

SOLICITATION, OFFER AND AWARD			1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING	PAGE OF PAGES 1 29	
2. CONTRACT NO. W911QY20D0018		3. SOLICITATION NO.		4. TYPE OF SOLICITATION [] SEALED BID (IFB) [] NEGOTIATED (RFP)		5. DATE ISSUED	
7. ISSUED BY W6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702		CODE W911QY		8. ADDRESS OFFER TO (If other than Item 7) See Item 7		CODE	
TEL:		FAX:		TEL:		FAX:	

NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder".

SOLICITATION

9. Sealed offers in original and _____ copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if handcarried, in the depository located in _____ until _____ local time _____ (Hour) (Date)

CAUTION - LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in this solicitation.

10. FOR INFORMATION CALL:	A. NAME	B. TELEPHONE (Include area code) (NO COLLECT CALLS)	C. E-MAIL ADDRESS
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OFFER (Must be fully completed by offeror)

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within _____ calendar days (60 calendar days unless a different period is inserted by the offeror) from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT (See Section I, Clause No. 52.232-8)			
14. ACKNOWLEDGMENT OF AMENDMENTS (The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated):		AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR MAXIM BIOMEDICAL, INC. 1500 EAST GUDE DRIVE ROCKVILLE MD 20850-5307		CODE 4EJW3	FACILITY	16. NAME AND TITLE OF PERSON AUTHORIZED TO SIGN OFFER (Type or print)	
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15B. TELEPHONE NO (Include area code)	<input type="checkbox"/>	15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.	17. SIGNATURE	18. OFFER DATE
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AWARD (To be completed by Government)

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT \$45,100,000.00	21. ACCOUNTING AND APPROPRIATION	
22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input checked="" type="checkbox"/> 10 U.S.C. 2304(c)(2) <input type="checkbox"/> 41 U.S.C. 253(c)()		23. SUBMIT INVOICES TO ADDRESS SHOWN IN	ITEM
24. ADMINISTERED BY (If other than Item 7) See Item 7		25. PAYMENT WILL BE MADE BY DEFENSE FINANCE AND ACCOUNTING SERVICE DFAS-INDY VP GFEEBS 8899 E 56TH STREET INDIANAPOLIS IN 46249-3800	
26. NAME OF CONTRACTING OFFICER (Type or print) (b) (6) TEL: (b) (6) EMAIL: (b) (6)		27. UNITED STATES OF AMERICA (b) (6) (Signature of Contracting Officer)	28. AWARD DATE 11-May-2020

IMPORTANT - Award will be made on this Form, or on Standard Form 26, or by other authorized official written notice.

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
0001	SARS-CoV-2 LFI Kit FFP Lateral Flow Immunoassay kit for detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) antigen to include nasal swab and appropriate amount of clinical buffer. FOB: Destination MFR PART NR: TBD PSC CD: 6550	(b) (4)	Each	(b) (4)	\$45,000,000.00
MAX NET AMT					\$45,000,000.00

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
0002	Shipping COST Costs for shipping of SARS-CoV-2 kits should be billed against this Cost Reimbursable Shipping CLIN. Ship To Addresses will be included on individual Delivery Orders. FOB: Destination MFR PART NR: TBD PSC CD: 6550	(b) (4)	Job	(b) (4)	\$100,000.00
MAX COST					\$100,000.00

CONTRACT MINIMUM/MAXIMUM QUANTITY AND CONTRACT VALUE

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

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

MINIMUM QUANTITY	MINIMUM AMOUNT	MAXIMUM QUANTITY	MAXIMUM AMOUNT
(b) (4)	\$75,000.00	(b) (4)	\$45,000,000.00

DELIVERY/TASK ORDER MINIMUM/MAXIMUM QUANTITY AND ORDER VALUE

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

MINIMUM QUANTITY	MINIMUM AMOUNT	MAXIMUM QUANTITY	MAXIMUM AMOUNT
(b) (4)	\$75,000.00	(b) (4)	\$45,000,000.00

CLIN MINIMUM/MAXIMUM QUANTITY AND CLIN VALUE

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

CLIN	MINIMUM QUANTITY	MINIMUM AMOUNT	MAXIMUM QUANTITY	MAXIMUM AMOUNT
0001	(b) (4)	\$75,000.00	(b) (4)	\$45,000,000.00

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

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

CLIN	MINIMUM QUANTITY	MINIMUM AMOUNT	MAXIMUM QUANTITY	MAXIMUM AMOUNT
0001	(b) (4)	\$75,000.00	(b) (4)	\$45,000,000.00
0002		\$		\$

Section C - Descriptions and Specifications

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

1.0 Scope. The scope of this work includes all activities required for a SARS-CoV-2 lateral flow immunoassay (LFI) test system, including the optimization and production of antigen screening test and all verification, validation, and regulatory activities required to achieve Food and Drug Administration (FDA) Emergency Use Authorization (EUA). Although, FDA Licensure is anticipated, it is not part of this effort. The end product shall be suitable as an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 virus in specimens from infected persons or persons suspected of exposure to SARS-CoV-2 and shall be intended for use at the point of care. The determination of an FDA sponsor will be reviewed during the ordering period.

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

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

3.0 Requirements

3.1 Manufacturing Facility

3.1.1 Have manufacturing yield sufficient to meet Government delivery order requirements of up to 1,000,000 kits per month (250,000 per week) specifically 5,000 kits/week by 15 May 2020, scalable to 250,000 kits/week by 15 July 2020. This quantity shall not include kits intended for third party

conformance testing and contractor's internal testing.

3.1.2 Inventory management procedures to store antigens, antibodies and assays under the appropriate storage conditions as required by the label to maximize performance integrity and shelf life.

3.1.3 Security monitoring, temperature and humidity controlled for production area, with appropriate BioSafety Level and storage areas for assay materials including emergency backup power.

3.1.4 Standard Operating Procedures for all procedures associated with manufacturing, storage, and shipping of SARS-CoV-2 kits to assure compliance with contractual requirements and all local, state, and federal regulations and Standards.

3.3 SARS-CoV-2 Lateral Flow Immunoassay Kit

3.3.1 Deliverables

3.3.1.1 SARS-CoV-2 LFI kits for the detection of SARS-CoV-2 virus, nasal swabs and appropriate clinical buffer labeled in accordance with Research Only Use (ROU) or as a EUA once approved. These kits shall be delivered while maintaining product integrity.

3.3.1.2 Certificate of Conformance that includes specifications and results of internal conformance testing with each manufacturing lot of SARS-CoV-2 LFI kits.

3.3.2 Reagents

3.3.2.1 The Contractor shall be responsible for the production or procurement of the reagents required for the manufacture of this SARS-CoV-2 LFI kit such as recombinant viral capsid proteins; capture and detector antibodies, secondary antibodies, reference standards, near neighbor panel for specificity testing, negative controls etc. The government will not provide these reagents as government furnished materials.

3.3.2.2 The Contractor shall assume all risks and responsibilities in connection with the handling, storage, disposal, transfer, and use of the assay materials including appropriate safety and handling precautions to minimize health or environmental risk. The Contractor shall agree that any activity undertaken with the manufacture of this assay will be conducted in compliance with all applicable guidelines, laws and regulations, including Department of Defense Instruction 5210.89 (DoDI 5210.89) for DoD recipients.

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

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

CLAUSES INCORPORATED BY REFERENCE

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

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	POP 11-MAY-2020 TO 10-MAY-2021	N/A	N/A FOB: Destination	
0002	POP 11-MAY-2020 TO 10-MAY-2021	N/A	N/A FOB: Destination	

CLAUSES INCORPORATED BY REFERENCE

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

DELIVERY DATES

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

ORDERING PERIODS

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

Section G - Contract Administration Data

CLAUSES INCORPORATED BY REFERENCE

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

CLAUSES INCORPORATED BY FULL TEXT

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

(a) Definitions. As used in this clause—

“Department of Defense Activity Address Code (DoDAAC)” is a six position code that uniquely identifies a unit, activity, or organization.

“Document type” means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

“Local processing office (LPO)” is the office responsible for payment certification when payment certification is done external to the entitlement system.

“Payment request” and “receiving report” are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall—

(1) Have a designated electronic business point of contact in the System for Award Management at <https://www.sam.gov>; and

(2) Be registered to use WAWF at <https://wawf.eb.mil/> following the step-by-step procedures for self-registration available at this web site.

(d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the “Web Based Training” link on the WAWF home page at <https://wawf.eb.mil/>.

(e) WAWF methods of document submission. Document submissions may be via web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:

(1) Document type. The Contractor shall submit payment requests using the following document type(s):

(i) For cost-type line items, including labor-hour or time-and-materials, submit a cost voucher.

(ii) For fixed price line items—

(A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.

COMBO

(B) For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.

(iii) For customary progress payments based on costs incurred, submit a progress payment request.

(iv) For performance based payments, submit a performance based payment request.

(v) For commercial item financing, submit a commercial item financing request.

(2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.

(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	HQ0490
Issue By DoDAAC	W911QY
Admin DoDAAC**	W911QY
Inspect By DoDAAC	W56XNH
Ship To Code	W56XNH

(4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.

(5) Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.

(g) WAWF point of contact.

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

(b) (6) [REDACTED], Deputy Director of Finance

(b) (6) [REDACTED]

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

(End of clause)

Section H - Special Contract Requirements

H.1 Most Favored Customer

A. Awardee agrees that during the term of this contract and for a period of 5 years thereafter, that it shall not offer, sell or otherwise provide the production model of the CLIN 0001 end items (for the avoidance of doubt, CLIN 0001 end items in this clause shall mean a finished good of like material, like quality, to be used in a similar applications, and shall not include more general products to any entity at a price lower than that offered to the DoD. In the event that Awardee sells the production model at a lower unit price than that price sold to the DoD, Awardee shall immediately notify the Contracting Officer in writing of the lower price. For prior purchases, the Awardee shall reimburse the DoD, the difference between the lower price sold to the other customer(s) and the price sold to the DoD multiplied by the number of items sold. Such reimbursement shall occur within thirty days (30) of the Awardee discovering that the lower price was given to another customer. Notwithstanding the foregoing, the Parties may agree to apply the difference in price paid by the other customer(s) and DoD into additional quantities required by the DoD.

