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Section B - Supplies or Services and Prices

ITEM NO SUPPLIES/SERVICES MAX UNIT UNIT PRICE MAX AMOUNT

0001 (b) (4) Each (b) (4) \$60,000,000.00

SARS-CoV-2 LFI Kit

FFP

Lateral Flow Immunoassay kit for detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) antigen to include nasal swab and appropriate amount of clinical buffer.

QUANTITY

FOB: Destination MFR PART NR: TBD PSC CD: 6550

> MAX \$60,000,000.00 NET AMT

ITEM NO SUPPLIES/SERVICES MAX UNIT UNIT PRICE MAX AMOUNT QUANTITY

0002 UNDEFINED Job UNDEFINED \$100,000.00

Shipping COST

Costs for shipping of SARS-Co V-2 kits should be billed against this Cost Reimbursable Shipping CLIN. Ship To Addresses will be included on individual

Delivery Orders. FOB: Destination MFR PART NR: TBD PSC CD: 8145

MAX COST \$100,000.00

CONTRACT MINIMUM/MAXIMUM QUANTITY AND CONTRACT VALUE

The minimum quantity and contract value for all orders issued against this contract shall not be less than the minimum quantity and contract value stated in the following table. The maximum

quantity and contract value for all orders issued against this contract shall not exceed the maximum quantity and contract value stated in the following table.

MINIMUM	MINIMUM	MAXIMUM	MAXIMUM
QUANTITY	AMOUNT	QUANTITY	AMOUNT
(b) (4)	\$100,000.00	(b) (4)	\$60,000,000.00

DELIVERY/TASK ORDER MINIMUM/MAXIMUM QUANTITY AND ORDER VALUE

The minimum quantity and order value for each Delivery/Task Order issued shall not be less than the minimum quantity and order value stated in the following table. The maximum quantity and order value for each Delivery/Task Order issued shall not exceed the maximum quantity and order value stated in the following table.

MINIMUM	MINIMUM	MAXIMUM	MAXIMUM
QUANTITY	AMOUNT	QUANTITY	AMOUNT
(b) (4)		(b) (4)	

CLIN MINIMUM/MAXIMUM QUANTITY AND CLIN VALUE

The minimum quantity(s) and CLIN value(s) for all orders issued against the CLIN(s) on this contract shall not be less than the minimum quantity(s) and CLIN value(s) stated in the following table. The maximum quantity(s) and CLIN value(s) for all orders issued against the CLIN(s) on this contract shall not exceed the maximum quantity(s) and CLIN value(s) stated in the following table.

	MINIMUM	MINIMUM	MAXIMUM	MAXIMUM
CLIN	QUANTITY	AMOUNT	QUANTITY	AMOUNT
0001	(b) (4)		(b) (4)	

CLIN DELIVERY/TASK ORDER MINIMUM/MAXIMUM QUANTITY AND CLIN ORDER VALUE

The minimum quantity and order value for the given Delivery/Task Order issued for this CLIN shall not be less than the minimum quantity and order value stated in the following table. The maximum quantity and order value for the given Delivery/Task Order issued for this CLIN shall not exceed the maximum quantity and order value stated in the following table.

MINIMUM	MAXIMUM	MAXIMUM
AMOUNT	QUANTITY	AMOUNT
\$		\$
\$		S
	AMOUNT	AMOUNT QUANTITY

Statement of Work Manufacture of Lateral Flow Immunoassays for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) For Defense Biological Product Assurance Office (DBPAO)

- 1.0 Scope. The scope of this work includes all activities required for a SARS-CoV-2 lateral flow immunoassay (LFI) test system, including the optimization and production of antigen screening test and all verification, validation, and regulatory activities required to achieve Food and Drug Administration (FDA) Emergency Use Authorization (EUA). Although, FDA Licensure is anticipated, it is not part of this effort. The end product shall be suitable as an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 virus in specimens from infected persons or persons suspected of exposure to SARS-CoV-2 and shall be intended for use at the point of care. The determination of an FDA sponsor will be reviewed during the ordering period.
- 2.0 Background. The DBPAO was established in 1997 by the Joint Program Executive Office Chemical Biological Radiological Nuclear Defense (JPEO-CBRND) to support the need for an integrated biological defense capability. The DBPAO serves as the principal source of high quality validated and standardized biological reference materials, reagents and assays that meet the technology development and sustainment needs of the Department of Defense (DoD) and its partners. The DBPAO facilitates the transition of new technologies and coordinates their advanced development, efficient production and timely distribution.

DBPAO has been tasked by the Acting Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight (HRP&O) to support SARS-CoV-2 response by rapidly developing and distributing antigen detection immunoassays that will serve as a screening test for the novel coronavirus, SARS-CoV-2. These screening tests will be used by DoD civilians and service members, medical healthcare workers at military health facilities and other health agencies.

- 3.0 Requirements
- 3.1 Manufacturing Facility
- 3.1.1 Have manufacturing yield sufficient to meet Government delivery order requirements of up to 1,000,000 kits per month (250,000 per week) specifically 5,000 kits/week by 15 May 2020, scalable to 250,000 kits/week by 15 July 2020. This quantity shall not include kits intended for third party conformance testing and contractor's internal testing.

- 3.1.2 Inventory management procedures to store antigens, antibodies and assays under the appropriate storage conditions as required by the label to maximize performance integrity and shelf life.
- 3.1.3 Security monitoring, temperature and humidity controlled for production area, with appropriate BioSafety Level and storage areas for assay materials including emergency backup power.
- 3.1.4 Standard Operating Procedures for all procedures associated with manufacturing, storage, and shipping of SARS-CoV-2 kits to assure compliance with contractual requirements and all local, state, and federal regulations and Standards.
 - 3.3 SARS-CoV-2 Lateral Flow Immunoassay Kit
 - 3.3.1 Deliverables
 - 3.3.1.1 SARS-CoV-2 LFI kits for the detection of SARS-CoV-2 virus, nasal swabs and appropriate clinical buffer labeled in accordance with Research Only Use (ROU) or as a EUA once approved. These kits shall be delivered while maintaining product integrity.
 - 3.3.1.2 Certificate of Conformance that includes specifications and results of internal conformance testing with each manufacturing lot of SARS-CoV-2 LFI kits.
 - 3.3.2 Reagents
- 3.3.2.1 The Contractor shall be responsible for the production or procurement of the reagents required for the manufacture of this SARS-CoV-2 LFI kit such as recombinant viral capsid proteins; capture and detector antibodies, secondary antibodies, reference standards, near neighbor panel for specificity testing, negative controls etc. The government will not provide these reagents as government furnished materials.
- 3.3.2.2 The Contractor shall assume all risks and responsibilities in connection with the handling, storage, disposal, transfer, and use of the assay materials including appropriate safety and handling precautions to minimize health or environmental risk. The Contractor shall agree that any activity undertaken with the manufacture of this assay will be conducted in compliance with all applicable guidelines, laws and regulations, including Department of Defense Instruction 5210.89 (DoDI 5210.89) for DoD recipients.

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
0002	Destination	Government	Destination	Government

CLAUSES INCORPORATED BY REFERENCE

52.246-2	Inspection Of SuppliesFixed Price	AUG 1996
52.246-16	Responsibility For Supplies	APR 1984

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	POP 29-MAY-2020 TO 28-MAY-2021	N/A	N/A FOB: Destination	
0002	POP 29-MAY-2020 TO 28-MAY-2021	N/A	N/A FOB: Destination	

CLAUSES INCORPORATED BY REFERENCE

52.242-15	Stop-Work Order	AUG 1989
52.247-34	F.O.B. Destination	NOV 1991

DELIVERY DATE INFORMATION

Delivery of CLIN 0001 end items shall be 180 days After Receipt of Order, unless a different delivery schedule is agreed to by the contractor and DBPAO.

ORDERING PERIODS

The Period of Performances cited above represent the dates which supplies can be ordered. Each Delivery Order shall specify the delivery date and delivery location.

CLAUSES INCORPORATED BY REFERENCE

252.232-7003 Electronic Submission of Payment Requests and Receiving DEC 2018 Reports

CLAUSES INCORPORATED BY FULL TEXT

252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (DEC 2018)

- (a) Definitions. As used in this clause—
- "Department of Defense Activity Address Code (DoDAAC)" is a six position code that uniquely identifies a unit, activity, or organization.
- "Document type" means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).
- "Local processing office (LPO)" is the office responsible for payment certification when payment certification is done external to the entitlement system.
- "Payment request" and "receiving report" are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.
- (b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.
- (c) WAWF access. To access WAWF, the Contractor shall-
- (1) Have a designated electronic business point of contact in the System for Award Management at https://www.sam.gov; and
- (2) Be registered to use WAWF at https://wawf.eb mil/ following the step-by-step procedures for self-registration available at this web site.
- (d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at https://wawf.eb.mil/.
- (e) WAWF methods of document submission. Document submissions may be via web entry, Electronic Data Interchange, or File Transfer Protocol.
- (f) WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:
- (1) Document type. The Contractor shall submit payment requests using the following document type(s):

- (i) For cost-type line items, including labor-hour or time-and-materials, submit a cost voucher.
- (ii) For fixed price line items-
- (A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.

COMBO

- (B) For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.
- (iii) For customary progress payments based on costs incurred, submit a progress payment request.
- (iv) For performance based payments, submit a performance based payment request.
- (v) For commercial item financing, submit a commercial item financing request.
- (2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.

[Note: The Contractor may use a WAWF "combo" document type to create some combinations of invoice and receiving report in one step.]

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table*

Field Name in WAWF	Data to be entered in WAWF
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W911QY
Admin DoDAAC**	W911QY
Inspect By DoDAAC	W56XNH
Ship To Code	W56XNH

- (4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.
- (5) Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.
- (g) WAWF point of contact.
- The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.



(2) Contact the WAWF helpdesk at 866-618-5988, if assistance is needed.

