiologic basis of disease and pathogen virulence. This research provides government regulatory agencies and the livestock industries with improved intervention strategies against priority diseases. Additional information about research 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.

* Including viruses and prions.

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:	740 m^2
BSL-4:	0 m^2
Total laboratory floor area:	1,840 m^2

During the reported calendar year, the Southeast Poultry Research BSL-3 laboratory space used for biodefense research and development underwent a physical remodel, resulting in an increase of 116 m^2.

4. The organizational structure of each facility:

(i) Total number of personnel: 30

(ii) Division of personnel:

Military	0
Civilian	30

(iii) Division of personnel by category:

Scientists	12
Engineers	0
Technicians	13
Administrative and support staff	5

(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	$ 7,837,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 7,837,000

(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. Brown C, Zhang J, Pantin Jackwood MJ, Dimitrov K, Ferreira H, Suarez DL. In situ gene expression in early stage of virulent Newcastle disease in chickens. Vet Pathol. 2022; 59(1):75-81. https://doi.org/10.1177/03009858211045945.
2. Chung DH, Torchetti MK, Killian ML, Swayne DE, Lee D. Transmission dynamics of low pathogenicity avian influenza (H2N2) viruses in live bird markets of the Northeast United States of America, 2013-2019. Virus Evol. 2022; 8(1): veac009. https://doi.org/10.1093/ve/veac009.
3. Kapczynski DR, Sweeney RP, Spackman E, Pantin Jackwood MJ, Suarez DL. Development of an in vitro model for animal species susceptibility to SARS-CoV-2 replication based on expression of ACE2 and TMPRSS2 in avian cells. Virology. 2022; 569:1-12. https://doi.org/10.1016/j.virol.2022.01.014.
4. Kariithi H, Christy N, Decanini EL, Lemiere S, Volkening JD, Afonso CL, et al. Detection and genome sequence analysis of avian metapneumovirus subtype A viruses circulating in commercial chicken flocks in Mexico. Vet Sci. 2022; 9(10):579. https://doi.org/10.3390/vetsci9100579.
5. Leyson CM, Criado MF, Youk S, Pantin Jackwood MJ. Low pathogenicity H7N3 avian influenza viruses have higher within-host genetic diversity than a closely related high pathogenicity H7N3 virus in infected turkeys and chickens. Viruses. 2022; 14(3):554. https://doi.org/10.3390/v14030554.
6. Mo J, Stephens CB, Jordan B, Ritz C, Swayne DE, Spackman E. Optimizing sample collection methods for detection of respiratory viruses in poultry housing environments. Transbound Emerg Dis. 2022; 69(5): e2111-e2121. https://doi.org/10.1111/tbed.14547.
7. Mo J, Stephens CB, Spackman E. The thermal stability of Newcastle disease virus in poultry litter. Avian Dis. 2022; 66(2):131-134. https://doi.org/10.1637/aviandiseases-D-21-00113.
8. Parris JD, Kariithi H, Suarez DL. Non-target RNA depletion strategy to improve sensitivity of next-generation sequencing for the detection of RNA viruses in poultry. J Vet Diagn Invest. 2022; 34(4):638-645. https://doi.org/10.1177/10406387221102430.
9. Youk S, Leyson C, Killian ML, Torchetti MK, Lee D, Suarez DL, et al. Evolution of the North American lineage H7 avian influenza viruses in association with H7 virus's introduction to poultry. J Virol. 2022; 96(14): e00278-22. https://doi.org/10.1128/jvi.00278-22
10. Youk S, Leyson C, Parris D, Kariithi H, Suarez DL, Pantin Jackwood MJ. 2022. Phylogenetic analysis, molecular changes, and adaptation to chickens of Mexican lineage H5N2 low-pathogenic avian influenza viruses from 1994 to 2019. Transbound Emerg Dis. 2022; 69(5): e1445-e1459. https://doi.org/10.1111/tbed.14476.
11. Butt SL, Kariithi HM, Volkening JD, Taylor TL, Leyson C, Pantin-Jackwood M, et al. Comparable outcomes from long and short read random sequencing of total RNA for detection of pathogens in

chicken respiratory samples. Front Vet Sci. 2022 Dec 1; 9:1073919. https://doi.org/10.3389/fvets.2022.1073919
12. Ghorbani A, Ngunjiri JM, Edward C Abundo M, Pantin-Jackwood M, Kenney SP, Lee CW Development of in Ovo-Compatible NS1-truncated live attenuated influenza vaccines by modulation of hemagglutinin cleavage and polymerase Acidic X Frameshifting sites. Vaccine. 2023 Jan 18: S0264-410X(23)00029-4. https://doi.org/10.1016/j.vaccine.2023.01.018
13. Youk S, Cho AY, Lee DH, Jeong S, Kim YJ, Lee S, et al. Detection of newly introduced Y280-lineage H9N2 avian influenza viruses in live bird markets in Korea. Transbound Emerg Dis. 2022 Mar;69(2):881-885. https://doi.org/10.1111/tbed.14014.
14. Clark AA, Eid S, Hassan MK, Carter K, Swayne DE. Reducing zoonotic avian influenza transmission at household poultry slaughter using a behaviour change tool for limited literacy audiences. Zoonoses Public Health. 2022 Dec;69(8):956-965. https://doi.org/10.1111/zph.12993

