

<b>AWARD/CONTRACT</b>		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING	PAGE OF PAGES 1   40	
2. CONTRACT (Proc. Inst. Ident.) NO. W911NF2190001		3. EFFECTIVE DATE 13 Oct 2020		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0011560601		
5. ISSUED BY US ARMY ACC-APG-RTP W911NF 800 PARK OFFICE DRIVE SUITE 4229 RESEARCH TRIANGLE PARK NC 27709		CODE W911NF	6. ADMINISTERED BY (If other than Item 5) DCMA SAN D EGO 9174 SKY PARK CT, SUITE 100 SAN D EGO CA 92123-4363		CODE S0514A	SCD: C
7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code) CUE NC. 11100 ROSELLE ST STE A SAN D EGO CA 92121-1210				8. DELIVERY <input checked="" type="checkbox"/> FOB ORIGIN <input type="checkbox"/> OTHER (See below)		
				9. DISCOUNT FOR PROMPT PAYMENT		
				10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN:		ITEM
CODE 7V/PK0		FACILITY CODE		12. PAYMENT WILL BE MADE BY DFAS COLUMB-WEST ENTITLEMENT OPERATIONS DFAS-COMWEST ENTITLEMENT OPERATIONS PO BOX 182381 COLUMBUS OH 43218-2381		
11. SHIP TO/MARK FOR JPM MEDICAL JPM CBRN MEDICAL 1564 FREEDMAN DRIVE FORT DETRICK, MD MD 21702		CODE W56XNH	CODE HQ0339			
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304(c)( ) <input type="checkbox"/> 41 U.S.C. 253(c)( )			14. ACCOUNTING AND APPROPRIATION DATA <b>See Schedule</b>			
15A. ITEM NO.	15B. SUPPLIES/ SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT	
<b>SEE SCHEDULE</b>						
<b>15G. TOTAL AMOUNT OF CONTRACT</b>						<b>\$480,916,636.62</b>
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<b>CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE</b>						
17 <input checked="" type="checkbox"/> CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 3 copies to issuing office) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein)				18 <input type="checkbox"/> SEALED-BID AWARD (Contractor is not required to sign this document) Your bid on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract)		
19A. NAME AND TITLE OF SIGNER (Type or print)				20A. NAME OF CONTRACTING OFFICER <b>(b) (6)</b> TEL: <b>(b) (6)</b> EMAIL: <b>(b) (6)</b>		
19B. NAME OF CONTRACTOR BY _____ (Signature of person authorized to sign)		19C. DATE SIGNED		20B. UNITED STATES OF AMERICA <b>(b) (6)</b> BY _____ (Signature of Contracting Officer)		20C. DATE SIGNED 13-Oct-2020

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	Industrial Expansion (FFP)FFP INDUSTRIAL EXPANSION IN ACCORDANCE WITH AWARD SPECIFICATIONS FOB: Origin (Shipping Point) PURCHASE REQUEST NUMBER: 0011560601 PSC CD: AN14	1	Lot	(b) (4)	(b) (4)

NET AMT

(b) (4)

ACRN AA  
CIN: GFEBS001156060100001

(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002	Test Cartridges (FFP)FFP COVID-19 TEST CARTRIDGES AS SPECIFIED IN AWARD NARRATIVE FOB: Origin (Shipping Point) PURCHASE REQUEST NUMBER: 0011560601 PSC CD: AN14	6,000,000	Each	(b) (4)	(b) (4)

NET AMT

(b) (4)

ACRN AA  
CIN: GFEBS001156060100002

(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003	Monitoring Systems (FFP)FFP MONITORING SYSTEMS AS SPECIFIED IN AWARD NARRATIVE FOB: Origin (Shipping Point) PURCHASE REQUEST NUMBER: 0011560601 PSC CD: AN14	30,000	Each	(b) (4)	(b) (4)

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NET AMT

(b) (4)

ACRN AA  
CIN: GFEBS001156060100003

(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004	Swab Packs (FFP)FFP SWAB PACKS AS SPECIFIED IN AWARD NARRATIVE FOB: Origin (Shipping Point) PURCHASE REQUEST NUMBER: 0011560601 PSC CD: AN14	60,000	Each	(b) (4)	(b) (4)

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NET AMT

(b) (4)

ACRN AA  
CIN: GFEBS001156060100004

(b) (4)

Section C - Descriptions and Specifications

OTHER TRANSACTION AGREEMENT

**OTHER TRANSACTION AUTHORITY FOR PROTOTYPE  
AGREEMENT  
BETWEEN**

**Cue Health, Inc. (Awardee)  
And  
Army Contracting Command – Aberdeen Proving Ground - Research Triangle Park, NC DIVISION  
(Government)  
800 Park Office Drive Research Triangle Park, NC 27529**

**Effective Date:** October 13, 2020

**Agreement No.:** W911NF-21-9-0001

**Total Amount of the Agreement:** \$480,916,636

**Awardee  
Signature**

**Government  
Signature**

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(b) (6)

**Printed Name**

**CEO**

**Printed Name**

**Agreements Officer**

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## **OTHER TRANSACTION AUTHORITY FOR PROTOTYPE AGREEMENT**

This Other Transaction Authority for Prototype Agreement is entered into between the United States of America, hereinafter called the “Government”, pursuant to and under U.S. Federal law and Cue Health Inc., a small business and non-traditional defense contractor, hereinafter called the “Awardee”. The United States of America and Awardee are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”

WHEREAS, the Awardee is eligible for an Other Transaction Authority for Prototype Agreement in accordance with 10 USC § 2371b(d)(1)(A) as amended by the National Defense Authorization Act for Fiscal Year 2018 as they are non-traditional defense contractor, attesting to “An entity that is not currently performing and has not performed, for at least the one-year period preceding the solicitation of sources by the Department of Defense for the procurement or transaction, any contract or subcontract for the Department of Defense that is subject to the full coverage under the cost accounting standards prescribed pursuant to Section 1502 of title 41 and the regulations implementing such section”;

WHEREAS, the DoD currently has authority under 10 U.S.C. § 2371b to award “other transactions” (OTs) in certain circumstances for prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the DoD, or to improve platforms, systems, components, or materials in use by the Armed Forces;

WHEREAS, a prototype can generally be described as a physical or virtual model used to evaluate the technical or manufacturing feasibility or military utility of a particular technology or process, concept, end item, or system;

WHEREAS, this Agreement meets the criteria for a prototype project;

NOW THEREFORE, the Parties have agreed as follows:

### **ARTICLE 1: BACKGROUND, DEFINITIONS AND SCOPE OF THE AGREEMENT**

#### **A. Background**

The Department of Health and Human Services through DoD requires the ability to procure reliable point of care testing assays and devices in sufficient quantities to meet the demand to respond to the on-going COVID-19 Pandemic. The unprecedented demand for rapid and accurate molecular diagnostic testing continues to exceed national testing capacity. Awardee, through funding provided by HHS, has already developed and received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for a rapid, portable, point of care COVID-19 test capable of detecting SARS-CoV-2, the virus that causes COVID-19. The ability to deploy substantial quantities of the Cue POC COVID-19 test will not only increase national test capacity, but significantly reduce the time to inform patients of their result. The Cue Health test is anticipated to be used primarily in particular settings of concern, such as nursing homes, long term care facilities and schools. It will also be beneficial to the armed services and the US population at large, at other locations where a laboratory capability is not readily accessible. The Cue COVID-19 Test consists of: 1.) the Cue COVID-19 Test Cartridge pack which includes a single use test cartridge and a single use Sample Wand (swab); 2.) The Cue Health Monitoring System (reader); The Cue COVID-19 External Control Swabs Pack. Hereafter, the components of the test as necessary for a single use are collectively referred to as a “COVID-19 Test”.

#### **B. Definitions**

**Agreement Invention:** Any invention conceived or first actually reduced to practice in the performance of the Prototype Project under this Agreement.

**Agreements Officer or AO:** Warranted contracting officer authorized to sign the final OTA for the Government.

**Agreement's Officer's Representative or AOR:** The individual designated by the Government to monitor all technical aspects and assist in agreement administration of the Prototype Project. The AOR shall only assist in agreement administration of the Prototype Project to the extent delegated such administration authority in writing in the AOR delegation letter by the responsible Agreements Officer.

**Background Invention:** Background Invention means any Invention, or improvement to any Invention, other than an Agreement Invention, that was conceived, designed, developed, produced, and/or reduced to practice prior to performance of this Agreement, or outside the scope of work performed under this Agreement.

**Cause:** An event or issue that has been discovered that the Government believes may impact successful performance of the OTA.

**Date of Completion:** The date on which all work is completed or the date on which the period of performance ends.

- **Deliverable(s):** Any documentation (e.g. report, Executive Summary, Letter) given to the Government by the Awardee as described in the second column of Table 1 in Article I, Section C.7 under the heading "Deliverable."
- **Effective Date:** The date of execution of this Agreement by the Parties.
- **Field:** COVID-19 Diagnostic testing.
- **Government:** The United States of America, as represented by The Department of Defense and the Department of Health and Human Services.
- **Government Purpose Rights:** As defined in DFARS 252.227-7013(a)(13).
- **Invention:** Any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.
- **Know-How:** Information, practical knowledge, techniques, and skill development by Awardee in the performance of the Prototype Project and which is necessary for the Practical Application of an Agreement Invention within the Field.
- **Limited Rights:** As defined in DFARS 252.227-7013(a)(14).
- **Party:** Each of the Government and Awardee. (collectively, "Parties").
- **Practical Application:** With respect to an Agreement Invention, to manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions so as to establish that the Agreement Invention is capable of being utilized.
- **Program:** Prototype efforts being conducted by the Parties pursuant to this Agreement.
- **Prototype Project:** Has the meaning given in Article 1.C.
- **Project Coordination Team or PCT:** Agreements Officer, Agreements Officer's Representative, Subject Matter Experts and Team Leader(s) acting in support of Operation Warp Speed and responsible for periodic and ad-hoc reporting to Operation Warp Speed Leadership.
- **Property:** Any tangible personal property other than property actually consumed during the execution of work under this Agreement.
- **Under this Agreement:** When used, for example but without limitation, in the definitions of Data, Know-How, Property, and Agreement Inventions, means activities conducted pursuant to this Agreement that are Government funded.

