

# ORDER FOR SUPPLIES OR SERVICES

1. CONTRACT/PURCH. ORDER/ AGREEMENT NO. <b>W911QY20P0141</b>		2. DELIVERY ORDER/ CALL NO. <b>W911QY</b>		3. DATE OF ORDER/CALL (YYYYMMDD) <b>2020 Apr 17</b>		4. REQ/PURCH. REQUEST NO. <b>0011477047-0001</b>		5. PRIORITY		
6. ISSUED BY W 6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702				7. ADMINISTERED BY (if other than 6) <b>SEE ITEM 6</b>				8. DELIVERY FOB <input checked="" type="checkbox"/> DESTINATION <input type="checkbox"/> OTHER  (See Schedule if other)		
9. CONTRACTOR NAME AND ADDRESS <b>ANP TECHNOLOGIES, INC. 824 INTERCHANGE BLVD NEWARK DE 19711-3570</b>			CODE <b>3AVW6</b>		FACILITY		10. DELIVER TO FOB POINT BY (Date) (YYYYMMDD) <b>SEE SCHEDULE</b>		11. MARK IF BUSINESS IS <input type="checkbox"/> SMALL <input type="checkbox"/> SMALL DISADVANTAGED <input type="checkbox"/> WOMEN-OWNED	
							12. DISCOUNT TERMS Net 30 Days		13. MAIL INVOICES TO THE ADDRESS IN BLOCK See Item 15	
14. SHIP TO MEDICAL COUNTERMEASURE SYSTEMS JPL EB 110 THOMAS JOHNSON DRIVE FORT DETRICK MD 21702			CODE <b>W56XNH</b>		15. PAYMENT WILL BE MADE BY CODE <b>HQ0490</b> DEFENSE FINANCE AND ACCOUNTING SERVICE DFAS-INDY VP GFEB5 8899 E 56TH STREET INDIANAPOLIS IN 46249-3800				<b>MARK ALL PACKAGES AND PAPERS WITH IDENTIFICATION NUMBERS IN BLOCKS 1 AND 2.</b>	
16. TYPE OF ORDER	DELIVERY/ CALL	This delivery order/call is issued on another Government agency or in accordance with and subject to terms and conditions of above numbered contract.								
	PURCHASE	<input checked="" type="checkbox"/>	Reference your quote dated Furnish the following on terms specified herein. REF:							
ACCEPTANCE. THE CONTRACTOR HEREBY ACCEPTS THE OFFER REPRESENTED BY THE NUMBERED PURCHASE ORDER AS IT MAY PREVIOUSLY HAVE BEEN OR IS NOW MODIFIED, SUBJECT TO ALL OF THE TERMS AND CONDITIONS SET FORTH, AND AGREES TO PERFORM THE SAME.										
NAME OF CONTRACTOR			SIGNATURE			TYPED NAME AND TITLE			DATE SIGNED (YYYYMMDD)	
<input checked="" type="checkbox"/> If this box is marked, supplier must sign Acceptance and return the following number of copies: <b>1</b>										
17. ACCOUNTING AND APPROPRIATION DATA/ LOCAL USE  <b>See Schedule</b>										
18. ITEM NO.	19. SCHEDULE OF SUPPLIES/ SERVICES				20. QUANTITY ORDERED/ ACCEPTED*	21. UNIT	22. UNIT PRICE		23. AMOUNT	
	<b>SEE SCHEDULE</b>									
* If quantity accepted by the Government is same as quantity ordered, indicate by X. If different, enter actual quantity accepted below quantity ordered and encircle.			24. UNITED STATES OF AMERICA TEL: <b>(b) (6)</b> EMAIL: <b>(b) (6)</b> BY: <b>(b) (6)</b>		<b>(b) (6)</b>			5. TOTAL	\$766,254.00	
27 a. QUANTITY IN COLUMN 20 HAS BEEN	<input type="checkbox"/> INSPECTED	<input type="checkbox"/> RECEIVED	<input type="checkbox"/> ACCEPTED, AND CONFORMS TO THE CONTRACT EXCEPT AS NOTED	6. DIFFERENCES						
b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE				c. DATE (YYYYMMDD)		d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE				
e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE					28. SHIP NO.	29. DO VOUCHER NO.	30. INITIALS			
f. TELEPHONE NUMBER		g. E-MAIL ADDRESS			<input type="checkbox"/> PARTIAL <input type="checkbox"/> FINAL	32. PAID BY		33. AMOUNT VERIFIED CORRECT FOR		
36. I certify this account is correct and proper for payment.					31. PAYMENT <input type="checkbox"/> COMPLETE <input type="checkbox"/> PARTIAL <input type="checkbox"/> FINAL		34. CHECK NUMBER			
a. DATE (YYYYMMDD)	b. SIGNATURE AND TITLE OF CERTIFYING OFFICER						35. BILL OF LADING NO.			
37. RECEIVED AT		38. RECEIVED BY		39. DATE RECEIVED (YYYYMMDD)	40. TOTAL CONTAINERS	41. S/R ACCOUNT NO.	42. S/R VOUCHER NO.			

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	Development of LFI's FFP The contractor shall develop (b) (4)	(b)	Each	(b) (4)	(b) (4)
	devices for testing and evaluation in accordance with specifications at Section C and Section J. Note: (b) (4) devices to be shipped (b) (4), (b) (4) devices shipped (b) (4), remaining devices to be held until further instruction)				
	FOB: Destination MFR PART NR: TBD PURCHASE REQUEST NUMBER: 0011477047-0001 PSC CD: 6550				

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NET AMT

(b) (4)

ACRN AA  
CIN: GFEB001147704700001

(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002 OPTION	Technical Data Package FFP Technical Data Package to be negotiated. FOB: Destination MFR PART NR: TBD PSC CD: 6550				NSP

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## Section C - Descriptions and Specifications

STATEMENT OF WORK (SOW)

