AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 12

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00001	See Block 16C		

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
ASPR-BARDA	ASPR-BARDA	ASPR-BARDA	ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

ASPR-BARDA
US DEPT OF HEALTH & HUMAN SERVICES
BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT
200 INDEPENDENCE AVE, S.W.
Washington DC 20201

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

GENMARK DIAGNOSTICS, INC. 1487360
GENMARK DIAGNOSTICS, INC.
5964 LA PLACE CT
CARLSBAD CA 920088829

CODE	FAC LITY CODE
1487360	

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

x 10A. MOD FICATION OF CONTRACT/ORDER NO.
75A50120C00022

10B. DATED *(SEE ITEM 13)*
03/20/2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended , by one of the following methods: (a) By completing tems 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted ; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted , such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
See Schedule

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE N THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIF ED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation data, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER *(Specify type of modification and authority)* FAR 52.243-1 Alt. V - Changes - Fixed Price (Apr 1984)

E. IMPORTANT Contractor ☐ is not ☒ s required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

Tax ID Number: 95-4529072
DUNS Number: 962104217

A) In accordance with FAR 52.243-1 Alt. V - Changes - Fixed Price (Apr 1984), the purpose of this modification is the following:

1. Revise Attachment 1 - SOW based upon mutually agreed upon changes that are within scope.

B) This is a bilateral modification. The total obligated dollar amount of all CLINs that are currently being performed remains unchanged. The parties bilaterally agree to the changes in the terms and conditions of the contract. All other terms and conditions of the contract remain unchanged.

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect .

15A. NAME AND TITLE OF SIGNER *(Type or print)*	16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*
Scott O'Brien SVP Global Marketing & I	(b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
DocuSigned by: Scott O'Brien *(Signature of person authorized to sign)*	5/28/2020	(b) (6) *(Signature of Contracting Officer)*	(b) (6)

NAME OF OFFEROR OR CONTRACTOR
GENMARK DIAGNOSTICS, INC. 1487360

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT D)	UNIT PRICE (E)	AMOUNT (F)
	Period of Performance: 03/20/2020 to 07/20/2020				

Attachment 1

Biomedical Advanced Research and Development Authority (BARDA)
Broad Agency Announcement BAA-20-100-SOL-0002

GenMark Dx ePlex® Respiratory
Pathogen Panel 2 (ePlex RP2 Panel)
Area of Interest #4.1-A (COVID-19)

Statement of Work (SOW)

PREAMBLE

Independently, and not as an agent of the government, the contractor shall furnish all necessary services; qualified professional, technical, and administrative personnel; and material, equipment, and facilities not otherwise provided by the government under the terms of this contract, as needed to perform the tasks set forth below.

The government reserves the right to modify the budget, progress, schedule, or milestones to add or delete processes, schedules, or deliverables if the need arises. Because of the nature of this research and development (R&D) contract and the complexities inherent in this and prior programs, at designated milestones the government will evaluate whether work should be redirected or removed, or whether schedule or budget adjustments should be made. The government reserves the right to change the product, process, schedule, or events to add or delete part or all of these elements as the need arises.

Overall Objectives and Scope

The overall objective of this contract is to develop an updated and expanded version of the ePlex Respiratory Pathogen (RP) Panel to include assay(s) for the detection of SARS-CoV-2 in upper respiratory tract specimens, referred to in the remainder of the document as ePlex RP2 Panel. The Design Verification and Validation Plan and subsequent testing will be used to address all the studies required to support the regulatory submission(s) to FDA for the indication of Emergency Use Authorization of the ePlex RP2 Panel.

The scope of work for this contract includes incorporation of the assay(s) of the EUA (*submitted*) ePlex SARS-CoV-2 Test, previously developed as a single target test cartridge, into an expanded version of the ePlex RP v1 Panel, which is a highly multiplexed FDA 510(k)-cleared diagnostic test. The ePlex RP v1 Panel is a comprehensive test that identifies and detects the most common viral and bacterial organisms causing respiratory illness and including SARS-CoV-2 on this panel will streamline detection and identification and enable clinicians to optimize patient care based on the pathogen detected. Development to include SARS-CoV-2 as a target on the ePlex RP v1 Panel is expected to require a minimum of 3-4 months of work (to be completed before August 2020). While initial development demonstrated that a SARS-CoV-2 assay is sensitive and specific for its intended target, this work will focus on optimizing the performance of this test in combination with more than 20 other assays for additional targets. Once the ideal testing parameters have been identified, performance will be formally verified with analytical and clinical studies sponsored by GenMark. The FDA-510(k)-cleared targets on the currently marketed ePlex Respiratory Pathogen

Panel are provided in Table 1.