(End of clause)

Section H - Special Contract Requirements

MOST FAVORED CUSTOMER

H.1 Most Favored Customer

- A. Awardee agrees that during the term of this contract and for a period of 5 years thereafter, that it shall not offer, sell or otherwise provide the production model of the CLIN 0001 end items (for the avoidance of doubt, CLIN 0001 end items in this clause shall mean a finished good of like material, like quality, to be used in a similar applications, and shall not include more general products to any entity at a price lower than that offered to the DoD. In the event that Awardee sells the production model at a lower unit price than that price sold to the DoD, Awardee shall immediately notify the Contracting Officer in writing of the lower price. For prior purchases, the Awardee shall reimburse the DoD, the difference between the lower price sold to the other customer(s) and the price sold to the DoD multiplied by the number of items sold. Such reimbursement shall occur within thirty days (30) of the Awardee discovering that the lower price was given to another customer. Notwithstanding the foregoing, the Parties may agree to apply the difference in price paid by the other customer(s) and DoD into additional quantities required by the DoD.
- B. If Awardee develops a like product (commercialized version or derivative of the production model) with similar capability and intended application, but at a lower unit price (""Like Product"") regardless of quantity, Awardee shall make the DoD aware of that similar product and the technical and price differences between that product and the DoD Product. Such notification shall be made to the Contracting Officer in writing, of which email is an acceptable form, within thirty (30) days of such offering. Awardee agrees that no entity shall receive a lower price for any Like Product than the DoD for like purchase quantities.

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.202-1	Definitions	NOV 2013
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	MAY 2014
52.203-6	Restrictions On Subcontractor Sales To The Government	SEP 2006
52.203-7	Anti-Kickback Procedures	MAY 2014
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal of	
32.203-6	Improper Activity	11VIA 1 2014
52.203-10	Price Or Fee Adjustment For Illegal Or Improper Activity	MAY 2014
52.203-12	Limitation On Payments To Influence Certain Federal	OCT 2010
	Transactions	
52.203-13	Contractor Code of Business Ethics and Conduct	OCT 2015
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber	MAY 2011
	Content Paper	
52.204-10	Reporting Executive Compensation and First-Tier	OCT 2018
	Subcontract Awards	
52.204-19	Incorporation by Reference of Representations and	DEC 2014
	Certifications.	
52.204-23	Prohibition on Contracting for Hardware, Software, and	JUL 2018
	Services Developed or Provided by Kaspersky Lab and Other	r
	Covered Entities.	
52.204-25	Prohibition on Contracting for Certain Telecommunications	AUG 2019
	and Video Surveillance Services or Equipment.	
52.209-6	Protecting the Government's Interest When Subcontracting	OCT 2015
	With Contractors Debarred, Suspended, or Proposed for	
	Debarment	
52.209-9	Updates of Publicly Available Information Regarding	OCT 2018
	Responsibility Matters	
52.209-10	Prohibition on Contracting With Inverted Domestic	NOV 2015
	Corporations	
52.211-5	Material Requirements	AUG 2000
52.215-2	Audit and RecordsNegotiation	OCT 2010
52.215-8	Order of PrecedenceUniform Contract Format	OCT 1997
52.215-11	Price Reduction for Defective Certified Cost or Pricing Data-	- AUG 2011
	Modifications	
52.215-12	Subcontractor Certified Cost or Pricing Data	OCT 2010
52.215-13	Subcontractor Certified Cost or Pricing DataModifications	OCT 2010
52.215-14	Integrity of Unit Prices	OCT 2010
52.215-19	Notification of Ownership Changes	OCT 1997
52.215-23	Limitations on Pass-Through Charges	OCT 2009
52.216-7	Allowable Cost And Payment	AUG 2018
52.219-8	Utilization of Small Business Concerns	OCT 2018
52.219-14	Limitations On Subcontracting	MAR 2020
52.219-28	Post-Award Small Business Program Rerepresentation	MAY 2020
52.222-19	Child Labor Cooperation with Authorities and Remedies	JAN 2020
52.222-20	Contracts for Materials, Supplies, Articles, and Equipment	MAY 2014
	Exceeding \$15,000	
52.222-21	Prohibition Of Segregated Facilities	APR 2015
52.222-35	Equal Opportunity for Veterans	OCT 2015
52.222-36	Equal Opportunity for Workers with Disabilities	JUL 2014
52.222-37	Employment Reports on Veterans	FEB 2016

52.222-40	Notification of Employee Rights Under the National Labor Relations Act	DEC 2010
52.222-50	Combating Trafficking in Persons	JAN 2019
52.222-54	Employment Eligibility Verification	OCT 2015
52.223-6	Drug-Free Workplace	MAY 2001
52.223-9	Estimate of Percentage of Recovered Material Content for	MAY 2008
	EPA-Designated Items	
52.223-18	Encouraging Contractor Policies To Ban Text Messaging While Driving	AUG 2011
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.227-1	Authorization and Consent	DEC 2007
52.227-11	Patent RightsOwnership By The Contractor	MAY 2014
52.229-3	Federal, State And Local Taxes	FEB 2013
52.232-8	Discounts For Prompt Payment	FEB 2002
52.232-9	Limitation On Withholding Of Payments	APR 1984
52.232-11	Extras	APR 1984
52.232-17	Interest	MAY 2014
52.232-20	Limitation Of Cost	APR 1984
52.232-22	Limitation Of Funds	APR 1984
52.232-25	Prompt Payment	JAN 2017
52.232-33	Payment by Electronic Funds TransferSystem for Award	OCT 2018
32.232-33	Management	001 2010
52.233-1	Disputes	MAY 2014
52.233-3	Protest After Award	AUG 1996
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.242-13	Bankruptcy	JUL 1995
52.243-1	ChangesFixed Price	AUG 1987
52.244-5	Competition In Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	AUG 2019
52.245-1	Government Property	JAN 2017
52.246-23	Limitation Of Liability	FEB 1997
52.249-2	Termination For Convenience Of The Government (Fixed-	APR 2012
	Price)	AFK 2012
52.249-8	Default (Fixed-Price Supply & Service)	APR 1984
52.253-1	Computer Generated Forms	JAN 1991
252.201-7000	Contracting Officer's Representative	DEC 1991
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	SEP 2011
252.203-7002	Requirement to Inform Employees of Whistleblower Rights	SEP 2013
252.203-7003	Agency Office of the Inspector General	AUG 2019
252.203-7004	Display of Hotline Posters	AUG 2019
252.204-7000	Disclosure Of Information	OCT 2016
252.204-7003	Control Of Government Personnel Work Product	APR 1992
252.204-7006	Billing Instructions	OCT 2005
252.204-7012	Safeguarding Covered Defense Information and Cyber	DEC 2019
	Incident Reporting	
252.211-7003	Item Unique Identification and Valuation	MAR 2016
252.222-7006	Restrictions on the Use of Mandatory Arbitration Agreements	DEC 2010
252.223-7001	Hazard Warning Labels	DEC 1991
252.225-7012	Preference For Certain Domestic Commodities	DEC 2017
252.225-7048	Export-Controlled Items	JUN 2013
252.226-7001	Utilization of Indian Organizations and Indian-Owned	APR 2019
	Economic Enterprises, and Native Hawaiian Small Business	
	Concerns	
252.227-7016	Rights in Bid or Proposal Information	JAN 2011

252.227-7030	Technical DataWithholding Of Payment	MAR 2000
252.227-7037	Validation of Restrictive Markings on Technical Data	SEP 2016
252.227-7039	PatentsReporting Of Subject Inventions	APR 1990
252.231-7000	Supplemental Cost Principles	DEC 1991
252.232-7007	Limitation Of Government's Obligation	APR 2014
252.232-7010	Levies on Contract Payments	DEC 2006
252.235-7010	Acknowledgment of Support and Disclaimer	MAY 1995
252.243-7001	Pricing Of Contract Modifications	DEC 1991
252.243-7002	Requests for Equitable Adjustment	DEC 2012
252.244-7000	Subcontracts for Commercial Items	JUN 2013
252.246-7001	Warranty Of Data	MAR 2014
252.247-7023	Transportation of Supplies by Sea	FEB 2019

CLAUSES INCORPORATED BY FULL TEXT

52.216-18 ORDERING. (OCT 1995)

- (a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from 29 May 2020 through 28 May 2021.
- (b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.
- (c) If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

(End of clause)

52.216-19 ORDER LIMITATIONS (OCT 1995)

- (a) Minimum order. When the Government requires supplies or services covered by this contract in an amount of less than \$10,000, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.
- (b) Maximum order. The Contractor is not obligated to honor -
- (1) Any order for a single item in excess of the maximum quantities stated in Section B;
- (2) Any order for a combination of items in excess of the maximum quantities stated in Section B; or
- (3) A series of orders from the same ordering office within 60 days that together call for quantities exceeding the limitation in paragraph (b) (1) or (2) of this section.
- (c) If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) of this section.
- (d) Notwithstanding paragraphs (b) and (c) of this section, the Contractor shall honor any order exceeding the

maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within 5 days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

(End of clause)

52.216-22 INDEFINITE QUANTITY. (OCT 1995)

- (a) This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.
- (b) Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum". The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum".
- (c) Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.
- (d) Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after 28 May 2021.