## Scope of the Agreement

- 1. Prototype Project:** The prototype project under this Agreement is the demonstration by Awardee of the rapid, large scale supply and logistics capability to manufacture and deliver to the Government within 5 months of the effective date of this Agreement 6 million Cue COVID-19 Assay Cartridges, 60,000 COVID-19 Control Swab Packs, and 30,000 Monitoring Systems by achieving a sustained average per day production rate of at least 100,000 EUA or 510(k) cleared Cue COVID-19 Assay Cartridges over the last 7 days of the 5 month delivery period. The expansion of Awardee's manufacturing capability will likely entail several actions. The company will increase their overall output of assay cartridges by installing additional high capacity automated lines. Additionally the Awardee will upgrade their bio production capability to ensure enough reagent materials are available to meet end-state test cartridge manufacturing goals. In addition Awardee will perform activities required to onshore Monitoring System manufacturing to be performed either in-house, with a US-based contract manufacturing organization or both. The demonstrated manufacturing capability will be in compliance with ISO 13485 standards as well as the Quality System Regulations at 21 CFR Part 820. In order to ensure the successful and expeditious completion of this prototype project, Awardee agrees and represents that, commencing on the effective date of this Agreement, the Government will be the exclusive purchaser of the entire production of Awardee's COVID-19 Test until the prototype project has been successfully completed. This exclusive purchaser condition is waived under the following circumstances:

The prototype project will be successfully completed when Awardee has achieved a sustained average per day production rate of at least 100,000 EUA or 510(k) cleared COVID-19 Assay Cartridges over a 7 day period, and has delivered a total of 6 million Cue COVID-19 Assay Cartridges, 30,000 monitoring systems, and 60,000 control swab packs.

- 2. Associated Production:** It is the intention of the Parties to enter into a separate, but associated, sole-source FAR-based contract for the continued production of COVID-19 Tests. Subject to applicable law and regulation, the Parties shall take all steps necessary to negotiate and enter into such a FAR-based contract in good faith with the intent of promptly signing such FAR-based contract as soon as possible after this Agreement. Follow-on production pursuant to 10 USC 2371b is not anticipated for this project. (b) (4)

- 3. Manufacturing Equipment Purchased With Government Funds:** In recognition of, and in consideration for, the Government's significant funding for the development of Awardee's enhanced manufacturing capability, the Awardee agrees to never re-locate outside of the United States or its Territories any of the Automated Assembly Line equipment purchased with Government funds under this Agreement.
- 4. Performance by Affiliates:** The Government acknowledges and agrees that Awardee may perform its obligations under this Agreement through one or more of its affiliates and/or subcontractors, provided that Awardee will be responsible for the full and timely performance as and when due under, and observance of, all the covenants, terms, conditions and agreements set forth in this Agreement by its affiliates and/or subcontractors.
- 5. Audits:** Until such time as all tests, Monitoring Systems and control packs have been delivered under this Agreement, and in no event after expiration of the Period of Performance, audits under this Prototype Agreement may include Government Quality Assurance audits – periodic, *ad hoc* or for cause – of Awardee's or sub-agreement holders' facilities included in the supply chain. The Government will provide notification of a periodic or *ad hoc* audit at least fourteen (14) calendar days prior to the intended audit date and both parties will work in good faith to accommodate the audit and determine scheduling. In all audits, the Government will comply with the Person in Plant requirements set forth in Article 1.C.7.

Additionally, Awardee

shall grant the Government the right to place such orders as Priority Orders (as defined below) for which Government purchase orders will be prioritized by Awardee as if they were "rated orders" subject to 15 CFR § 700.14, subject to the priority afforded to orders that are expressly identified as HRPAS or DPAS rated orders.

6. **Person in Plant:** The Government may request to have a government representative in place at Awardee’s facility, with no fewer than fourteen (14) calendar days’ advance notice of the desired date for that person to be in place. The name, role, scope and duration will be mutually agreed between the Parties in writing in advance. The Government representative will adhere to the agreed scope and to the Awardee’s policies, procedures and instructions at all times. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a Awardee plant.  
If considered for cause, the Government may place representatives in place at Awardee’s facility, with no fewer than 5 (five) business days’ advance notice of the desired date for the person(s) to be in place, subject to applicable COVID protocols. The names, roles, scope, and duration will be provided to the Awardee in advance. The Government representative will adhere to the Awardee’s policies, procedures and instructions regarding facility regulations at all times. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a Awardee plant.
7. **Deliverables:** Deliverables under this Agreement are listed in Table 1.  
**Variations:** Awardee shall promptly notify the Government of any anticipated shortage in quantity or deviation from any delivery date specified herein. The Government and the Awardee shall cooperate in good faith to adjust Table 1 to reflect reasonable variations in the delivery schedule, provided that the total scheduled quantities are delivered and Awardee demonstrates a production capacity of 100,000 units per day within not more than 180 days after award.

**Table 1: Deliverables**

Item	14* Days After Award	28* Days	42* Days	56* Days	70* Days	84* Days	98* Days	112* Days	126* Days	140* Days	154* Days
COVID-19 Test Cartridges	8,000	10,000	40,000	60,000	180,000	400,000	650,000	912,000	1,100,000	1,240,000	1,400,000
Health Monitoring Systems	100	500	1,000	2,000	2,400	4,000	4,000	4,000	4,000	4,000	4,000
COVID-19 External Control Swab Packs	80	100	400	600	1800	4000	6500	9,120	11,000	12,400	14,000

\* Delivery dates and quantities subject to adjustment as provided herein.

Deliverable	Delivery Date	Method for Acceptance
Increase Industrial Base Manufacturing Capability to 100K Cue COVID-19 Test cartridges per day	6 Million EUA or 510(k) cleared COVID-19 Test Cartridges (per delivery schedule above) 30K Health Monitoring Systems (per delivery schedule above) 60K COVID-19 External Control Swab Packs (per delivery schedule above)	Periodic Inspection & Random Sampling (DCMA and AOR)
Monthly Progress Reports	10 <sup>th</sup> of the month, every month during PoP	Progress Report (AOR)
Weekly Progress Meetings	Weekly, as agreed upon	Progress Meeting (AOR)
Quarterly In Process Review	Every 90 days	Progress Meeting (AOR)
Final Report	5 days after last scheduled delivery	Progress Report (AOR)
Subcontractor Supply Chain Plans	5 days after award	Progress Report (AOR)
Manufacturing Plan	15 days after award	Progress Report (AOR)
Distribution Plan	15 days after award	Progress Report (AOR)
Quality Management Plan	15 days after award	Progress Report (AOR)

**Monthly Progress Reports.** The Awardee shall submit monthly progress reports no later than the 10th of the month. Awardee format acceptable. Electronic submission acceptable in MS Office or PDF format. Financial information shall be MS Excel format. Monthly reports shall NOT be marked proprietary, and shall have Distribution Statement C (US Government and their contractors). Each monthly report shall, at a minimum, contain the following:

- Summary of monthly progress for each of the Awardee's facilities/capabilities associated with this effort.
- Summary of progress towards established milestones for each facility/capability.
- Identification of any milestone that is slipping or missed, and discussion of path forward to bring milestone back to schedule, and impact on other milestones.
- Summary of risks, discussion of potential impacts and efforts to mitigate.
- Summary of overall schedule and changes from previous month.
- Status updates from Manufacturing plan
- Status updates from Distribution plan
- Report any customer complaints
- Report any known deficiencies of the materials and/or products
- Financial summary of Awardee deliveries month to date, invoices submitted, and Government payments made.

To the extent trade secret or other proprietary information is relevant to a monthly report, an appropriately marked supplement may be provided.

**Manufacturing Plan.** The Awardee shall provide a detailed plan of action (contractor format acceptable) to increase cartridge-manufacturing capability to meet the government's delivery schedule (i.e. ramp up to 100K cartridges per day) and associated on-shoring component manufacturing within 15 days of contract award. The Awardee's plan of action shall at a minimum, include the following:

- a. Timeline, materials required and strategy to set up and begin V2.0 manufacturing lines to manufacture the cartridges;
- b. Timeline, materials required and strategy to upgrade the bioproduction capability to manufacture sufficient cartridge reagents;
- c. Timeline, materials required and strategy to onshore manufacturing of reagents and cartridge subcomponents;
- d. Information on the US based manufacturing organization to replace existing organization;
- e. Current GMP manufacturing status and plan to achieve GMP manufacturing, if not currently GMP;
- f. Quality Assurance plan and Acceptance metrics;
- g. Plan to comply with FDA EUA Letter of Authorization.

**Quality Management Plan.** Cue Health, Inc. will, in the level of detail and format that Cue Health, Inc. solely elects (provided such format provides a reasonable and industry-standard level of detail), provide a quality management plan for manufacturing efforts that conform to ISO 13485 standards as well as the Quality System Regulations at 21 CFR Part 820 which may include, but is not limited to, the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation.

**Distribution Plan.** Cue Health, Inc. will, in the level of detail and format that Cue Health, Inc. solely elects (provided such format provides a reasonable and industry-standard level of detail), provide a Distribution Plan within 15 days of contract award, which shall provide a detailed distribution plan for how all Test Cartridge Packs, Monitoring Systems and External Control Swabs Packs will be shipped and delivered to required delivery locations within the United States and its Territories. The Awardee's distribution plan shall at a minimum, include the following:

- a. Current distribution processes;
- b. Timeline and strategy to increase distribution process and shipping to handle the increase in number and volume of shipments.

**Subcontractor Supply Chain Plans.** Cue Health Inc. will provide plans from key US subcontractors (swab manufacturer, fluid transfer automation, etc) describing how they plan to expand their production capacities in support

of the Awardee. Cue Health Inc. will describe the source of capital such subcontractors expect to be utilized to increase their production rates.

**Final Report.** Final Report shall NOT be marked proprietary, and shall have Distribution Statement C. Contractor format acceptable. Electronic submission acceptable in MS Office or PDF format. Financial information shall be MS Excel format. Final report summarizing stated objectives and the progress that was achieved in meeting those objectives; summary of risks incurred, impacts and mitigation; quantitative discussion of production throughput improvements achieved; financial summary of project; schedule summary for project, comparing original schedule to final schedule; lessons learned for future similar endeavors, and recommendations for path forward as applicable.

8. **Milestones:** Payable milestones under this Agreement are listed in Table 2a and 2b.