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: 2

(ii) Division of personnel:

Military	0
Civilian	2

(iii) Division of personnel by category:

Scientists	2
Engineers	0
Technicians	0
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	$ 566,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 566,000

(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.):

None.

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

***Objectives*:** The specific research objectives in this project include studies on detection, host range, epidemiology and control of bacterial wilt and are included in the ARS Research Project entitled "Detection, Identification, and Characterization of New and Emerging Viral and Bacterial Diseases of Ornamental Plants". Specifically, these research objectives include studies on detection, host range, disease mechanisms, and control of bacterial wilt. The overall approach is to develop knowledge and tools that will aid U.S. regulatory agencies to establish effective pathogen testing protocols, and U.S. floriculture companies to improve clean stock production for new vegetatively propagated annuals and perennials. The goals of the current research project include 1) identification and characterization of genes and/or regulatory elements, 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, 2023

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

Human Disease Events

Human Infection with Influenza A (H5N1) variant virus (Colorado): On 29 April 2022, the United States IHR National Focal Point (NFP) reported to PAHO/WHO a laboratory confirmed case of avian influenza A(H5) infection in a human detected in the State of Colorado. The case is a male patient from the State of Colorado. On 20 April 2022, he developed fatigue following participation in poultry depopulation (culling) activities from 18 to 22 April 2022, at a commercial poultry facility in Colorado where influenza A (H5N1) virus had been confirmed in poultry.

On 20 April 2022, a respiratory sample was collected from the case, upon request of the organization providing personnel for poultry depopulation at this facility. On 22 April, the Colorado Department of Public Health and Environment Laboratory Services received the sample and testing was completed on 25 April 2022. Influenza A virus was detected by RT-PCR but lacked reactivity with RT-PCR tests for the hemagglutinin (HA) gene of contemporary seasonal influenza viruses of H1pdm09 or H3 subtypes. The sample was forwarded to the Influenza Division of the United States Centers for Disease Control and Prevention (U.S. CDC) for further testing. It was received and tested at U.S. CDC on 27 April 2022, where influenza A(H5) virus was confirmed by RT-PCR. The N1 subtype was subsequently confirmed by sequence analysis. This is the first human to test positive for influenza A(H5N1) virus in the United States of America.

According to the U.S. CDC, it is possible that the detection of H5 virus in this specimen is a result of surface contamination of the nasal membrane. On 26 April 2022, the patient was isolated and treated with antivirals following U.S. CDC guidance. The patient did not report symptoms other than fatigue, was not hospitalized, and has since recovered. On 20 April 2022, a total of 9 samples from close contacts of the case and persons who participated in depopulation at the same facility were collected; all tested negative for influenza. Additional respiratory specimens were obtained on 28 April 2022 and tested negative for influenza. Nine close contacts of the patient have been recommended to receive influenza antiviral prophylaxis.

All individuals who were exposed to poultry and involved in depopulation activities at this facility were monitored for symptoms for 10 days following the last date of their last exposure and tested if symptomatic in accordance with CDC and United States Department of Agriculture guidance. Close contacts of the index case were also being monitored. Thus far, no evidence of human-to-human transmission of influenza A (H5) virus in this event has been identified.

The World Health Organization (WHO) published the following Disease Outbreak News (DON) update on Avian Influenza A(H5N1) – the United States of America: https://www.who.int/emergencies/disease-outbreak-news/item/2022-DON379. Information regarding this A(H5N1) case can be found at: https://www.cdc.gov/media/releases/2022/s0428-avian-flu.html.

Human Infection with Mpox (Massachusetts): On 18 May 2022, the United States IHR National Focal Point notified PAHO/WHO of a confirmed case of mpox in a male resident of Massachusetts who self-identified as having sex with men (MSM). On 28 April, the case travelled to Canada by private vehicle and returned to Massachusetts on 1 May. On 4 May, the case developed lesions and sought care at an outpatient clinic. The illness progressed (including additional lesions, fever, and lymphadenopathy) and

the case was admitted to a hospital on 12 May. On 17 May, laboratory testing of the patient's lesion specimens conducted by the Massachusetts LRN Laboratory were confirmed for Orthopoxvirus infection, and on 18 May, the patient's lesion specimens were confirmed to have DNA sequences specific for a) mpox virus and b) West African clade mpox virus via real-time PCR assays conducted at the United States Centers for Disease Control and Prevention (US CDC) Poxvirus and Rabies Branch Laboratory. Information regarding this mpox case can be found at: https://www.cdc.gov/media/releases/2022/s0518-monkeypox-case.html.