(End of clause)

52.228-7 INSURANCE--LIABILITY TO THIRD PERSONS (MAR 1996)

- (a)(1) Except as provided in subparagraph (a)(2) of this clause, the Contractor shall provide and maintain workers' compensation, employer's liability, comprehensive general liability (bodily injury), comprehensive automobile liability (bodily injury and property damage) insurance, and such other insurance as the Contracting Officer may require under this contract.
- (2) The Contractor may, with the approval of the Contracting Officer, maintain a self-insurance program; provided that, with respect to workers' compensation, the Contractor is qualified pursuant to statutory authority.
- (3) All insurance required by this paragraph shall be in a form and amount and for those periods as the Contracting Officer may require or approve and with insurers approved by the Contracting Officer.
- (b) The Contractor agrees to submit for the Contracting Officer's approval, to the extent and in the manner required by the Contracting Officer, any other insurance that is maintained by the Contractor in connection with the performance of this contract and for which the Contractor seeks reimbursement.
- (c) The Contractor shall be reimbursed—

- (1) For that portion (i) of the reasonable cost of insurance allocable to this contract, and (ii) required or approved under this clause; and
- (2) For certain liabilities (and expenses incidental to such liabilities) to third persons not compensated by insurance or otherwise without regard to and as an exception to the limitation of cost or the limitation of funds clause of this contract. These liabilities must arise out of the performance of this contract, whether or not caused by the negligence of the Contractor or of the Contractor's agents, servants, or employees, and must be represented by final judgments or settlements approved in writing by the Government. These liabilities are for--
- (i) Loss of or damage to property (other than property owned, occupied, or used by the Contractor, rented to the Contractor, or in the care, custody, or control of the Contractor); or
- (ii) Death or bodily injury.
- (d) The Government's liability under paragraph (c) of this clause is subject to the availability of appropriated funds at the time a contingency occurs. Nothing in this contract shall be construed as implying that the Congress will, at a later date, appropriate funds sufficient to meet deficiencies.
- (e) The Contractor shall not be reimbursed for liabilities (and expenses incidental to such liabilities)--
- (1) For which the Contractor is otherwise responsible under the express terms of any clause specified in the Schedule or elsewhere in the contract;
- (2) For which the Contractor has failed to insure or to maintain insurance as required by the Contracting Officer; or
- (3) That result from willful misconduct or lack of good faith on the part of any of the Contractor's directors, officers, managers, superintendents, or other representatives who have supervision or direction of--
- (i) All or substantially all of the Contractor's business;
- (ii) All or substantially all of the Contractor's operations at any one plant or separate location in which this contract is being performed; or
- (iii) A separate and complete major industrial operation in connection with the performance of this contract.
- (f) The provisions of paragraph (e) of this clause shall not restrict the right of the Contractor to be reimbursed for the cost of insurance maintained by the Contractor in connection with the performance of this contract, other than insurance required in accordance with this clause; provided, that such cost is allowable under the Allowable Cost and Payment clause of this contract.
- (g) If any suit or action is filed or any claim is made against the Contractor, the cost and expense of which may be reimbursable to the Contractor under this contract, and the risk of which is then uninsured or is insured for less than the amount claimed, the Contractor shall--
- (1) Immediately notify the Contracting Officer and promptly furnish copies of all pertinent papers received;
- (2) Authorize Government representatives to collaborate with counsel for the insurance carrier in settling or defending the claim when the amount of the liability claimed exceeds the amount of coverage; and
- (3) Authorize Government representatives to settle or defend the claim and to represent the Contractor in or to take charge of any litigation, if required by the Government, when the liability is not insured or covered by bond. The Contractor may, at its own expense, be associated with the Government representatives in any such claim or litigation.

(End of clause)

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

https://www.acquisition.gov/content/regulations https://www.acquisition.gov/

(End of clause)

252.216-7006 ORDERING (SEP 2019)

- (a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the contract schedule. Such orders may be issued from 29 May 2020 through 28 May 2021.
- (b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.
- (c)(1) If issued electronically, the order is considered ``issued" when a copy has been posted to the Electronic Data Access system, and notice has been sent to the Contractor.
- (2) If mailed or transmitted by facsimile, a delivery order or task order is considered ``issued" when the Government deposits the order in the mail or transmits by facsimile. Mailing includes transmittal by U.S. mail or private delivery services.
- (3) Orders may be issued orally only if authorized in the schedule.

(End of Clause)

252.227-7013 RIGHTS IN TECHNICAL DATA--NONCOMMERCIAL ITEMS (FEB 2014)

- (a) Definitions. As used in this clause--
- (1) Computer data base means a collection of data recorded in a form capable of being processed by a computer. The term does not include computer software.
- (2) Computer program means a set of instructions, rules, or routines recorded in a form that is capable of causing a computer to perform a specific operation or series of operations.
- (3) Computer software means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated, or recompiled. Computer software does not include computer data bases or computer software documentation.

- (4) Computer software documentation means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.
- (5) Covered Government support contractor means a contractor (other than a litigation support contractor covered by 252.204-7014) under a contract, the primary purpose of which is to furnish independent and impartial advice or technical assistance directly to the Government in support of the Government's management and oversight of a program or effort (rather than to directly furnish an end item or service to accomplish a program or effort), provided that the contractor--
- (i) Is not affiliated with the prime contractor or a first-tier subcontractor on the program or effort, or with any direct competitor of such prime contractor or any such first-tier subcontractor in furnishing end items or services of the type developed or produced on the program or effort; and
- (ii) Receives access to technical data or computer software for performance of a Government contract that contains the clause at 252.227-7025, Limitations on the Use or Disclosure of Government-Furnished Information Marked with Restrictive Legends.
- (6) Detailed manufacturing or process data means technical data that describe the steps, sequences, and conditions of manufacturing, processing or assembly used by the manufacturer to produce an item or component or to perform a process.
- (7) Developed means that an item, component, or process exists and is workable. Thus, the item or component must have been constructed or the process practiced. Workability is generally established when the item, component, or process has been analyzed or tested sufficiently to demonstrate to reasonable people skilled in the applicable art that there is a high probability that it will operate as intended. Whether, how much, and what type of analysis or testing is required to establish workability depends on the nature of the item, component, or process, and the state of the art. To be considered "developed," the item, component, or process need not be at the stage where it could be offered for sale or sold on the commercial market, nor must the item, component, or process be actually reduced to practice within the meaning of Title 35 of the United States Code.
- (8) Developed exclusively at private expense means development was accomplished entirely with costs charged to indirect cost pools, costs not allocated to a government contract, or any combination thereof.
- (i) Private expense determinations should be made at the lowest practicable level.
- (ii) Under fixed-price contracts, when total costs are greater than the firm-fixed-price or ceiling price of the contract, the additional development costs necessary to complete development shall not be considered when determining whether development was at government, private, or mixed expense.
- (9) Developed exclusively with government funds means development was not accomplished exclusively or partially at private expense.
- (10) Developed with mixed funding means development was accomplished partially with costs charged to indirect cost pools and/or costs not allocated to a government contract, and partially with costs charged directly to a government contract.
- (11) Form, fit, and function data means technical data that describes the required overall physical, functional, and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.
- (12) Government purpose means any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations, or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive

procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose technical data for commercial purposes or authorize others to do so.

- (13) Government purpose rights means the rights to--
- (i) Use, modify, reproduce, release, perform, display, or disclose technical data within the Government without restriction; and
- (ii) Release or disclose technical data outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that data for United States government purposes.
- (14) Limited rights means the rights to use, modify, reproduce, release, perform, display, or disclose technical data, in whole or in part, within the Government. The Government may not, without the written permission of the party asserting limited rights, release or disclose the technical data outside the Government, use the technical data for manufacture, or authorize the technical data to be used by another party, except that the Government may reproduce, release, or disclose such data or authorize the use or reproduction of the data by persons outside the Government if-
- (i) The reproduction, release, disclosure, or use is--
- (A) Necessary for emergency repair and overhaul; or
- (B) A release or disclosure to--
- (1) A covered Government support contractor in performance of its covered Government support contract for use, modification, reproduction, performance, display, or release or disclosure to a person authorized to receive limited rights technical data; or
- (2) A foreign government, of technical data other than detailed manufacturing or process data, when use of such databy the foreign government is in the interest of the Government and is required for evaluational or informational purposes;
- (ii) The recipient of the technical data is subject to a prohibition on the further reproduction, release, disclosure, or use of the technical data; and
- (iii) The contractor or subcontractor asserting the restriction is notified of such reproduction, release, disclosure, or use.
- (15) Technical data means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.
- (16) Unlimited rights means rights to use, modify, reproduce, perform, display, release, or disclose technical data in whole or in part, in any manner, and for any purpose whatsoever, and to have or authorize others to do so.
- (b) Rights in technical data. The Contractor grants or shall obtain for the Government the following royalty free, world-wide, nonexclusive, irrevocable license rights in technical data other than computer software documentation (see the Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation clause of this contract for rights in computer software documentation):
- (1) Unlimited rights.

The Government shall have unlimited rights in technical data that are-

- (i) Data pertaining to an item, component, or process which has been or will be developed exclusively with Government funds;
- (ii) Studies, analyses, test data, or similar data produced for this contract, when the study, analysis, test, or similar work was specified as an element of performance;
- (iii) Created exclusively with Government funds in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes;
- (iv) Form, fit, and function data;
- (v) Necessary for installation, operation, maintenance, or training purposes (other than detailed manufacturing or process data);
- (vi) Corrections or changes to technical data furnished to the Contractor by the Government;
- (vii) Otherwise publicly available or have been released or disclosed by the Contractor or subcontractor without restrictions on further use, release or disclosure, other than a release or disclosure resulting from the sale, transfer, or other assignment of interest in the technical data to another party or the sale or transfer of some or all of a business entity or its assets to another party;
- (viii) Data in which the Government has obtained unlimited rights under another Government contract or as a result of negotiations; or
- (ix) Data furnished to the Government, under this or any other Government contract or subcontract thereunder, with-
- (A) Government purpose license rights or limited rights and the restrictive condition(s) has/have expired; or
- (B) Government purpose rights and the Contractor's exclusive right to use such data for commercial purposes has expired.
- (2) Government purpose rights.
- (i) The Government shall have government purpose rights for a five-year period, or such other period as may be negotiated, in technical data--
- (A) That pertain to items, components, or processes developed with mixed funding except when the Government is entitled to unlimited rights in such data as provided in paragraphs as provided in paragraphs (b)(1)(ii) and (b)(1)(iv) through (b)(1)(ix) of this clause; or
- (B) Created with mixed funding in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes.
- (ii) The five-year period, or such other period as may have been negotiated, shall commence upon execution of the contract, subcontract, letter contract (or similar contractual instrument), contract modification, or option exercise that required development of the items, components, or processes or creation of the data described in paragraph (b)(2)(i)(B) of this clause. Upon expiration of the five-year or other negotiated period, the Government shall have unlimited rights in the technical data.
- (iii) The Government shall not release or disclose technical data in which it has government purpose rights unless-
- (A) Prior to release or disclosure, the intended recipient is subject to the non-disclosure agreement at 227.7103-7 of the Defense Federal Acquisition Regulation Supplement (DFARS); or