Table 1. Current ePlex Respiratory Pathogen Panel (v1)

VIRAL TARGETS	
Adenovirus	Coronavirus (229E, HKU1, NL63, OC43)
Human Metapneumovirus	Human Rhinovirus/Enterovirus
Influenza A	Influenza A H1
Influenza A H1-2009	Influenza A H3
Influenza B	Parainfluenza 1
Parainfluenza 2	Parainfluenza 3
Parainfluenza 4	Respiratory Syncytial Virus A
Respiratory Syncytial Virus B	
BACTERIAL TARGETS	
Mycoplasma pneumoniae	*Chlamydia pneumoniae*

The R&D effort for development of the **GenMark ePlex Respiratory Pathogen Panel 2 (ePlex RP2 Panel)** will progress in work segments with key Deliverables being due during the Base Period of performance of the contract (the Base Period will be labeled Contract Line Item Number (CLIN) 0001). Each Deliverable will require a concrete work segment with a well-defined objective, scope of work, and success metric for accomplishing the Deliverable. The work segments for each Deliverable may occur sequentially or simultaneously based on the pathway and needs of the project.

In addition to the requirements outlined under "Section F.2 Deliverables" of the contract, the following deliverables are defined for this project:

1. **Deliverable 1 –** Project Plan
2. **Deliverable 2 –** Feasibility and Development
3. **Deliverable 3 –** Verification/Validation and Clinical Study

1. Deliverable 1: Project Plan

Objective:
The plan will outline the goals, deliverables, and intended pathway for the project, including a Gantt Chart, Risk Management Plan, and tools/techniques used to track and monitor the progress of the project.

Scope of Work:
The Project Manager will establish a project plan and communicate the plan to the Product Approval Committee (PAC). The purpose of the project plan is to identify, manage and control the product development and commercialization activities for the product. This project plan shall cover the activities associated with the development and market release of the ePlex RP2 Panel and the associated deliverables.

The Project Manager will be responsible for managing the master schedule, tracking major project deliverables, and scheduling appropriate reviews. This work will be to establish and update (as needed) the project timeline and ensure the timely completion of project deliverables; to provide risk assessment and communicate critical issues impacting product quality to management; to ensure that participants at each Design Review include representatives from all functions concerned with the design stage being

reviewed; to communicate the progress and status of the project to the Core Team through meetings, meeting notes and/or email.

The development and commercialization of this project will be performed in multiple phases. The different components encompassed within this project may enter into the various phases of development at different times. Design validation and verification activities will be separated where needed to accommodate this plan. Reviews for design and development activities in support of this project will be scheduled as needed and may overlap, be combined, or delayed as needed to meet the requirements of each phase of the project. Reviews may include technical review, review of project status, project risk evaluation, Product Approval Committee (PAC) review and approval, or any combination of these and additional elements. Multiple reviews for different elements of a single milestone may be scheduled at different times to meet the requirements of a project phase. These reviews will be scheduled and combined as needed and will be tracked on the Project Schedule.

A cross-functional Core Team with representatives from appropriate departments will be assigned to the project. Additional support will be obtained as needed. In some instances, a Core Team member may represent more than one organizational area.

The activities required for the project will be identified in the project plan. The members of the Core Team will be identified. The project plan will be used to communicate the scope and status of the project. The Core Team will meet informally to manage the details of the project and drive research, development, and tactical actions. These informal meetings will not require formal documentation, nor do they require full Core Team representation at each meeting.

Success Metric for Completion of Deliverable 1:
The completion and approval by Project Approval Committee (PAC) of a project plan for an ePlex RP2 Panel for the inclusion of a SARS-CoV-2 assay. The completion of a Risk Management Plan with input from the project Core Team.

2. **Deliverable 2: Feasibility and Development**

Objective:
To demonstrate the feasibility of adding a SARS-CoV-2 assay to the ePlex Respiratory Pathogen Panel cartridge that includes the previously characterized, FDA-cleared pathogen targets and optimize the performance of this test in combination with the more than 20 other assays on the panel.