Human Infection with Polio (New York): On 22 July 2022, the United States IHR National Focal Point reported a confirmed human poliovirus infection in an unvaccinated person with no recent history of international travel, although the case traveled to Poland and Hungary in March 2022. The case resides in the Rockland County of the State of New York and had travel history to New York City. The case was confirmed initially as a VDPV type 2 by the Centers for Disease Control and Prevention (US CDC), further information on these initial findings was published on the EIS posting published on 26 July 2022.

On 8 September 2022, United States IHR National Focal Point reported additional findings related to the case reported in July. According to the report, the environmental wastewater specimens from the case-patient's county of residence, Rockland County, and nearby counties (Orange and Sullivan) collected from 21 April through 26 August 2022 have been consistently positive for Sabin-like type 2 viruses with related genetic sequences to the case-patient's virus, and genetically related to viruses detected in sewage specimens from the United Kingdom and Israel in July 2022. These viral sequences did not cross the definition threshold for a circulating vaccine-derived poliovirus (cVDPV) as there were <6 nucleotide differences to the Sabin strain in the genome region encoding the VP1 capsid protein. However, recent detections in wastewater from August show the identification of VDPV2, with two environmental viral sequences (collected on 3 August and 11 August) having >5 nucleotide changes and both linked to the case reported in Rockland County. The detection of these new VDPV2, viruses that are genetically related, show community transmission, and should be classified as circulating VDPV type 2 (cVDPV2).

Additional enhanced surveillance for acute flaccid weakness in New York State and New York City have not yielded any additional cases of paralytic polio to date. Information regarding the polio case can be found at: https://www.cdc.gov/mmwr/volumes/71/wr/mm7133e2.htm.

Human Infection with Influenza A(H3N2)v variant virus (West Virginia): On 5 August 2022, the United States IHR National Focal Point (NFP) reported to PAHO/WHO a laboratory confirmed human infection caused by influenza A(H3N2)v virus, detected in the State of West Virginia.
On 2 August, RT-PCR testing at the West Virginia State Public Health Laboratory identified a presumptive influenza A H3 variant virus A(H3)v virus. The respiratory specimen was sent to the Centers for Disease Control and Prevention (US CDC) for further testing. On 4 August 2022, the US CDC confirmed an influenza A(H3N2)v virus by RT-PCR.

The patient participated in an agricultural fair, where pigs tested positive for flu and had direct contact with swine on multiple days beginning six days prior to illness onset. The patient was not hospitalized and is recovering from their illness. One close contact of the patient has reported illness, further investigation of this contact is ongoing. Two other attendees of this agricultural event, both with direct swine contact, have reported respiratory illness: one has tested negative for influenza, and one has tested positive for influenza A (further laboratory testing of this latter specimen is pending). Both patients who had respiratory specimens that were positive for influenza have been treated with influenza antiviral medication.

No person-to-person transmission of A(H3N2)v virus associated with this event has been confirmed. The public health authorities in West Virginia have notified local physicians to ask patients presenting with influenza-like illness about recent fair attendance or exposure to swine and to test these patients when influenza virus infection is suspected. Since 2005, when human infection with novel influenza A became notifiable in the United States, a total of 440 human infections with influenza A(H3N2)v have been reported in the United States. This is the first influenza A(H3N2)v virus human infection identified in the United States during 2022. Information regarding this A(H3N2)v variant case can be found at: https://www.cdc.gov/flu/swineflu/h3n2v-situation.htm.

Human Infection with influenza A(H1N2) variant virus (Oregon) USA: On 19 August 2022, the United States of America IHR National Focal Point (NFP) reported to PAHO/WHO a laboratory confirmed human infection caused by influenza A(H1N2)v virus, detected in the State of Oregon.

The case is a male patient <18 years of age, from Oregon State. On 28 July 2022, he developed respiratory illness with symptoms of fever, pharyngitis, and fatigue, and sought outpatient medical care on 29 July. That same day, a nasopharyngeal swab was collected, and the patient tested positive for influenza A virus. On 11 August, the specimen was then tested at the Oregon State Public Health Laboratory where RT-PCR analysis indicated it was positive for influenza A virus but lacked reactivity with diagnostic tests for contemporary human influenza viruses representing either H1pdm09 or H3 subtypes. The respiratory specimen was sent to the Centers for Disease Control and Prevention (US CDC) for further testing. On 18 August 2022, subsequent research testing and genetic sequencing and analysis indicated that the specimen contained an influenza A(H1N2)v virus. The patient was not hospitalized and has since recovered from their illness.