B. If Awardee develops a like product (commercialized version or derivative of the production model) with similar capability and intended application, but at a lower unit price ("Like Product") regardless of quantity, Awardee shall make the DoD aware of that similar product and the technical and price differences between that product and the DoD Product. Such notification shall be made to the Contracting Officer in writing, of which email is an acceptable form, within thirty (30) days of such offering. Awardee agrees that no entity shall receive a lower price for any Like Product than the DoD for like purchase quantities.

Note: This clause does not preclude Maxim from negotiating more favorable prices with partners who will assist with manufacturing, further development, and licensing-royalty relationships. In the event Maxim provides a more favorable price utilizing the above mentioned methods, Maxim is to disclose this information to the Contracting Officer, as soon as practicable.

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.202-1	Definitions	NOV 2013
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	MAY 2014
52.203-6	Restrictions On Subcontractor Sales To The Government	SEP 2006
52.203-7	Anti-Kickback Procedures	MAY 2014
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	MAY 2014
52.203-10	Price Or Fee Adjustment For Illegal Or Improper Activity	MAY 2014
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	OCT 2010
52.203-13	Contractor Code of Business Ethics and Conduct	OCT 2015
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	MAY 2011
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	OCT 2018
52.204-19	Incorporation by Reference of Representations and Certifications.	DEC 2014
52.204-23	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities.	JUL 2018
52.204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.	AUG 2019
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	OCT 2015
52.209-9	Updates of Publicly Available Information Regarding Responsibility Matters	OCT 2018
52.209-10	Prohibition on Contracting With Inverted Domestic Corporations	NOV 2015
52.211-5	Material Requirements	AUG 2000
52.215-2	Audit and Records--Negotiation	OCT 2010
52.215-8	Order of Precedence--Uniform Contract Format	OCT 1997
52.215-11	Price Reduction for Defective Certified Cost or Pricing Data-- Modifications	AUG 2011
52.215-13	Subcontractor Certified Cost or Pricing Data--Modifications	OCT 2010
52.215-14	Integrity of Unit Prices	OCT 2010
52.215-19	Notification of Ownership Changes	OCT 1997
52.215-23	Limitations on Pass-Through Charges	OCT 2009
52.216-7	Allowable Cost And Payment	AUG 2018
52.216-22	Indefinite Quantity	OCT 1995
52.219-8	Utilization of Small Business Concerns	OCT 2018
52.219-14	Limitations On Subcontracting	MAR 2020
52.219-28	Post-Award Small Business Program Rerepresentation	MAR 2020
52.222-19	Child Labor -- Cooperation with Authorities and Remedies	JAN 2020
52.222-20	Contracts for Materials, Supplies, Articles, and Equipment Exceeding \$15,000	MAY 2014
52.222-21	Prohibition Of Segregated Facilities	APR 2015
52.222-35	Equal Opportunity for Veterans	OCT 2015
52.222-35	Equal Opportunity for Veterans	OCT 2015
52.222-36	Equal Opportunity for Workers with Disabilities	JUL 2014

52.222-37	Employment Reports on Veterans	FEB 2016
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	DEC 2010
52.222-50	Combating Trafficking in Persons	JAN 2019
52.222-54	Employment Eligibility Verification	OCT 2015
52.223-6	Drug-Free Workplace	MAY 2001
52.223-9	Estimate of Percentage of Recovered Material Content for EPA-Designated Items	MAY 2008
52.223-18	Encouraging Contractor Policies To Ban Text Messaging While Driving	AUG 2011
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.227-1	Authorization and Consent	DEC 2007
52.227-11	Patent Rights--Ownership By The Contractor	MAY 2014
52.229-3	Federal, State And Local Taxes	FEB 2013
52.232-8	Discounts For Prompt Payment	FEB 2002
52.232-9	Limitation On Withholding Of Payments	APR 1984
52.232-11	Extras	APR 1984
52.232-17	Interest	MAY 2014
52.232-20	Limitation Of Cost	APR 1984
52.232-22	Limitation Of Funds	APR 1984
52.232-25	Prompt Payment	JAN 2017
52.232-33	Payment by Electronic Funds Transfer--System for Award Management	OCT 2018
52.233-1	Disputes	MAY 2014
52.233-3	Protest After Award	AUG 1996
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.242-13	Bankruptcy	JUL 1995
52.243-1	Changes--Fixed Price	AUG 1987
52.244-5	Competition In Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	AUG 2019
52.246-23	Limitation Of Liability	FEB 1997
52.249-2	Termination For Convenience Of The Government (Fixed-Price)	APR 2012
52.249-8	Default (Fixed-Price Supply & Service)	APR 1984
52.253-1	Computer Generated Forms	JAN 1991
252.201-7000	Contracting Officer's Representative	DEC 1991
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	SEP 2011
252.203-7001	Prohibition On Persons Convicted of Fraud or Other Defense-Contract-Related Felonies	DEC 2008
252.203-7003	Agency Office of the Inspector General	AUG 2019
252.203-7004	Display of Hotline Posters	AUG 2019
252.204-7000	Disclosure Of Information	OCT 2016
252.204-7003	Control Of Government Personnel Work Product	APR 1992
252.204-7006	Billing Instructions	OCT 2005
252.211-7003	Item Unique Identification and Valuation	MAR 2016
252.222-7006	Restrictions on the Use of Mandatory Arbitration Agreements	DEC 2010
252.223-7001	Hazard Warning Labels	DEC 1991
252.225-7012	Preference For Certain Domestic Commodities	DEC 2017
252.225-7048	Export-Controlled Items	JUN 2013
252.226-7001	Utilization of Indian Organizations and Indian-Owned Economic Enterprises, and Native Hawaiian Small Business Concerns	APR 2019
252.227-7016	Rights in Bid or Proposal Information	JAN 2011
252.227-7030	Technical Data--Withholding Of Payment	MAR 2000

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

CLAUSES INCORPORATED BY FULL TEXT

52.204-10 REPORTING EXECUTIVE COMPENSATION AND FIRST-TIER SUBCONTRACT AWARDS (OCT 2018)

(a) Definitions. As used in this clause:

Executive means officers, managing partners, or any other employees in management positions.

First-tier subcontract means a subcontract awarded directly by the Contractor for the purpose of acquiring supplies or services (including construction) for performance of a prime contract. It does not include the Contractor's supplier agreements with vendors, such as long-term arrangements for materials or supplies that benefit multiple contracts and/or the costs of which are normally applied to a Contractor's general and administrative expenses or indirect costs.

Month of award means the month in which a contract is signed by the Contracting Officer or the month in which a first-tier subcontract is signed by the Contractor.

Total compensation means the cash and noncash dollar value earned by the executive during the Contractor's preceding fiscal year and includes the following (for more information see 17 CFR 229.402(c)(2)):

- (1) Salary and bonus.
- (2) Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Financial Accounting Standards Board's Accounting Standards Codification (FASB ASC) 718, Compensation-Stock Compensation.
- (3) Earnings for services under non-equity incentive plans. This does not include group life, health, hospitalization or medical reimbursement plans that do not discriminate in favor of executives, and are available generally to all salaried employees.
- (4) Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.
- (5) Above-market earnings on deferred compensation which is not tax-qualified.
- (6) Other compensation, if the aggregate value of all such other compensation (e.g., severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds \$10,000.

(b) Section 2(d)(2) of the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109-282), as amended by section 6202 of the Government Funding Transparency Act of 2008 (Pub. L. 110-252), requires the Contractor to report information on subcontract awards. The law requires all reported information be made public, therefore, the Contractor is responsible for notifying its subcontractors that the required information will be made public.

(c) Nothing in this clause requires the disclosure of classified information.

(d)(1) Executive compensation of the prime contractor. As a part of its annual registration requirement in the System for Award Management (SAM) (FAR provision 52.204-7), the Contractor shall report the names and total compensation of each of the five most highly compensated executives for its preceding completed fiscal year, if—

(i) In the Contractor's preceding fiscal year, the Contractor received—

(A) 80 percent or more of its annual gross revenues from Federal contracts (and subcontracts), loans, grants (and subgrants), cooperative agreements, and other forms of Federal financial assistance; and

(B) \$25,000,000 or more in annual gross revenues from Federal contracts (and subcontracts), loans, grants (and subgrants), cooperative agreements, and other forms of Federal financial assistance; and

(ii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at <http://www.sec.gov/answers/execomp.htm>.)

(2) First-tier subcontract information. Unless otherwise directed by the contracting officer, or as provided in paragraph (g) of this clause, by the end of the month following the month of award of a first-tier subcontract with a value of \$30,000 or more, the Contractor shall report the following information at <http://www.frs.gov> for that first-tier subcontract. (The Contractor shall follow the instructions at <http://www.frs.gov> to report the data.)

(i) Unique entity identifier for the subcontractor receiving the award and for the subcontractor's parent company, if the subcontractor has a parent company.

(ii) Name of the subcontractor.

(iii) Amount of the subcontract award.

(iv) Date of the subcontract award.

(v) A description of the products or services (including construction) being provided under the subcontract, including the overall purpose and expected outcomes or results of the subcontract.

(vi) Subcontract number (the subcontract number assigned by the Contractor).

(vii) Subcontractor's physical address including street address, city, state, and country. Also include the nine-digit zip code and congressional district.

(viii) Subcontractor's primary performance location including street address, city, state, and country. Also include the nine-digit zip code and congressional district.

(ix) The prime contract number, and order number if applicable.

(x) Awarding agency name and code.

(xi) Funding agency name and code.

(xii) Government contracting office code.

(xiii) Treasury account symbol (TAS) as reported in FPDS.

(xiv) The applicable North American Industry Classification System code (NAICS).

(3) Executive compensation of the first-tier subcontractor.