Scope of Work:
For the scope of this deliverable, the distinct phases of Feasibility (CP1) and Planning & Development (CP2) of the GenMark product development process will be combined into a single deliverable. Intent of the Feasibility phase will be to execute the feasibility study plan/report for the addition of a SARS-CoV-2 assay(s) to the RP v1 panel while still meeting the requirements established by the Core Team. the

The purpose of the feasibility study plan will entail all R&D activities and testing required to optimize the inclusion of a SARS-CoV-2 Wuhan-2 (N2) and/or Wuhan-3 (N1) assays on the current ePlex RP v1 consumable using dried reagents at the limit of detection for the assay targets. The intent will be to demonstrate feasibility of sample processing through detection on the ePlex RP consumable by adding the Wuhan-2 and Wuhan-3 primer and probes to the regions with area available for additional multiplex reactions on the consumable (Figure 1) while taking into consideration the performance of the amplification and detection reactions so as not to impact the established regulatory status of the existing assays (and not require additional FDA clearance for the existing assays). An assessment of performance

of all RP v1 Panel targets and the Wuhan-2 and Wuhan-3 assays will be performed and based on acceptance criteria the formulation will be locked or the location will be changed until the optimal performance and sensitivity of the Wuhan-2 and Wuhan-3 SARS-CoV-2 assay(s) is reached. Once the optimal performance is achieved, the design and formulation of the ePlex RP2 Panel will be locked.

(b) (4)

Acceptance criteria for the ePlex RP2 Panel design will be:

Category	Requirement
Accuracy	Have a PPA and NPA of >90% compared to the ePlex SARS-CoV-2 Assay.
Analytical Sensitivity and Specificity	Have analytical sensitivity and specificity equivalent to (within 1 log or better) than the ePlex SARS-CoV-2 consumable.
	The Assay shall detect SARS-CoV-2 in a mixed infection with viral pairs at 1x LoD and 10^5 copies/mL or $TCID_{50}$/ml in the same sample.
Cross-reactivity	The Assay shall not detectably cross-react with other organisms of similar or shared sequence homology or with viral types, viral sub-types, or bacteria on the panel.

And, no meaningful changes should be observed for the following ePlex RP v1 product requirements:

1. Time to result for the consumable should remain consistent (≤102 minutes on average from start to end).
2. No meaningful impact to the on-consumable assay controls.

Success Metric for Completion of Deliverable 2:

Assay formulation lock and the completion of all deliverables required for Phase 1 and 2 must by verified. Satisfaction of the acceptance of the criteria established for this milestone as part of the required Phase Gate Review by the Product Approval Committee (PAC) which consists of senior leaders in the company. The deliverable will be considered met when success metrics are met and reports have been received and

accepted.

Completion and approval of the following documents:

- Team/PAC Planning & Development Phase Review Records
- Development Summary Report covering the outcome of key studies supporting the assay lock requirements and decision

3. Deliverable 3: Verification/Validation and Clinical Study

Objective:
To verify and/or validate the performance of the addition of a SARS-CoV-2 assay to the ePlex Respiratory Pathogen Panel version 2 on the ePlex Instrument. The Verification and Validation Plan and subsequent testing will be used to address all the studies required to support the regulatory submission to FDA for Emergency Use Authorization.

Scope of Work:

Design Verification and Validation
The Research and Development team shall perform verification and validation activities that align with the IVD validation requirements identified in FDA's policy document entitled *Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency* (March 16, 2020). The data from the testing will be presented to the Core Team for review and approval. The results of the V&V activities will be appropriately documented (e.g., in a Technical Summary Report) and cross-functionally reviewed/approved.

The following describes the testing that will be performed to address the addition of a SARS-CoV-2 assay(s) to the ePlex Respiratory Pathogen Panel to support the regulatory submission(s) of the ePlex RP2 Panel for Emergency Use Authorization. These study designs align with the validation study recommendations cited in FDA's policy document entitled *Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency* (March 16, 2020) for molecular diagnostics.