An investigation by local public health officials did not identify contact with swine or agricultural fair attendance by the patient within 10 days prior to illness onset. Additional investigations did not identify respiratory illness in any of the patient's household contacts. No person-to-person transmission of A(H1N2)v virus associated with this patient has been identified. Since 2005, there have been 504 influenza A variant virus infections in the United States of America (subtypes; H1N1v, H1N2v, H3N2v and H1v), including 32 human infections with influenza A (H1N2)v viruses. Information regarding this A(H1N2) variant case can be found at: https://www.cdc.gov/flu/swineflu/spotlights/swineflu-infection.htm.

Detection of poliovirus in wastewater (Utah): On 10 December 2022, the United States IHR National Focal Point reported a detection of a vaccine derived polio virus type 2 (VDPV2) in a sample of wastewater collected in February 2022 from Box Elder County, Utah, United States. According to the report, the specimen was collected as part of an activity to look at SARS-CoV-2 variants in stored specimens from across the United States, which were first tested for SARS-CoV-2 and then tested for poliovirus after the alert due to the detection of a paralytic poliomyelitis case in July 2022 and the detection of circulating vaccine-derived poliovirus type 2 (cVDPV2) in wastewater in New York State.

On 13 October 2022, the sample tested positive for poliovirus and was immediately sent to the Centers for Disease Control and Prevention (CDC) for confirmation and sequencing. Preliminary testing completed on 27 October 2022, at the CDC confirmed the presence of poliovirus. On 27 November a near-complete genome sequence of this positive specimen was completed and showed 8 changes in the VP1 capsid region, enough nucleotide changes to classify the virus as VDPV2. This specimen was the only poliovirus positive specimen; all other specimens collected in Utah during January and February 2022 tested negative. The CDC confirmed that the genetic sequence of this VDPV2 is not genetically related to the virus isolated from the New York State case in July 2022, nor to any other poliovirus

sequence in the global database. Additional specimens from Box Elder County, Utah collected at the same time from different locations in January and February2022 tested negative at CDC.

Between 11 and 13 October 2022, additional specimens were collected from the same location to determine if circulation of this VDPV2 was ongoing; these samples tested negative for poliovirus at CDC. No human cases of paralytic polio have been detected in Utah, and poliovirus has not been found in wastewater in any other Utah jurisdiction. Utah has no confirmed cases of acute flaccid myelitis in 2022, according to CDC surveillance data for this polio-like illness. Polio vaccination coverage in Utah is high, ranging from 91-94% over the past 7 years.

This single detection of poliovirus likely reflects a single importation in February 2022 and, as subsequent specimens were negative, poses no threat of additional exposure to persons residing in this county and state. Upon notification of the poliovirus-positive specimen, CDC, Utah Department of Health, and local health authorities launched an investigation and response. Activities included enhancing surveillance, testing wastewater from Box Elder County, Utah and assessing vaccination coverage.

SARS-CoV-2 in the United States: The COVID-19 pandemic continued throughout 2022 and the following variants of concern as classified by WHO were detected in the U.S. during 2022: Delta (first detected in 2021), and Omicron (first detected in 2021). Please see the United States' 2021 CBM report for more details. General information about variants and the SARS-CoV-2 virus are available at the CDC COVID Data Tracker: https://covid.cdc.gov/covid-data-tracker/#variant-proportions.495.

Animal Disease Events

Summary of Reports: In 2022, the United States submitted 5 immediate notifications (IN) and 117 follow-up animal disease reports to the World Organization for Animal Health (WOAH) representing 5 separate disease events. Events included the following: 1 Rabbit Hemorrhagic Disease Virus-2 (RHDV2) event, 1 Infectious Salmon Anemia Virus (ISAV) event, 1 Severe Acute Respiratory Syndrome Coronavirus Disease (SARS-CoV-2) event, 1 Highly Pathogenic Avian Influenza (HPAI) H5N1 event (includes 3 separate IN notifications for WOAH Poultry, WOAH Non-poultry including wild birds, and WOAH Non-poultry unusual host species), and 1 HPAI H5N4 event. Two events from 2021 continued into 2022, including one RHDV2 event and the SARS-CoV-2 event.

Event summaries can be found on the WOAH website: https://wahis.woah.org/#/home.

2022 Immediate and follow-up WOAH Reports:

Severe Acute Respiratory Syndrome-Coronavirus Disease (SARS-CoV-2)—United States
WOAH Follow-up Reports January 1, 2022 — Open at the end of 2022

SARS-CoV-2 is considered to be an emerging disease by WOAH. 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 2022, the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection (APHIS) continued to confirm and report SARS-CoV-2 detections in animals. WOAH reporting included 128 individual animals from 11 different species groups and 37 states. Cases occurred in 1 mink (antibody only); household companion animals, including 19 dogs and 14 cats; zoo animals, including 14 gorillas, 14 lions, 12 tigers, 2 snow leopards, 1 mandrill, and 1 squirrel monkey; and in wildlife, including 49 white-tailed deer and 1 mule deer. A complete list of detections to date can be found at: https://www.aphis.usda.gov/aphis/dashboards/tableau/sars-dashboard.