**Statement of Work (SOW)**  
**Development of COVID-19 Lateral Flow Immunoassay (LFI) Assay Kits**  
**For the Joint Product Lead- Enabling Biotechnologies (JPL-EB) Defense Biological**  
**Product Assurance Office (DBPAO)**

Task/Deliverable 1 & 2 – LFI Formulation Development, In-house Testing and Production:

Development of a rapid, simple to use, handheld LFI for detecting SARS-CoV-2 virus in specimens from infected or suspected viral exposed persons. Offeror plans to produce an antigen screening test for detecting SARS-CoV-2 in nasopharyngeal swab specimens. Dendrimers and their corresponding conjugates with different antibodies or binding pairs will be designed and synthesized by the ANP synthesis team. Upon testing with recombinant protein or live or inactivated COVID-19 virus preparations, fine tuning of capture and detector antibody formulations will be needed in order to identify the final optimized assay configuration. The scope of this effort may include a medical device that is regulated by the US FDA which requires FDA pre-market approval or clearance before commercial marketing may begin please reference attachment 1 (FDA Guidance In Support of Diagnostic Emergency Use Authorization) and 2 (Regulatory Rights).

Specifically,

**1. Dynamic range** (and LOD range-finding) using both inactivated/killed virus and recombinant surface antigen protein will be tested to determine dynamic range. A half-log serial dilution scheme will be tested up to seven different concentrations of virus/antigen spiked into ANP specified buffer solution.

**2. Analytical sensitivity** using inactivated/killed virus or recombinant surface antigen protein in ANP-specified buffer will be tested to determine the LOD. Based on the replicates during range finding, additional rounds will be tested at 2X the initial LOD, if any of the starting 32 elicit a failure at the candidate LoD established during range finding above. Each round will consist of Quality Control Blanks (QCBs) totaling (b) (4) individual tests per LFI. Final LOD for each LFI shall be defined as the lowest tested concentration which produces positive results for (b) (4) LFI replicates.

**3. Analytical specificity** (Cross-reactivity/Exclusivity) of up (b) (4) near neighbors and pooled human nasal wash containing various respiratory microflora will be evaluated in triplicate totaling (b) (4) per LFI. We plan to test the following panel of near neighbors: **SARS**, **MERS**, human coronaviruses **229E**, human coronaviruses **OC43** and human coronaviruses **NL63**. Near neighbors will be tested in ANP-specified buffer at the highest stock concentration reasonably allowed for. In lieu of clinical samples, ANP will utilize contrived samples for testing.

**4. Interference testing** of (b) (4) interferents will be evaluated for any false positive and/or false negative results at concentrations similar to or greater than that which may be present in respiratory samples. Samples tested will consist of recombinant antigen diluted in the ANP-specified buffer. False positives are

determined by testing antigen-negative samples containing the potentially interfering substance in triplicate while false negatives will be determined by running spiked samples at 1X LOD in triplicate followed by confirmation testing at 10X LOD in the event that a negative result is observed at 1X LOD. A PCR comparator test may also be used under the same testing conditions to compare with the LFI performance. In addition, assay robustness and stability testing at various temperatures for at least one year will also be carried out during the proposed effort.

**5. Specificity** evaluation with contrived specimens in different media formulations will be done as a series of specimens prepared with nasopharyngeal swab samples collected from virus negative individuals in up to three different formulated medias. (b) (4) swabs are collected per media and the resulting NP media from each is to be tested in three iterations as follows:

(b) (4)

*Task/Deliverable 3 – Deliver First Article Test Lot to Government Contracted Conformance Testing Lab*

Within (b) (4) days of verbal notification to start effort, offeror will deliver a First Article Testing (FAT) (b) (4) devices along with appropriate ANP buffer/reagents/controls and nasal swabs, deliver (b) (4) devices for testing and evaluation by a contracted third party, and deliver (b) (4) devices for study. In addition, a final report encompassing test data and details to informing the third party test lab and the Government program management office.

**The Conformance Testing Plan for Lateral Flow Immunoassays (LFIs) for Biosurveillance of SARS-CoV-2 (2019-nCoV) describing how the LFIsy will be evaluated by independent conformance test laboratory is included as Attachment 3. The evaluation factors and rating criteria for LFI performance that the Defense Biological Product Assurance Office (DBPAO) will use is included as Attachment 4.**

**The contractor will deliver the required materials and information to independent conformance test laboratory (b) (4) to:**

(b) (6)

**The contractor will ship (b) (4) required materials and information to Naval Health Research Center (NHRC) for field testing (b) (4) to:**

(b) (6)

(b) (6)

**In accordance with 252.227-7013 Rights in Technical Data--Noncommercial Items, the Government reserves the right to obtain for a technical data package which may include all applicable technical data such as drawings, associated lists, specifications, design descriptions, design databases, standards, performance requirements, quality assurance provisions, manufacturing design and packaging details.**

**Attachment 1 FDA Guidance In Support of Diagnostic Emergency Use Authorization**

**Attachment 2 Regulatory Rights**

**Attachment 3 Conformance Test Plan**

**Attachment 4 Evaluation factors and rating criteria**

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	N/A	N/A	N/A	Government
0002	N/A	N/A	N/A	Government

## Section F - Deliveries or Performance

## DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	24-APR-2020	(b)	MEDICAL COUNTERMEASURE SYSTEMS W56XNH JPL EB 110 THOMAS JOHNSON DRIVE FORT DETRICK MD 21702 FOB: Destination	
0002	N/A	N/A	N/A	N/A

Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

AA: 09720202021013000018170446463255 S.0025760.7.5.1 6100.9000021001  
COST CODE: AHPII  
AMOUNT: \$766,254.00

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	0001	GFEB001147704700001	\$766,254.00