**Payable Milestones**

**Table 2a Industrial Expansion Milestones**

Milestone #	Milestone Description	Due Date	Demonstration of Milestone	Total Funds
1	Advance payment for upfront Industrial Expansion costs	Upon award	Award	(b) (4)

**Table 2b COVID-19 Test Delivery Milestones\***

Item	14 Days Post Award		28 Days		42 Days		56 Days		70 Days		84 Days	
	Qty	Payment	Qty	Payment	Qty	Payment	Qty	Payment	Qty	Payment	Qty	Payment
COVID-19 Test Cartridges	8000	(b) (4)	10,000	(b) (4)	40,000	(b) (4)	60,000	(b) (4)	180,000	(b) (4)	400,000	(b) (4)
Health Monitoring Systems	100	(b) (4)	500	(b) (4)	1000	(b) (4)	2000	(b) (4)	2400	(b) (4)	4000	(b) (4)
COVID-19 External Control Swab Packs	80	(b) (4)	100	(b) (4)	400	(b) (4)	600	(b) (4)	1800	(b) (4)	4000	(b) (4)

Item	98 Days		112 Days		126 Days		140 Days		154 Days	
	Qty	Payment	Qty	Payment	Qty	Payment	Qty	Payment	Qty	Payment
COVID-19 Test Cartridges	650,000	(b) (4)	912,000	(b) (4)	1,100,000	(b) (4)	1,240,000	(b) (4)	1,400,000	(b) (4)
Health Monitoring Systems	4000	(b) (4)	4000	(b) (4)	4000	(b) (4)	4000	(b) (4)	4000	(b) (4)
COVID-19 External Control Swab Packs	6,500	(b) (4)	9,120	(b) (4)	11,000	(b) (4)	12,400	(b) (4)	14,000	(b) (4)

**ARTICLE 2: TERM AND TERMINATION**

**A. Term of this Agreement**

The Term of this Agreement commences upon the Effective Date and extends through final payment. This Agreement is anticipated to end 5 months after the Effective Date, subject to mutually agreed

extensions pursuant to paragraph 2.D to facilitate the completion of the project(s). A transaction for a prototype project is complete upon the written determination of the appropriate official for the matter in question that efforts conducted under a Prototype OT: (1) met the key technical goals of a project, or (2) accomplished a particularly favorable or unexpected result that justifies the completion of the prototype.

• **B. Rights of Termination**

• In the event that Awardee notifies the Government that, as a result of emerging safety or efficacy data, no further efforts will be undertaken towards the development of the COVID-19 Test manufacturing and delivery, then, either Party may notify the other Party of its intent to terminate this Agreement, which termination shall be effective thirty (30) days after the date of such notice.

• Awardee shall have no liability to repay the Government for milestone payments made prior to the notification of termination, except as otherwise provided for under Article 14 or Termination for Cause below. With respect to milestones which have not been completed, Awardee shall be entitled to payment based on a percentage of the work performed toward said milestones, plus reasonable charges the Awardee can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. By way of example, these costs may include, but are not necessarily limited to, costs associated with non-cancellable agreements with vendors to obtain manufacturing capacity or supplies in the performance of this prototype project agreement. Awardee shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit Awardee's records. Awardee shall not be paid for any work performed which reasonably could have been avoided.

• From and after the effective date of any such termination, Awardee shall have no further obligation to deliver any test cartridges, Monitoring Systems or external controls, and the Government shall have no further obligation to accept any such deliverables.

• The Government and the Awardee will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination, including disposition of materials acquired for research use. Failure of the Parties to agree to a reasonable adjustment will be resolved pursuant to Article 7, Disputes. In the event of termination, the Parties shall negotiate in good faith a reasonable wind-down plan and neither Party shall have any continuing obligations to perform under the Program except as otherwise specified herein.

Termination for Convenience: The Government may terminate this Agreement for any or no reason by providing at least thirty (30) calendar days' prior written notice to the Awardee. The Government and Awardee will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination by the Government for convenience, provided that Awardee shall retain all payments for work performed prior to the effective date of the termination consistent with the terms of this Agreement, subject to the Government retaining the right to place Priority Orders for up to twelve (12) months after the date of such termination, as defined in Article 1, Paragraph C., subparagraph 2., for other diagnostic tests manufactured using the manufacturing equipment purchased with Government funds under this Agreement.

Termination for Cause: If the Awardee materially fails to comply with the provisions of this Agreement, including unjustifiably failing to maintain EUA or advance to 510(k) clearance for Awardee's COVID-19 Test, the Other Transaction Agreement Officer (OTAO), after issuance of a cure notice and failure of the Awardee to cure the defect within ten (10) business days or the time allowed by the OTAO after Awardee's receipt of the cure notice, whichever is longer, may take one or more of the following actions as appropriate:

- (i) temporarily withhold payments pending correction of the deficiency,
- (ii) disallow all or part of the price attributable to the activity or action not in compliance,
- (iii) wholly or partly suspend or terminate this Agreement,
- (iv) withhold further funding, or
- (v) take any other legally available remedies.

If this Agreement is terminated for Cause, Awardee will grant the Government a non-exclusive, paid up, perpetual license to the Awardee and subawardee patents and documentation necessary for the purpose of developing the Prototype. The Awardee shall provide the Government or its designee with a non-exclusive, paid up, license to any patent, copyright, technical data or regulatory information held by the Awardee that relates to the technology to permit the Government to pursue commercialization of the technology with a third party, on terms to be agreed between the

Parties and subject to rights granted or held by third parties. The terms of this section and the obligations herein will be included in any exclusive license given by the Awardee to a third party for any intellectual property covered by this Agreement, on terms to be agreed between Awardee and such third party. This clause will survive the acquisition or merger of the Awardee by or with a third party.

In addition to the Government's remedies prescribed in this Article 2.B, Termination for Cause, after the finalization of a termination for default hereunder, where defaulted Awardee has exited or abandoned its business in the Field or has unreasonably abandoned its efforts to maintain EUA or advance to 510(k) clearance for Awardee's COVID-19 Test, the Government may upon 30 days written notice to Awardee, take possession of and title to all manufacturing equipment purchased using Government funds provided under this Agreement.

#### **C. Survival**

In the event of Termination, all rights, obligations, and duties hereunder, which by their nature or by their express terms extend beyond the expiration or termination of this Agreement, including but not limited to warranties, indemnifications, intellectual property (including rights to and protection of Intellectual Property and Proprietary Information), and product support obligations shall survive the expiration or termination of this Agreement.

#### **• D. Stop Work Orders**

• Except as required by applicable law or regulation, or judicial or administrative order, the Government shall not have the authority to issue a stop work order to halt the work contemplated under the Statement of Work.

#### **E. Extension of Term**

The Parties may extend by mutual written agreement the Period of Performance if funding availability and research and development or prototype demonstration opportunities reasonably warrant.

### **ARTICLE 3: PROJECT MANAGEMENT AND MODIFICATIONS**

Technical and project management of the prototype project and associated scope within the Statement of Work shall be managed as detailed in this Article.

**A. Project Governance.** Awardee is responsible for the overall management of the Prototype Project and related decisions. The Government and Awardee are bound to each other by a duty of good faith in achieving the Prototype Project as defined in Article 1. As such, the Government will have continuous involvement with Awardee shall provide project results in accordance with the Deliverables schedule identified in Table 1.

**B. Project Management.** Awardee and the Government will each designate an individual responsible for facilitating the communications, reporting, and meetings between the Parties. For Awardee the individual will serve as PM, and for the Government the individual will be the AOR.

**C. Project Reviews.** Awardee and the Government will hold periodic project review meetings as determined by the Awardee Project Manager and AOR, however, these meetings shall not occur more frequently than every fourteen (14) calendar days.

**D. Reviews Resulting in Modifications.** During the performance of this Prototype Agreement, as described above, it may be necessary to modify the scope of the Prototype Project or delivery timeframes. No communications, whether oral or in writing, that purport to change this Agreement are valid unless and until a modification is issued by the AO. The Parties hereby agree that any mutually agreed upon written request for modification shall be executed in an expedited timeframe. Modifications to subawards and/or new subcontracts under this Agreement that could reasonably impact the technical approach proposed and accepted by the Government require the approval of the AOR prior to being executed.

**E. Bilateral Modifications.** Awardee or the Government may propose modifications to this Agreement. A modification that materially changes the obligations of either the Government or Awardee must be in writing and signed by the AO and Awardee authorized official. Awardee requests for modifications shall detail the technical, chronological and financial impact of the proposed change on the Statement of Work or delivery timeframes.

**F. Unilateral Modifications.** The AO may ONLY issue minor or administrative modifications, which do not change the obligations of Awardee in any adverse manner, such as changes to the paying office or appropriations data, or changes to Government personnel identified in the Agreement. Unilateral modifications will only be signed by the AO.

**G.** The AO has assigned an Agreements Officer's Representative (AOR) for this agreement. The Awardee will receive a copy of the written designation outlining the roles and responsibilities of the AOR and specifying the extent of the AOR's authority to act on behalf of the OTA. The AOR is not authorized to make any commitments or changes that will affect price, quality, quantity, delivery, or any other term or condition of the contract.

**H. Agreement Administration**

In no event shall any understanding or agreement, modification, change order, or other matter in deviation from the terms of this Agreement between the Awardee and a person other than the AO be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the AO.

Government Points of Contact:

Agreements Officer (AO)

NAME: (b) (6)  
MAILING ADDRESS: 800 Park Office Drive, Research Triangle Park (RTP), NC 27529  
EMAIL: (b) (6)  
PHONE: (b) (6)  
AGENCY NAME/DIVISION/SECTION: Army Contracting Command – Aberdeen Proving Ground – RTP Division

Agreements Officer Representative (AOR)

NAME: (b) (6)  
MAILING ADDRESS: 110 Thomas Johnson Drive, Suite 200, Frederick, MD 21702  
EMAIL: (b) (6)  
PHONE: (b) (6)

Cue Health, Inc. Points of Contact:

Project Manager (PM)

NAME:  
MAILING ADDRESS:  
EMAIL:  
PHONE:

(will be provided within 30 calendar days after award)

**ARTICLE 4: MANAGEMENT OF THE PROJECT**

**A. Document Review**

- The Awardee shall provide the PCT sufficient opportunity to review study protocols, reports, and project plans. PCT's comments on these documents will be viewed as advisory in nature.

**B. Sub-agreement Holders**

- 1. The Government acknowledges that, in order to combat the global pandemic and provide the test cartridges, Monitoring Systems and external controls as quickly as possible, Awardee has entered into a number of contracts prior to the Execution Date, and the Government agrees that it will not require these contracts to be

renegotiated. Therefore, except as otherwise expressly set forth in this Article 4.B, any provision requiring Awardee to flow-down an obligation to its sub-agreement holders will apply only to sub-agreements executed by Awardee following the Execution Date of this Agreement.

- 2. For clarity, as detailed within the Articles themselves, the following Articles require flow-down to sub-agreements/contracts executed after the Execution Date:
  - (i) Article 8: Confidential Information.
  - (ii) Article 13.E: Subawards where the sub-agreement holder may propose publishing the results of its work under the subaward.
  - (iii) The Awardee will flow-down the provisions of Article 19 (Prohibition on the Use of Certain Telecommunications and Video Surveillance Services or Equipment) to all of its sub-agreements/contracts as provided in Article 19.
- 

#### **ARTICLE 5: "PREP ACT" COVERAGE**

In accordance with the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of Health and Human Service's ("HHS") Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012, and on June 8, 2020, 85 Fed. Reg. 34740 (together, the "Prep Act Declaration"):

(i) This Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;

(ii) Awardee performance of this Agreement falls within the scope of the "Recommended Activities" for responding to the COVID-19 public health emergency in accordance with Section III of the PREP Act Declaration; and

(iii) Awardee is a "Covered Person" per Section V of the PREP Act Declaration.