Rabbit Hemorrhagic Disease Virus-2 (RHDV2) — Georgia, New York, Florida, Kentucky, Mississippi, South Dakota, Minnesota, Tennessee
WOAH Follow-up Reports January 1, 2022 — closed May 12, 2022

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. One disease outbreak occurred in Tennessee in January 2022. Clinical signs included incontinence, recumbency, and sudden death. This outbreak was closed on May 12, 2022. All other state outbreaks noted in the RHDV2 event report closed prior to this date. With the release of domestically produced vaccine, RHDV2 has been considered stable throughout the United States since February 2022; therefore, all further detections will be reported to WOAH on applicable 6-month reports. For more information: https://wahis.woah.org/#/in-event/3807/dashboard.

- Tennessee – RHDV2 detected in domestic rabbit (Oryctolagus Cuniculus)

Infectious Salmon Anemia Virus (ISAV) — Maine
WOAH Immediate and Follow-up Reports July 23, 2022 — closed August 24, 2022

Infectious Salmon Anemia (ISA) is a viral disease caused by the infectious salmon anemia virus (ISAV), of the genus Isavirus in the Orthomyxoviridae family. Clinical infection with ISAV is characterized by severe anemia, multifocal external and internal petechial hemorrhages, and widespread organ damage. One event occurred in Maine in 2022. As part of routine monthly surveillance, North American highly polymorphic region-deleted ISAV was confirmed in tissues from farmed Atlantic salmon collected under the USDA APHIS Veterinary Services ISAV Control Program in Maine. There were no clinical signs of disease observed and no increased mortality. Surveillance sampling and testing continued through the harvest, and there were no additional ISAV detections. The event was closed on August 24, 2022. For more information: https://wahis.woah.org/#/in-review/4538.

Highly Pathogenic Avian Influenza (HPAI) H5N1 in WOAH Poultry, Non-Poultry, and Unusual Hosts – U.S.-wide
WOAH Immediate and Follow-Up Reports February 9, 2022 – Open at the end of 2022

Avian influenza (AI) is caused by an influenza type A virus which can infect poultry (such as chickens, turkeys, pheasants, quail, domestic ducks, geese, and guinea fowl) and wild birds (especially waterfowl). HPAI virus strains are extremely infectious, often fatal to chickens, and can spread rapidly from flock to flock. For details on HPAI findings in the United States during 2022, see: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/avian/avian-influenza/hpai-2022/2022-hpai-commercial-backyard-flocks and https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/avian/avian-influenza/hpai-2022/2022-hpai-wild-birds.

- HPAI H5N1 in WOAH poultry reported in 2022: https://wahis.woah.org/#/in-review/4309?reportId=158421&fromPage=event-dashboard-url.
- HPAI H5N1 in WOAH non-poultry reported in 2022: https://wahis.woah.org/#/in-review/4247?reportId=158450&fromPage=event-dashboard-url.
- HPAI H5N1 in WOAH non-poultry unusual hosts reported in 2022: https://wahis.woah.org/#/in-review/4451?reportId=157987&fromPage=event-dashboard-url.

HPAI H5N4 in Poultry – Montana
WOAH Immediate and Follow-Up Reports September 10, 2022 – Open at the end of 2022 (closed January 18, 2023)

AI is caused by an influenza type A virus which can infect poultry (such as chickens, turkeys, pheasants, quail, domestic ducks, geese, and guinea fowl) and wild birds (especially waterfowl). HPAI virus strains are extremely infectious, often fatal to chickens, and can spread rapidly from flock-to-flock. HPAI H5N4, Eurasian lineage goose/Guangdong clade 2.3.4.4b was confirmed on one backyard producer premises in Teton County, Montana. Clinical signs included lethargy, depression, and death. Control measures were implemented on September 9, 2022 (including quarantine, movement controls, surveillance, stamping out, disposal and disinfection) and were completed on September 21, 2022. The premises quarantine was released on October 14, 2022. The WOAH event was open at the end of 2022 and closed on January 18, 2023, as no further H5N4 infections were identified in the United States. For additional information, see: https://wahis.woah.org/#/in-review/4655?reportId=157585&fromPage=event-dashboard-url.