- (B) The recipient is a Government contractor receiving access to the data for performance of a Government contract that contains the clause at DFARS 252.227-7025, Limitations on the Use or Disclosure of Government-Furnished Information Marked with Restrictive Legends.
- (iv) The Contractor has the exclusive right, including the right to license others, to use technical data in which the Government has obtained government purpose rights under this contract for any commercial purpose during the time period specified in the government purpose rights legend prescribed in paragraph (f)(2) of this clause.
- (3) Limited rights.
- (i) Except as provided in paragraphs (b)(1)(ii) and (b)(1)(iv) through (b)(1)(ix) of this clause, the Government shall have limited rights in technical data--
- (A) Pertaining to items, components, or processes developed exclusively at private expense and marked with the limited rights legend prescribed in paragraph (f) of this clause; or
- (B) Created exclusively at private expense in the performance of a contract that does not require the development, manufacture, construction, or production of items, components, or processes.
- (ii) The Government shall require a recipient of limited rights data for emergency repair or overhaul to destroy the data and all copies in its possession promptly following completion of the emergency repair/overhaul and to notify the Contractor that the data have been destroyed.
- (iii) The Contractor, its subcontractors, and suppliers are not required to provide the Government additional rights to use, modify, reproduce, release, perform, display, or disclose technical data furnished to the Government with limited rights. However, if the Government desires to obtain additional rights in technical data in which it has limited rights, the Contractor agrees to promptly enter into negotiations with the Contracting Officer to determine whether there are acceptable terms for transferring such rights. All technical data in which the Contractor has granted the Government additional rights shall be listed or described in a license agreement made part of the contract. The license shall enumerate the additional rights granted the Government in such data.
- (iv) The Contractor acknowledges that--
- (A) Limited rights data are authorized to be released or disclosed to covered Government support contractors;
- (B) The Contractor will be notified of such release or disclosure;
- (C) The Contractor (or the party asserting restrictions as identified in the limited rights legend) may require each such covered Government support contractor to enter into a non-disclosure agreement directly with the Contractor (or the party asserting restrictions) regarding the covered Government support contractor's use of such data, or alternatively, that the Contractor (or party asserting restrictions) may waive in writing the requirement for a non-disclosure agreement; and
- (D) Any such non-disclosure agreement shall address the restrictions on the covered Government support contractor's use of the limited rights data as set forth in the clause at 252.227-7025, Limitations on the Use or Disclosure of Government-Furnished Information Marked with Restrictive Legends. The non-disclosure agreement shall not include any additional terms and conditions unless mutually agreed to by the parties to the non-disclosure agreement.
- (E) The Contractor shall provide a copy of any such non-disclosure agreement or waiver to the Contracting Officer, upon request.
- (4) Specifically negotiated license rights.

The standard license rights granted to the Government under paragraphs (b)(1) through (b)(3) of this clause, including the period during which the Government shall have government purpose rights in technical data, may be modified by mutual agreement to provide such rights as the parties consider appropriate but shall not provide the Government lesser rights than are enumerated in paragraph (a)(14) of this clause. Any rights so negotiated shall be identified in a license agreement made part of this contract.

(5) Prior government rights.

Technical data that will be delivered, furnished, or otherwise provided to the Government under this contract, in which the Government has previously obtained rights shall be delivered, furnished, or provided with the pre-existing rights, unless--

- (i) The parties have agreed otherwise; or
- (ii) Any restrictions on the Government's rights to use, modify, reproduce, release, perform, display, or disclose the data have expired or no longer apply.
- (6) Release from liability.

The Contractor agrees to release the Government from liability for any release or disclosure of technical data made in accordance with paragraph (a)(14) or (b)(2)(iii) of this clause, in accordance with the terms of a license negotiated under paragraph (b)(4) of this clause, or by others to whom the recipient has released or disclosed the data and to seek relief solely from the party who has improperly used, modified, reproduced, released, performed, displayed, or disclosed Contractor data marked with restrictive legends.

- (c) Contractor rights in technical data. All rights not granted to the Government are retained by the Contractor.
- (d) Third party copyrighted data. The Contractor shall not, without the written approval of the Contracting Officer, incorporate any copyrighted data in the technical data to be delivered under this contract unless the Contractor is the copyright owner or has obtained for the Government the license rights necessary to perfect a license or licenses in the deliverable data of the appropriate scope set forth in paragraph (b) of this clause, and has affixed a statement of the license or licenses obtained on behalf of the Government and other persons to the data transmittal document.
- (e) Identification and delivery of data to be furnished with restrictions on use, release, or disclosure. (1) This paragraph does not apply to restrictions based solely on copyright.
- (2) Except as provided in paragraph (e)(3) of this clause, technical data that the Contractor asserts should be furnished to the Government with restrictions on use, release, or disclosure are identified in an attachment to this contract (the Attachment). The Contractor shall not deliver any data with restrictive markings unless the data are listed on the Attachment.
- (3) In addition to the assertions made in the Attachment, other assertions may be identified after award when based on new information or inadvertent omissions unless the inadvertent omissions would have materially affected the source selection decision. Such identification and assertion shall be submitted to the Contracting Officer as soon as practicable prior to the scheduled date for delivery of the data, in the following format, and signed by an official authorized to contractually obligate the Contractor: Identification and Assertion of Restrictions on the Government's Use, Release, or Disclosure of Technical Data.

The Contractor asserts for itself, or the persons identified below, that the Government's rights to use, release, or disclose the following technical data should be restricted--

			Page 23 G	SI 27
(LIST)	(LIST)	(LIST)	(LIST)	
	is applicable to items, con items, component, or pro		reloped at private expense, identify both th	e
is the only basis for pertaining to such private expense. It	or asserting restrictions on items, components, or pro	the Government's rights to ocesses. Indicate whether of	rivate expense, either exclusively or partial ouse, release, or disclose technical data development was exclusively or partially a specific reason for asserting that the	
	nother contract, limited or		ghts from a prior contract, rights in SBIR d is under this or a prior contract, or specific	
	ndividual, or other person,			
Printed Name and	Title			
Signature				
(End of identificat	ion and assertion)			
Contracting Office Contractor's assert	er to evaluate the Contract	or's assertions. The Contra d validate any listed assert	rovide sufficient information to enable the acting Officer reserves the right to add the tion, at a later date, in accordance with the ta clause of this contract.	
Government's right under this contract this clause, only the paragraph (f)(2) of	ats to use, modify, reprodu t by marking the deliverab ne following legends are an f this clause; the limited ri	ce, release, perform, displused to restriction the data subject to restriction thorized under this contraghts legend at paragraph (appliers, may only assert restrictions on the ay, or disclose technical data to be delivered on. Except as provided in paragraph (f)(5) eact: the government purpose rights legend of f)(3) of this clause; or the special license rights prescribed under 17 U.S.C. 401 or 402.	ed of at
mark the appropri placed on the trans containing technic subject to the asse appropriate identific contain a notice of	ate legend on all technical smittal document or storag cal data for which restriction rted restrictions, such port fier. Technical data transm	data that qualify for such ge container and, for printe ons are asserted. When onlions shall be identified by aitted directly from one corroductions of technical da	s or suppliers, shall conspicuously and legi markings. The authorized legends shall be ed material, each page of the printed material by portions of a page of printed material are circling, underscoring, with a note, or other mputer or computer terminal to another shall ta or any portions thereof subject to asserts	ial e er all
(2) Government pr shall be marked as		ata delivered or otherwise	furnished to the Government purpose righ	ts
Government Purp	ose Rights			
Contract No.				

Contractor Name
Contractor Address
Expiration Date
The Government's rights to use, modify, reproduce, release, perform, display, or disclose these technical data are restricted by paragraph (b)(2) of the Rights in Technical DataNoncommercial Items clause contained in the above identified contract. No restrictions apply after the expiration date shown above. Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings.
(End of legend)
(3) Limited rights markings. Data delivered or otherwise furnished to the Government with limited rights shall be marked with the following legend:
Limited Rights
Contract No
Contractor Name
Contractor Address
The Government's rights to use, modify, reproduce, release, perform, display, or disclose these technical data are restricted by paragraph (b)(3) of the Rights in Technical DataNoncommercial Items clause contained in the above identified contract. Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings. Any person, other than the Government, who has been provided access to such data must promptly notify the above named Contractor.
(End of legend)
(4) Special license rights markings. (i) Data in which the Government's rights stem from a specifically negotiated license shall be marked with the following legend:
Special License Rights
The Government's rights to use, modify, reproduce, release, perform, display, or disclose these data are restricted by Contract No (Insert contract number), License No (Insert license identifier) Any reproduction of technical data or portions thereof marked with this legend must also reproduce the markings.
(End of legend)
(ii) For purposes of this clause, special licenses do not include government purpose license rights acquired under a prior contract (see paragraph (b)(5) of this clause).
(5) Pre-existing data markings. If the terms of a prior contract or license permitted the Contractor to restrict the

Government's rights to use, modify, reproduce, release, perform, display, or disclose technical data deliverable under this contract, and those restrictions are still applicable, the Contractor may mark such data with the appropriate

restrictive legend for which the data qualified under the prior contract or license. The marking procedures in paragraph (f)(1) of this clause shall be followed.