Therefore, in accordance with Sections IV and VII of the PREP Act Declaration, as well as the PREP Act (42 U.S.C. § 247d-6d), the Department of Defense contracting via assisted acquisition on behalf of the HHS, expressly acknowledges and agrees that the HHS Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this Agreement, as long as Awardee activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

The Government may not use, or authorize the use of, any products or materials provided under this Agreement, unless such use occurs in the United States (or a U.S. territory where U.S. law applies including, but not limited to, embassies, military installations and NATO installations) and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with Awardee prior to use and, if the Parties disagree on such use, the dispute will be resolved according to Article 7, "Disputes."

#### **ARTICLE 6: FINANCIAL MATTERS - OBLIGATION AND PAYMENT**

This Agreement is fixed-price type Other Transaction Authority agreement. The payments provided under this Agreement are intended to compensate the Awardee on a fixed price basis for performance under this Agreement.

##### **A. Obligation**

Except as specified in Article 7: Disputes, the Government's liability to make payments to the Awardee is limited only to those funds obligated under this Agreement or by modification to the Agreement. The ACC-APG Contracting Activity may incrementally fund this Agreement. If modification becomes necessary in performance of this Agreement, pursuant

to Article 3 of this Agreement, the AO and the Awardee shall establish and execute a mutually agreed upon revised Schedule of Payable Milestones consistent with the current SOW.

## **B. Payments**

1. With the exception of test cartridges, Monitoring Systems and external control packs delivered either to Vendor-managed Inventory and/or Government distribution sites for which Government acceptance is detailed in Article 16, Awardee will provide AOR and AO notification of milestone success and any documentation that supports successful completion of the milestone. Within five (5) business days of receipt, the AO will either, 1) confirm milestone completion and authorize the Awardee to invoice against the completed milestone or, 2) notify the Awardee of any deficiencies, additional documentation or clarifications reasonably needed by the Government to complete its review of the milestone. The Parties agree that payments will be made upon the AOR's acceptance of completed milestones. These payments reflect value received by the Government toward the accomplishment of the Prototype Project goals.

Payments are based on amounts generated from the Awardee's financial or cost records. The Awardee shall be reimbursed for each element identified in the awarded cost proposal, executed and accomplished in accordance with the performance schedule.

2. After accomplishment of each milestone, the Awardee will submit the corresponding invoice through a Government provided invoicing and payment system, as detailed in Article 18.
3. Except as set forth in Article 7, Disputes, in no case shall the Government's financial liability exceed the amount obligated under this Agreement.
4. Payments will be made by the cognizant Defense Finance and Accounting Services office, as indicated below, in accordance with the Prompt Payment Act. Article 18 details how to submit and process invoices.
5. Payments shall be made in the amounts set forth in the SOW, provided the AOR has verified the completion of the applicable milestones. The Government will pay Awardee in US dollars.
6. The amounts payable by the Government to the Awardee pursuant to this Agreement shall not be reduced on account of any Taxes unless required by applicable law. The Awardee alone shall be responsible for paying any and all Taxes (other than withholding Taxes required to be paid by the Government under applicable law) levied on account of, or measured in whole or in part by reference to, any payments it receives. If the Awardee is entitled under any applicable Tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding Tax, it shall deliver to the Government or the appropriate governmental authority (with the assistance of the Government to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the Government of its obligation to withhold Tax, and the Government shall apply the reduced rate of withholding, or dispense with the withholding, as the case may be, to the extent it complies with the applicable Tax treaty. If, in accordance with the foregoing, the Government withholds any amount, it shall make timely payment to the proper Taxing Authority of the withheld amount, and send to the Awardee proof of such payment within 90 days following that payment.

As used herein: **Taxes** means all taxes of any kind, and all charges, fees, customs, levies, duties, imposts, required deposits or other assessments, including all federal, state, local or foreign net income, capital gains, gross income, gross receipt, property, franchise, sales, use, excise, withholding, payroll, employment, social security, worker's compensation, unemployment, occupation, capital stock, transfer, gains, windfall profits, net worth, asset, transaction and other taxes, and any interest, penalties or additions to tax with respect thereto, imposed upon any person by any Taxing Authority or other governmental authority under applicable law, whether disputed or not, and including any obligation to indemnify or otherwise assume or succeed to the Tax liability of any other person by law, by contract or otherwise. **Taxing Authority** means any governmental authority or any subdivision, agency, commission or authority thereof or any quasi-governmental body exercising tax regulatory authority.

7. The Awardee shall maintain adequate records to account for all funding under this Agreement. Neither the Cost Accounting Standards nor any other aspect of the Federal Acquisition Regulation or its supplements apply to Awardee's accounting of costs under this Agreement. Cost shall be accounted for in accordance with Awardee's commercial accounting practices. Awardee has an established and agrees to maintain an established accounting

system which complies with Financial Reporting Standards and the requirements of this Agreement, and shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for Federal funds. An acceptable accounting system is one in which all costs, cash receipts and disbursements for which Awardee is entitled to reimbursement under Article 6 are controlled and documented properly.

A. Obligation. Under no circumstances shall the Government's financial obligation exceed the amount obligated in this Agreement or by amendment to the Agreement. The amount of Government funds obligated by this Agreement and available for Payment is set forth on page 1, Line of Accounting and Appropriation. The Government may incrementally fund this agreement.

B. The Government is not obligated to provide payment to the Awardee for amounts in excess of the amount of obligated funds allotted by the Government.

C. The Government shall pay the Awardee, upon submission of proper invoices, the costs stipulated in this Agreement for work delivered or rendered and accepted, less any deductions provided in this Agreement. Unless otherwise specified, payment shall be made upon acceptance of any portion of the work delivered or rendered for which a price is separately stated in the Agreement. Payments will be made within thirty (30) calendar days of receipt of a request for payment.

D. Prior written approval by the AO, or the AOR, is required for all travel directly and identifiably funded by the Government under this agreement. The Awardee shall present to the AO or AOR, an itinerary for each planned trip, showing the name of the traveler, purpose of the trip, origin/destination, dates of travel, and estimated cost broken down by line item as far in advanced of the proposed travel as possible, but no less than two weeks before travel is planned to commence. In the event that emergency travel is required (e.g. in the event of an outbreak) that would make two weeks' notice impractical, travel requests may be submitted to the Government for an expedited review. Emergency travel requests shall be labelled as such and shall include a brief summary of the emergency situation and rationale for expedited review.

#### E. WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (MAY 2013)

(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.

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

(c) WAWF access. To access WAWF, the Awardee shall (i) have a designated electronic business point of contact in the System for Award Management at <https://www.acquisition.gov>; and (ii) be registered to use WAWF at <https://wawf.eb mil/> following the step-by-step procedures for self-registration available at this website.

(d) WAWF training. The Awardee 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 Awardee must use the following information when submitting payment requests and receiving reports in WAWF for this Agreement:

(1) Document type. The Awardee shall use the following document type:  
Voucher

(2) Inspection/acceptance location. The Awardee shall select the following inspection/acceptance location(s) in WAWF, as specified by the contracting officer.

(3) Document routing. The Awardee 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	HQ0339
Issue By DoDAAC	W911NF
Admin DoDAAC	S0514A
Inspect By DoDAAC	W56XNH

(4) Payment request and supporting documentation. The Awardee shall ensure a payment request includes appropriate contract line item and subline item descriptions of the work performed or supplies delivered, costs, fee (if applicable), and all relevant back-up documentation in support of each payment request.

(5) WAWF email notifications. The Awardee shall enter the email address identified below in the "Send Additional Email Notifications" field of WAWF once a document is submitted in the system.

(b) (6)

(g) WAWF point of contact.

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

(2) For technical WAWF help, contact the WAWF helpdesk at 866-618-5988.  
(End of Clause)

1. The AOR identified in Supplement 4, "Agreement Administration" shall continue to formally inspect and accept the deliverables/milestones. To the maximum extent practicable, the AOR shall review the deliverable(s) milestone report(s) and either:

i. provide a written notice of rejection to the Awardee which includes feedback regarding deficiencies requiring correction or

ii. written notice of acceptance to the AO, and acceptance in the WAWF system.

2. Acceptance within the WAWF system shall be performed by the AOR.

Note for DFAS: The Agreement shall be entered into the DFAS system by CLIN - Milestone association (MS)/ACRN as delineated in Section B of the Award. The Agreement is to be paid out by CLIN (MS)/ACRN. Payments shall be made using the CLIN (MS)/ACRN association as delineated at Section B of this Award.

Awardee Information: As identified at Central Contractor Registration, i.e., Commercial and Government Entity (CAGE) Code, Dun & Bradstreet number (DUNS), and Tax Identification Number (TIN). Payments shall be made in the amounts set forth in the SOW, provided the AOR has verified the completion of the milestones.

F. Comptroller General Access to Records: To the extent that the total Government payments under this Agreement exceed \$5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine records of any Party to the Agreement or any entity that participates in the performance of this Agreement that directly pertain to, and involve transactions relating to, the Agreement for a period of three (3) years after final payment is made. This requirement shall not apply with respect to any Party to this Agreement or any entity that participates in the performance of the Agreement, or any subordinate element of such Party or entity, that has not entered into any other agreement (contract, grant, cooperative agreement, or "other transaction") that provides for audit access by a government entity in the year prior to the date of this Agreement. This paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law. The terms of this paragraph shall be included in all sub-agreements to the Agreement other than sub-agreements with a component of the U.S. Government. The Comptroller General may not examine records pursuant to a clause included in an agreement more than three years after the final payment is made by the United States under the agreement.

**C. Comptroller Access Financial Records and Reports:**

Awardee shall maintain adequate records to account for Federal funds received under this Agreement and shall maintain adequate records to account for funding provided under this Agreement. Awardee relevant financial records are subject to examination or audit by or on behalf of the Comptroller General, Contracting Activity AO, or other Government Official for a period not to exceed three (3) years after expiration of the term of the Agreement. The Comptroller General, AO or designee shall have direct access to sufficient records and information of any party to this agreement or any entity that participates in the performance of this agreement to ensure full accountability for all funding under this Agreement. Such audit, examination or access shall be performed during business hours on business days upon prior written notice and shall be subject to the security requirements of the audited party. Any audit required during the course of the program may be conducted by the Comptroller General or other Government Official using Government auditors or, at the request of Awardee's external CPA accounting firm at the expense of the Awardee.

**1. Lower Tier Agreements**

The Performer shall include this Article, suitably modified to identify the Parties, in all subcontracts or lower tier agreements entered into solely in connection with this Agreement.