Form C

BWC - Confidence Building Measure

Encouragement of Publication of Results and Promotion of Use of Knowledge

United States of America

April 15, 2023

CDC, Federal Select Agent Program, **2021 Annual Report of the Federal Select Agent Program,** released in September 2022. https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2021_508.pdf	The *2021 Annual Report of the Federal Select Agent Program***,** released in September 2022, summarizes 2021 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**, 2021 Federal Select Agent Program (FSAP) Inspection Report Processing Annual Summary**, released in July 2022. https://www.selectagents.gov/resources/publications/docs/2021-FSAP-Inspection-Report-Processing-Annual-Summary_508.pdf	The FSAP Inspection Report summarizes timeliness data related to FSAP-issued inspection reports for the Federal Select Agent Program in 2021.
The U.S. Office of Research Integrity FY 2021 Annual Report, released in March 2022. https://ori.hhs.gov/sites/default/files/2022-07/FY2021%20ORI%20Annual%20Report.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 except for 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.
Guidance For Implementing National Security Presidential Memorandum 33 (NSPM-33) on National Security Strategy for United States Government – Supported Research and Development, released in January 2022. https://www.whitehouse.gov/wp-content/uploads/2022/01/010422-NSPM-33-Implementation-Guidance.pdf	The purpose of this document is to provide guidance to Federal departments and agencies regarding their implementation of National Security Presidential Memorandum 33 on National Security Strategy for U.S. Government-Supported Research and Development.
Biennial Report to Congress on International Science & Technology Cooperation, released in September 2022. https://www.whitehouse.gov/wp-content/uploads/2022/09/09-2022-Biennial-Report-to-Congress-on-International-Science-Technology-Cooperation.pdf	The aim of this biennial report is to provide a high-level view of where the United States stands with respect to international S&T. The "Areas of Excellence in the U.S. Approach to International S&T" section presents findings and recommendations for areas in which the United States is succeeding and providing global leadership, both internationally and because of the

	domestic U.S. S&T enterprise. The "Gaps in the U.S. Approach to International S&T Engagement" section presents findings and recommendations for areas in which the United States risks falling behind. These recommendations, if prioritized, may require either Executive or Legislative action. The final section, "Looking Forward", summarizes the U.S. position if these recommendations are put into action.

Form E

BWC - Confidence Building Measure

Declaration of legislation, regulations and other measures

United States of America

April 15, 2023

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	No
(c) Imports of micro-organisms† and toxins	Yes	Yes	Yes	No
(d) Biosafety‡ and biosecurity§	Yes	Yes	Yes	Yes[1]

EXPLANATORY NOTES

[1] (d) Biosafety and biosecurity:

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

  - Exclusion of the attenuated *Brucella melitensis* strain ΔnorD ΔznuA *Brucella melitensis*-mCherry in the FSAP: Effective March 16, 2022, the Federal Select Agent Program (FSAP) excluded the attenuated ΔnorD ΔznuA *Brucella melitensis*-mCherry (znBM-mC) strain from the select agent regulations [42 CFR 73.4€ and 9 CFR 121.4(e)]. The znBM-mC strain contains the same two mutations as a previously excluded *Brucella abortus* strain [ΔnorDΔznuA *Brucella abortus*-lacZ (vaccine strain)] and a *B. melitensis* strain (ΔnorD ΔznuA Brucella melitensis-lacZ (znBM-lacZ). The ΔnorD ΔznuA *B. melitensis*-mCherry strain was excluded based on data provided that demonstrated that the deletion of two virulence genes (norD and znuA) resulted in attenuation in both in vivo and in vitro assays. For more information: https://www.selectagents.gov/sat/exclusions/index.htm.

  - Inclusion of Venezuelan Equine Encephalitis Virus (VEEV) strain TC-83(A3G) in the FSAP: Effective September 1, 2022, the FSAP clarified through publication in the Federal Register that a modification to the excluded attenuated strain Venezuelan Equine Encephalitis Virus (VEEV) TC-83 (A3G) has been shown to increase its virulence. Therefore, the modified VEEV strain TC-83 (A3G) is a select agent and subject to the select agent regulations. For more information: https://www.selectagents.gov/sat/exclusions/index.htm and https://www.federalregister.gov/documents/2022/09/01/2022-18973/select-agent-determination-that-vaccine-strain-tc-83a3g-of-venezuelan-equine-encephalitis-virus-veev.

- **Policy statements and regulatory interpretations concerning Select Agent and Toxin Regulations (Public Health Security and Bioterrorism Preparedness and Response Act of 2002**

* 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.

and the Agricultural Bioterrorism Protection Act of 2002 concerning the Federal Select Agent Program):

- Draft Policy Statement for Biosafety Level 4 (BSL-4) and Animal BSL-4 (ABSL-4) Laboratory Verification (1/19/2022): The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announced the opening of a docket to obtain comment on a draft policy statement regarding Biosafety Level 4 (BSL-4)/Animal Biosafety Level 4 (ABSL-4) verification requirements. The policy statement, once finalized, will assist individuals and entities in verifying that the facility design parameters and operational procedures, including heating, ventilation, and air conditioning (HVAC) systems, in BSL-4 and/or ABLS-4 laboratories are functioning as intended to meet the biosafety sufficiency requirement in the select agent regulations (42 CFR 73.12(b)). Once complete, FSAP will publish the policy statement in the Federal Register. https://www.federalregister.gov/documents/2022/01/19/2022-00928/draft-policy-statement-for-biosafety-level-4-bsl-4-and-animal-bsl-4-absl-4-laboratory-verification.