Unless otherwise directed by the Contracting Officer, by the end of the month following the month of award of a first-tier subcontract with a value of \$30,000 or more, and annually thereafter (calculated from the prime contract award date), the Contractor shall report the names and total compensation of each of the five most highly compensated executives for that first-tier subcontractor for the first-tier subcontractor's preceding completed fiscal year at <http://www.fsrs.gov>, if—

(i) In the subcontractor's preceding fiscal year, the subcontractor received—

(A) 80 percent or more of its annual gross revenues from Federal contracts (and subcontracts), loans, grants (and subgrants), cooperative agreements, and other forms of Federal financial assistance; and

(B) \$25,000,000 or more in annual gross revenues from Federal contracts (and subcontracts), loans, grants (and subgrants), cooperative agreements, and other forms of Federal financial assistance; and

(ii) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at <http://www.sec.gov/answers/excomp.htm>.)

(e) The Contractor shall not split or break down first-tier subcontract awards to a value less than \$30,000 to avoid the reporting requirements in paragraph (d) of this clause.

(f) The Contractor is required to report information on a first-tier subcontract covered by paragraph (d) when the subcontract is awarded. Continued reporting on the same subcontract is not required unless one of the reported data elements changes during the performance of the subcontract. The Contractor is not required to make further reports after the first-tier subcontract expires.

(g)(1) If the Contractor in the previous tax year had gross income, from all sources, under \$300,000, the Contractor is exempt from the requirement to report subcontractor awards.

(2) If a subcontractor in the previous tax year had gross income from all sources under \$300,000, the Contractor does not need to report awards for that subcontractor.

(h) The FSRS database at <http://www.fsrs.gov> will be prepopulated with some information from SAM and the FPDS database. If FPDS information is incorrect, the contractor should notify the contracting officer. If the SAM information is incorrect, the contractor is responsible for correcting this information.

(End of clause)

52.209-9 UPDATES OF PUBLICLY AVAILABLE INFORMATION REGARDING RESPONSIBILITY MATTERS (OCT 2018)

(a) The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the System for Award Management Management via <https://www.sam.gov>.

(b) As required by section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111-212), all information posted in FAPIS on or after April 15, 2011, except past performance reviews, will be publicly available. FAPIS consists of two segments--

(1) The non-public segment, into which Government officials and the Contractor post information, which can only be viewed by--

(i) Government personnel and authorized users performing business on behalf of the Government; or

(ii) The Contractor, when viewing data on itself; and

(2) The publicly-available segment, to which all data in the non-public segment of FAPIS is automatically transferred after a waiting period of 14 calendar days, except for--

(i) Past performance reviews required by subpart 42.15;

(ii) Information that was entered prior to April 15, 2011; or

(iii) Information that is withdrawn during the 14-calendar-day waiting period by the Government official who posted it in accordance with paragraph (c)(1) of this clause.

(c) The Contractor will receive notification when the Government posts new information to the Contractor's record.

(1) If the Contractor asserts in writing within 7 calendar days, to the Government official who posted the information, that some of the information posted to the non-public segment of FAPIS is covered by a disclosure exemption under the Freedom of Information Act, the Government official who posted the information must within 7 calendar days remove the posting from FAPIS and resolve the issue in accordance with agency Freedom of Information procedures, prior to reposting the releasable information. The contractor must cite 52.209-9 and request removal within 7 calendar days of the posting to FAPIS.

(2) The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.

(3) As required by section 3010 of Pub. L. 111-212, all information posted in FAPIS on or after April 15, 2011, except past performance reviews, will be publicly available.

(d) Public requests for system information posted prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.

(End of clause)

52.216-18 ORDERING. (OCT 1995)

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from 11 May 2020 through 10 May 2021.

(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

(c) If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

(End of clause)

52.216-19 ORDER LIMITATIONS (OCT 1995)

(a) Minimum order. When the Government requires supplies or services covered by this contract in an amount of less than \$10,000, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

(b) Maximum order. The Contractor is not obligated to honor -

(1) Any order for a single item in excess of the maximum quantities stated in Section B;

(2) Any order for a combination of items in excess of the maximum quantities stated in Section B; or

(3) A series of orders from the same ordering office within 60 days that together call for quantities exceeding the limitation in paragraph (b) (1) or (2) of this section.

(c) If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) of this section.

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

(End of clause)

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

(a)(1) Except as provided in subparagraph (a)(2) of this clause, the Contractor shall provide and maintain workers' compensation, employer's liability, comprehensive general liability (bodily injury), comprehensive automobile liability (bodily injury and property damage) insurance, and such other insurance as the Contracting Officer may require under this contract.

(2) The Contractor may, with the approval of the Contracting Officer, maintain a self-insurance program; provided that, with respect to workers' compensation, the Contractor is qualified pursuant to statutory authority.

(3) All insurance required by this paragraph shall be in a form and amount and for those periods as the Contracting Officer may require or approve and with insurers approved by the Contracting Officer.

(b) The Contractor agrees to submit for the Contracting Officer's approval, to the extent and in the manner required by the Contracting Officer, any other insurance that is maintained by the Contractor in connection with the performance of this contract and for which the Contractor seeks reimbursement.

(c) The Contractor shall be reimbursed—

(1) For that portion (i) of the reasonable cost of insurance allocable to this contract, and (ii) required or approved under this clause; and

(2) For certain liabilities (and expenses incidental to such liabilities) to third persons not compensated by insurance or otherwise without regard to and as an exception to the limitation of cost or the limitation of funds clause of this contract. These liabilities must arise out of the performance of this contract, whether or not caused by the negligence of the Contractor or of the Contractor's agents, servants, or employees, and must be represented by final judgments or settlements approved in writing by the Government. These liabilities are for--

(i) Loss of or damage to property (other than property owned, occupied, or used by the Contractor, rented to the Contractor, or in the care, custody, or control of the Contractor); or

(ii) Death or bodily injury.

(d) The Government's liability under paragraph (c) of this clause is subject to the availability of appropriated funds at the time a contingency occurs. Nothing in this contract shall be construed as implying that the Congress will, at a later date, appropriate funds sufficient to meet deficiencies.

(e) The Contractor shall not be reimbursed for liabilities (and expenses incidental to such liabilities)--

(1) For which the Contractor is otherwise responsible under the express terms of any clause specified in the Schedule or elsewhere in the contract;

(2) For which the Contractor has failed to insure or to maintain insurance as required by the Contracting Officer; or

(3) That result from willful misconduct or lack of good faith on the part of any of the Contractor's directors, officers, managers, superintendents, or other representatives who have supervision or direction of--

(i) All or substantially all of the Contractor's business;

(ii) All or substantially all of the Contractor's operations at any one plant or separate location in which this contract is being performed; or

(iii) A separate and complete major industrial operation in connection with the performance of this contract.

(f) The provisions of paragraph (e) of this clause shall not restrict the right of the Contractor to be reimbursed for the cost of insurance maintained by the Contractor in connection with the performance of this contract, other than insurance required in accordance with this clause; provided, that such cost is allowable under the Allowable Cost and Payment clause of this contract.

(g) If any suit or action is filed or any claim is made against the Contractor, the cost and expense of which may be reimbursable to the Contractor under this contract, and the risk of which is then uninsured or is insured for less than the amount claimed, the Contractor shall--

- (1) Immediately notify the Contracting Officer and promptly furnish copies of all pertinent papers received;
- (2) Authorize Government representatives to collaborate with counsel for the insurance carrier in settling or defending the claim when the amount of the liability claimed exceeds the amount of coverage; and
- (3) Authorize Government representatives to settle or defend the claim and to represent the Contractor in or to take charge of any litigation, if required by the Government, when the liability is not insured or covered by bond. The Contractor may, at its own expense, be associated with the Government representatives in any such claim or litigation.

(End of clause)

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

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

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

(End of clause)

252.216-7006 ORDERING (SEP 2019)

- (a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the contract schedule. Such orders may be issued from 11 May 2020 through 10 May 2021.
- (b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.
- (c)(1) If issued electronically, the order is considered ``issued" when a copy has been posted to the Electronic Data Access system, and notice has been sent to the Contractor.
- (2) If mailed or transmitted by facsimile, a delivery order or task order is considered ``issued" when the Government deposits the order in the mail or transmits by facsimile. Mailing includes transmittal by U.S. mail or private delivery services.
- (3) Orders may be issued orally only if authorized in the schedule.

(End of Clause)

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

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

- (1) Computer data base means a collection of data recorded in a form capable of being processed by a computer. The term does not include computer software.
- (2) Computer program means a set of instructions, rules, or routines recorded in a form that is capable of causing a computer to perform a specific operation or series of operations.
- (3) Computer software means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated, or recompiled. Computer software does not include computer data bases or computer software documentation.
- (4) Computer software documentation means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.
- (5) Covered Government support contractor means a contractor (other than a litigation support contractor covered by 252.204-7014) under a contract, the primary purpose of which is to furnish independent and impartial advice or technical assistance directly to the Government in support of the Government's management and oversight of a program or effort (rather than to directly furnish an end item or service to accomplish a program or effort), provided that the contractor--
 - (i) Is not affiliated with the prime contractor or a first-tier subcontractor on the program or effort, or with any direct competitor of such prime contractor or any such first-tier subcontractor in furnishing end items or services of the type developed or produced on the program or effort; and
 - (ii) Receives access to technical data or computer software for performance of a Government contract that contains the clause at 252.227-7025, Limitations on the Use or Disclosure of Government-Furnished Information Marked with Restrictive Legends.
- (6) Detailed manufacturing or process data means technical data that describe the steps, sequences, and conditions of manufacturing, processing or assembly used by the manufacturer to produce an item or component or to perform a process.
- (7) Developed means that an item, component, or process exists and is workable. Thus, the item or component must have been constructed or the process practiced. Workability is generally established when the item, component, or process has been analyzed or tested sufficiently to demonstrate to reasonable people skilled in the applicable art that there is a high probability that it will operate as intended. Whether, how much, and what type of analysis or testing is required to establish workability depends on the nature of the item, component, or process, and the state of the art. To be considered "developed," the item, component, or process need not be at the stage where it could be offered for sale or sold on the commercial market, nor must the item, component, or process be actually reduced to practice within the meaning of Title 35 of the United States Code.
- (8) Developed exclusively at private expense means development was accomplished entirely with costs charged to indirect cost pools, costs not allocated to a government contract, or any combination thereof.
 - (i) Private expense determinations should be made at the lowest practicable level.
 - (ii) Under fixed-price contracts, when total costs are greater than the firm-fixed-price or ceiling price of the contract, the additional development costs necessary to complete development shall not be considered when determining whether development was at government, private, or mixed expense.
- (9) Developed exclusively with government funds means development was not accomplished exclusively or partially at private expense.