**ARTICLE 7: DISPUTES**

**A. General**

The Parties shall communicate with one another in good faith and in a timely, responsive, and cooperative manner when raising issues under this Article.

**B. Dispute Resolution Procedures**

1. Any claim or dispute between the Government and Awardee concerning questions of fact or law arising from or in connection with this Agreement, and, whether or not involving an alleged breach of this Agreement, shall be raised and resolved under this Article.
2. Whenever legal disputes or claims arise, the Parties shall attempt to resolve the issue(s) by discussion and come to mutual agreement on a resolution as soon as practicable. In no event shall a dispute, disagreement or misunderstanding of which the aggrieved Party became aware more than six (6) months prior to the notification made under sub-section B.3 of this Article constitute the basis for relief under this Article unless one level above the AO, in the interests of justice, waives this requirement.

3. Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party (through the AO Awardee's POC, as the case may be) in writing of the relevant facts, identifying unresolved issues, and specifying the clarification or remedy sought. Within five (5) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a joint decision by the ACC-APG Division Chief for and senior executive appointed by Awardee. The other Party shall submit a written response on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The Division Chief and the Awardee senior executive shall conduct a review of the matter(s) in dispute and attempt to render a mutually agreeable decision in writing within thirty (30) calendar days of receipt of such written position. Any such joint decision is final and binding.
4. In the absence of a joint decision, upon written request to the ACC-APG Associate Director made within thirty (30) calendar days of the expiration of the time for a decision under sub-section B.3 above, the dispute shall be further reviewed. The Associate Director may elect to conduct this review personally or through a designee or jointly with a senior executive appointed by Awardee. Following the review, the Associate Director or designee will resolve the issue(s) and notify the Parties in writing. This decision may be appealed to any federal court of competent jurisdiction.
5. Notwithstanding any other provisions of this Article, the Parties agree that Awardee shall have the right to pursue any contract dispute arising under this Agreement in any federal court of competent jurisdiction, including the appropriate Court of Appeals, or the Supreme Court, at any time without any administrative exhaustion requirements, and the timing requirements described above will not limit any claim in such tribunals.

#### **C. Limitation of Damages**

Claims for damages of any nature whatsoever pursued under this Agreement shall be limited to direct damages only up to the aggregate amount of Government funding obligated as of the time the dispute arises, except with respect to violations of Articles 5, 8, 9, or 10 of this Agreement.

#### **ARTICLE 8: CONFIDENTIAL INFORMATION**

- A.** “**Confidential Information,**” as used in this Article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
- B.** The Agreements Officer and the Awardee may, by mutual consent, identify elsewhere in this Agreement specific information and/or categories of information which the Government will furnish to the Awardee or that the Awardee is expected to generate which is confidential. Similarly, the Agreements Officer and the Awardee may, by mutual consent, identify such Confidential Information from time to time during the Period of Performance. Failure to agree will be settled pursuant to the “Disputes” clause.
- C.** If it is established elsewhere in this Agreement that information to be utilized under this Agreement, or a portion thereof, is subject to the Privacy Act, the Awardee will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. § 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
- D.** The Receiving Party shall not directly or indirectly, divulge or reveal to any person or entity any Confidential Information of another Party without the Disclosing Party’s prior written consent, or use such Confidential Information except as permitted under this Agreement. Confidential Information shall be subject to the same prohibitions on disclosure as provided for under FAR Part 24.202. Further, any reproduction of Confidential Information or portions thereof that is disseminated within the Government, CMF, or Awardee, shall be shared strictly on a need to know basis for the purposes of this Agreement and is subject to the restrictions of this provision. In addition to the above, Confidential Information is subject to the protections of the Trade Secrets Act as well as any other remedies available under this Agreement or the law.
- E.** Such obligation of confidentiality shall not apply to information which the Receiving Party can demonstrate through competent evidence: (i) was at the time of disclosure in the public domain; (ii) has come into the public domain after disclosure through no breach of this contract; (iii) was known to the Receiving Party prior to disclosure thereof by the Disclosing Party; (iv) was lawfully disclosed to the Receiving Party by a Third Party which was not under an obligation of confidence to the Disclosing Party with respect thereto; or (v) was approved for public release by prior written permission of the Disclosing Party.
- F.** Whenever the Awardee is uncertain with regard to the proper handling of material under the Agreement, or if the material in question is subject to the Privacy Act or is Confidential Information subject to the provisions of

this Article, the Awardee shall obtain a written determination from the Agreements Officer prior to any release, disclosure, dissemination, or publication.

- G. Agreements Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.
- H. The provisions of paragraph (D) of this Article shall not supersede conflicting or overlapping provisions applicable Federal, State or local laws.
- I. The obligations of the Receiving Party under this Article shall continue for a period of seven (7) years from conveyance of the Confidential Information.

Subject to Article 4.B, all above requirements MUST be passed to all Sub-awards.

## ARTICLE 9: INTELLECTUAL PROPERTY RIGHTS

- A. Awardee represents that, to its knowledge, the intellectual property license(s) and other rights held by or granted to Awardee, are sufficient to enable Awardee to perform its obligations under this Agreement.
- B. **Background IP and Materials.** Awardee and the Government each retain any intellectual property (IP) rights to their own materials, technical data (as defined in 48 DFARS 252.227-7013), technology, information, documents, or Know-How—or potential rights, such as issued patents, patent applications, invention disclosures, copyrighted works, or other written documentation—that exist prior to execution of this Agreement or are developed outside the scope of this Agreement (“**Background IP**”). For avoidance of confusion, Background IP includes but is not limited to Background Inventions. Awardee agrees to provide, within 30 days of the effective date of this Agreement, a list of all Background Inventions relevant to Awardee’s performance of the prototype project. Any material defect identified in the Background Invention disclosure that could materially negatively impact performance of the prototype project, will be addressed between the AOR and the Awardee’s designee.
- C. **Government’s Background IP.** The Government has Background IP as constituted under contract number HHSO100201800016C, including all executed modifications.
- D. **Agreement Inventions.** In the unlikely event that an invention is conceived or first actually reduced to practice in the performance of this Agreement (“Agreement Invention”), ownership of any Agreement Invention, regardless of whether it is not patentable, or is patentable under U.S. patent law that is conceived or first reduced to practice under this Agreement will follow inventorship in accordance with U.S. patent law. Neither the Government nor Awardee anticipate the conception or reduction to practice of any Agreement Invention. The Government acknowledges that in the absence of any Agreement Invention, the Bayh-Dole Act (35 U.S.C. §§ 200-212) does not apply to, nor govern, this Agreement. Since, in the absence of any Agreement Invention, the Bayh-Dole Act, does not apply to this Agreement, as such, title to Agreement Invention will accrue to the inventor or inventor-organization. In the absence of any Agreement Invention, the Government shall not have any rights to “march-in,” as that term is defined in 35 U.S.C. § 203, and Awardee is not subject to the manufacturing requirements of 35 U.S.C. § 204.

In the event an Agreement Invention arises, the Parties represent and warrant that each inventor will assign his or her rights in any such Agreement Inventions to his or her employing organization. If an Agreement Invention is made either by a Awardee employee (“**Sole Recipient Agreement Invention**”) or made by a Government employee (“**Sole Government Agreement Invention**”) the entire rights to that sole Awardee Agreement Invention or Sole Government Agreement Invention will be respectively assigned to the Awardee or to the Government. If an Awardee employee and a Government employee jointly make an Agreement invention (“**Joint Agreement Invention**”), it will be owned jointly by the Awardee and the Government. Ownership of inventions made in whole or in part with sub-Awardee or collaborator employees, including employees of other components of the Government, will be determined solely pursuant to an agreement between the Awardee and the applicable sub-Awardee or collaborator. Notwithstanding the foregoing, neither the Government nor Awardee anticipate the Government making a Sole Government Agreement Invention, nor the Parties jointly making a Joint Agreement Invention, as Awardee employees are solely responsible, as between the Parties, for performing the Prototype Project under this Agreement.

- E. **Patent Applications.** Each Party shall report any Agreement Inventions to the other Party within 60 days of the time the inventor discloses it in writing to its personnel responsible for patent matters. The Parties will respectively have the option, in their discretion, to file a patent application claiming any Agreement Invention made solely by their respective employees (but, for clarity, are not obligated to file patent applications claiming

any Agreement Invention, and will not forfeit title by electing to hold an Agreement Invention as a trade secret). The Parties will consult with each other regarding the options for filing a patent application claiming a joint Agreement Invention. Within one (1) year of being notified of the discovery of an Agreement Invention, each Party will provide notice of any filing of a patent application to the other Party. The Parties will reasonably cooperate with each other in the preparation, filing, and prosecution of any patent application claiming a Joint Agreement Invention. Any Party filing a patent application will bear expenses associated with filing and prosecuting the application, as well as maintaining any patents that issue from the application, unless otherwise agreed by the Parties. Executive Order No. 9424 of 18 February 1944 requires all executive Departments and agencies of the Government to forward through appropriate channels to the Commissioner of Patents and Trademarks, for recording, all Government interests in patents or applications for patents.

- F. Patent Prosecution.** Awardee agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patents and patent applications that are relevant to the work performed under this Agreement. Awardee shall keep the Government reasonably advised on the status of Awardee Background IP by providing an annual report on the status of Awardee Background IP. With respect to a Sole Awardee Agreement Invention or a Joint Agreement Invention, prior to acting on a decision by Awardee to abandon or not file in any country a patent or patent application covering a Sole Awardee Agreement Invention or a Joint Agreement Invention, Awardee shall so inform the Government in a timely manner to allow Awardee to thoughtfully consider the Government's comments regarding such a proposed decision.

If the Licensor shall continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a Joint Agreement Invention on behalf of Awardee, Awardee shall notify the Government within thirty (30) days. If the Licensor notifies Awardee that it declines to continue prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a Joint Agreement Invention, Awardee shall notify the Government within thirty (30) days after receipt of such notice.

- G. Patent Enforcement.** Awardee will have the first option to enforce any patent rights covering a Joint Agreement Invention at Awardee's expense. If Awardee chooses not to exercise this option, the Government may enforce patent rights covering a Joint Agreement Invention.

**H. Licenses.**

**Background IP.** The Government has the rights in Background IP constituted under contract number HHSO100201800016C, including all executed modifications. .

**Agreement Inventions.** Any Sole Awardee Agreement Invention is subject to a nonexclusive, nontransferable, irrevocable, paid-up license for the Government, to practice and have practiced the Agreement Invention on behalf of the Government. For any Sole Government Agreement Invention, upon the Awardee's request, the Government agrees to enter into good faith negotiations with the Awardee regarding the Awardee's receipt of a nonexclusive commercialization license covering the Government's interest in any Sole Government Agreement Invention.