- Regulatory interpretation regarding transfer of excluded or permissible amounts of HHS toxins: The FSAP received a request for a regulatory interpretation that requested clarification on the requirements for the transfer of less than or equal to permissible toxin amounts outlined in 42 CFR §73.3(d)(7) by or to entities registered to possess the toxin. To read the full regulatory interpretation, please visit https://www.selectagents.gov/regulations/interpretations/excluded-transfer-hhs.htm.

- Request for Interpretation on Constructs of Botulinum Neurotoxin Genes Subject to the Select Agent Regulations as Outlined in 42 CFR §73.3(c)(2): The FSAP received a request for a regulatory interpretation regarding constructs of botulinum neurotoxin genes. To read the full regulatory interpretation, please visit https://www.selectagents.gov/regulations/interpretations/botulinum.htm.

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

  - Updated Suitability Guidance: The FSAP has updated the training section of its Suitability Guidance document to clarify that entities with Tier 1 select agents and toxins must conduct annual insider threat awareness briefings for all FSAP-approved personnel on the entity's registration. The updated Suitability Guidance document is available on the FSAP website: https://www.selectagents.gov/compliance/guidance/suitability/index.htm.

  - Guidance on the Inventory of Select Agents and Toxins: The FSAP updated the Inventory Guidance document adding a labeling guidance appendix and other edits to enhance material accountability. The updated Guidance on the Inventory of Select Agents and Toxins can be found on the FSAP website: https://www.selectagents.gov/compliance/guidance/inventory/index.htm.

  - U.S. Government Guidance on Waste Management Contaminated with Category A Infectious Substances: The 2022 US Government guidance on Managing Solid Waste Contaminated with a Category A Infectious Substance addresses planning for Category A waste management activities, including considerations for developing, evaluating, and revising organizational or jurisdictional plans and protocols. Overarching planning considerations and governmental roles and responsibilities as they relate to Category A waste are also addressed. This document contains information for and describe responsibilities of those who generate, treat, or inactivate,

transport, and dispose of Category A waste. Also included is a section on worker health and safety discusses protecting employees involved in waste management activities from initial generation to final disposition. The guidance is supplemented by several appendices that provide additional resources, assist with decision making, and address questions and answers about Category A waste. https://www.phe.gov/s3/BioriskManagement/biocontainment/Pages/waste-management.aspx.

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

  - Review of United States Government dual use research oversight policies**:** In February 2022, the U.S. Government charged the National Science Advisory Board for Biosecurity (NSABB) with evaluating and providing recommendations on the effectiveness of two major U.S. biosecurity policy frameworks governing: i) Research with enhanced potential pandemic pathogens (PPPs), including the White House Office of Science and Technology Policy (OSTP) Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO), and the Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens; and ii) Dual Use Research of Concern (DURC), including the USG Policy for Oversight of Life Sciences DURC and the USG Policy for Institutional Oversight of Life Sciences DURC. More information about NSABB meetings and recommendations from the NSABB can be found here: https://osp.od.nih.gov/policies/national-science-advisory-board-for-biosecurity-nsabb#tab0/.

  - Review and Revision of the Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA: In April 2022, the U.S. Department of Health and Human Services issued a Request for Public Comment regarding the prospective draft revision of this Guidance, which would seek to reduce the risk that individuals with ill intent may exploit the application of nucleic acid synthesis technology. https://aspr.hhs.gov/legal/syndna/Pages/default.aspx.

  - Evidence-based Laboratory Biorisk Management Science & Technology Roadmap: In April 2022, the National Science and Technology Council (NSTC) published the Evidence-based Laboratory Biorisk Management Science & Technology Roadmap, which offers recommendations on how to advance applied biorisk research and employ the findings. https://www.whitehouse.gov/wp-content/uploads/2022/04/04-2022-NSTC-ST-Biorisk-Research-Roadmap_FINAL.pdf.

  - Executive Order 14081, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy: On September 12, 2022, President Biden issued Executive Order 14081, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy which prescribes a "whole-of-government approach to advance biotechnology and biomanufacturing towards innovative solutions in health, climate change, energy, food security, agriculture, supply chain resilience, and national and economic security" and aims, inter alia, to advance biosafety and biosecurity and elevate biological risk management as an integral part of the life cycle of biotechnology research and development and biomanufacturing, including by providing for investment in applied biosafety research and biosecurity innovation. https://www.whitehouse.gov/briefing-room/presidential-actions/2022/09/12/executive-order-on-advancing-biotechnology-and-biomanufacturing-innovation-for-a-sustainable-safe-and-secure-american-bioeconomy/.