## Section I - Contract Clauses

## CLAUSES INCORPORATED BY REFERENCE

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
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	OCT 2010
52.203-17	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights	APR 2014
52.204-19	Incorporation by Reference of Representations and Certifications.	DEC 2014
52.209-10	Prohibition on Contracting With Inverted Domestic Corporations	NOV 2015
52.223-18	Encouraging Contractor Policies To Ban Text Messaging While Driving	AUG 2011
52.232-2	Payments Under Fixed-Price Research And Development Contracts	APR 1984
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
252.204-7012	Safeguarding Covered Defense Information and Cyber Incident Reporting	DEC 2019
252.209-7002	Disclosure Of Ownership Or Control By A Foreign Government	JUN 2010
252.211-7003	Item Unique Identification and Valuation	MAR 2016
252.225-7048	Export-Controlled Items	JUN 2013
252.232-7010	Levies on Contract Payments	DEC 2006
252.235-7010	Acknowledgment of Support and Disclaimer	MAY 1995
252.235-7011	Final Scientific or Technical Report	DEC 2019
252.243-7001	Pricing Of Contract Modifications	DEC 1991

## CLAUSES INCORPORATED BY FULL TEXT

## 52.213-4 TERMS AND CONDITIONS--SIMPLIFIED ACQUISITIONS (OTHER THAN COMMERCIAL ITEMS) (JAN 2020)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses that are incorporated by reference:

(1) The clauses listed below implement provisions of law or Executive order:

(i) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(ii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(iii) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).

- (iv) 52.222-3, Convict Labor (JUN 2003) (E.O. 11755).
  - (v) 52.222-21, Prohibition of Segregated Facilities (APR 2015).
  - (vi) 52.222-26, Equal Opportunity (SEPT 2016) (E.O. 11246).
  - (vii) 52.225-13, Restrictions on Certain Foreign Purchases (JUN 2008) (E.O.s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
  - (viii) 52.233-3, Protest After Award (AUG 1996) (31 U.S.C. 3553).
  - (ix) 52.233-4, Applicable Law for Breach of Contract Claim (OCT 2004) (Pub. L. 108-77, 108-78 (19 U.S.C. 3805 note)).
- (2) Listed below are additional clauses that apply:
- (i) 52.232-1, Payments (APR 1984).
  - (ii) 52.232-8, Discounts for Prompt Payment (FEB 2002).
  - (iii) 52.232-11, Extras (APR 1984).
  - (iv) 52.232-25, Prompt Payment (JAN 2017).
  - (v) 52.232-39, Unenforceability of Unauthorized Obligations (JUN 2013).
  - (vi) 52.232-40, Providing Accelerated Payments to Small Business Subcontractors (DEC 2013).
  - (vii) 52.233-1, Disputes (MAY 2014).
  - (viii) 52.244-6, Subcontracts for Commercial Items (AUG 2019).
  - (ix) 52.222-55, Minimum Wages Under Executive Order 13658 (MAR 2016) (Applies when 52.222-6 or 52.222-41 are in the contract and performance in whole or in part is in the United States (the 50 States and the District of Columbia)).
- (b) The Contractor shall comply with the following FAR clauses, incorporated by reference, unless the circumstances do not apply:
- (1) The clauses listed below implement provisions of law or Executive order:
- (i) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (Oct 2018) (Pub. L. 109-282) (31 U.S.C. 6101 note) (Applies to contracts valued at \$30,000 or more).
  - (ii) 52.222-19, Child Labor--Cooperation with Authorities and Remedies (Jan 2020) (E.O. 13126). (Applies to contracts for supplies exceeding the micro-purchase threshold).
  - (iii) 52.222-20, Contracts for Materials, Supplies, Articles, and Equipment Exceeding \$15,000 (MAY 2014) (41 U.S.C. chapter 65) (Applies to supply contracts over \$15,000 in the United States, Puerto Rico, or the U.S. Virgin Islands).
  - (iv) 52.222-35, Equal Opportunity for Veterans (Oct 2015) (38 U.S.C. 4212) (applies to contracts of \$150,000 or more).

(v) 52.222-36, Equal Employment for Workers with Disabilities (JUL 2014) (29 U.S.C. 793) (Applies to contracts over \$15,000, unless the work is to be performed outside the United States by employees recruited outside the United States). (For purposes of this clause, ``United States" includes the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.)

(vi) 52.222-37, Employment Reports on Veterans (Feb 2016) (38 U.S.C. 4212) (Applies to contracts of \$150,000 or more).

(vii) 52.222-41, Service Contract Labor Standards (AUG 2018) (41 U.S.C. chapter 67) (Applies to service contracts over \$2,500 that are subject to the Service Contract Labor Standards statute and will be performed in the United States, District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, Johnston Island, Wake Island, or the outer Continental Shelf).

(viii)(A) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O. 13627) (Applies to all solicitations and contracts).

(B) Alternate I (MAR 2015) (Applies if the Contracting Officer has filled in the following information with regard to applicable directives or notices: Document title(s), source for obtaining document(s), and contract performance location outside the United States to which the document applies).

(ix) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2015) (Executive Order 13658) (Applies when 52.222-6 or 52.222-41 are in the contract and performance in whole or in part is in the United States (the 50 States and the District of Columbia)).

(x) 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706) (Applies when 52.222-6 or 52.222-41 are in the contract and performance in whole or in part is in the United States (the 50 States and the District of Columbia.))

(xi) 52.223-5, Pollution Prevention and Right-to-Know Information (MAY 2011) (E.O. 13423) (Applies to services performed on Federal facilities).

(xii) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (June, 2016) (E.O. 13693)(applies to contracts for products as prescribed at FAR 23.804(a)(1)).

(xiii) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (June, 2016) (E.O. 13693) (Applies to maintenance, service, repair, or disposal of refrigeration equipment and air conditioners).

(xiv) 52.223-15, Energy Efficiency in Energy-Consuming Products (DEC 2007) (42 U.S.C. 8259b) (Unless exempt pursuant to 23.204, applies to contracts when energy-consuming products listed in the ENERGY STAR ® Program or Federal Energy Management Program (FEMP) will be--

(A) Delivered;

(B) Acquired by the Contractor for use in performing services at a Federally-controlled facility;

(C) Furnished by the Contractor for use by the Government; or

(D) Specified in the design of a building or work, or incorporated during its construction, renovation, or maintenance).