## **ARTICLE 10: DATA RIGHTS**

- A. Background Data.** "Background Data" shall mean all data, that exists prior to execution of this Agreement, or are developed outside the scope of this Agreement. Awardee's Background Data includes, but is not limited to, the following technical data, to the extent such data exists prior to execution of this Agreement or is developed outside the scope of this Agreement:

1. Technical data as defined at DFARS 252.227-7013 ("Technical Data"),
2. All data relating to the development, commercialization, manufacture of the test kits,
3. All data relating to the manufacturing, quality control testing (including in-process, release and stability testing), processing, releasing, or packaging of the test kits; and
4. Any and all data relating to preparatory work for distributing, importing, exporting, selling, offering for sale, supplying, offering for supply or otherwise exploiting the Awardee COVID 19 tests.

All Background Data shall be owned by the Awardee, subject to the Government's rights in Background Data developed or produced in the performance of contract number HHSO100201800016C, including all executed modifications thereto. Awardee hereby grants the Government a non-exclusive license subject to the limitations

specified in Article 10.C to use any Background Data, other than clinical data, or financial, administrative, cost, pricing or management information, solely to the extent necessary for the Government to perform its obligations under this Agreement and meet its objective of facilitating administration of the COVID-19 Tests delivered under this Agreement in accordance with FDA and other applicable regulations.

- B. Subject Data.** "Subject Data" is defined as all Technical Data generated by or on behalf of Awardee in the performance of this Agreement. Subject Data shall be owned by the Awardee. The Government shall obtain "Unlimited rights", as this term is defined in DFARS 252.227-7013(a)(16) in Subject Data specified for delivery under this Agreement and Government Purpose Rights, as the term is defined in DFARS 252.227-7013(a)(13), in Subject Data not specified for delivery under this Agreement. . The Awardee agrees to retain and maintain in a clear and readable manner, until seven (7) years after completion or termination of this Agreement, all Subject Data.
- C. Restrictions on Government License Rights.** Subject to the Government's pre-existing rights under contract HHSO100201800016C as modified:
- a. Background Data other than computer software in which the Government has rights under Article 10.A shall be received by the Government subject to Limited Rights as defined at DFARS 252.227-7013.
  - b. Background Data that is computer software in which the Government has rights under Article 10.A shall be received by Government subject to Restricted Rights as defined at DFARS 252.227-7014, except that the Government shall instead receive commercial software license rights in such software that is a commercial item as defined at FAR 2.101.
- D. Marking of Data.** The Awardee will mark any Data delivered under this Agreement with the following legend:

"Use, duplication, or disclosure is subject to the restrictions as stated in Agreement No. W911NF-21-9-0001 between the Government and the Awardee."

The Awardee may further mark Data furnished with the rights specified in Article 10.C as "Limited Rights Data," "Restricted Rights Software," or "Commercial-Rights Software," as appropriate. Any rights that the Awardee or the Government may have in Data delivered under this Agreement, whether arising under this Agreement or otherwise, will not be affected by Awardee's failure to mark Data pursuant to this Article.

All Subject Data, Technical Data and Software (each term as defined under DFARS 252.227- 7013) which shall be delivered under this Agreement with less than Unlimited Rights shall be identified in reasonable specificity and particular rights granted (Government Purpose, Limited or Restricted (all as defined in DFARS 252.227-7013)). If the data is marked "Limited Rights", the Awardee shall provide, upon request by the Government, an explanation to the Government as to why the data does not fall within the deliverables, and thus should not be accorded Unlimited Rights status.

## **ARTICLE 11: REGULATORY RIGHTS**

The Awardee shall provide the Government with all material communications and summaries thereof, both formal and informal, to or from FDA, regarding the Awardee's EUA for its COVID-19 Test or the prototype project within 48 hours, and make best efforts to ensure that the Government representatives are invited to participate in any formal or informal meetings with FDA. Awardee shall (1) ensure that the Government representatives are consulted and are invited to participate in any formal or informal meetings with FDA related to Awardee's COVID-19 Test and the prototype project; and (2) notify the FDA that the Government has the right to discuss with FDA any development efforts regarding the prototype project. In addition to the foregoing, Awardee shall use diligent efforts to notify the Government within 48 hours of any event, risk, formal or informal FDA communication, or other issue that would be reasonably expected to materially impact the Awardee's EUA For the COVID-19 Test or ability to advance to final 510(k) clearance of the Awardee's COVID-19 Test.

## **ARTICLE 12: FOREIGN ACCESS TO DATA**

- A.** The Parties will comply with any applicable U.S. export control statutes and regulations in performing this Agreement.

### **ARTICLE 13: SCIENTIFIC PUBLICATIONS AND PRESS RELEASES**

- A.** Neither Awardee nor the Government shall make, or permit any person to make, any public announcement concerning the existence, subject matter or terms of this Agreement, the transactions contemplated by it, or the relationship between the Awardee and the Government hereunder, without the prior written consent of the other, such consent not to be unreasonably withheld or delayed, except as required by law, any governmental or regulatory authority (including, without limitation, any relevant securities exchange), any court or other authority of competent jurisdiction.
- B.** Notwithstanding the foregoing, Awardee and (its upstream licensor) retains the right, but not the obligation, to prepare and submit scientific publications and release information to the public about its COVID-19 development program, without the Government's consent or involvement. The Awardee shall inform the AOR when any abstract article or other publication is published, and furnish a copy of it as finally published.
- C.** Unless authorized in writing by the AO, the Awardee shall not display Government logos including Operating Division or Staff Division logos on any publications.
- D.** The Awardee shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies Government approval or endorsement of the product(s) or service(s) provided.
- E.** Subject to Article 4.B, the Awardee shall include this clause, including this section (d) in all subawards where the sub-agreement holder may propose publishing the results of its work under the subaward. The Awardee shall acknowledge the support of the Government whenever publicizing the work under this Agreement in any written media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part by the U.S. Government under Agreement No. W911NF-21-9-00XX. The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

### **ARTICLE 14: ENSURING SUFFICIENT SUPPLY OF THE PRODUCT**

- A.** In recognition of the Government's significant funding for the development and manufacturing of the COVID-19 Test and the Government's need to provide sufficient quantities of a COVID-19 tests to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of test kits to meet the needs of the public health or national security. This remedy is not available to the Government unless and until any of the following conditions is met, and is not available as a result of a termination under Article 2(B) of this Agreement:
  - i. Awardee gives notice, required to be submitted to the Government no later than 30 business days, following any formal management decision to terminate the product development effort, including a decision not to maintain EUA or proceed to 510(k) clearance during the term of this Agreement or three (3) years thereafter;
  - ii. Awardee gives written notice, required to be submitted to the Government no later than 15 business days, of any filing that anticipates Federal bankruptcy protection during the term of this Agreement or three (3) years thereafter.
- B.** If one or more of the conditions listed in Section 14.A occurs, Awardee, upon the request of the Government, subject to the terms of the pre-existing agreement with Licensor, shall provide the following items necessary for the Government to pursue licensure/authorization and manufacturing of the Technology with a third party for exclusive sale to the U.S. Government:
  - i. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Awardee Background IP and Background Data, as those terms are defined in of this Agreement, necessary to manufacture or have manufactured the Technology;
  - ii. any outstanding Deliverables contemplated or materials and possession of and title to manufacturing equipment purchased with Government funds under this Agreement.

- C. This Article will survive the acquisition or merger of the Awardee by or with a third party. This Article will survive the expiration of this agreement.

#### **ARTICLE 15: INSPECTION AND ACCEPTANCE**

- A. **Delivery and Acceptance.** Awardee shall notify the AO and AOR at least 7 calendar days prior to initial delivery of first shipment of test kits. Exceptions are permitted if approved by the AO. Upon notification, the AOR will instruct the Awardee to deliver kits to either up to three centralized Government-designated distribution sites within the continental United States or up to three additional specific individual final destinations within the continental United States. Upon delivery of product, notification of delivery quantities shall be made to the AOR.

Upon receipt of the provided certificates and any inspection of product at the origin or destination site(s) that was timely requested (physical or representative, i.e., pictures), the AOR will review and recommend acceptance or rejection. The Government shall accept product that conforms to contract requirements based on Certificates of Analysis and certificate(s) of cGMP conformity provided by Awardee and review of temperature monitoring data. The AO will correspondingly notify Awardee of acceptance or rejection. However, the Government's acceptance of product will be deemed to have occurred if the Government does not provide written notice of acceptance or rejection within fourteen (14) calendar days of Awardee's provision of all applicable certificates.

A. Inspection: The Government has the right to inspect and test all work called for by this Agreement, to the extent practicable at all places and times, including the period of performance, and in any event before acceptance. The Government may also inspect the premises of the Awardee. The Government shall perform inspections and tests in a manner that will not unduly delay the work. If the Government performs any inspection or test on the premises of the Awardee, the Awardee shall furnish, at no increase in price, all reasonable facilities and assistance for the safe and convenient performance of these duties. Except as otherwise provided in the Agreement, the Government shall bear the expense of Government inspections or tests made at other than the Awardee's premises.

B. The Government shall inspect/accept or reject the work as promptly as practicable after completion/delivery, unless otherwise specified in the Agreement. Government failure to inspect and accept or reject the work shall not relieve the Awardee from responsibility, nor impose liability on the Government, for nonconforming work. Work is nonconforming when it is defective in material or workmanship or is otherwise not in conformity with Agreement requirements. The Government has the right to reject nonconforming work. Inspection/Acceptance of the Prototype performed should not exceed 90 days after completion.

- B. **Vendor-managed Inventory.** Product to be stored as VMI will be shipped to Awardee's own warehouse locations or its third party vendor's site, and may be stored for a period not longer than five (5) months. Prior to expiration of this five (5) month period, the Government must either (a) provide Awardee with disposition instructions in sufficient time to transfer and take possession of physical material from Awardee, (b) bilaterally modify this agreement to extend the period of vendor management of storage, or (c) bilaterally modify this Agreement to include destruction of remaining doses.

When held in VMI, these materials will be maintained in Awardee's or its designated representative's quality and inventory systems. Product held in VMI is subject to the following requirements:

- i. Provide temperature controlled storage at the manufacturer's site approved by the Government, according to cGMP and product specifications.
- ii. Where possible, store Project Agreement products physically segregated from other products. If physical separation is not possible, separation of Project Agreement products must be controlled by a logical warehouse management system (WMS) at the case and pallet level.
- iii. Ensure proper labeling of stored materials as USG property.

- iv. Provide the Government access to review the security systems in place and request updates as needed in accordance with the Security Plan.
- v. Make appropriate updates to the regulatory documentation supporting the continued use of the stored material for pandemic response.
- vi. If using a storage site, provide the quality agreement, specify the location and terms of the storage contract and receive approval by the Government.