(10) Developed with mixed funding means development was accomplished partially with costs charged to indirect cost pools and/or costs not allocated to a government contract, and partially with costs charged directly to a government contract.

(11) Form, fit, and function data means technical data that describes the required overall physical, functional, and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.

(12) Government purpose means any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations, or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose technical data for commercial purposes or authorize others to do so.

(13) Government purpose rights means the rights to--

(i) Use, modify, reproduce, release, perform, display, or disclose technical data within the Government without restriction; and

(ii) Release or disclose technical data outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that data for United States government purposes.

(14) Limited rights means the rights to use, modify, reproduce, release, perform, display, or disclose technical data, in whole or in part, within the Government. The Government may not, without the written permission of the party asserting limited rights, release or disclose the technical data outside the Government, use the technical data for manufacture, or authorize the technical data to be used by another party, except that the Government may reproduce, release, or disclose such data or authorize the use or reproduction of the data by persons outside the Government if--

(i) The reproduction, release, disclosure, or use is--

(A) Necessary for emergency repair and overhaul; or

(B) A release or disclosure to--

(1) A covered Government support contractor in performance of its covered Government support contract for use, modification, reproduction, performance, display, or release or disclosure to a person authorized to receive limited rights technical data; or

(2) A foreign government, of technical data other than detailed manufacturing or process data, when use of such 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 With Restrictions \1/	Basis for Assertion \2/	Asserted Rights Category \3/	Name of Person Asserting Restrictions \4/
(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)

Section J - List of Documents, Exhibits and Other Attachments

Attachments

Attachment 1 Conformance Test Plan

Attachment 2 Evaluation factors and rating criteria

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE	PAGE OF PAGES	
			J	1	13
2. AMENDMENT/MODIFICATION NO. P00001	3. EFFECTIVE DATE 19-May-2020	4. REQUISITION/PURCHASE REQ. NO.		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)		CODE	
		See Item 6			
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) MAXIM BIOMEDICAL, INC. 1500 EAST GUDE DRIVE ROCKVILLE MD 20850-5307			9A. AMENDMENT OF SOLICITATION NO.		
			9B. DATED (SEE ITEM 11)		
			X	10A. MOD. OF CONTRACT/ORDER NO. W911QY20D0018	
			X	10B. DATED (SEE ITEM 13) 11-May-2020	
CODE 4EJW3	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.					
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).					
X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: By mutual agreement of both parties.					
D. OTHER (Specify type of modification and authority)					
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> 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 Contract Data Requirement List (CDRL) CLINs 0003-0011, add CLN 0012 for Regulatory Support/Emergency Use Authorization (EUA), revise Section C, the Statement of Work to include additional work for Regulatory Support and Emergency Use Authorization (EUA) at paragraph 3.3.2, and revise Section J to include CDRL exhibits. All other terms and conditions remain the same are 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) / CONTRACTING OFFICER		
			TEL: (b) (6) EMAIL: (b) (6)		
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA		16C. DATE SIGNED	
_____ (Signature of person authorized to sign)		BY (b) (6)		19-May-2020	
		(Signature of Contracting Officer)			

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by \$7,035.00 from \$45,100,000.00 to \$45,107,035.00.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0003 is added as follows:

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
0003	CDRL FFP First Article Qualification Test Plan and Procedures, See Section J Attachment A001 FOB: Destination MFR PART NR: TBD PSC CD: 6550	█	Each	(b) (4)	\$130.00
					<hr/>
					MAX NET AMT
					\$130.00

CLIN 0004 is added as follows:

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
0004	CDRL FFP Quality Control Inspection and Test Plan, See Section J Attachment A002	█	Each	(b) (4)	\$195.00
					MAX NET AMT
					\$195.00

CLIN 0005 is added as follows:

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
0005	CDRL FFP First Article Test/Inspection Report, See Section J Attachment A003	█	Each	(b) (4)	\$325.00
					MAX NET AMT
					\$325.00

CLIN 0006 is added as follows:

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
0006	CDRL FFP Progress Report, See Section J Attachment A004 FOB: Destination MFR PART NR: TBD PSC CD: 6550	(b) (4)	Each	(b) (4)	\$1,560.00
MAX NET AMT					\$1,560.00

CLIN 0007 is added as follows:

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
0007	CDRL FFP Configuration Management Plan, See Section J Attachment A009 FOB: Destination MFR PART NR: TBD PSC CD: 6550	(b) (4)	Each	(b) (4)	\$130.00
MAX NET AMT					\$130.00

CLIN 0008 is added as follows:

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
0008	CDRL FFP Quality Assurance Plan, See Section J Attachment A010 FOB: Destination MFR PART NR: TBD PSC CD: 6550	█	Each	(b) (4)	\$195.00
MAX NET AMT					\$195.00

CLIN 0009 is added as follows:

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
0009	CDRL FFP Small Business Utilization Plan, See Section J Attachment A011 FOB: Destination MFR PART NR: TBD PSC CD: 6550	█	Each	(b) (4)	\$100.00
MAX NET AMT					\$100.00

CLIN 0010 is added as follows:

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
0010	CDRL FFP Contractor Program Management Plan, See Section J Attachment A014 FOB: Destination MFR PART NR: TBD PSC CD: 6550	█	Each	(b) (4)	\$650.00
					MAX NET AMT
					\$650.00

CLIN 0011 is added as follows:

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
0011	CDRL FFP As required CDRLs to include: A005 - General Incident Report A006 - Request For Deviation (RFD) A007 - Specification Change Notice (SCN) A008 - Engineering Change Proposal (ECP) A012 - Contractor Analytical Test Report FOB: Destination MFR PART NR: TBD PSC CD: 6550	5	Each		NSP
					MAX NET AMT

CLIN 0012 is added as follows:

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
0012	Regulatory EUA FFP Work for regulatory submit and EUA, in accordance with updated Section C, Statement of Work (SOW), paragraph 3.3.2 FOB: Destination MFR PART NR: TBD PSC CD: 6550	█	Each	(b) (4)	\$3,750.00
MAX NET AMT					\$3,750.00

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:

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

1.0 Scope. The scope of this work includes all activities required for a SARS-CoV-2 lateral flow immunoassay (LFI) test system, including the optimization and production of antigen screening test and all verification, validation, and regulatory activities required to achieve Food and Drug Administration (FDA) Emergency Use Authorization (EUA). Although, FDA Licensure is anticipated, it is not part of this effort. The end product shall be suitable as an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 virus in specimens from infected persons or persons suspected of exposure to SARS-CoV-2 and shall be intended for use at the point of care. The determination of an FDA sponsor will be reviewed during the ordering period.

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

(DoD) and its partners. The DBPAO facilitates the transition of new technologies and coordinates their advanced development, efficient production and timely distribution.

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

3.0 Requirements

3.1 Manufacturing Facility

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

3.1.2 Inventory management procedures to store antigens, antibodies and assays under the appropriate storage conditions as required by the label to maximize performance integrity and shelf life.

3.1.3 Security monitoring, temperature and humidity controlled for production area, with appropriate BioSafety Level and storage areas for assay materials including emergency backup power.

3.1.4 Standard Operating Procedures for all procedures associated with manufacturing, storage, and shipping of SARS-CoV-2 kits to assure compliance with contractual requirements and all local, state, and federal regulations and Standards.

3.3 SARS-CoV-2 Lateral Flow Immunoassay Kit

3.3.1 Deliverables

3.3.1.1 SARS-CoV-2 LFI kits for the detection of SARS-CoV-2 virus, nasal swabs and appropriate clinical buffer labeled in accordance with Research Only Use (ROU) or as a EUA once approved. These kits shall be delivered while maintaining product integrity.

3.3.1.2 Certificate of Conformance that includes specifications and results of internal conformance testing with each manufacturing lot of

SARS-CoV-2 LFI kits.

3.3.2 Regulatory Work/Emergency Use Authorization

Perform work delineated below from 18 May 2020 to 29 May 2020:

3.3.2.1 4 hours engagement with the Program Office and Government Regulatory Team (ONE-RAQA); comprised of two weekly one-hour meetings that to analyze the Government Furnished Information (GFI)

3.3.2.2 Conduct an analysis of assay manufacturing design changes to determine what additional testing is needed based on the Antigen-EUA template and the GFI generated from MRI.

3.3.2.3 Provide rationale/justification with supporting raw data of why certain studies are not needed.

3.3.3 Reagents

3.3.3.1 The Contractor shall be responsible for the production or procurement of the reagents required for the manufacture of this SARS-CoV-2 LFI kit such as recombinant viral capsid proteins; capture and detector antibodies, secondary antibodies, reference standards, near neighbor panel for specificity testing, negative controls etc. The government will not provide these reagents as government furnished materials.

3.3.3.2 The Contractor shall assume all risks and responsibilities in connection with the handling, storage, disposal, transfer, and use of the assay materials including appropriate safety and handling precautions to minimize health or environmental risk. The Contractor shall agree that any activity undertaken with the manufacture of this assay will be conducted in compliance with all applicable guidelines, laws and regulations, including Department of Defense Instruction 5210.89 (DoDI 5210.89) for DoD recipients.