(xv) 52.223-20, Aerosols (June, 2016) (E.O. 13693) (Applies to contracts for products that may contain high global warming potential hydrofluorocarbons as a propellant or as a solvent; or contracts for maintenance or repair of electronic or mechanical devices).

(xvi) 52.223-21, Foams (June, 2016) (E.O. 13693) (Applies to contracts for products that may contain high global warming potential hydrofluorocarbons or refrigerant blends containing hydrofluorocarbons as a foam blowing agent; or contracts for construction of buildings or facilities.

(xvii) 52.225-1, Buy American--Supplies (MAY 2014) (41 U.S.C. chapter 67) (Applies to contracts for supplies, and to contracts for services involving the furnishing of supplies, for use in the United States or its outlying areas, if the value of the supply contract or supply portion of a service contract exceeds the micro-purchase threshold and the acquisition--

(A) Is set aside for small business concerns; or

(B) Cannot be set aside for small business concerns (see 19.502-2), and does not exceed \$25,000).

(xviii) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (MAY 2014) (42 U.S.C. 1792) (Applies to contracts greater than \$25,000 that provide for the provision, the service, or the sale of food in the United States).

(xix) 52.232-33, Payment by Electronic Funds Transfer--System for Award Management (OCT 2018) (Applies when the payment will be made by electronic funds transfer (EFT) and the payment office uses the System for Award Management (SAM) as its source of EFT information.)

(xx) 52.232-34, Payment by Electronic Funds Transfer--Other than System for Award Management (JUL 2013) (Applies when the payment will be made by EFT and the payment office does not use the SAM database as its source of EFT information.)

(xxi) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (FEB 2006) (46 U.S.C. App. 1241) (Applies to supplies transported by ocean vessels (except for the types of subcontracts listed at 47.504(d).)

(2) Listed below are additional clauses that may apply:

(i) 52.204-21, Basic Safeguarding of Covered Contractor Information Systems (June, 2016) (Applies to contracts when the contractor or a subcontractor at any tier may have Federal contract information residing in or transiting through its information system.

(ii) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (Oct 2015) (Applies to contracts over \$35,000).

(iii) 52.211-17, Delivery of Excess Quantities (SEP 1989) (Applies to fixed-price supplies).

(iv) 52.247-29, F.o.b. Origin (FEB 2006) (Applies to supplies if delivery is f.o.b. origin).

(v) 52.247-34, F.o.b. Destination (NOV 1991) (Applies to supplies if delivery is f.o.b. destination).

(c) FAR 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):

(Insert one or more Internet addresses)

(d) Inspection/Acceptance. The Contractor shall tender for acceptance only those items that conform to the requirements of this contract. The Government reserves the right to inspect or test any supplies or services that have been tendered for acceptance. The Government may require repair or replacement of nonconforming supplies or

reperformance of nonconforming services at no increase in contract price. The Government must exercise its postacceptance rights--

(1) Within a reasonable period of time after the defect was discovered or should have been discovered; and

(2) Before any substantial change occurs in the condition of the item, unless the change is due to the defect in the item.

(e) Excusable delays. The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence, such as acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. The Contractor shall notify the Contracting Officer in writing as soon as it is reasonably possible after the commencement of any excusable delay, setting forth the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch, and shall promptly give written notice to the Contracting Officer of the cessation of such occurrence.

(f) Termination for the Government's convenience. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges that the Contractor can demonstrate to the satisfaction of the Government, using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred that reasonably could have been avoided.

(g) Termination for cause. The Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

(h) Warranty. The Contractor warrants and implies that the items delivered hereunder are merchantable and fit for use for the particular purpose described in this contract.

(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 data by 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--

Technical data to be Furnished	Basis for Assertion \2/	Asserted Rights Category \3/	Name of Person Asserting Restrictions \4/
With Restrictions \1/			

(LIST)

(LIST)

(LIST)

(LIST)

\1/ If the assertion is applicable to items, components or processes developed at private expense, identify both the data and each such items, component, or process.

\2/ Generally, the development of an item, component, or process at private expense, either exclusively or partially, is the only basis for asserting restrictions on the Government's rights to use, release, or disclose technical data pertaining to such items, components, or processes. Indicate whether development was exclusively or partially at private expense. If development was not at private expense, enter the specific reason for asserting that the Government's rights should be restricted.

\3/ Enter asserted rights category (e.g., government purpose license rights from a prior contract, rights in SBIR data generated under another contract, limited or government purpose rights under this or a prior contract, or specifically negotiated licenses).

\4/ Corporation, individual, or other person, as appropriate.

Date \_\_\_\_\_

Printed Name and Title \_\_\_\_\_

\_\_\_\_\_

Signature \_\_\_\_\_

(End of identification and assertion)

(4) When requested by the Contracting Officer, the Contractor shall provide sufficient information to enable the Contracting Officer to evaluate the Contractor's assertions. The Contracting Officer reserves the right to add the Contractor's assertions to the Attachment and validate any listed assertion, at a later date, in accordance with the procedures of the Validation of Restrictive Markings on Technical Data clause of this contract.

(f) Marking requirements. The Contractor, and its subcontractors or suppliers, may only assert restrictions on the Government's rights to use, modify, reproduce, release, perform, display, or disclose technical data to be delivered under this contract by marking the deliverable data subject to restriction. Except as provided in paragraph (f)(5) of this clause, only the following legends are authorized under this contract: the government purpose rights legend at paragraph (f)(2) of this clause; the limited rights legend at paragraph (f)(3) of this clause; or the special license rights legend at paragraph (f)(4) of this clause; and/or a notice of copyright as prescribed under 17 U.S.C. 401 or 402.