- (g) Contractor procedures and records. Throughout performance of this contract, the Contractor and its subcontractors or suppliers that will deliver technical data with other than unlimited rights, shall--
- (1) Have, maintain, and follow written procedures sufficient to assure that restrictive markings are used only when authorized by the terms of this clause; and
- (2) Maintain records sufficient to justify the validity of any restrictive markings on technical data delivered under this contract.
- (h) Removal of unjustified and nonconforming markings. (1) Unjustified technical data markings. The rights and obligations of the parties regarding the validation of restrictive markings on technical data furnished or to be furnished under this contract are contained in the Validation of Restrictive Markings on Technical Data clause of this contract. Notwithstanding any provision of this contract concerning inspection and acceptance, the Government may ignore or, at the Contractor's expense, correct or strike a marking if, in accordance with the procedures in the Validation of Restrictive Markings on Technical Data clause of this contract, a restrictive marking is determined to be unjustified.
- (2) Nonconforming technical data markings. A nonconforming marking is a marking placed on technical data delivered or otherwise furnished to the Government under this contract that is not in the format authorized by this contract. Correction of nonconforming markings is not subject to the validation of Restrictive Markings on Technical Data clause of this contract. If the Contracting Officer notifies the Contractor of a nonconforming marking and the Contractor fails to remove or correct such marking within sixty (60) days, the Government may ignore or, at the Contractor's expense, remove or correct any nonconforming marking.
- (i) Relation to patents. Nothing contained in this clause shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right otherwise granted to the Government under any patent.
- (j) Limitation on charges for rights in technical data. (1) The Contractor shall not charge to this contract any cost, including, but not limited to, license fees, royalties, or similar charges, for rights in technical data to be delivered under this contract when--
- (i) The Government has acquired, by any means, the same or greater rights in the data; or
- (ii) The data are available to the public without restrictions.
- (2) The limitation in paragraph (j)(1) of this clause--
- (i) Includes costs charged by a subcontractor or supplier, at any tier, or costs incurred by the Contractor to acquire rights in subcontractor or supplier technical data, if the subcontractor or supplier has been paid for such rights under any other Government contract or under a license conveying the rights to the Government; and
- (ii) Does not include the reasonable costs of reproducing, handling, or mailing the documents or other media in which the technical data will be delivered.
- (k) Applicability to subcontractors or suppliers. (1) The Contractor shall ensure that the rights afforded its subcontractors and suppliers under 10 U.S.C. 2320, 10 U.S.C. 2321, and the identification, assertion, and delivery processes of paragraph (e) of this clause are recognized and protected.
- (2) Whenever any technical data for noncommercial items, or for commercial items developed in any part at Government expense, is to be obtained from a subcontractor or supplier for delivery to the Government under this contract, the Contractor shall use this same clause in the subcontract or other contractual instrument, including

subcontracts or other contractual instruments for commercial items, and requireits subcontractors or suppliers to do so, without alteration, except to identify the parties. This clause will govern the technical data pertaining to noncommercial items or to any portion of a commercial item that was developed in any part at Government expense, and the clause at 252.227-7015 will govern the technical data pertaining to any portion of a commercial item that was developed exclusively at private expense. No other clause shall be used to enlarge or diminish the Government's, the Contractor's, or a higher-tier subcontractor's or supplier's rights in a subcontractor's or supplier's technical data.

- (3) Technical data required to be delivered by a subcontractor or supplier shall normally be delivered to the next higher-tier contractor, subcontractor, or supplier. However, when there is a requirement in the prime contract for data which may be submitted with other than unlimited rights by a subcontractor or supplier, then said subcontractor or supplier may fulfill its requirement by submitting such data directly to the Government, rather than through a higher-tier contractor, subcontractor, or supplier.
- (4) The Contractor and higher-tier subcontractors or suppliers shall not use their power to award contracts as economic leverage to obtain rights in technical data from their subcontractors or suppliers. (5) In no event shall the Contractor use its obligation to recognize and protect subcontractor or supplier rights in technical data as an excuse for failing to satisfy its contractual obligations to the Government.

(End of clause)

Section J - List of Documents, Exhibits and Other Attachments

Attachment 1 Conformance Test Plan Attachment 2 Evaluation factors and rating criteria

			1. CONTRACT ID	CODE	PAGE OF PAGES
AMENDMENT OF SOLICIT	ATION/MODII	FICATION OF CONTRACT	J		1 5
2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5	. PROJECT	'NO.(Ifapplicable)
P00001	23-Jun-2020				
6. ISSUED BY CODE	W911QY	7. ADMINISTERED BY (Ifother than item6)	CODE	3	
W6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702		See Item 6			
8. NAME AND ADDRESS OF CONTRACTOR	(No. Street County	State and Zin Code)	9A. AMENDMEN	NT OF SO	LICITATION NO.
ANP TECHNOLOGIES, INC. 824 INTERCHANGE BLVD NEWARK DE 19711-3570	(1101, Breet, County,	- State and Esp code)	9B. DATED (SEE	EITEM 1	1)
		x	10A. MOD. OF CONTRACT/ORDER NO. W911QY20D0019		
			10B. DATED (S		
CODE 3AVW6	FACILITY CO	DE X	29-May-2020		
11.	THIS ITEM ONLY	APPLIES TO AMENDMENTS OF SOLICIT	TATIONS		
The above numbered solicitation is amended as set for Offer must acknowledge receipt of this amendment pri (a) By completing Items 8 and 15, and returning or (c) By separate letter or telegram which includes a received ATTHE PLACE DESIGNATED FOR TREJECTION OF YOUR OFFER. If by virtue of this a provided each telegramor letter makes reference to the 12. ACCOUNTING AND APPROPRIATION D	or to the hour and date spe copies of the amendme eference to the solicitation HE RECEIPT OF OFFERS mendment you desire to ch solicitation and this amen	cified in the solicitation or as amended by one of the int; (b) By acknowledging receipt of this amendment and amendment numbers. FAILURE OF YOUR ACT PRIOR TO THE HOUR AND DATE SPECIFIED Mange an offer already submitted, such change may be receipted.	on each copy of the offer KNOWLEDGMENT TO IAY RESULT IN made by telegramor lette) BE	ilacu.
12. ACCOUNTING AND APPROPRIATION D	ATA (II required)				
		TO MODIFICATIONS OF CONTRACTS/C CT/ORDER NO. AS DESCRIBED IN ITEM			
A. THIS CHANGE ORDER IS ISSUED PURS CONTRACT ORDER NO. IN ITEM 10A.	UANT TO: (Specify	authority) THE CHANGES SET FORTH IN	ITEM 14 ARE MA	ADE IN T	HE
B. THE ABOVE NUMBERED CONTRACT/0 office, appropriation date, etc.) SET FOR		TO REFLECT THE ADMINISTRATIVE SUANT TO THE AUTHORITY OF FAR		changes in	n paying
X C. THIS SUPPLEMENT AL AGREEMENT IS By mutual agreement of both parties.	S ENTERED INTO P	URSUANT TO AUTHORITY OF:			
D. OTHER (Specify type of modification and	authority)				
E. IMPORTANT: Contractor is not,	X is required to si	gn this document and return 1 co	opies to the issuing	office.	1
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: (b) (6) The purpose of this modification is to: 1) Add Firm Fixed Price CL N 0003 valued at (6) (4) meetings in support of Emergency Use Authorization (EUA), see paragraph 3.3.3. 2) Update Section J, Attachment 01 by replacing it in its entirety with Attachment 1, Conformance Testing Plan, dated 06 June 2020. All other terms and conditions remain the same and in full force and effect.					
Except as provided herein, all terms and conditions of the d	ocument referenced in Item	19A or 10A, as heretofore changed, remains unchange	ed and in full force and et	llect.	
15A. NAME AND TITLE OF SIGNER (Type or		16A. NAME AND TITLE OF CONT			or print)
		/CONTRACTING OFFICER TEL: (6)	EMAIL: (b) (6)		
15B. CONTRACT OR/OFFEROR	15C. DATE SIGNE				C. DATE SIGNED
(Signature of person authorized to sign)		(Signature of Contracting Office	er)	2	23-Jun-2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by \$5,096.00 from \$60,100,000.00 to \$60,105,096.00.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0003 is added as follows:

ITEM NO SUPPLIES/SERVICES MAX UNIT UNIT PRICE MAX AMOUNT

QUANTITY

0003 Each 5)(4)

\$5,096.00

Regulatory/EUA Meetings

FFP

Meetings to discuss regulatory requirements and Emergency Use Authorization, in accordance with Section C, Statement of Work (SOW), paragraph 3.3.3.

FOB: Destination MFR PART NR: TBD PSC CD: 6550

> MAX \$5,096.00 NET AMT

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:

Statement of Work Manufacture of Lateral Flow Immunoassays for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) For Defense Biological Product Assurance Office (DBPAO)

1.0 Scope. The scope of this work includes all activities required for a SARS-CoV-2 lateral flow immunoassay (LFI) test system, including the optimization and production of antigen screening test and all verification,

validation, and regulatory activities required to achieve Food and Drug Administration (FDA) Emergency Use Authorization (EUA). Although, FDA Licensure is anticipated, it is not part of this effort. The end product shall be suitable as an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 virus in specimens from infected persons or persons suspected of exposure to SARS-CoV-2 and shall be intended for use at the point of care. The determination of an FDA sponsor will be reviewed during the ordering period.

2.0 Background. The DBPAO was established in 1997 by the Joint Program Executive Office Chemical Biological Radiological Nuclear Defense (JPEO-CBRND) to support the need for an integrated biological defense capability. The DBPAO serves as the principal source of high quality validated and standardized biological reference materials, reagents and assays that meet the technology development and sustainment needs of the Department of Defense (DoD) and its partners. The DBPAO facilitates the transition of new technologies and coordinates their advanced development, efficient production and timely distribution.

DBPAO has been tasked by the Acting Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight (HRP&O) to support SARS-CoV-2 response by rapidly developing and distributing antigen detection immunoassays that will serve as a screening test for the novel coronavirus, SARS-CoV-2. These screening tests will be used by DoD civilians and service members, medical healthcare workers at military health facilities and other health agencies.