- The 2022 National Biodefense Strategy and Implementation Plan on Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security: In October of 2022, the U.S. Government released the "National Biodefense Strategy and Implementation Plan on Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security" and the "National Security Memorandum on Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security," which supersedes the 2018 National Biodefense Strategy and accompanying Presidential Memorandum on Support for National Biodefense (NSPM-14). The Strategy provides a whole-of-government framework that organizes how the U.S. Government manages its activities to more effectively detect, prevent, prepare for, respond to, and recover from biological threats whether naturally occurring, accidental, or deliberate. The Strategy and Implementation Plan takes a holistic approach by encompassing efforts addressing biological threats to human, animal, and plant health as well as the environmentalt. https://www.whitehouse.gov/wp-content/uploads/2022/10/National-Biodefense-Strategy-and-Implementation-Plan-Final.pdf and https://www.whitehouse.gov/briefing-room/presidential-actions/2022/10/18/national-security-memorandum-on-countering-biological-threats-enhancing-pandemic-preparedness-and-achieving-global-health-security/.

- 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 2022, the FBI responded to multiple incidents that involved known or suspected biological material and led investigations predicated by potential violations of 18 USC 175.

- FBI Security Risk Assessments (SRAs): 3944 SRAs Completed in 2022: 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 2022, 3944 SRAs were processed by the FBI (Criminal Justice Information Services Division, Bioterrorism Risk Assessment Group). Of the 3944 individual SRAs processed, 17 BSAT access candidates were determined to meet the criteria of a "restricted person." The FBI's adjudication is provided to the Department of Health and Human Services or the Department of Agriculture, which decides whether to grant or deny the requesting entity or individual access to BSAT.

- FBI Biosecurity Outreach: During 2022, the FBI conducted over 30 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 2022 included, but were not limited to:

- Domestic and international engagement on synthetic biology (International Genetically Engineered Machine Competition, SynBio Africa's Global Catastrophic Biological Risk Initiative, etc.) and on biosafety/biosecurity best practices at relevant conferences;
- Teaching tools development sharing with: (1) the United Nations Interregional Crime and Justice Research Institute for biosecurity, biosafety, and bioethics and (2) industry for food defense to help mitigate against the threat of intentional food contamination.; and (3) information portal for the International Biosecurity and Prevention Forum;
- Training and workshop development for: (1) Animal-Plant Health Joint Criminal-Epidemiological Investigations for veterinary professionals, customs/border control officials, academia, and first responders for potentially deliberate disease events and (2) Joint Criminal-Epidemiological Investigations.

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, 2023

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, 2023

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 March 1, 2023). Trade names are included when provided by the manufacturer. Specific and current information about a vaccine, and contact information for the manufacturer, are available by following the hyperlinks provided on the above website.

Form G

Declaration of vaccine production facilities

1. Name of facility
Barr Laboratories, Inc.

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

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

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
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*, respectively.

Vaccines:
- Tetanus and Diphtheria Toxoids Adsorbed - [TDVAX]

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 15-valent Conjugate Vaccine [VAXNEUVANCE]
- 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
ModernaTX, Inc.

2. Location (Mailing Address)
200 Technology Square
Cambridge, MA 02139

3. General description of the types of diseases covered:
Active immunization against coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus in persons 18 years of age and older.

Vaccines:
- COVID-19 Vaccine, mRNA - [SPIKEVAX]

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:
For active immunization against disease caused by influenza A subtype viruses and influenza type B viruses.

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]
- 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]

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]

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
Goatpox virus	USDA Select Agent
Guanarito virus	HHS Select Agent + NIAID Category A
Hantaviruses	NIAID Category A
Hendra virus	Overlap Select Agent
Influenza A virus, reconstructed replication-competent pandemic 1918 strains	HHS Select Agent
Junin virus	HHS Select Agent + NIAID Category A
Kyasanur Forest disease virus	HHS Select Agent
Lassa virus	HHS Select Agent + NIAID Category A
Lujo virus	HHS Select Agent + NIAID Category A
Lymphocytic choriomeningitis virus	NIAID Category A
Machupo virus	HHS Select Agent + NIAID Category A
Marburg virus	HHS Select Agent + NIAID Category A
Monkeypox virus	HHS Select Agent
Mycoplasma mycoides	USDA Select Agent
Newcastle disease virus	USDA Select Agent
Nipah virus	Overlap Select Agent
Omsk hemorrhagic fever virus	HHS Select Agent
Peste-des-petits-ruminants virus	USDA 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
Sheep pox virus	USDA 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