(1) General marking instructions. The Contractor, or its subcontractors or suppliers, shall conspicuously and legibly mark the appropriate legend on all technical data that qualify for such markings. The authorized legends shall be placed on the transmittal document or storage container and, for printed material, each page of the printed material containing technical data for which restrictions are asserted. When only portions of a page of printed material are subject to the asserted restrictions, such portions shall be identified by circling, underscoring, with a note, or other appropriate identifier. Technical data transmitted directly from one computer or computer terminal to another shall contain a notice of asserted restrictions. Reproductions of technical data or any portions thereof subject to asserted restrictions shall also reproduce the asserted restrictions.

(2) Government purpose rights markings. Data delivered or otherwise furnished to the Government purpose rights shall be marked as follows:

Government Purpose 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 Data--Noncommercial 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 Data--Noncommercial 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 requires 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)

#### 252.227-7017 IDENTIFICATION AND ASSERTION OF USE, RELEASE, OR DISCLOSURE RESTRICTIONS. (JAN 2011)

(a) The terms used in this provision are defined in following clause or clauses contained in this solicitation--

(1) If a successful offeror will be required to deliver technical data, the Rights in Technical Data--Noncommercial Items clause, or, if this solicitation contemplates a contract under the Small Business Innovation Research Program, the Rights in Noncommercial Technical Data and Computer Software--Small Business Innovation Research (SBIR) Program clause.

(2) If a successful offeror will not be required to deliver technical data, the Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation clause, or, if this solicitation contemplates a contract under the Small Business Innovation Research Program, the Rights in Noncommercial Technical Data and Computer Software--Small Business Innovation Research (SBIR) Program clause.

(b) The identification and assertion requirements in this provision apply only to technical data, including computer software documents, or computer software to be delivered with other than unlimited rights. For contracts to be awarded under the Small Business Innovation Research Program, the notification requirements do not apply to technical data or computer software that will be generated under the resulting contract. Notification and identification is not required for restrictions based solely on copyright.

(c) Offers submitted in response to this solicitation shall identify, to the extent known at the time an offer is submitted to the Government, the technical data or computer software that the Offeror, its subcontractors or suppliers, or potential subcontractors or suppliers, assert should be furnished to the Government with restrictions on use, release, or disclosure.

(d) The Offeror's assertions, including the assertions of its subcontractors or suppliers or potential subcontractors or suppliers shall be submitted as an attachment to its offer in the following format, dated and signed by an official authorized to contractually obligate the Offeror:

Identification and Assertion of Restrictions on the Government's Use, Release, or Disclosure of Technical Data or Computer Software.

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

Technical Data or Computer Software to be Furnished	Name of Person Asserting
With Restrictions * Basis for Assertion ** Asserted Rights Category ***	Restrictions ****
(LIST) *****	(LIST) (LIST) (LIST)

\*For technical data (other than computer software documentation) pertaining to items, components, or processes developed at private expense, identify both the deliverable technical data and each such items, component, or process. For computer software or computer software documentation identify the software or documentation.

\*\*Generally, development at private expense, either exclusively or partially, is the only basis for asserting restrictions. For technical data, other than computer software documentation, development refers to development of the item, component, or process to which the data pertain. The Government's rights in computer software documentation generally may not be restricted. For computer software, development refers to the software. Indicate whether development was accomplished exclusively or partially at private expense. If development was not accomplished at private expense, or for computer software documentation, enter the specific basis for asserting restrictions.

\*\*\*Enter asserted rights category (e.g., government purpose license rights from a prior contract, rights in SBIR data generated under another contract, limited, restricted, or government purpose rights under this or a prior contract, or specially negotiated licenses).

\*\*\*\*Corporation, individual, or other person, as appropriate.

\*\*\*\*\*Enter "none" when all data or software will be submitted without restrictions.

Date \_\_\_\_\_

Printed Name and Title \_\_\_\_\_

Signature \_\_\_\_\_

(End of identification and assertion)

(e) An offeror's failure to submit, complete, or sign the notification and identification required by paragraph (d) of this provision with its offer may render the offer ineligible for award.

(f) If the Offeror is awarded a contract, the assertions identified in paragraph (d) of this provision shall be listed in an attachment to that contract. Upon request by the Contracting Officer, the Offeror shall provide sufficient information to enable the Contracting Officer to evaluate any listed assertion.

(End of provision)

252.232-7003 ELECTRONIC SUBMISSION OF PAYMENT REQUESTS AND RECEIVING REPORTS (DEC 2018)

(a) Definitions. As used in this clause--

Contract financing payment means an authorized Government disbursement of monies to a contractor prior to acceptance of supplies or services by the Government.

(1) Contract financing payments include--

(i) Advance payments;

(ii) Performance-based payments;

(iii) Commercial advance and interim payments;

(iv) Progress payments based on cost under the clause at Federal Acquisition Regulation (FAR) 52.232-16, Progress Payments;

(v) Progress payments based on a percentage or stage of completion (see FAR 32.102(e)), except those made under the clause at FAR 52.232-5, Payments Under Fixed-Price Construction Contracts, or the clause at FAR 52.232-10, Payments Under Fixed-Price Architect-Engineer Contracts; and

(vi) Interim payments under a cost reimbursement contract, except for a cost reimbursement contract for services when Alternate I of the clause at FAR 52.232-25, Prompt Payment, is used.

(2) Contract financing payments do not include--

(i) Invoice payments;

(ii) Payments for partial deliveries; or

(iii) Lease and rental payments.

Electronic form means any automated system that transmits information electronically from the initiating system to affected systems.

Invoice payment means a Government disbursement of monies to a contractor under a contract or other authorization for supplies or services accepted by the Government.

(1) Invoice payments include--

(i) Payments for partial deliveries that have been accepted by the Government;

(ii) Final cost or fee payments where amounts owed have been settled between the Government and the contractor;

(iii) For purposes of subpart 32.9 only, all payments made under the clause at 52.232-5, Payments Under Fixed-Price Construction Contracts, and the clause at 52.232-10, Payments Under Fixed-Price Architect-Engineer Contracts; and

(iv) Interim payments under a cost-reimbursement contract for services when Alternate I of the clause at 52.232-25, Prompt Payment, is used.