SECTION E - INSPECTION AND ACCEPTANCE

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

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for CLIN 0004:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for CLIN 0005:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for CLIN 0006:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for CLIN 0007:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for CLIN 0008:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for CLIN 0009:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for CLIN 0010:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for CLIN 0011:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for CLIN 0012:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for CLIN 0003 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAY-2020 TO 10-MAY-2021	N/A	N/A FOB: Destination	

The following Delivery Schedule for CLIN 0004 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAY-2020 TO 10-MAY-2021	N/A	N/A FOB: Destination	

The following Delivery Schedule for CLIN 0005 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAY-2020 TO 10-MAY-2021	N/A	N/A FOB: Destination	

The following Delivery Schedule for CLIN 0006 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAY-2020 TO 10-MAY-2021	N/A	N/A FOB: Destination	

The following Delivery Schedule for CLIN 0007 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAY-2020 TO 10-MAY-2021	N/A	N/A FOB: Destination	

The following Delivery Schedule for CLIN 0008 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAY-2020 TO 10-MAY-2021	N/A	N/A FOB: Destination	

The following Delivery Schedule for CLIN 0009 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAY-2020 TO 10-MAY-2021	N/A	N/A FOB: Destination	

The following Delivery Schedule for CLIN 0010 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAY-2020 TO 10-MAY-2021	N/A	N/A FOB: Destination	

The following Delivery Schedule for CLIN 0011 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAY-2020 TO 10-MAY-2021	N/A	N/A FOB: Destination	

The following Delivery Schedule for CLIN 0012 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAY-2020 TO 29-MAY-2020	N/A	N/A FOB: Destination	

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Attachments

Attachment 1 Conformance Test Plan

Attachment 2 Evaluation factors and rating criteria

Exhibits

CDRLs	DID
A001 – First Article Test (FAT) Plan	DI-NDTI-81307A
A002 – Inspection and Test Plan	DI-QCIC-81110
A003 – FAT Inspection Report	DI-NDTI-80809B
A004 – Status Report	DI-MGMT-80368A
A005 – General Incident Report	DI-CMAN-80643C
A006 – Request for Deviation (RFD)	DI-CMAN-80639C
A007 – Specification Change Notice (SCN)	DI-CMAN-80858B
A008 – Engineering Change Proposal (ECP)	DI-QCIC-81722
A009 – Configuration Management Plan	DI-MGMT-81178
A010 – Quality Assurance Plan	DI-CMAN-80640C
A011 – Small Business Utilization Report	DI-MGMT-82041
A012 – Contractor Analytical Test Report	DI-MS-80711A
A013 – Not applicable	N/A
A014 – Program Management Plan	DI-MGMT-80004A

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE	PAGE OF PAGES	
			J	1 7	
2. AMENDMENT/MODIFICATION NO. P00002	3. EFFECTIVE DATE 01-Jun-2020	4. REQUISITION/PURCHASE REQ. NO.		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)		CODE	
		See Item 6			
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) MAXIM BIOMEDICAL, INC. 1500 EAST GUDE DRIVE ROCKVILLE MD 20850-5307			9A. AMENDMENT OF SOLICITATION NO.		
			9B. DATED (SEE ITEM 11)		
			X	10A. MOD. OF CONTRACT/ORDER NO. W911QY20D0018	
			X	10B. DATED (SEE ITEM 13) 11-May-2020	
CODE 4EJW3	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.					
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).					
X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: By mutual agreement of both parties.					
D. OTHER (Specify type of modification and authority)					
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> 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: 1. Increase the quantity of CL N 0005 by (b) (4) for CDRL A003 First Article Test/Inspection Reports. 2. Increase the total price of CLIN 0012 by (b) (4). 3. Extend the period of performance end date for CL N 0012 from 29 May 2020 to 12 June 2020. 4. Section C, is hereby revised to add paragraphs 3.3.4., 3.3.4.1-4 for First Article Testing and update paragraphs 3.3.2 and 3.3.2.1. 5. Add CL N 0013 for a quantity of 1 First Article Testing Lot requirements. 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) / CONTRACTING OFFICER		
			TEL: (b) (6) EMAIL: (b) (6)		
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA		16C. DATE SIGNED	
(Signature of person authorized to sign)		BY (b) (6)		01-Jun-2020	
		(Signature of Contracting Officer)			

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by \$411,300.00 from \$45,107,035.00 to \$45,518,335.00.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0005

The pricing detail quantity has increased by (b) (4) from (b) (4) to (b) (4).

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

CLIN 0012

The unit price amount has increased by (b) (4) from (b) (4) to (b) (4).

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

CLIN 0013 is added as follows:

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
0013	First Article Testing Lot FFP First Article Testing Lot, in accordance with updated Section C, Statement of Work (SOW), paragraphs 3.3.4.1, 3.3.4.2, 3.3.4.3, 3.3.4.4. FOB: Destination MFR PART NR: TBD PSC CD: 6550	(b) (4)	Each	(b) (4)	\$409,000.00
MAX NET AMT					\$409,000.00

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:

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

1.0 Scope. The scope of this work includes all activities required for a SARS-CoV-2 lateral flow immunoassay (LFI) test system, including the optimization and production of antigen screening test and all verification, validation, and regulatory activities required to achieve Food and Drug Administration (FDA) Emergency Use Authorization (EUA). Although, FDA Licensure is anticipated, it is not part of this effort. The end product shall be suitable as an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 virus in specimens from infected persons or persons suspected of exposure to SARS-CoV-2 and shall be intended for use at the point of care. The determination of an FDA sponsor will be reviewed during the ordering period.

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

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

3.0 Requirements

3.1 Manufacturing Facility

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

3.1.2 Inventory management procedures to store antigens, antibodies and assays under the appropriate storage conditions as required by the label to maximize performance integrity and shelf life.

3.1.3 Security monitoring, temperature and humidity controlled for production area, with appropriate BioSafety Level and storage areas for assay materials including emergency backup power.

3.1.4 Standard Operating Procedures for all procedures associated with manufacturing, storage, and shipping of SARS-CoV-2 kits to assure compliance with contractual requirements and all local, state, and federal regulations and Standards.

3.3 SARS-CoV-2 Lateral Flow Immunoassay Kit

3.3.1 Deliverables

3.3.1.1 SARS-CoV-2 LFI kits for the detection of SARS-CoV-2 virus, nasal swabs and appropriate clinical buffer labeled in accordance with Research Only Use (ROU) or as a EUA once approved. These kits shall be delivered while maintaining product integrity.

3.3.1.2 Certificate of Conformance that includes specifications and results of internal conformance testing with each manufacturing lot of SARS-CoV-2 LFI kits.

3.3.2 Regulatory Work/Emergency Use Authorization

Perform work delineated below from 18 May 2020 to **12 June 2020**:

3.3.2.1 **8 hours engagement** with the Program Office and Government Regulatory Team (ONE-RAQA); comprised of two weekly one-hour meetings to analyze the Government Furnished Information (GFI)

3.3.2.2 Conduct an analysis of assay manufacturing design changes to determine what additional testing is needed based on the Antigen-EUA template and the GFI generated from MRI.

3.3.2.3 Provide rationale/justification with supporting raw data of why certain studies are not needed.

3.3.3 Reagents

3.3.3.1 The Contractor shall be responsible for the production or procurement of the reagents required for the manufacture of this SARS-

CoV-2 LFI kit such as recombinant viral capsid proteins; capture and detector antibodies, secondary antibodies, reference standards, near neighbor panel for specificity testing, negative controls etc. The government will not provide these reagents as government furnished materials.

3.3.3.2 The Contractor shall assume all risks and responsibilities in connection with the handling, storage, disposal, transfer, and use of the assay materials including appropriate safety and handling precautions to minimize health or environmental risk. The Contractor shall agree that any activity undertaken with the manufacture of this assay will be conducted in compliance with all applicable guidelines, laws and regulations, including Department of Defense Instruction 5210.89 (DoDI 5210.89) for DoD recipients.

3.3.4 First Article Testing Lot

3.3.4.1 First Article Testing (FAT) SARS-CoV-2. The contractor and any subcontractor that manufactures LFIs shall perform testing on the First Article on the LFI in accordance with the CDRL A003 - FAT Inspection Report DI-NDTI-80809B. A FAT is required on the first lot of SARS-CoV-2 assay manufactured as a result of identification of a new improved antibody pairing or a new lot of antibody. A First Article Test is considered a new assay therefore may require re-submission/modification to FDA certifications.

3.3.4.2 The first article lot shall be manufactured using the same methods, materials, equipment, processes, inspections, in-process tests and facilities as will be used during regular production. The FAT shall be performed on LFIs incorporated into the final kit. The contractor shall deliver a subset of each First Article lot in kit (assay, swabs and buffer) configuration to a Government-appointed Test Facility for additional testing per conformance test plan only after receiving written approval from DBPAO.

3.3.4.3 The Government will review results from the Conformance Test Laboratory's (CTL's) First Article and production testing and will approve/disapprove based on the results. An overall rating of green and above, the lot will be approved. This rating criteria may be updated at a later date as the Government better understands how the assay performs against live virus.

3.3.4.4 A FAT Report shall be submitted for Government review 10 days after First Article Test completion and shall include raw data, compiled and calculated data and conclusions. The Government will respond with comments or approval 15 days following receipt of report. A final FAT Report shall be submitted 10 days after receipt of Government comments.

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0013:

INSPECT AT Destination	INSPECT BY Government	ACCEPT AT Destination	ACCEPT BY Government
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SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule item for CLIN 0005 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAY-2020 TO 10-MAY-2021	N/A	N/A FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAY-2020 TO 10-MAY-2021	N/A	N/A FOB: Destination	

The following Delivery Schedule item for CLIN 0012 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAY-2020 TO 29-MAY-2020	N/A	N/A FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAY-2020 TO 12-JUN-2020	N/A	N/A FOB: Destination	

The following Delivery Schedule for CLIN 0013 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 01-JUN-2020 TO 10-MAY-2021	N/A	N/A FOB: Destination	

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE J	PAGE OF PAGES 1 5
2. AMENDMENT/MODIFICATION NO. P00003	3. EFFECTIVE DATE 22-Jun-2020	4. REQUISITION/PURCHASE REQ. NO.		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) See Item 6		CODE
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) MAXIM BIOMEDICAL, INC. 1500 EAST GUDE DRIVE ROCKVILLE MD 20850-5307			9A. AMENDMENT OF SOLICITATION NO.	
			9B. DATED (SEE ITEM 11)	
			X	10A. MOD. OF CONTRACT/ORDER NO. W911QY20D0018
			X	10B. DATED (SEE ITEM 13) 11-May-2020
CODE 4EJW3	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.				
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).				
X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: By mutual agreement of both parties.				
D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> 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: 1) Extend the delivery date of CLIN 0012 from 12 June 2020 to 26 June 2020. 2) Update Section C, SOW, paragraph 3.3.2 to extend delivery date to 26 June 2020. 3) Increase CLIN 0012 by (b) (4). 4) Replace Attachment 1 in its entirety with updated Conformance Testing Plan, dated 06 June 2020. All other terms and conditions remain the same and in full force and effect.				
Except as provided herein, all terms and conditions of the 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) / CONTRACTING OFFICER TEL: (b) (6) EMAIL: (b) (6)	
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY (b) (6) (Signature of Contracting Officer)		16C. DATE SIGNED 22-Jun-2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by \$3,750.00 from \$45,518,335.00 to \$45,522,085.00.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0012

The unit price amount has increased by (b) (4) from (b) (4) to (b) (4).