1. Analytical Sensitivity (Limit of Detection)

a. Scope: Establish and verify the Limit of Detection (LoD) for the ePlex RP2 Panel. The study will be conducted in three parts: (1) the preliminary LoD of a SARS-CoV-2 assay will be determined in a range finder study; (2) the LoD of a SARS-CoV-2 assay will be confirmed by testing additional replicates at the preliminary LoD and (3) the established LoDs of any ePlex RP Panel assays multiplexed with the SARS-CoV-2 assay will be verified.

i. **Range Finder Study**: A dilution series of at least three replicates per concentration will be tested to identify the preliminary LoD. Test samples will be contrived using viral RNA or inactivated virus spiked into simulated or clinical matrix.

ii. **Verification Study**: Twenty (20) replicates will be tested at the preliminary LoD concentration and detection of ≥95% of replicates will be verified. If 95% positivity is not achieved, an additional 20 replicates will be tested at a 1 log higher concentration. If 95% positivity is achieved, 20 additional replicates will be tested at a 1 log lower concentration..

iii. **Confirmation of established LoDs of any ePlex RP Panel assays multiplexed with the SARS-CoV-2 assay**: Twenty (20) replicates will be tested at the

established LoD concentration (K163636) and verified if ≥95% of replicates were detected.

b. Acceptance Criteria: The lowest concentration that results in ≥95% positive results will be tested and confirmed in the LoD verification study for a SARS-CoV-2 assay. Confirmation of the established ePlex RP Panel LoD will be demonstrated with ≥95% of replicates were detected.

2. Analytical Reactivity (Inclusivity)

a. Scope: Evaluate the inclusivity of a SARS-CoV-2 assay on the ePlex RP2 Panel. *In silico* analysis will be conducted to indicate the percent identity matches against publicly available SARS-CoV-2 sequences that can be detected by the ePlex RP2 Panel. In addition, the established inclusivity claims of any ePlex RP Panel assays multiplexed with the SARS-CoV-2 assay will be verified via wet testing.

b. Acceptance Criteria: GenMark anticipates that >99% of published SARS-CoV-2 sequences will be detectable with the selected primers and probes. Any published SARS-CoV-2 sequences that are not predicted to be detected by the ePlex RP2 Panel will be investigated and the appropriate justification will be documented. For the wet testing, confirmation of the established inclusivity claims of any affected ePlex RP Panel assays multiplexed with the SARS-CoV-2 assay will be demonstrated.

3. Cross Reactivity/Exclusivity

a. Scope: Evaluate cross reactivity of viral, bacterial or fungal strains with ePlex RP2 Panel . The scope of the cross-reactivity assessment will be limited to the SARS-CoV-2 assay and any ePlex RP Panel assays multiplexed with the SARS-CoV-2 assay.

i. This study will evaluate performance of the ePlex RP2 Panel in the presence of high concentrations of on-panel and off-panel analytes. Cross-reactivity will be assessed by analyzing the test results for the expected analyte.

ii. *In silico* analysis will be conducted for a SARS-CoV-2 assay to evaluate cross-reactivity.

b. Acceptance Criteria: For the wet testing, the ePlex RP2 Panel is expected to be 100% concordant with expected results.

Clinical Studies

The purpose of the study will be to establish the clinical performance characteristics on the ePlex RP2 Panel for detection of SARS-CoV-2 nucleic acids in nasopharyngeal swab (NPS) samples to support Emergency Use Authorization. The proposed study design tests a minimum of 30 known SARS-CoV-2 positive NPS clinical samples and 30 known SARS-CoV-2 negative NPS clinical samples at an external clinical site. In addition, verification of established clinical performance claims for any affected ePlex RP Panel assays multiplexed with the SARS-CoV-2 assay will be conducted using archived clinical specimens (i.e., from the previous ePlex RP Panel clinical performance study). Verification testing of these archived clinical samples will be conducted at GenMark.

Success Metric for Completion of Deliverable 3:

Regulatory documentation to support distribution of the ePlex RP2 Panel, namely Certification that GenMark has completed all of the recommended validation studies per FDA's Policy document, FDA letter of receipt of the ePlex RP2 Panel EUA submission, or FDA letter to authorize emergency use of the ePlex RP2 Panel. In addition, GenMark will provide a Technical Summary Report of data generated during the design verification and validation phase. The deliverable will be considered met when success

metrics are met and reports have been received and accepted.

Budget Impact Resulting from Changes in Study Design:

We expect a decrease in the costs for the clinical studies, previously estimated to be $65,500 for 3 sites, to ~$22,000 for a single clinical site. We are still purchasing samples from external sites, but will not run the study at those sites. In addition, a sum $44,000 will be reallocated to consumables as the assay development team pursues improvement in the SARS-CoV-2 target LoD on RP2. The team is investigating updates to the sample delivery device and assay cycling parameters which will require additional consumables for both development and LoD studies.