(2) Invoice payments do not include contract financing payments.

Payment request means any request for contract financing payment or invoice payment submitted by the Contractor under this contract or task or delivery order.



Receiving report means the data prepared in the manner and to the extent required by Appendix F, Material Inspection and Receiving Report, of the Defense Federal Acquisition Regulation Supplement.

(b) Except as provided in paragraph (d) of this clause, the Contractor shall submit payment requests and receiving reports in electronic form using Wide Area WorkFlow (WAWF). The Contractor shall prepare and furnish to the Government a receiving report at the time of each delivery of supplies or services under this contract or task or delivery order.

(c) Submit payment requests and receiving reports to WAWF in one of the following electronic formats:

(1) Electronic Data Interchange.

(2) Secure File Transfer Protocol.

(3) Direct input through the WAWF website.

(d) The Contractor may submit a payment request and receiving report using methods other than WAWF only when-

(1) The Contractor has requested permission in writing to do so, and the Contracting Officer has provided instructions for a temporary alternative method of submission of payment requests and receiving reports in the contract administration data section of this contract or task or delivery order;

(2) DoD makes payment for commercial transportation services provided under a Government rate tender or a contract for transportation services using a DoD-approved electronic third party payment system or other exempted vendor payment/invoicing system (e.g., PowerTrack, Transportation Financial Management System, and Cargo and Billing System);

(3) DoD makes payment on a contract or task or delivery order for rendered health care services using the TRICARE Encounter Data System; or

(4) The Governmentwide commercial purchase card is used as the method of payment, in which case submission of only the receiving report in WAWF is required.

(e) Information regarding WAWF is available at <https://wawf.eb.mil/>.

(f) In addition to the requirements of this clause, the Contractor shall meet the requirements of the appropriate payment clauses in this contract when submitting payment requests.

(End of clause)

#### 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.

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(Contracting Officer: Insert applicable invoice and receiving report document type(s) for fixed price line items that require shipment of a deliverable.)

(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.

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(Contracting Officer: Insert either “Invoice 2in1” or the applicable invoice and receiving report document type(s) for fixed price line items for services.)

(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\*

<i>Field Name in WAWF</i>	<i>Data to be entered in WAWF</i>
Pay Official DoDAAC	_____
Issue By DoDAAC	_____
Admin DoDAAC**	_____
Inspect By DoDAAC	_____
Ship To Code	_____
Ship From Code	_____
Mark For Code	_____
Service Approver (DoDAAC)	_____
Service Acceptor (DoDAAC)	_____
Accept at Other DoDAAC	_____
LPO DoDAAC	_____
DCAA Auditor DoDAAC	_____
Other DoDAAC(s)	_____

(\*Contracting Officer: Insert applicable DoDAAC information. If multiple ship to/acceptance locations apply, insert “See Schedule” or “Not applicable.”)

(\*\*Contracting Officer: If the contract provides for progress payments or performance-based payments, insert the DoDAAC for the contract administration office assigned the functions under FAR 42.302(a)(13).)

(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.

(1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity’s WAWF point of contact.

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(Contracting Officer: Insert applicable information or “Not applicable.”)

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

(End of clause)

## Section J - List of Documents, Exhibits and Other Attachments

ATTACHMENTS

Attachment No.	Description	Number of Pages
1	FDA Guidance In Support of Diagnostic Emergency Use Authorization	3
2	Regulatory Rights	3
3	Conformance Testing Plan	4
4	Evaluation Factors and Rating Criteria	3

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1 CONTRACT ID CODE J	PAGE OF PAGES 1   2
2 AMENDMENT/MODIFICATION NO P00001	3 EFFECTIVE DATE 24-Apr-2020	4 REQUISITION/PURCHASE REQ NO 0011477047-0001		5 PROJECT NO (If applicable)
6 ISSUED BY W6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	CODE W911QY	7 ADMINISTERED BY (If other than item 6) <b>See Item 6</b>		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) ANP TECHNOLOG ES, INC. 824 NTERCHANGE BLVD NEWARK DE 19711-3570		9A. AMENDMENT OF SOLICITATION NO.		
		9B. DATED (SEE ITEM 11)		
		X	10A. MOD. OF CONTRACT/ORDER NO. W911QY20P0141	
		X	10B. DATED (SEE ITEM 13) 17-Apr-2020	
CODE 3AVW6	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended. Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.				
12. ACCOUNTING AND APPROPRIATION DATA (If required)				
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.				
X	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).			
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:				
D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input checked="" type="checkbox"/> is not, <input type="checkbox"/> is required to sign this document and return _____ copies to the issuing office.				
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 add a delivery date of 31 May 2020 to unexercised option CLIN 0002. 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 9A or 10A, as heretofore changed, remains unchanged and in full force and effect				
15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) (b) (6) TEL: (b) (6) EMAIL: (b) (6)		
15B. CONTRACTOR/OFFEROR  (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA  BY (Signature of Contracting Officer)	16C. DATE SIGNED 24-Apr-2020	

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

**SUMMARY OF CHANGES**

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0002

The pricing detail quantity has been added.  
The unit of issue Each has been added.

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for CLIN 0002 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
31-MAY-2020		MEDICAL COUNTERMEASURE SYSTEMS W56XNH JPL EB 110 THOMAS JOHNSON DRIVE FORT DETRICK MD 21702 FOB: Destination	

(End of Summary of Changes)

**Attachment 1**  
**FDA Guidance In Support of Diagnostic Emergency Use Authorization**  
**Surveillance assay status from Food and Drug Administration (FDA)**

The government is intending to use these LFI tests on human clinical samples but not as an Emergency Use Authorization (EUA) approved assay. Hence, it is seeking FDA’s advice and guidance on how to treat these assays as an intermediate between Laboratory Developed Test (LDT) and a EUA test. Based on the outcomes of these discussion, the labeling and shipping requirements for the final assay kits will be determined prior to shipping to the conformance test lab. It is recommended that the offeror initiate discussions with FDA on the following aspects: a) request a template for FDA submission; b) declare their intention to submit an EUA application; c) participate/attend FDA conference calls/meetings/town halls to familiarize with the requirements for submission. The EUA submission for COVID diagnostics has different requirements and templates. The intention is to initiate the process in case the Government desires to take an LFI assay through the process to obtain an EUA. Information from the FDA and frequently asked questions for manufacturers can be found at: <https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>. The FDA Division of Microbiology Devices can be reached at (301) 348-1778, or via e-mail at CDRH-EUA-Templates@fda.hhs.gov to obtain an antigen EUA template. The manufactures will need to have quality compliance and organizational accountability to support EUA for eventual diagnostic approval beyond initial screening use.