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

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:

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

1.0 Scope. The scope of this work includes all activities required for a SARS-CoV-2 lateral flow immunoassay (LFI) test system, including the optimization and production of antigen screening test and all verification, validation, and regulatory activities required to achieve Food and Drug Administration (FDA) Emergency Use Authorization (EUA). Although, FDA Licensure is anticipated, it is not part of this effort. The end product shall be suitable as an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 virus in specimens from infected persons or persons suspected of exposure to SARS-CoV-2 and shall be intended for use at the point of care. The determination of an FDA sponsor will be reviewed during the ordering period.

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

and timely distribution.

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

3.0 Requirements

3.1 Manufacturing Facility

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

3.1.2 Inventory management procedures to store antigens, antibodies and assays under the appropriate storage conditions as required by the label to maximize performance integrity and shelf life.

3.1.3 Security monitoring, temperature and humidity controlled for production area, with appropriate BioSafety Level and storage areas for assay materials including emergency backup power.

3.1.4 Standard Operating Procedures for all procedures associated with manufacturing, storage, and shipping of SARS-CoV-2 kits to assure compliance with contractual requirements and all local, state, and federal regulations and Standards.

3.3 SARS-CoV-2 Lateral Flow Immunoassay Kit

3.3.1 Deliverables

3.3.1.1 SARS-CoV-2 LFI kits for the detection of SARS-CoV-2 virus, nasal swabs and appropriate clinical buffer labeled in accordance with Research Only Use (ROU) or as a EUA once approved. These kits shall be delivered while maintaining product integrity.

3.3.1.2 Certificate of Conformance that includes specifications and results of internal conformance testing with each manufacturing lot of SARS-CoV-2 LFI kits.

3.3.2 Regulatory Work/Emergency Use Authorization

Perform work delineated below from 18 May 2020 to **26 June 2020**:

3.3.2.1 **Twelve (12) hours engagement** with the Program Office and Government Regulatory Team (ONE-RAQA); comprised of two weekly one-hour meetings to analyze the Government Furnished Information (GFI)

3.3.2.2 Conduct an analysis of assay manufacturing design changes to determine what additional testing is needed based on the Antigen-EUA template and the GFI generated from MRI.

3.3.2.3 Provide rationale/justification with supporting raw data of why certain studies are not needed.

3.3.3 Reagents

3.3.3.1 The Contractor shall be responsible for the production or procurement of the reagents required for the manufacture of this SARS-CoV-2 LFI kit such as recombinant viral capsid proteins; capture and detector antibodies, secondary antibodies, reference standards, near neighbor panel for specificity testing, negative controls etc. The government will not provide these reagents as government furnished materials.

3.3.3.2 The Contractor shall assume all risks and responsibilities in connection with the handling, storage, disposal, transfer, and use of the assay materials including appropriate safety and handling precautions to minimize health or environmental risk. The Contractor shall agree that any activity undertaken with the manufacture of this assay will be conducted in compliance with all applicable guidelines, laws and regulations, including Department of Defense Instruction 5210.89 (DoDI 5210.89) for DoD recipients.

3.3.4 First Article Testing Lot

3.3.4.1 First Article Testing (FAT) SARS-CoV-2. The contractor and any subcontractor that manufactures LFIs shall perform testing on the First Article on the LFI in accordance with the CDRL A003 - FAT Inspection Report DI-NDTI-80809B. A FAT is required on the first lot of SARS-CoV-2 assay manufactured as a result of identification of a new improved antibody pairing or a new lot of antibody. A First Article Test is considered a new assay therefore may require re-submission/modification to FDA certifications.

3.3.4.2 The first article lot shall be manufactured using the same methods, materials, equipment, processes, inspections, in-process tests and facilities as

will be used during regular production. The FAT shall be performed on LFIs incorporated into the final kit. The contractor shall deliver a subset of each First Article lot in kit (assay, swabs and buffer) configuration to a Government-appointed Test Facility for additional testing per conformance test plan only after receiving written approval from DBPAO.

3.3.4.3 The Government will review results from the Conformance Test Laboratory's (CTL's) First Article and production testing and will approve/disapprove based on the results. An overall rating of green and above, the lot will be approved. This rating criteria may be updated at a later date as the Government better understands how the assay performs against live virus.

3.3.4.4 A FAT Report shall be submitted for Government review 10 days after First Article Test completion and shall include raw data, compiled and calculated data and conclusions. The Government will respond with comments or approval 15 days following receipt of report. A final FAT Report shall be submitted 10 days after receipt of Government comments.

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule item for CLIN 0012 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAY-2020 TO 12-JUN-2020	N/A	N/A FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAY-2020 TO 26-JUN-2020	N/A	N/A FOB: Destination	

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE J	PAGE OF PAGES 1 2
2. AMENDMENT/MODIFICATION NO. P00004	3. EFFECTIVE DATE 15-Jul-2020	4. REQUISITION/PURCHASE REQ. NO.		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) See Item 6		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) MAXIM BIOMEDICAL, INC. 1500 EAST GUDE DRIVE ROCKVILLE MD 20850-5307		9A. AMENDMENT OF SOLICITATION NO.		
		9B. DATED (SEE ITEM 11)		
		X 10A. MOD. OF CONTRACT/ORDER NO. W911QY20D0018		
		X 10B. DATED (SEE ITEM 13) 11-May-2020		
CODE 4EJW3	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.				
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).				
X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: by mutual agreement of both parties.				
D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> is required to sign this document and return <u>1</u> 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 reduce the unit price for CL N 0013 by (b) (4) from (b) (4) to (b) (4) and remove delivery date to be delineated in subsequent delivery order modification. 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) / CONTRACTING OFFICER TEL: (b) (6) EMAIL: (b) (6)		
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY (b) (6) (Signature of Contracting Officer)	16C. DATE SIGNED 15-Jul-2020	

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was decreased by \$37,500.00 from \$45,522,085.00 to \$45,484,585.00.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0013

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4).

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

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for CLIN 0013 has been deleted:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 01-JUN-2020 TO 10-MAY-2021	N/A	N/A FOB: Destination	

(End of Summary of Changes)

CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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

A. CONTRACT LINE ITEM NO. 0007	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM	E. CONTRACT/PR NO. W911QY-20-D-0018	F. CONTRACTOR Maxim Biomedical
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1. DATA ITEM NO. A001	2. TITLE OF DATA ITEM First Article Qualification Test Plan and Procedures	3. SUBTITLE First Article Test Plan
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4. AUTHORITY (Data Acquisition Document No.) DI-NDTI-81307A	5. CONTRACT REFERENCE	6. REQUIRING OFFICE JPL EB DBPAO
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY (b) (4)	12. DATE OF FIRST SUBMISSION see blk 16	14. DISTRIBUTION		
8. APP CODE see Blk 16		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION	a. ADDRESSEE	b. COPIES	
					Draft	Final
						Reg
						Repro

16. REMARKS Blk 4. DID can be obtained from http://quicksearch.dla.mil . A First Article and Production Article Test Plan shall include First Article Test (FAT) plan on the first lot of SARS-CoV-2 assay and a Production Article Test (PAT) plan for each lot of SARS-CoV-2 assays manufactured. Blk 13. Provide final First Article and Production Article Test Plan for Government approval (b) (4) Blk 14. and Blk 15. Submit via e-mail in Microsoft Office format to: (b) (6)	See address in blk 16			
	15. TOTAL →	0	1	0

G. PREPARED BY (b) (6) Assistant Product Manage	H. DATE	I. APPROVED BY	J. DATE
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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

A. CONTRACT LINE ITEM NO. 0008	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM	E. CONTRACT/PR NO. W911QY-20-D-0018	F. CONTRACTOR Maxim Biomedical
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1. DATA ITEM NO. A002	2. TITLE OF DATA ITEM Inspection and Test Plan	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.) DI-QCIC-81110	5. CONTRACT REFERENCE	6. REQUIRING OFFICE JPL EB DBPAO
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY (b) (4)	12. DATE OF FIRST SUBMISSION see blk 16	14. DISTRIBUTION		
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION	a. ADDRESSEE	b. COPIES	
					Draft	Final
						Reg
						Repro

16. REMARKS
Blk 4. DID can be obtained from <http://quicksearch.dla.mil>.

The Quality Control Inspection and Test Plan shall include First Article and Production Lot Testing, Stability Test Plan, and Sampling Plan (using ANSI/ASQC Standard Z1.4-2003 or equivalent for reference).

The Inspection and Test Plan shall include processes for inspection of components upon receipt, in-process inspections, physical inspections of test kits, operational testing of test kits (i.e., testing in the Hand Held Assay configuration).