- 3.0 Requirements
- 3.1 Manufacturing Facility
- 3.1.1 Have manufacturing yield sufficient to meet Government delivery order requirements of up to 1,000,000 kits per month (250,000 per week) specifically 5,000 kits/week by 15 May 2020, scalable to 250,000 kits/week by 15 July 2020. This quantity shall not include kits intended for third party conformance testing and contractor's internal testing.
- 3.1.2 Inventory management procedures to store antigens, antibodies and assays under the appropriate storage conditions as required by the label to maximize performance integrity and shelf life.
- 3.1.3 Security monitoring, temperature and humidity controlled for production area, with appropriate BioSafety Level and storage areas for assay materials including emergency backup power.
- 3.1.4 Standard Operating Procedures for all procedures associated with manufacturing, storage, and shipping of SARS-CoV-2 kits to assure

compliance with contractual requirements and all local, state, and federal regulations and Standards.

- 3.3 SARS-CoV-2 Lateral Flow Immunoassay Kit
- 3.3.1 Deliverables
- 3.3.1.1 SARS-CoV-2 LFI kits for the detection of SARS-CoV-2 virus, nasal swabs and appropriate clinical buffer labeled in accordance with Research Only Use (ROU) or as a EUA once approved. These kits shall be delivered while maintaining product integrity.
- 3.3.1.2 Certificate of Conformance that includes specifications and results of internal conformance testing with each manufacturing lot of SARS-CoV-2 LFI kits.
- 3.3.2 Reagents
- 3.3.2.1 The Contractor shall be responsible for the production or procurement of the reagents required for the manufacture of this SARS-CoV-2 LFI kit such as recombinant viral capsid proteins; capture and detector antibodies, secondary antibodies, reference standards, near neighbor panel for specificity testing, negative controls etc. The government will not provide these reagents as government furnished materials.
- 3.3.2.2 The Contractor shall assume all risks and responsibilities in connection with the handling, storage, disposal, transfer, and use of the assay materials including appropriate safety and handling precautions to minimize health or environmental risk. The Contractor shall agree that any activity undertaken with the manufacture of this assay will be conducted in compliance with all applicable guidelines, laws and regulations, including Department of Defense Instruction 5210.89 (DoDI 5210.89) for DoD recipients.

3.3.3 Regulatory Work/Emergency Use Authorization

- 3.3.3.1 Perform work delineated below from 15 June 2020 to 26 June 2020:
- 3.3.3.2 Four (4) hours engagement with the Program Office and Government Regulatory Team (ONE-RAQA); Two one-hour meetings per week to analyze the Government Furnished Information (GFI).

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0003:

INSPECT AT INSPECT BY ACCEPT AT
Destination Government Destination

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for CLIN 0003 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC /
			CAGE

POP 23-JUN-2020 TO N/A N/A

26-JUN-2020 FOB: Destination

(End of Summary of Changes)

			1. CONTRACT ID O	CODE	PAGE OF PAGES
AMENDMENT OF SOLICIT	ATION/MODII	FICATION OF CONTRACT	J		1 4
2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.		PROJECT NO	.(Ifapplicable)
P00002	01-Jul-2020				(PF)
6. ISSUED BY CODE	W911QY	7. ADMINISTERED BY (If other than item 6)	CODE		
W6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702		See Item 6			
8. NAME AND ADDRESS OF CONTRACTOR	(No., Street, County,	State and Zip Code)	9A. AMENDMEN	T OF SOLIC	CITATION NO.
ANP TECHNOLOGIES, INC. 824 INTERCHANGE BLVD NEWARK DE 19711-3570	,		9B. DATED (SEE	9B. DATED (SEE ITEM 11)	
		×	10A. MOD. OF CO W911QY20D0019	10A. MOD. OF CONTRACT/ORDER NO. W911QY20D0019	
			10B. DATED (SE	E ITEM 13))
CODE 3AVW6	FACILITY CO		Lo way Lozo		
The above numbered solicitation is amended as set for		APPLIES TO AMENDMENTS OF SOLICI		is not extended	
Offer must acknowledge receipt of this amendment pri (a) By completing Items 8 and 15, and returning or (c) By separate letter or telegram which includes a r RECEIVED ATTHE PLACE DESIGNATED FOR T REJECTION OF YOUR OFFER. If by virtue of this a provided each telegram or letter makes reference to the 12. ACCOUNTING AND APPROPRIATION D	copies of the amendme eference to the solicitation HE RECEIPT OF OFFERS mendment you desire to ch solicitation and this amen	nt; (b) By acknowledging receipt of this amendment and amendment numbers. FAILURE OF YOUR AC PRIOR TO THE HOUR AND DATE SPECIFIED N ange an offer already submitted, such change may be	on each copy of the offer s KNOWLEDGMENTTO IAY RESULT IN mde by telegramor letter,	BE	
		TO MODIFICATIONS OF CONTRACTS/C CT/ORDER NO. AS DESCRIBED IN ITEM			
A. THIS CHANGE ORDER IS ISSUED PURS CONTRACT ORDER NO. IN ITEM 10A.				DE IN THE	
B. THE ABOVE NUMBERED CONTRACT/Office, appropriation date, etc.) SET FOR		O TO REFLECT THE ADMINISTRATIVE RSUANT TO THE AUTHORITY OF FAR		changes in pa	aying
X C. THIS SUPPLEMENTAL AGREEMENT IS By mutual agreement of both parties.	SENTERED INTO P	URSUANT TO AUTHORITY OF:			
D. OTHER (Specify type of modification and	authority)				
E. IMPORTANT: Contractor is not,	X is required to si	gn this document and return 1 c	opies to the issuing of	ffice.	
14. DESCRIPTION OF AMENDMENT/MODIF where feasible.) Modification Control Number: The purpose of this modification is to: 1) Extend the delivery date for CLIN 0003 from 2) Increase the unit price of CL N 0003 by 151 All other terms and conditions remain the same	m 26 June 2020 to 10	July 2020.	tion/contract subject	matter	
Except as provided herein, all terms and conditions of the c					
15A. NAME AND TITLE OF SIGNER (Type of	print)	16A. NAME AND TITLE OF CON'		R (Type or p	print)
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNE	ED 16B. UNITED STATES OF AMERIC BY (b) (6)	EMAIL: (A) (A)		DATE SIGNED
(Signature of person authorized to sign)		(Signature of Contracting Office	er)	U1-J	lul-2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by \$5,096.00 from \$60,105,096.00 to \$60,110,192.00.

SECTION B - SUPPLIES OR SERVICES AND PRICES

	N		

The unit price amount has increased by (b) (4)

The total cost of this line item has increased by (b) (4)

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:

Statement of Work Manufacture of Lateral Flow Immunoassays for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) For Defense Biological Product Assurance Office (DBPAO)

- 1.0 Scope. The scope of this work includes all activities required for a SARS-CoV-2 lateral flow immunoassay (LFI) test system, including the optimization and production of antigen screening test and all verification, validation, and regulatory activities required to achieve Food and Drug Administration (FDA) Emergency Use Authorization (EUA). Although, FDA Licensure is anticipated, it is not part of this effort. The end product shall be suitable as an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 virus in specimens from infected persons or persons suspected of exposure to SARS-CoV-2 and shall be intended for use at the point of care. The determination of an FDA sponsor will be reviewed during the ordering period.
- 2.0 Background. The DBPAO was established in 1997 by the Joint Program Executive Office Chemical Biological Radiological Nuclear Defense (JPEO-CBRND) to support the need for an integrated biological defense capability. The DBPAO serves as the principal source of high quality validated and standardized biological reference materials, reagents and assays that meet the technology development and sustainment needs of the Department of Defense (DoD) and its partners. The DBPAO facilitates the transition of new technologies and coordinates their advanced development, efficient production and timely distribution.

DBPAO has been tasked by the Acting Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight (HRP&O) to support SARS-CoV-2 response by rapidly developing and distributing antigen detection immunoassays that will serve as a screening test for the novel coronavirus, SARS-CoV-2. These screening tests will be used by DoD civilians and service members, medical healthcare workers at military health facilities and other health agencies.

- 3.0 Requirements
- 3.1 Manufacturing Facility
- 3.1.1 Have manufacturing yield sufficient to meet Government delivery order requirements of up to 1,000,000 kits per month (250,000 per week) specifically 5,000 kits/week by 15 May 2020, scalable to 250,000 kits/week by 15 July 2020. This quantity shall not include kits intended for third party conformance testing and contractor's internal testing.
- 3.1.2 Inventory management procedures to store antigens, antibodies and assays under the appropriate storage conditions as required by the label to maximize performance integrity and shelf life.
- 3.1.3 Security monitoring, temperature and humidity controlled for production area, with appropriate BioSafety Level and storage areas for assay materials including emergency backup power.
- 3.1.4 Standard Operating Procedures for all procedures associated with manufacturing, storage, and shipping of SARS-CoV-2 kits to assure compliance with contractual requirements and all local, state, and federal regulations and Standards.
 - 3.3 SARS-CoV-2 Lateral Flow Immunoassay Kit
 - 3.3.1 Deliverables
 - 3.3.1.1 SARS-CoV-2 LFI kits for the detection of SARS-CoV-2 virus, nasal swabs and appropriate clinical buffer labeled in accordance with Research Only Use (ROU) or as a EUA once approved. These kits shall be delivered while maintaining product integrity.
 - 3.3.1.2 Certificate of Conformance that includes specifications and results of internal conformance testing with each manufacturing lot of SARS-CoV-2 LFI kits.
 - 3.3.2 Reagents

DODAAC /

- 3.3.2.1 The Contractor shall be responsible for the production or procurement of the reagents required for the manufacture of this SARS-CoV-2 LFI kit such as recombinant viral capsid proteins; capture and detector antibodies, secondary antibodies, reference standards, near neighbor panel for specificity testing, negative controls etc. The government will not provide these reagents as government furnished materials.
- 3.3.2.2 The Contractor shall assume all risks and responsibilities in connection with the handling, storage, disposal, transfer, and use of the assay materials including appropriate safety and handling precautions to minimize health or environmental risk. The Contractor shall agree that any activity undertaken with the manufacture of this assay will be conducted in compliance with all applicable guidelines, laws and regulations, including Department of Defense Instruction 5210.89 (DoDI 5210.89) for DoD recipients.