FDA recommends that the following validation studies be conducted for a SARS-CoV-2 antigen test – which the 3<sup>rd</sup> party test evaluation aligns with:

- Limit of Detection/Analytical Sensitivity
- Cross-reactivity/Analytical Specificity
- Microbial Interference
- Clinical Agreement Study (JPEO is drafting agreement with the Naval Health Research Center (NHRC) to support this with select performers during production phase)

Due to the pandemic, the FDA has allowed for a reasonable period of time after the manufacturer validates the test to the submission of an Emergency Authorization (EUA) request. The FDA believes that 15 business days is a reasonable period of time to prepare an EUA submission for a test whose performance characteristics have already been validated.

The following table contains the FDA recommendations and requirements for antigen based tests from a manufacturer (not italicized). It has been laid out in a table to *demonstrate/provide additional guidance on activities (in italics)* that can be done in parallel to ensure a rapid transition from development to distribution.

<b>Phase 1: Development and Validation Phase</b>	
<b>Validation:</b> All clinical tests should be validated prior to use. In the context of a public health emergency, it is especially important that tests are validated as false	<i>Activities that can be done concurrently with development and validation activities:</i> <ul style="list-style-type: none"> <li>• Request an EUA Template from <a href="mailto:CDRH-EUA-Templates@fda.hhs.gov">CDRH-EUA-Templates@fda.hhs.gov</a></li> </ul>



**Attachment 1**  
**FDA Guidance In Support of Diagnostic Emergency Use Authorization**  
**Surveillance assay status from Food and Drug Administration (FDA)**

<p>results can have broad public health impact beyond that to the individual patient. FDA has provided recommendations regarding the minimum testing that should be performed to ensure analytical and clinical validity in section V below. FDA encourages laboratories to discuss any alternative testing with FDA that they would like to conduct.</p> <p>FDA defines SARS-CoV-2 antigen diagnostic tests as those that detect SARS-CoV-2 antigens directly from clinical specimens. FDA recommends that the following validation studies be conducted for a SARS-CoV-2 antigen test:</p> <ul style="list-style-type: none"> <li>· Limit of Detection/Analytical Sensitivity</li> <li>· Cross-reactivity/Analytical Specificity</li> <li>· Microbial Interference</li> <li>· Clinical Agreement Study</li> </ul> <p>The clinical agreement study is intended to establish the performance characteristics (e.g., sensitivity/PPA, specificity/NPA) of the test. FDA believes that clinical agreement should be established on human specimens, preferably leftover specimens from patients with or without SARS-CoV-2 infection. If SARS-CoV-2 positive clinical specimens cannot be obtained, it is acceptable to spike leftover specimens with SARS-CoV-2 materials. For devices claiming multiple clinical matrices, the most challenging matrix should be used in your validation studies.</p>	<p><i>If you need additional information for completing the EUA template, would like to know how to submit your Pre-EUA/EUA submission to FDA, or wish to consider use an alternative specimen type, please contact the Division of Microbiology Devices at (301) 348-1778 or the above email address</i></p> <p><b>Information you begin to consider, or activities you can complete prior to/for the template, includes but is not limited to:</b></p> <ul style="list-style-type: none"> <li>• <i>The intended use of the product and whether it is a qualitative or quantitative type of procedure, e.g., screening, physician's office, etc.</i></li> <li>• <i>You should have a system or procedure in place to collect or track and process reports of nonconforming product or adverse events and report them to FDA per <a href="#">21 CFR 803</a>.</i></li> <li>• <i>You should have a website available for users to report adverse events, obtain product support, download product documentation</i></li> <li>• <i>Product Documentation: you will need to create an Instructions For Use, a Fact Sheet for Health Care Providers, and a Fact Sheet for Patients</i></li> <li>• <i>You will need to provide your current manufacturing capabilities, including the approximate number of units/products that can currently be manufactured per week, the number that could be manufacturing in the event of a surge in demand, etc.</i></li> <li>• <i>FDA recommends that you consider registration and listing your EUA product once you have been issued an EUA. Please see FDA's website for process <a href="#">here</a></i></li> </ul>
<b>Phase 2: Post-Validation Initial Distribution Phase</b>	
<p><b>Notify:</b> Following completion of assay validation, manufacturers should notify FDA</p>	<p><b>Reporting of Results</b></p>

**Attachment 1**  
**FDA Guidance In Support of Diagnostic Emergency Use Authorization**  
**Surveillance assay status from Food and Drug Administration (FDA)**