(b) (4)

Blk 13. A final Inspection and Test Plan shall be provided for Government review
(b) (4)

Blk 14. and Blk 15. Submit via e-mail in Microsoft Office format to:

(b) (6)

15. TOTAL → 0 1 0

G. PREPARED BY (b) (6) Assistant Product Manage	H. DATE	I. APPROVED BY	J. DATE
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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

A. CONTRACT LINE ITEM NO. 0009	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM	E. CONTRACT/PR NO. W911QY-20-D-0018	F. CONTRACTOR Maxim Biomedical
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1. DATA ITEM NO. A003	2. TITLE OF DATA ITEM Test/Inspection Report	3. SUBTITLE First Article Test Report
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4. AUTHORITY (Data Acquisition Document No.) DI-NDTI-80809B	5. CONTRACT REFERENCE	6. REQUIRING OFFICE JPL EB DBPAO
---	------------------------------	--

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY (b) (4)	12. DATE OF FIRST SUBMISSION see blk 16	14. DISTRIBUTION		
8. APP CODE see Blk 16		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION see blk 16	a. ADDRESSEE	b. COPIES	
					Draft	Final
					Reg	Repro

16. REMARKS Blk 4. DID can be obtained from http://quicksearch.dla.mil . Blk 10. and Blk 12. The Contractor shall submit FAT report (b) (4) after test completion, including raw data, compiled and calculated data, and conclusions. Blk 8. The Government will respond with comments or approval (b) (4) following receipt of report. Blk 13. Submit final report (b) (4) after receipt of Government comments. Blk 14. and Blk 15. Submit via e-mail in Microsoft Office format to: (b) (6)	See address in blk 16	1	1	
	15. TOTAL →		1	1

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

G. PREPARED BY (b) (6) Assistant Product Manage	H. DATE	I. APPROVED BY	J. DATE
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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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

A. CONTRACT LINE ITEM NO. 0010	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM	E. CONTRACT/PR NO. W911QY-20-D-0018	F. CONTRACTOR Maxim Biomedical
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1. DATA ITEM NO. A004	2. TITLE OF DATA ITEM Status Report	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-80368A	5. CONTRACT REFERENCE	6. REQUIRING OFFICE JPL EB DBPAO
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY (b) (4)	12. DATE OF FIRST SUBMISSION see blk 16	14. DISTRIBUTION		
8. APP CODE		11. AS OF DATE award date	13. DATE OF SUBSEQUENT SUBMISSION see blk 16	a. ADDRESSEE	b. COPIES	
					Draft	Final

16. REMARKS Blk 4. DID's can be obtained from http://quicksearch.dla.mil . Blk 12. Provide (b) (4) reports (b) (4) (b) (4). The status reports shall include cumulative test data, progress made during the reporting period including problem areas encountered, and plans for the following reporting period. Blk 13. The monthly status report is due (b) (4). Provide a final report to include description of all work accomplished for the entire performance work statement period and total contractual work expenditures. Blk 14. and Blk 15. Submit via email in Microsoft Office format to: (b) (6)	See address in blk 16			
	15. TOTAL	0	1	0

G. PREPARED BY (b) (6) Assistant Product Manage	H. DATE	I. APPROVED BY	J. DATE
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0011	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM	E. CONTRACT/PR NO. W911QY-20-D-0018	F. CONTRACTOR Maxim Biomedical
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1. DATA ITEM NO. A005	2. TITLE OF DATA ITEM Report, Production or Delivery Problem(s)	3. SUBTITLE General Incident Report
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4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-81178	5. CONTRACT REFERENCE	6. REQUIRING OFFICE JPL EB DBPAO
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY (b) (4)	12. DATE OF FIRST SUBMISSION see blk 16	14. DISTRIBUTION		
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION	a. ADDRESSEE See address in blk 16	b. COPIES	
					Draft	Final

16. REMARKS Blk 4. DID's can be obtained from http://quicksearch.dla.mil . Blk 10. and Blk 12. The Contractor shall report any incident to the Government that could result in a program, production, or delivery delay (refer to paragraph 3.2 of DID for examples). Telephonically contact the Government within one day of incident. A written report shall be submitted within three business days of an incident. Blk 14. and Blk 15. Submit via e-mail in Microsoft Office format to: (b) (6)							
15. TOTAL	→	0	1	0			

G. PREPARED BY (b) (6) Assistant Product Manage	H. DATE	I. APPROVED BY	J. DATE
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0011	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM	E. CONTRACT/PR NO. W911QY-20-D-0018	F. CONTRACTOR Maxim Biomedical
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1. DATA ITEM NO. A008	2. TITLE OF DATA ITEM Engineering Change Proposal (ECP)	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.) DI-CMAN-80639C	5. CONTRACT REFERENCE	6. REQUIRING OFFICE JPL EB DBPAO
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY (b) (4)	12. DATE OF FIRST SUBMISSION see blk 16	14. DISTRIBUTION															
8. APP CODE see Blk 16		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th style="width:60%; text-align:left;">a. ADDRESSEE</th> <th colspan="3" style="text-align:center;">b. COPIES</th> </tr> <tr> <td rowspan="2" style="padding: 2px;">See address in blk 16</td> <td style="padding: 2px; text-align:center;">Draft</td> <td colspan="2" style="padding: 2px; text-align:center;">Final</td> </tr> <tr> <td style="padding: 2px;"></td> <td style="padding: 2px; text-align:center;">Reg</td> <td style="padding: 2px; text-align:center;">Repro</td> </tr> <tr> <td style="padding: 2px;"></td> <td style="padding: 2px;"></td> <td style="padding: 2px; text-align:center;">1</td> <td style="padding: 2px;"></td> </tr> </table>	a. ADDRESSEE	b. COPIES			See address in blk 16	Draft	Final			Reg	Repro			1	
a. ADDRESSEE	b. COPIES																		
See address in blk 16	Draft	Final																	
		Reg	Repro																
		1																	

16. REMARKS

Blk 4. DIDs can be obtained from <http://quicksearch.dla.mil>.

Blk 8. Government will respond with comments or approval (b) (4)

Blk 10. and Blk 12. Submit for permanent changes to existing Government owned technical documentation such as performance specifications and engineering drawings.

Blk 14. and Blk 15. Submit via e-mail (in Microsoft Office format for text and documentation and Mechanical Desktop or Solidworks for CAD drawings) to:
(b) (6)

15. TOTAL →	0	1	0
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G. PREPARED BY (b) (6) Assistant Product Manage	H. DATE	I. APPROVED BY	J. DATE
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0012	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM	E. CONTRACT/PR NO. W911QY-20-D-0018	F. CONTRACTOR Maxim Biomedical
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1. DATA ITEM NO. A009	2. TITLE OF DATA ITEM Configuration Management Plan	3. SUBTITLE
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4. AUTHORITY (Data Acquisition Document No.) DI-CMAN-80858B	5. CONTRACT REFERENCE	6. REQUIRING OFFICE JPL EB DBPAO
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY (b) (4)	12. DATE OF FIRST SUBMISSION see blk 16	14. DISTRIBUTION		
8. APP CODE see Blk 16		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION see blk 16	a. ADDRESSEE	b. COPIES	
					Draft	Final

16. REMARKS Blk 4. DID's can be obtained from http://quicksearch.dla.mil . Blk 8. Government will respond with comments (b) (4) following receipt of detailed plan. Blk 12. Submit a detailed plan (b) (4) for Government review and comment. Blk 13. Submit final plan (b) (4) after receipt of Government comments. Blk 14. and Blk 15. Submit via e-mail in Microsoft Office format to: (b) (6)	See address in blk 16	1	1	
	15. TOTAL →	1	1	0

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

G. PREPARED BY (b) (6) Assistant Product Manage	H. DATE	I. APPROVED BY	J. DATE
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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0013	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM	E. CONTRACT/PR NO. W911QY-20-D-0018	F. CONTRACTOR Maxim Biomedical
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1. DATA ITEM NO. A010	2. TITLE OF DATA ITEM Quality Program Plan	3. SUBTITLE Quality Assurance Plan
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4. AUTHORITY (Data Acquisition Document No.) DI-QCIC-81722	5. CONTRACT REFERENCE	6. REQUIRING OFFICE JPL EB DBPAO
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY (b) (4)	12. DATE OF FIRST SUBMISSION see blk 16	14. DISTRIBUTION		
8. APP CODE		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION	a. ADDRESSEE	b. COPIES	
					Draft	<table style="width:100%"> <tr><td colspan="2">Final</td></tr> <tr><td>Reg</td><td>Repro</td></tr> </table>
Final						
Reg	Repro					

16. REMARKS
Blk 4. DID can be obtained from <http://quicksearch.dla.mil>.

Blk 13. Provide final Quality Assurance Plan for Government approval **(b) (4)**
(b) (4)

Blk 14. and Blk 15. Submit via e-mail in Microsoft Office format to:
(b) (6)

See address in blk 16	Draft	Reg	Repro	Final
		1		
15. TOTAL	→	0	1	0

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

G. PREPARED BY (b) (6) Assistant Product Manage	H. DATE	I. APPROVED BY	J. DATE
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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0014 **B. EXHIBIT** A **C. CATEGORY:** TDP _____ TM _____ OTHER Small Business Utilization

D. SYSTEM/ITEM TBD **E. CONTRACT/PR NO.** W911QY-20-D-0018 **F. CONTRACTOR** Maxim Biomedical

1. DATA ITEM NO. A011 **2. TITLE OF DATA ITEM** Small Business Utilization Report **3. SUBTITLE** Small Business Participation

4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-82041 **5. CONTRACT REFERENCE** **6. REQUIRING OFFICE**

7. DD 250 REQ LT	9. DIST STATEMENT REQUIRED	10. FREQUENCY See Blk 16	12. DATE OF FIRST SUBMISSION See Blk 16	14. DISTRIBUTION		
8. APP CODE A		11. AS OF DATE See Blk 16	13. DATE OF SUBSEQUENT SUBMISSION See Blk 16	a. ADDRESSEE	b. COPIES	
					Draft	Final
					Reg	Repro

16. REMARKS

Block 4: Contractor format is acceptable.

Block 8: Government approval/disapproval and comments will be provided (b) (4) after receipt of submittal or revision, unless otherwise specified. If the Government provides any comments, submit an update incorporating Government comments (b) (4) unless otherwise specified.

Block 10-13: A (b) (4) report shall be submitted during contract performance for the periods (b) (4). Reports are due (b) (4) after the close of each reporting period, unless otherwise specified. A summary report is also required for each contract (b) (4). Reports are required when due, regardless of whether there has been any activity since inception of the contract or the previous reporting period.