3.3.3 Regulatory Work/Emergency Use Authorization

- 3.3.3.1 Perform work delineated below from 15 June 2020 to 10 July 2020:
- 3.3.3.2 Eight (8) hours engagement with the Program Office and Government Regulatory Team (ONE-RAQA); Two one-hour meetings per week to analyze the Government Furnished Information (GFI).

SECTION F - DELIVERIES OR PERFORMANCE

DELIVERY DATE

The following Delivery Schedule item for CLIN 0003 has been changed from:

QUANTITY

				CAGE
	POP 23-JUN-2020 TO 26-JUN-2020	N/A	N/A FOB: Destination	
То:				
	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
	POP 23-JUN-2020 TO 10-JUL-2020	N/A	N/A FOB: Destination	

SHIP TO ADDRESS

(End of Summary of Changes)

			1. CONTRACT ID COI	DE PAGE OF PAGES				
AMENDMENT OF SOLICIT	ATION/MODII	FICATION OF CONTRACT	J	1 2				
2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PR	OJECT NO.(If applicable)				
P00003	21-Jul-2020							
6. ISSUED BY CODE	W911QY	7. ADMINISTERED BY (If other than item 6)	CODE					
W6OK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702		See Item 6						
8. NAME AND ADDRESS OF CONTRACTOR	(No Street County	State and Zin Code)	9A. AMENDMENT	OF SOLICITATION NO.				
ANP TECHNOLOGIES, INC. 824 INTERCHANGE BLVD NEWARK DE 19711-3570	(No., Breet, County,	State and Zip code)	9B. DATED (SEE IT					
		x	10A. MOD. OF CON' W911QY20D0019	ΓRACT/ORDER NO.				
			10B. DATED (SEE I					
CODE 3AVW6	FACILITY CO	DE X						
11	. THIS ITEM ONLY	APPLIES TO AMENDMENTS OF SOLICIT	TATIONS					
The above numbered solicitation is amended as set for	th in Item 14. The hour and	I date specified for receipt of Offer	is extended, is n	ot extended.				
RECEIVED AT THE PLACE DESIGNATED FOR TREJECTION OF YOUR OFFER. If by virtue of this is	reference to the solicitation HE RECEIPT OF OFFERS amendment you desire to ch e solicitation and this amen	ent; (b) By acknowledging receipt of this amendment of and amendment numbers. FAILURE OF YOUR ACI PRIOR TO THE HOUR AND DATE SPECIFIED Mange an offer already submitted, such change may be numbered, and is received prior to the opening hour and	KNOWLEDGMENT TO BE IAY RESULT IN made by telegramor letter,	itted;				
		TO MODIFICATIONS OF CONTRACTS/C CT/ORDER NO. AS DESCRIBED IN ITEM						
A. THIS CHANGE ORDER IS ISSUED PURS CONTRACT ORDER NO. IN ITEM 10A	UANT TO: (Specify			IN THE				
X B. THE ABOVE NUMBERED CONTRACTA office, appropriation date, etc.) SET FOR		O TO REFLECT THE ADMINISTRATIVE RSUANT TO THE AUTHORITY OF FAR		nges in paying				
C. THIS SUPPLEMENT AL AGREEMENT 1	S ENTERED INTO P	URSUANT TO AUTHORITY OF:						
D. OTHER (Specify type of modification and	l authority)							
E. IMPORTANT: Contractor X is not,	is required to si	gn this document and return co	opies to the issuing offic	e.				
 14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: (b) (6) The purpose of this modification is to change CLIN 0003 as stated below: 1. The quantity is changed from (5) (4) 2. The unit price changed from (5) (4) 3. The delivery information is removed, delivery information specified in each delivery order. All other terms and conditions remain the same and in full force and effect. 								
Except as provided herein, all terms and conditions of the	document referenced in Item	19A or 10A, as heretofitre changed remains unchanged	d and in full force and effect					
15A. NAME AND TITLE OF SIGNER (Type of		16A. NAME AND TITLE OF CONT		Гуре or print)				
7.1	5 TO 2	/CONTRACTING OFFICER TEL: (6) (6)	EMAIL: (b) (6)					
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNE			16C. DATE SIGNED 21-Jul-2020				
(Signature of person authorized to sign)		(Signature of Contracting Office	er)	Z I OUFEVEV				

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0003

The pricing detail quantity has increased by (b) (4)

The unit price amount has decreased by (b) (4)

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for CLIN 0003 has been deleted:

DELIVERY DATE QUANTITY SHIP TO ADDRESS DODAAC / CAGE

POP 23-JUN-2020 TO N/A N/A

10-JUL-2020 FOB: Destination

(End of Summary of Changes)

(1 Data Item)

Form Approved OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services and Communications Directorate (9/704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the

Government issuing	Contracting Officer for the	Contract/PR No.	listed in Block E.							1
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(1 Data Item)

DD FORM 1423-1, FEB 2001

Form Approved OMB No. 0704-0188

The public reporting burden for this collection of information is estimated to average 110 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services and Communications Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for falling to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.

7. DD 250 REQ 9. DIST STATEMENT REQUIRED 10, FREQUENCY 12, DATE OF FIRST SUBMISSION see blk 16 b. COPIES	A. CONTRACT		B. EXHIBIT		ATEGORY:							
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Blk 13. Provide a final Inspection and Test Plan for Government review (5) (4) (b) (4) Blk 14. and Blk 15. Submit via e-mail in Microsoft Office format to: (b) (6) G. PREPARED BY H. DATE L. APPROVED BY J. DATE	16. REMARKS		1				See addre	ess in		1	1	1
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Form Approved OMB No. 0704-0188

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INSTRUCTIONS FOR COMPLETING DD FORM 1423

(See DoD 5010.12-M for detailed instructions.)

FOR GOVERNMENT PERSONNEL

- Item A. Self-explanatory.
- Item B. Self-explanatory.
- Item C. Mark (X) appropriate category: TDP Technical Data Package; TM Technical Manual; Other other category of data, such as "Provisioning," "Configuration Management," etc.
- Item D. Enter name of system/item being acquired that data will support.
- Item E. Self-explanatory (to be filled in after contract award).
- Item F. Self-explanatory (to be filled in after contract award).
- Item G. Signature of preparer of CDRL.
- Item H. Date CDRL was prepared.
- Item I. Signature of CDRL approval authority.
- Item J. Date CDRL was approved.
- Item 1. See DoD FAR Supplement Subpart 4.71 for proper numbering.
- Item 2. Enter title as it appears on data acquisition document cited in Item 4.
- Item 3. Enter subtitle of data item for further definition of data item (optional entry).
- Item 4. Enter Data Item Description (DID) number, military specification number, or military standard number listed in DoD 5010.12-L (AMSDL), or one-time DID number, that defines data content and format requirements.
- Item 5. Enter reference to tasking in contract that generates requirement for the data item (e.g., Statement of Work paragraph number).
- Item 6. Enter technical office responsible for ensuring adequacy of the data item.
- Item 7. Specify requirement for inspection/acceptance of the data item by the Government.
- Item 8. Specify requirement for approval of a draft before preparation of the final data item.
- Item 9. For technical data, specify requirement for contractor to mark the appropriate distribution statement on the data (ref. DoDD 5230.24).
- Item 10. Specify number of times data items are to be delivered.
- Item 11. Specify as-of date of data item, when applicable.
- Item 12. Specify when first submittal is required.
- Item 13. Specify when subsequent submittals are required, when applicable.
- Item 14. Enter addressees and number of draft/final copies to be delivered to each addressee. Explain reproducible copies in Item 16.
- Item 15. Enter total number of draft/final copies to be delivered.
- Item 16. Use for additional/clarifying information for Items 1 through 15. Examples are: Tailoring of documents cited in Item 4; Clarification of submittal dates in Items 12 and 13; Explanation of reproducible copies in Item 14.; Desired medium for delivery of the data item.

FOR THE CONTRACTOR

- Item 17. Specify appropriate price group from one of the following groups of effort in developing estimated prices for each data item listed on the DD Form 1423.
- a. Group I. Definition Data which is not otherwise essential to the contractor's performance of the primary contracted effort (production, development, testing, and administration) but which is required by DD Form 1423.

Estimated Price - Costs to be included under Group I are those applicable to preparing and assembling the data item in conformance with Government requirements, and the administration and other expenses related to reproducing and delivering such data items to the Government.

b. Group II. Definition - Data which is essential to the performance of the primary contracted effort but the contractor is required to perform additional work to conform to Government requirements with regard to depth of content, format, frequency of submittal, preparation, control, or quality of the data item.

Estimated Price - Costs to be included under Group II are those incurred over and above the cost of the essential data item without conforming to Government requirements, and the administrative and other expenses related to reproducing and delivering such data item to the Government.

c. Group III. Definition - Data which the contractor must develop for his internal use in performance of the primary contracted effort and does not require any substantial change to conform to Government requirements with regard to depth of content, format, frequency of submittal, preparation, control, and quality of the data item.

Estimated Price - Costs to be included under Group III are the administrative and other expenses related to reproducing and delivering such data item to the Government.

d. Group IV. Definition - Data which is developed by the contractor as part of his normal operating procedures and his effort in supplying these data to the Government is minimal.

Estimated Price - Group IV items should normally be shown on the DD Form 1423 at no cost.

Item 18. For each data item, enter an amount equal to that portion of the total price which is estimated to be attributable to the production or development for the Government of that item of data. These estimated data prices shall be developed only from those costs which will be incurred as a direct result of the requirement to supply the data, over and above those costs which would otherwise be incurred in performance of the contract if no data were required. The estimated data prices shall not include any amount for rights in data. The Government's right to use the data shall be governed by the pertinent provisions of the contract.

(1 Data Item)

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Form Approved OMB No. 0704-0188

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PREVIOUS EDITION MAY BE USED.