<p>(e.g., e-mail to <a href="mailto:CDRH-EUA-Templates@FDA.HHS.GOV">CDRH-EUA-Templates@FDA.HHS.GOV</a>) that their assay has been validated and they intend to begin distribution. This notification should include the name of the manufacturer, address, contact person, and a copy of the instructions for use including summary of assay performance. FDA will acknowledge receipt of this notification via auto-reply.</p> <p>As noted above, FDA recommends that manufacturers submit a completed EUA request within 15 business days of the initial communication to FDA that the assay has been successfully validated.</p> <p>Manufacturers should provide information on testing capacity, as well as the number of laboratories in the U.S. with the required platforms installed (if necessary). This information will help the Agency and Department monitor the landscape as we work to ensure adequate testing capacity across the country.</p>	<p>While awaiting FDA determination on the EUA request, and in order to provide transparency, FDA recommends that test reports include a general statement that the test has been validated but FDA’s independent review of this validation is pending.</p> <p><b>Labeling</b></p> <p>While awaiting FDA determination on the EUA request, FDA recommends that manufacturers make publicly available on their website the instructions for use, including a summary of assay performance.</p> <p><i>See (<a href="https://www.fda.gov/medical-devices/device-labeling/vitro-diagnostic-device-labeling-requirements#inserts">https://www.fda.gov/medical-devices/device-labeling/vitro-diagnostic-device-labeling-requirements#inserts</a>) for standard IVD labeling guidance re: IFU and performance.</i></p>
<p><b>Phase 3: Request an EUA</b> (Occurs in parallel with data generation; FDA interactive review)</p>	
<p>FDA has made available, through download from their website, a template for test kit manufacturers that is intended to facilitate the preparation, submission and authorization of an EUA. Manufacturers can use alternative approaches. Manufacturers who intend to use alternative approaches should consider seeking FDA’s feedback or advice to help them through the pre-EUA and EUA process. FDA encourages manufacturers to discuss any alternative technological approaches with FDA through <a href="mailto:CDRH-EUA-Templates@FDA.HHS.GOV">CDRH-EUA-Templates@FDA.HHS.GOV</a>.</p> <p>FDA will communicate any questions or concerns regarding the completed EUA request or EUA template to the manufacturer. FDA will also work collaboratively to address any potential concerns or safety considerations raised in the request and will contact the manufacturer regarding a final determination on the EUA request.</p> <p>If FDA is not able to authorize an EUA, FDA intends to notify the manufacturer. FDA would expect the manufacturer to suspend distribution and conduct a recall of the test.</p> <p>Modifications to a manufacturer’s EUA-authorized test are submitted as an amendment to the EUA. Where validation data supporting the modification has been submitted in the amendment, FDA does not intend to object to implementation of the modification while FDA conducts its review.</p>	

## **Attachment 2 Regulatory Rights**

This Agreement may include research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. Subject to further negotiation between the parties, the Contractor or the Government may serve as the Sponsor of the Regulatory Application (an Investigational New Drug Application (IND), Investigational Device Exemption (IDE), New Drug Application (NDA), Biologics License Application (BLA), Premarket Approval Application (PMA), or 510(k) Pre-Market Notification Filing (510(k)) or another regulatory filing submitted to FDA) that controls research under this agreement. The Sponsor of the Regulatory Application to FDA (as the terms “sponsor” and “applicant” are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20) has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

- a. With respect to any products regulated by the FDA for which the Contractor serves as Sponsor, the Contractor agrees to the following:
  - i. The Contractor shall provide to the Government all data, including top-line summaries and key conclusions from all studies, supporting the regulatory filing and commercial approval to the extent that such data, summaries, and conclusions are funded under this Agreement. In addition, the Contractor will offer the Government the opportunity to review and provide comments on a final draft of regulatory submissions which include data funded under this Agreement. The Government will review any such submissions promptly upon receipt. The Contractor shall reasonably consider any comments provided by the Government, and prior to submission shall provide notification to the Government of any additional edits or revisions. The Contractor shall keep the Government reasonably apprised of planned FDA meetings and post-meeting outcomes relating to activities funded under this Agreement.
  - ii. Communications. The Contractor shall provide the Government with all communications and summaries thereof, both formal and informal, to or from FDA regarding the regulatory submissions subject to this Agreement and ensure that the Government representatives are invited to participate in any formal Sponsor meetings with the FDA. The Contractor shall use its best efforts to ensure that the Government representatives are invited to participate in any informal Sponsor meetings with the FDA so long as the Contractor has 48 hour advance notice of such Sponsor meeting from the FDA prior to the scheduled meeting time.
  - iii. Non-compliance with section (a)(ii) may result in termination of the agreement.
- b. Product Development Failure. Certain product development failures may trigger certain remedies in Section (c) below for the Government advanced developer funding the development of the work in this Agreement. This remedy is not available to the Government for any cause outside of the following:
  - i. if this agreement is terminated for nonperformance; or
  - ii. the Contractor gives notice, required to be submitted to the Government no later than 30 business days, of any formal management decision to terminate this

## **Attachment 2 Regulatory Rights**

product development effort pre-market or to file for Federal bankruptcy protection.

- c. If any of the product development failures listed in section (b) occur, the Contractor, upon the request of the Government:
  - i. shall transfer possession, ownership and sponsorship or holdership of any Regulatory Application (including any associated expedited review designation, priority review voucher, or marketing exclusivity eligibility or award), regulatory correspondence, and supporting regulatory information related to the Technology to the Government or its designee;
  - ii. shall inform FDA of the transfer of sponsorship or holdership of the Regulatory Application transferred under section (c)(i) above; and
  - iii. shall negotiate in good faith a non-exclusive license, at customary industry rates and under reasonable terms and conditions, to any patent, copyright or other intellectual property owned or controlled by the Contractor, developed prior to or outside the scope of this agreement, or any technical data that is necessary for the Government to pursue commercialization of this technology with a third party for sale to the Government or otherwise.
- d. This agreement will survive the acquisition or merger of the Contractor by or with a third party. This agreement will also be included in any subcontracts/sub agreements relating to the development of the Technology. This agreement will survive the expiration of the contracted agreements.

**Attachment 3  
Conformance Testing Plan**

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

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### **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)
- 3) 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**

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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**

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**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**

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**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 4**  
**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.

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

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

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

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

Combined Scores					
Sensitivity		Specificity	Interference		Final Score
Limit of Detection	Sensitivity				
Blue	Green	Blue	Blue	→	Blue
Blue	Green	Blue	Green	→	Blue
Blue	Green	Green	Blue	→	Turquoise
Blue	Green	Green	Green	→	Turquoise
Green	Green	Blue	Blue	→	Turquoise
Green	Green	Blue	Green	→	Green
Green	Green	Green	Blue	→	Green
Green	Green	Green	Green	→	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.