For accepted product in VMI, Awardee must notify the AOR of any proposed movement of the product. Any deviations, out of specification (“OOS”) results, or other product issues, shall be reported to the USG within 3 calendar days of Awardee identification.

**C. Government Sites.** Product to be shipped to Government Sites shall be shipped trackable by GPS. Awardee will include the following information on the packing lists provided with bulk shipments to the centralized depots:

- i. Transaction Information (TI)
- ii. Transaction History (TH)
- iii. Transaction Statement (TS)

**D. Title and Physical Risk of Loss.** Risk of loss or damage to the supplies provided under this contract shall remain with the Contractor until, and shall pass to the Government upon delivery of the supplies to the Government at the destination specified in the contract, i.e., F.O.B. Destination.

Awardee will notify the AO and AOR of any storage or quality deviation for product held in VMI, within 3 calendar days. To the extent that Awardee is responsible for the correction, repair or replacement of Government property held in VMI and replacement upon loss or damage is feasible, the Government will accept replacement of such property. The Government understands that storage costs identified in this contract include insurance costs applicable to material that will become Government property, including product stored as VMI.

The AO and/or the AOR may perform inspection of materials and services. Inspections of material created under this Project Agreement may be made by a duly authorized Government representative, and with reasonable notice.

**E. Risk of Loss Due to Expiry.** Both parties acknowledge that risk of loss due to expiry is retained by the Government for all product accepted under this Agreement. In order to mitigate this risk, the Awardee will make kits available for delivery to VMI or Government distribution sites within 45 days of the date of manufacture. Provided this condition is met, the Awardee will have no obligation to replace product that has been accepted by the Government and expires prior to use.

## **ARTICLE 16: REPORTING REQUIREMENTS**

The Government will have continuous involvement with Awardee throughout the duration of the Period of Performance and is entitled to periodic reports as outlined below. Required components and frequency of such reporting is as follows:

**A. Weekly Progress Meetings:** Scheduled on a weekly basis, virtual format (either telephone or videoconference), between the Contractor and the Government. Duration: 2 hrs max. Review of previous weeks activities. Informative in nature to keep the USG apprised of project progress and to discuss issues that may require joint resolution, such as milestone changes, political impacts on objectives, schedule, funding and deliverables.

On a quarterly basis, at the request of the AOR, the Weekly Teleconference may be expanded in scope to allow for a progress review of the preceding three months and planning for the remainder of the period of performance.

**B. Daily and Ad hoc check-in, as requested by the PCT:** A program specific designee of the Awardee will hold a daily check-in with the AOR or AOR designee to discuss the performance of the Agreement. No agenda, presentation, or official minutes need to be maintained for the regular meeting. The AOR may cancel the daily check-in or substitute a technical or program specific meeting as a replacement. Daily check-ins are expected only on business days during normal business hours.

- C. **Confirmed, critical programmatic concerns, issues or probable risks that are likely to impact project schedule/cost/performance:** The Awardee will communicate and document all confirmed programmatic risks to the AOR within 48 hours of Awardee's awareness. Awardee shall communicate via email or telephone. Following resolution, Awardee will provide all associated deviation reports and corrective and preventative action plans to the AOR within 48 hours of finalization.

In addition, the Awardee will report to the government any activity or incident that is in violation of established security standards or indicates the loss or theft of government products within 24 hours of Awardee's awareness of the activity or incident. Awardee will communicate via email, oral or written communication.

- D. **Supply chain resiliency, including Awardee locations:** Within thirty (30) calendar days of award, the Awardee will provide the AOR with a supply chain resiliency plan. For each of the Awardee locations – including sub-agreement holders, the Awardee will provide address, point(s) of contact and a summary of work performed at the location.

- E. **Quarterly Financial Status Report:**

The Awardee shall submit a Quarterly Financial Status Report no later than twenty (20) calendar days after the end of each quarter of performance. The Government will have

ten (10) calendar days to respond to the report with any comments and the Awardee will have an additional ten (10) calendar days to revise the deliverable or respond to those comments. Reports will cover work performed every three (3) months for the duration of the Period of Performance (PoP).

For the industrial expansion effort, the Quarterly Financial Status Report shall include quarterly expenditure forecasts with both the quarterly planned accrual and the cumulative total. Expenditure forecast submissions shall include analysis of the cost drivers for Estimate to Complete changes, if any, from the previous projection. The Awardee shall provide all submissions in Excel format, including all formulas.

## ARTICLE 17. Miscellaneous Clauses.

A. No Consent. Nothing in the terms of this Agreement constitutes express or implied Government authorization and consent for Awardee or its subawardee(s) to utilize, manufacture or practice inventions covered by United States or foreign patents in the performance of work under this Agreement.

B. Patent Infringement. Each Party will advise the other Party promptly and in reasonable written detail, of each claim or lawsuit of patent infringement based on the performance of this Agreement. When requested by either Party, all evidence and information in possession of the Party pertaining to such claim or lawsuit will be provided to the other at no cost to the requesting Party.

C. Limitation of Liability. In no event will either Party be liable to the other Party or any third party claiming through such Party for any indirect, incidental, consequential or punitive damages, or claims for lost profits, arising under or relating to this Agreement, whether based in contract, tort or otherwise, even if the other Party has been advised of the possibility of such damages.

D. Disclosure of Information. Subject to Article 10, the Awardee shall not release to anyone outside the Awardee's organization any unclassified information, regardless of medium (e.g., film, tape, document), pertaining to any part of this Agreement or any program related to this Agreement, unless (i) the OTA0 has given prior written approval or (ii) the information is otherwise in the public domain before the date of release. For purposes of this clause, Awardee's Organization includes entities identified as Collaborators in

E. Force Majeure. Neither Party will be liable to the other Party for failure or delay in performing its obligations hereunder if such failure or delay arises from circumstances beyond the control and without the fault or negligence of the Party (a Force Majeure event). Examples of such circumstances are: authorized acts of the government in either its sovereign or contractual capacity, war, insurrection, freight embargos, fire, flood, or strikes. The Party asserting Force Majeure as an excuse must take reasonable steps to minimize delay or damages caused by unforeseeable events.

F. Severability. If any provision of this Agreement, or the application of any such provision to any person or set of circumstances, is determined to be invalid, unlawful, void or unenforceable to any extent, the remainder of this Agreement, and the application of such provision to persons or circumstances other than those as to which it is determined to be invalid, unlawful, void or unenforceable, will not be impaired or otherwise affected and will continue to be valid and enforceable to the fullest extent permitted by law.

G. Choice of Law. This Agreement and the resolution of disputes hereunder will be governed, construed, and interpreted by the statutes, regulations, and/or legal precedent applicable to the Government of the United States of America. Unless explicitly stated, the Parties do not intend that this Agreement be subject to the Federal Acquisition Regulation either directly or indirectly or by operation of law. When a specific FAR requirement is incorporated by reference in this Agreement, the text of the clause alone will apply without application or incorporation of other provisions of these regulations.

H. Order of Precedence. In the event of a conflict between the terms of this Agreement and the attachments incorporated herein, the conflict shall be resolved by giving precedence in descending order as follows: (i) the Articles of this Agreement, and the Appendices to the Agreement.

## **ARTICLE 18: PROHIBITION ON THE USE OF CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT**

a) *Definitions*. As used in this clause—

*Backhaul* means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (e.g., connecting cell phones/towers to the core telephone network). Backhaul can be wireless (e.g., microwave) or wired (e.g., fiber optic, coaxial cable, Ethernet).

*Covered foreign country* means The People's Republic of China.

*Covered telecommunications equipment or services* means—

- (1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);
- (2) For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);
- (3) Telecommunications or video surveillance services provided by such entities or using such equipment;  
or

- (4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

*Critical technology* means—

- (1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;
- (2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled-
  - (i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or
  - (ii) For reasons relating to regional stability or surreptitious listening;
- (3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);
- (4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);
- (5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or
- (6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

*Interconnection arrangements* means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (*e.g.*, connection of a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

*Reasonable inquiry* means an inquiry designed to uncover any information in the entity's possession about the identity of the producer or provider of covered telecommunications equipment or services used by the entity that excludes the need to include an internal or third-party audit.

*Roaming* means cellular communications services (*e.g.*, voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

*Substantial or essential component* means any component necessary for the proper function or performance of a piece of equipment, system, or service.

(b) *Prohibition.*

- (1) Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. The Contractor is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential

component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104.

(2) Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2020, from entering into a contract or agreement, or extending or renewing a contract or agreement, with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104. This prohibition applies to the use of covered telecommunications equipment or services, regardless of whether that use is in performance of work under a Federal contract or agreement.

(c) *Exceptions.* This clause does not prohibit contractors from providing—

(1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(2) Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(d) *Reporting requirement*

(1) In the event the Contractor identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during contract or agreement performance, or the Contractor is notified of such by a subcontractor at any tier or by any other source, the Contractor shall report the information in paragraph (d)(2) of this clause to the Agreements Officer, unless elsewhere in this contract or agreement are established procedures for reporting the information; in the case of the Department of Defense, the Contractor shall report to the website at <https://dibnet.dod.mil>.

(2) The Contractor shall report the following information pursuant to paragraph (d)(1) of this clause

(i) Within one business day from the date of such identification or notification: the contract number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier Commercial and Government Entity (CAGE) code (if known); brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.

(ii) Within 10 business days of submitting the information in paragraph (d)(2)(i) of this clause: any further available information about mitigation actions undertaken or recommended. In addition, the Contractor shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

(e) *Subcontracts.* The Contractor shall insert the substance of this clause, including this paragraph (e) and excluding paragraph (b)(2), in all subcontracts, subagreements and other contractual instruments, including subcontracts for the acquisition of commercial items.

## **Appendix A Statement of Work**

### Statement of Work (SOW): Point-of-Care (POC) Tests and Diagnostics

#### C.1. General Objectives.

The U.S. Government (USG) requires additional POC diagnostic test capacity, as the level of demand for diagnostic resources during this COVID-19 Pandemic is unprecedented. There is a need to secure additional POC diagnostics to test the US population in response to the Pandemic. The Government seeks to expand the production capacity for Monitoring Systems and COVID-19 Test Cartridges. The end deliverable of this effort is to provide the capacity to manufacture 100,000 cartridges per day.

As part of this effort, there shall result in an increase to its industrial base manufacturing capability for COVID-19 Test Cartridges within the U.S., to include critical supply chain providers to 100,000 cartridges per day. The Awardee shall also onshore its cartridge and reader subcomponents manufacturing to the maximum extent possible, to further reduce supply chain risk. The Awardee shall also develop a distribution process and increase shipping capability in order to ship all materials directly to the customer location.