Block 14: The reports shall be submitted via email to the Contracting Officer identified in the contract, as well as the U. S. Army Combat Capabilities Development Command, Army Research Laboratory, Office of Small Business Programs at:

usarmy.adelphi.rdecom-arl.list.smallbusiness@mail.mil

15. TOTAL	→	2	2	0

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

G. PREPARED BY (b) (6) **H. DATE** **I. APPROVED BY** **J. DATE**

CONTRACT DATA REQUIREMENTS LIST

(1 Data Item)

A. CONTRACT LINE ITEM NO. 0014	B. EXHIBIT A	C. CATEGORY: TDP _____ TM _____ OTHER <u>Small Business Utilization</u>
D. SYSTEM/ITEM TBD	E. CONTRACT/PR NO. W911QY-20-D-0018	F. CONTRACTOR Maxim Biomedical

16. REMARKS *(Continued)*

INSTRUCTIONS FOR COMPLETING DD FORM 1423

(See DoD 5010.12-M for detailed instructions.)

FOR GOVERNMENT PERSONNEL

Item A. Self-explanatory.

Item B. Self-explanatory.

Item C. Mark (X) appropriate category: TDP - Technical Data Package; TM - Technical Manual; Other - other category of data, such as "Provisioning," "Configuration Management," etc.

Item D. Enter name of system/item being acquired that data will support.

Item E. Self-explanatory (to be filled in after contract award).

Item F. Self-explanatory (to be filled in after contract award).

Item G. Signature of preparer of CDRL.

Item H. Date CDRL was prepared.

Item I. Signature of CDRL approval authority.

Item J. Date CDRL was approved.

Item 1. See DoD FAR Supplement Subpart 4.71 for proper numbering.

Item 2. Enter title as it appears on data acquisition document cited in Item 4.

Item 3. Enter subtitle of data item for further definition of data item (optional entry).

Item 4. Enter Data Item Description (DID) number, military specification number, or military standard number listed in DoD 5010.12-L (AMSDL), or one-time DID number, that defines data content and format requirements.

Item 5. Enter reference to tasking in contract that generates requirement for the data item (e.g., Statement of Work paragraph number).

Item 6. Enter technical office responsible for ensuring adequacy of the data item.

Item 7. Specify requirement for inspection/acceptance of the data item by the Government.

Item 8. Specify requirement for approval of a draft before preparation of the final data item.

Item 9. For technical data, specify requirement for contractor to mark the appropriate distribution statement on the data (ref. DoDD 5230.24).

Item 10. Specify number of times data items are to be delivered.

Item 11. Specify as-of date of data item, when applicable.

Item 12. Specify when first submittal is required.

Item 13. Specify when subsequent submittals are required, when applicable.

Item 14. Enter addressees and number of draft/final copies to be delivered to each addressee. Explain reproducible copies in Item 16.

Item 15. Enter total number of draft/final copies to be delivered.

Item 16. Use for additional/clarifying information for Items 1 through 15. Examples are: Tailoring of documents cited in Item 4; Clarification of submittal dates in Items 12 and 13; Explanation of reproducible copies in Item 14.; Desired medium for delivery of the data item.

FOR THE CONTRACTOR

Item 17. Specify appropriate price group from one of the following groups of effort in developing estimated prices for each data item listed on the DD Form 1423.

a. Group I. Definition - Data which is not otherwise essential to the contractor's performance of the primary contracted effort (production, development, testing, and administration) but which is required by DD Form 1423.

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

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

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

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

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

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

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

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

CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0015	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM	E. CONTRACT/PR NO. W911QY-20-D-0018	F. CONTRACTOR Maxim Biomedical
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1. DATA ITEM NO. A012	2. TITLE OF DATA ITEM Scientific and Technical Reports	3. SUBTITLE Contractor Analytical Test Report
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4. AUTHORITY (Data Acquisition Document No.) DI-MISC-80711A	5. CONTRACT REFERENCE See block 16	6. REQUIRING OFFICE JPL EB DBPAO
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7. DD 250 REQ Yes	9. DIST STATEMENT REQUIRED	10. FREQUENCY (b) (4)	12. DATE OF FIRST SUBMISSION See block 16	14. DISTRIBUTION			
8. APP CODE N/A		11. AS OF DATE N/A	13. DATE OF SUBSEQUENT SUBMISSION See block 16	a. ADDRESSEE	b. COPIES		
					Draft	Final	
						Reg	Repro

16. REMARKS Blk 4. DID can be obtained from http://quicksearch.dla.mil . The Contractor shall provide the (b) (4) Report IAW the SOW sections listed below. Blk 5. See SOW sections: 3.3.1.1 3.3.1.2 3.3.1.3 3.3.1.4 3.3.1.5 3.3.1.6 Blk 12 & 13. The Contractor shall submit for Government review and comment a draft Analytical Test Report that consolidates all analytical test results to support EUA submission. A final Contractor Analytical Test Report shall be submitted to the Government (b) (4). The Contractor shall submit to the Government a draft EUA request package (b) (4) after completion of the final Contractor Analytical Test Report. Blk 14 & 15. Submit via e-mail in Microsoft Office format to: (b) (6) usarmy.detrick.dod-jpeo-cbrnd.list.one-raqa-leadership@mail.mil	See address in block 16	1	1	
	15. TOTAL	→	1	1

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

G. PREPARED BY (b) (6) Assistant Product Manage	H. DATE	I. APPROVED BY	J. DATE
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CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0016	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM	E. CONTRACT/PR NO. W911QY-20-D-0018	F. CONTRACTOR Maxim Biomedical
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1. DATA ITEM NO. A013	2. TITLE OF DATA ITEM Research and Development of Medical Products Regulated by the U.S. Food and Drug Administration	3. SUBTITLE FDA EUA Submission
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4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040	5. CONTRACT REFERENCE See block 16	6. REQUIRING OFFICE JPL EB DBPAO
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7. DD 250 REQ No	9. DIST STATEMENT REQUIRED	10. FREQUENCY (b) (4)	12. DATE OF FIRST SUBMISSION See block 16	14. DISTRIBUTION			
8. APP CODE N/A		11. AS OF DATE N/A	13. DATE OF SUBSEQUENT SUBMISSION See block 16	a. ADDRESSEE	b. COPIES		
					Draft	Final	
						Reg	Repro

16. REMARKS
The Contractor shall provide FDA EUA request package to the Government IAW the SOW sections listed below. The FDA EUA request package format for each LFI IVD assay will be in accordance with FDA policy; "Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff: Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency" and feedback from FDA engagements.

Blk 5. See SOW Sections listed below:

- 3.3.1.1 (provide to Government only)
- 3.3.1.2
- 3.3.1.3
- 3.3.1.4
- 3.3.1.5
- 3.3.1.6
- 3.3.1.7

Blk 12 & 13. The Contractor shall submit the draft package for EUA submission (test plans, protocols and consent forms, pre-EUA submission(s), FDA communications, analytical and clinical reports) to the Government for review and comment (b) (4) prior to submission to the FDA for review and comment.

Blk 14 & 15. Submit via e-mail in Microsoft Office format to:

(b) (6)
usarmy.detrick.dod-jpeo-cbrnd.list.one-raqa-leadership@mail.mil

15. TOTAL →	1	1	0
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G. PREPARED BY (b) (6) Assistant Product Manage	H. DATE	I. APPROVED BY	J. DATE
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17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

CONTRACT DATA REQUIREMENTS LIST
(1 Data Item)

Form Approved
OMB No. 0704-0188

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A. CONTRACT LINE ITEM NO. 0017	B. EXHIBIT	C. CATEGORY: TDP _____ TM _____ OTHER _____
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D. SYSTEM/ITEM	E. CONTRACT/PR NO. W911QY-20-D-0018	F. CONTRACTOR Maxim Biomedical
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1. DATA ITEM NO. A014	2. TITLE OF DATA ITEM Management Plan	3. SUBTITLE Program Management Plan
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4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-80004A	5. CONTRACT REFERENCE	6. REQUIRING OFFICE JPL EB DBPAO
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7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY (b) (4)	12. DATE OF FIRST SUBMISSION see Blk 16	14. DISTRIBUTION		
8. APP CODE see Blk 16		11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION	a. ADDRESSEE	b. COPIES	
					Draft	Final
						Reg
						Repro

16. REMARKS Blk 4. DID can be obtained from http://quicksearch.dla.mil . The Contractor Program Management Plan shall include a Risk Management Plan that includes procedures to identify, monitor and mitigate risks and a Master Schedule that includes First Article Testing and Production Article Testing. Blk 13. Provide final Program Management Plan for Government review (b) (4) Blk 14 & 15. Submit via e-mail in Microsoft Office format to: (b) (6)	See address in blk 16			
	15. TOTAL →	0	1	0

17. PRICE GROUP
18. ESTIMATED TOTAL PRICE

G. PREPARED BY (b) (6) Assistant Product Manage	H. DATE	I. APPROVED BY	J. DATE
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**Attachment
Conformance Testing
Plan**

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

Overview of Planned Testing:

Six studies will be performed for each LFI:

- 1) Dynamic range (and LoD Range-finding)
- 2) Analytical sensitivity (Limit of detection)
- 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

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

Study 2: Analytical Sensitivity (Limit of Detection)

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

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

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

Study 4: Interfering Substances

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

**Attachment 3
Conformance Testing Plan**

Table 2. Test Scheme for Study 4

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

Study 5: Evaluation with Contrived Specimens in Various Media Formulations

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

Table 3. Test Scheme for Study 5

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

Study 6: Evaluation with PCR-Positive Patient Specimens

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

Attachment 3
Conformance Testing Plan

Materials and Information Required from Performers:

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

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

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

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

ATTACHMENT
Evaluation Factors and Rating Criteria

Lateral Flow Immunoassay Evaluation

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

Assay parameters

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

1. Sensitivity

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

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

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

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

ATTACHMENT 4
Evaluation Factors and Rating Criteria

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

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

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

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

ATTACHMENT 4
Evaluation Factors and Rating Criteria

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

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.