Attachment Conformance Testing Plan

Conformance Testing of Lateral Flow Immunoassays (LFIs) for Biosurveillance of SARS-CoV-2 (2019-nCoV)

Overview of Planned Testing:

Six studies will be performed for each LFI:

- 1) Dynamic range (and LoD Range-finding)
- 2) Analytical sensitivity (Limit of detection)
- Analytical specificity (Cross-reactivity/Exclusivity)
- 4) Interfering Substances
- 5) Evaluation with Contrived Specimens in Various Media Formulations
- 6) Evaluation with PCR-Positive Patient Specimens

For comparison, similar studies will also be performed using an Emergency Use Authorization (EUA) assay if available in for testing, otherwise an RUO version of the CDC's 2019-nCoV Real-time RT-PCR Diagnostic Panel and associated methods.

Study 1: Dynamic Range Testing and Limit of Detection (LoD) Range-Finding

Dynamic range testing will be determined for both live virus and the developer-provided antigen in the developer-specified buffer. To test the dynamic range with virus and antigen, a half-log (~3.16-fold) dilution series will be prepared for both, consisting of up to seven different levels of virus/antigen tested in triplicate (Table 1).

Table 1. Example Test Scheme for Study 1, which will be performed with both live virus and a developer-provided antigen preparation

Test level	Log/mL	Units/mL	Replicates
QCB	N/A	0	3
1	6.0	1,000,000	3
2	5.5	316,228	3
3	5.0	100,000	3
4	4.5	31,623	3
5	4.0	10,000	3
6	3.5	3,162	3
7	3.0	1,000	3

Note: Actual levels tested may vary based on stock concentrations, anticipated LoDs, and results obtained during the course of testing (e.g., lower levels will not be tested if negative results are obtained at higher levels).

Results interpretation will be performed both visually and with a CAMAG TLC Scanner 4. Visual interpretation will be performed independently by two analysts, and a test will be considered visually inconclusive if the analysts' interpretations do not match. The candidate

Attachment 3 Conformance Testing Plan

LoD for live virus and the candidate LoD for the developer's antigen will be identified as the lowest levels producing positive results for 3 of 3 replicates in their respective studies.

Study 2: Analytical Sensitivity (Limit of Detection)

The LoD will be determined for both live virus and the developer-provided antigen in the developer-specified buffer. Initially, 32 replicates will be tested at the candidate LoD established during range-finding. If there are any failures in the first round of testing, an additional 32 replicates will be performed at 2X the initial candidate LoD. Duplicate quality control blanks (QCBs) will also be tested in each round of LoD testing, so up to 68 tests will be required per LFI. The LoD of each LFI will be defined as the lowest level tested that produced positive results for 32 of 32 replicates.

Study 3: Analytical Specificity (Cross-reactivity/Exclusivity)

For analytical specificity testing, a minimum of five near neighbors (all coronaviruses) and a pooled human nasal wash (to include diverse respiratory microflora) will be tested in triplicate. Potential near neighbors include: SARS, MERS, human coronavirus 229E, human coronavirus OC43, human coronavirus NL63, human coronavirus HKU1, and two SARS-like bat coronaviruses. Final composition of the test panel will be based on stock availability at the time of testing. Each near neighbor will be tested in developer-specified buffer at the highest level the stock concentration reasonably allows. This study will require 18-27 tests per LFI, depending on the number of near neighbors available at the time of testing.

Study 4: Interfering Substances

Five interfering substances will be evaluated for their ability to cause false positive and/or false negative results at concentrations comparable to or greater than levels that may be present in respiratory samples (Table 2). All samples will consist of antigen diluted in the developer-specified buffer. Ability to cause false positive results will be determined by testing target-negative samples containing the potentially interfering substance in triplicate. Ability to cause false negative results will be similarly determined by testing samples spiked at 1X LoD in triplicate, with follow-up testing at 10X LoD if any negative results are obtained at 1X LoD. This will require 30-45 tests per LFI.

Attachment 3 Conformance Testing Plan

Table 2. Test Scheme for Study 4

Potentially Interfering Substance	Concentration to be Tested	Replicates without antigen	Replicates with antigen at 1X LoD	Replicates with antigen at 10X LoD (if applicable)	Total # of tests
Human whole blood	2% v/v	3	3	3	6-9
Mucin (purified salivary protein)	1 mg/mL	3	3	3	6-9
OTC Mouthwash	5% v/v	3	3	3	6-9
3 OTC nasal sprays (phenylephrine, oxymetazoline, and fluticasone)	5% v/v of each (15% total)	3	3	3	6-9
3 OTC throat spray (phenol, benzocaine, and zincum)	5% v/v of each (15% total)	3	3	3	6-9

Study 5: Evaluation with Contrived Specimens in Various Media Formulations

A series of contrived specimens will be prepared using NP swab specimens collected from negative donors and stored in one of three media formulations (Table 3). Five donor NP samples will be collected per media formulation, and NP media from each sample will be tested in three preparations: unspiked, spiked with live virus at 1X LoD, and spiked with live virus at 5X LoD.

Table 3. Test Scheme for Study 5

NP Medium	# of Donors	Tests per donor	Total # of tests
Developer's buffer (no intermediate transport buffer)	5	3	15
BD Universal Viral Transport Medium	5	3	15
Liquid Amies Transport Medium	5	3	15

Study 6: Evaluation with PCR-Positive Patient Specimens

Up to ten residual patient specimens that are PCR-positive for SARS-CoV-2 will be tested, as availability allows. All patient specimens will consist of NP swabs in Universal Transport Medium (UTM). LFI results will be reported alongside quantitative RT-PCR results to add context.

Attachment 3 Conformance Testing Plan

Materials and Information Required from Performers:

Materials to be provided by the LFI manufacturers as soon as possible:

- Draft Instructions for Use
- A list of any ancillary generic reagents/consumables that must be supplied by the user

Materials that can be provided by 24 April 2020, before initiating conformance testing:

- · Final Instructions for Use
- 250 LFI tests and any test-specific reagents/consumables required to run them

ATTACHMENT Evaluation Factors and Rating Criteria

Lateral Flow Immunoassay Evaluation

The relative order of importance of evaluation factors is as follows: Sensitivity which is more important than Specificity, which is more important than Interference (cross reactivity).

Assay parameters

Four parameters are required to be established and provided in the final package for any developed LFI assay:

1. Sensitivity

a. Dynamic range (and Limit of Detection (LoD) Range) - Establish assay results of serial dilution range of 7 log antigen concentration or any other dilution series appropriate for the stock concentration.

Technical Ratings				
Color	Rating	Description		
Blue	Outstanding	Assay is able to detect the 2nd lowest concentration per test plan (3,162 Units/mL).		
Green	Acceptable	Assay is able to detect concentrations from the 3rd to the 5 th lowest concentration per test plan (10,000, 31,623, 100,000 Units/mL).		
Red	Unacceptable	Assay is only able to detect from the 6 th and 7th lowest concentrations per test plan (316,228, 1,000,000, Units/mL).		

b. Analytical sensitivity - LoD determinations consisting of two rounds of testing. In the first round of testing, 32 replicates to be tested at the candidate LoD established during range-finding. In the second round of testing, 32 replicates to be tested at either 0.5X or 5X the candidate LoD, depending on performance in the first round of testing.

Technical Ratings				
Color	Description			
Pass	95-100 % performance of the replicates.			
Fail	<95 % performance of the replicates.			

ATTACHMENT 4 Evaluation Factors and Rating Criteria

2. Analytical specificity (Cross-reactivity/Exclusivity) - test target and near neighbor viral samples.

Technical Ratings					
Color	Rating	Description			
Blue	Outstanding	100% True positive and no FN results with respect inclusivity, no FP with cross reactivity and exclusivity.			
Green	Acceptable	95%-99% True positive and no FN results with respect inclusivity, no FP with cross reactivity and exclusivity.			
Poor	Uncertain	<95% True positive results with respect inclusivity, some FP with cross reactivity and exclusivity.			

3. Interfering substances- Five interfering substances to be evaluated for their ability to cause false positive and/or false negative results. Selection of potentially interfering substances to test will be based on further inputs from Government regarding anticipated sample matrices and use-case scenarios.

Technical Ratings					
Color	Rating	Description			
Blue	Outstanding	There are no positive non-specific reactions (100% TN).			
Green	Acceptable	There is some positive non-specific reaction (95%-99%)			
Red	Unacceptable	There is more than one positive non-specific reaction (<95%).			

ATTACHMENT 4 Evaluation Factors and Rating Criteria

The decision matrix for the overall Performance of Acceptable, Very Good and Outstanding scores (any Red rating is deemed unacceptable overall):

		Cor	mbined Scores		
Sens	sitvity	Specificity	Interference		Final Score
Limit of Detection	Sensitivity	speciality	imerierence		Final Score
Blue	Green	Blue	Blue	\rightarrow	Blue
Blue	Green	Blue	Green	\rightarrow	Blue
Blue	Green	Green	Blue	\rightarrow	Turquoise
Blue	Green	Green	Green	\rightarrow	Turquoise
Green	Green	Blue	Blue	\rightarrow	Turquoise
Green	Green	Blue	Green	\rightarrow	Green
Green	Green	Green	Blue	\rightarrow	Green
Green	Green	Green	Green	\rightarrow	Green

Performance matrix rating definitions:

	Overall Technical Ratings				
Color Rating		Description			
Blue	Outstanding	A <i>Blue</i> rating in LOD and Specificity, and no lower than a <i>Green</i> rating in other performance categories.			
Turquoise	Very Good	A <i>Blue</i> rating in LOD, and no lower a <i>Green</i> rating in other performance categories, or a <i>Green</i> rating in LOD and <i>Blue</i> ratings in both Specificity and Interference.			
Green	Acceptable	No lower than a <i>Green</i> rating in Sensitivity categories, and any combination of one <i>Blue</i> and/or <i>Green</i> ratings in Specificity and Interference or <i>Green</i> ratings in all.			
Red	Unacceptable	If any <i>Red</i> rating is scored in either Sensitivity factor, Specificity, and/or Interference.			