PROGRAM MANAGEMENT

The contractor shall provide the following as outlined below:

a) The overall management, integration, and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities;

b) A Principal Investigator (PI) or Project Manager (PM) responsible for project management, communication, tracking, monitoring, and reporting on status, progress, and modifications to the project requirements, deliverables and timelines, including projects undertaken by subcontractors;

c) A PM with responsibility for monitoring and tracking day-to-day progress and timelines of deliverables, coordinating communication and project activities, costs incurred, and program management.

d) A BARDA liaison (maybe be the PM) with responsibility for effective communication with the Contracting Officer (CO), Contract Specialist (CS), and Contracting Officer's Representative (COR);

e) Administrative and legal staff capable of developing compliant subcontracts, consulting, and other legal agreements, while also ensuring timely acquisition of all proprietary rights, including intellectual property (IP) rights and reporting all inventions made in the performance of the contract;

f) Administrative staff capable of financial management and reporting on all activities conducted by the contractor and any subcontractors;

g) Contract Review Meetings

The contractor shall participate in regular meetings to coordinate and oversee the contract effort conjointly with the CO, CS, and COR. Such meetings may include, but are not limited to, the following:

- Meeting with the contractors and subcontractors to discuss clinical manufacturing progress, product development, product assay development, scale-up manufacturing development, clinical sample assays development, preclinical/clinical study designs and regulatory issues.

- Meeting with individual contractors and other government officials to discuss the technical, regulatory, and ethical aspects of the program.

- Meeting with technical consultants to discuss technical data provided by the contractor.

h) The contractor shall participate in daily to twice monthly teleconferences with the CO, CS and COR to discuss the performance of the contract, unless otherwise directed. Teleconferences or additional face-to-face meetings may be more frequent at the request of the CO.

i) Gantt Chart

Within 15 business days of the effective date of the contract, the contractor shall submit a first draft of an updated Gantt Chart to the CO, CS and COR for review. The Gantt Chart shall be incorporated into the contract and will be used to monitor performance. The contractor shall include the key milestones, deliverables, and Go/No-Go decision gates.

j) Project Management Plan

In the management of this contract, the contractor is encouraged to utilize Project Management tools/techniques to track and monitor the cost and schedule of the project. The contractor and the government agree that at a minimum, the contractor shall utilize the cost and schedule tools/techniques in the contract deliverable project plan for project management purposes.

k) Risk Management Plan

The contractor shall develop a high-level risk management plan within 30 days of contract award highlighting potential problems or issues that may arise during the life of the contract, including the impact on cost, schedule, and performance. Appropriate remediation plans. should reference relevant work segments where appropriate. Updates to this plan shall be included, at a minimum, on a monthly basis (or as needed) in the monthly Project Status Report.

l) Monthly and Annual Reports

The contractor shall deliver Project Status Reports on a monthly basis. The reports shall address the items below cross referenced to the SOW or other Project Management Plan tool(s):

- Executive summary highlighting the progress, issues, and relevant manufacturing, non-clinical, clinical, and regulatory activities.
- Progress in meeting contract deliverables, detailing the planned progress and actual progress during the reporting period, explaining any differences between the two and corrective steps.
- Updated Risk Management Plan (monthly, or as needed).
- One-month rolling forecast of planned activities.
- Progress of regulatory submissions.

m) Data Management

The contractor shall:

- Develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data.

- Provide for the statistical design and analysis of data resulting from the research.

- Provide raw data or specific analyses of data generated with contract funding to the CO, CS, and COR, upon request.

REGULATORY

The contractor shall perform the following as outlined below:

a) Engage the Food and Drug Administration (FDA) on a path to support the use of the product for the Emergency Use Authorization.

b) Prepare materials for and requesting, scheduling, and participating in all meetings with the FDA, including meetings to review all data packages.

c) Provide BARDA with (1) initial draft minutes and final draft minutes of any formal meeting with the FDA, and (2) final draft minutes of any informal meeting with the FDA.

FACILITIES, EQUIPMENT, & OTHER RESOURCES

The contractor shall provide equipment, facilities, and other resources required for implementation of the SOW to comply with all Federal and HHS regulations in:

a) The humane care and use of vertebrate animals.

b) The acquisition, handling, storage, and shipment of potentially dangerous biological and chemical agents, including select agents under biosafety levels required for working with the biological agents under study.