#### C.2. Prototype Delivery.

C.2.2. The Awardee shall increase its industrial base manufacturing capability to manufacture 100,000 cartridges per day.

C.2.2.1. The Awardee shall increase the manufacturing capability for the COVID-19 Test Cartridges to 100,000 cartridges per day.

C.2.2.2. The Awardee shall onshore its cartridge and reader subcomponents manufacturing.

C.2.2.3. The Awardee shall develop and expand its distribution process in order to ship all materials directly to the customer location within the United States and its Territories.

#### C.3. Demonstration of Prototype Delivery.

C.3.1. The Awardee shall deliver 6 million COVID-19 Test Cartridge Packs.

C.3.2. The Awardee shall deliver 30,000 Health Monitoring Systems.

C.3.3. The Awardee shall deliver 60,000 COVID-19 External Control Swabs Packs.

C.3.4. The Awardee shall ship all deliverables to locations (TBD) within the United States.

C.3.5. The Awardee shall ensure appropriate quality assurance certification is supplied with each shipment.

#### C.4. Overall Management Objectives.

C.4.1. The Awardee shall be responsible for overall management and oversight of the work necessary to achieve the objectives of this contract. The Contractor shall provide the overall management, integration, and coordination of all contractual activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contractual activities.

The Contractor shall establish project milestones for each manufacturing capability/capacity for which expansion is planned. The Awardee shall provide incremental progress against each milestone to the USG in accordance with established deliverables (see C.6 below). The Awardee shall report to the USG any changes or deviations planned or incurred by the Contractor in pursuing the objectives of this contract. While primary responsibility for management and execution of the effort resides with the Awardee, the USG shall have input to the milestone review process and any changes to the objectives of the agreement.

#### C.5. Risk Management Objectives.

The Awardee shall identify all anticipated project risks categorized as moderate or high and report them to the USG in accordance with reporting requirements (see C.6 below). The Awardee shall manage all project risks using its in-house risk management capabilities, and report to the USG changes to all identified risks as they occur/arise. The USG shall be permitted to participate in the risk management and mitigation processes associated with this project.

#### C.6. Status Reporting.

C.6.1. Monthly Progress Reports. The Awardee shall submit monthly progress reports no later than the 10<sup>th</sup> of the month. Awardee format acceptable. Electronic submission acceptable in MS Office or PDF format. Financial information shall be MS Excel format. Monthly reports shall NOT be marked proprietary, and shall have Distribution Statement C (US Government and their contractors). Each monthly report shall, at a minimum, contain the following:

- Summary of monthly progress for each of the Awardee's facilities/capabilities associated with this effort.
- Summary of progress towards established milestones for each facility/capability.
- Identification of any milestone that is slipping or missed, and discussion of path forward to bring milestone back to schedule, and impact on other milestones.
- Summary of risks, discussion of potential impacts and efforts to mitigate.
- Summary of overall schedule and changes from previous month.
- Status updates from Manufacturing plan
- Status updates from Distribution plan
- Report any customer complaints
- Report any known deficiencies of the materials and/or products
- Financial summary of Awardee costs incurred by month to date, invoices submitted, and Government payments made.

C.6.2. Weekly Progress Meetings. Scheduled on a weekly basis, virtual format (either telephone or videoconference), between the Contractor and the Government. Duration: 2 hrs max. Review of previous weeks activities. Informative in nature to keep the USG apprised of project progress and to discuss issues that may require joint resolution, such as milestone changes, political impacts on objectives, schedule, funding and deliverables. Meeting minutes provided by the Awardee delivered to the USG within 2 days of the meeting.

C.6.3. Quarterly In Process Reviews. Scheduled as needed, generally not more frequently than quarterly, virtual format (either telephone or videoconference). Duration: 8 hrs max. Review of previous quarter's activities. Informative in nature to keep the USG apprised of project progress and to discuss issues that may require joint resolution, such as milestone changes, political impacts on objectives, schedule, funding. An agenda for the meeting provided by the Awardee 10 days prior to the scheduled meeting. Meeting minutes provided by the Awardee delivered to the USG within 5 days of the meeting.

C.6.4. Final Report. Final Report shall NOT be marked proprietary, and shall have Distribution Statement C. Contractor format acceptable. Electronic submission acceptable in MS Office or PDF format. Financial information shall be MS Excel format. Final report summarizing stated objectives and the progress that was achieved in meeting those objectives; summary of risks incurred, impacts and mitigation; quantitative discussion of production throughput improvements achieved; financial summary of project; schedule summary for project, comparing original schedule to final schedule; recommendations for path forward as applicable. Final Report due 5 days after the last scheduled delivery for prototype demonstration.

C.6.5. Manufacturing Plan. The Awardee shall provide a detailed plan of action (contractor format acceptable) to increase cartridge-manufacturing capability to meet the government's delivery schedule (i.e. ramp up to 100K cartridges per day) and associated on-shoring component manufacturing within 15 days of contract award.

The Awardee's plan of action shall at a minimum, include the following:

- a Timeline, materials required and strategy to set up and begin V2.0 manufacturing lines to manufacture the cartridges;
- b Timeline, materials required and strategy to upgrade the bioproduction capability to manufacture sufficient cartridge reagents;
  - c Timeline, materials required and strategy to onshore manufacturing of reagents and cartridge subcomponents;
  - d Information on the US based manufacturing organization to replace existing organization;
  - e Current GMP manufacturing status and plan to achieve GMP manufacturing, if not currently GMP;
  - f Quality Assurance plan and Acceptance metrics;
  - g Plan to comply with FDA EUA Letter of Authorization.

C.6.6. Distribution Plan. The Awardee shall provide a detailed distribution plan for how all Test Cartridge Packs, Monitoring Systems and External Control Swabs Packs will be shipped and delivered to required delivery locations within the United States and its Territories within 15 days of contract award.

The Awardee's distribution plan shall at a minimum, include the following: a Current distribution processes; b Timeline and strategy to increase distribution process and shipping to handle the increase in number and volume of shipments.

C.6.7 Quality Management Plan. The Awardee shall provide (contractor format acceptable) within 15 days of contract award, a quality management plan for manufacturing efforts that conform to ISO 13485 standards as well as the Quality System Regulations at 21 CFR Part 820 which may include, but is not limited to, the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation.

## **Appendix B**

### **Project Schedule/Milestone Payment Schedule**

The Government shall pay the Awardee, upon the submission of proper invoices or vouchers, the prices stipulated in this Agreement for supplies delivered and accepted or services rendered and accepted, less any deductions provided in this Agreement.

For the industrial expansion, expenditures shall be submitted based on the awarded budget. Federal funds are to be used only for work that a reasonable and prudent person would incur in carrying out the prototype project. An invoice will be submitted through Wide Area Work Flow (WAWF) in accordance with agreement requirements. Final payment of the Agreement shall be determined upon mutual agreement and settlement of any outstanding deliverables.

The Awardee shall proceed with the performance in accordance with the terms and conditions of this Agreement and its Appendices. However, the Government may require the Awardee to cease performance at any time prior to the commencement of any milestone or task. Such notice to cease performance must be from the OTA0 and be in writing, of which email is an acceptable form.

The Parties acknowledge that the nature of this Prototype Project requires flexibility and the ability to react to changing circumstances. Although the Statement of Work sets the scope for activities the Government may require under this Agreement, it is not intended to, and does not, prescribe with specificity each task that Awardee will perform. Instead, the Government shall direct Awardee to perform specific tasks under the framework established in Articles 3 and 8 of the Agreement, with

Government-approved tasks, funding, and deadlines. Awardee shall not perform any tasks that have not been explicitly authorized by the Government.

Awardee will be responsible for submission of SOW's, quotes, and proposals for price, performance, and schedule for those efforts not already identified, priced or otherwise negotiated. Government approval will be required prior to commencing work.

**Appendix C  
Key Personnel**

**1. Awardee's Organization and Key Personnel.**

a. The Awardee's organization shall be established with authority to effectively accomplish the objectives of the Statement of Work. This organization shall become effective upon award of the Agreement and its integrity shall be maintained for the duration of the effort.

b. The key personnel listed below are considered to be critical to the successful performance of this Agreement. Prior to replacing these key personnel, the Awardee shall obtain the written consent of the OTAO. In order to obtain such consent, the Awardee shall provide advance notice of the proposed changes and shall demonstrate that the qualifications of the proposed substitute personnel are generally equivalent to or better than the qualifications of the personnel being replaced.

c. Prior to permanently removing any of the specified individuals to other contracts, the Awardee shall provide the OTAO not less than thirty (30) calendar days advance notice and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No reassignment shall be made by the Awardee without written consent of the OTAO. The "Key Personnel" list presented in Table 2 below may be amended from time to time during the course of the Agreement to either add or delete personnel, as appropriate.

**Table 2: Key Personnel Summary**

**Appendix D Government  
Property**

Government Property: "Government Property" means any property (i) furnished by the Government and facilitating performance of this Agreement, (ii) acquired by the Awardee under cost reimbursement terms of this Agreement, or (iii) acquired by the Awardee under fixed price terms of this Agreement (FP-GP) if specifically identified in this Government Property Appendix. Except for commercial off the shelf software and licenses thereto, Government Property does not include intellectual property and software. The Government owns and holds title to all Government Property.

The Government shall deliver to the Awardee any Government Property required to be furnished as described in this Agreement together with related data and information needed for its intended use. The delivery and/or performance dates specified in this Agreement are based upon the expectation that the Government-furnished property will be suitable for performance and will be delivered to the Awardee by the dates stated in the Agreement. If not so suitable, the Awardee shall give timely written request to the OTAO who will advise the Awardee on a course of action to remedy the problem.

FPGP includes: [Mark N/A if none]:

N/A
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The Awardee shall have, initiate and maintain a system of internal controls to manage, control, use, preserve, protect, repair, account for and maintain Government Property in its possession and shall initiate and maintain the processes, systems, procedures, records required control and maintain accountability of Government Property. The Awardee shall include this clause in all subcontracts under which Government Property comes into the possession of any subawardee. Unless otherwise provided for in this Agreement or approved by the OTAO, the Awardee shall not: (i) use Government Property for any purpose other than to fulfill the requirements of this Agreement, or (ii) alter the Government Property.

The Awardee shall establish and implement property management plans, systems, and procedures regarding its acquisition of Government Property, its receipt of Government Property, in addition to, the status, dates furnished or acquired, identification, quantity, cost, marking, date placed in service, location, inventory and disposition of Government Property, to include a reporting process for all discrepancies, loss of Government Property, physical inventory results, audits and self-assessments, corrective actions, and other property related reports as directed by the OTAO.

Upon conclusion or termination of the Agreement, the Awardee shall submit a request in writing to the OTAO, for disposition/disposal instructions and shall store Government Property not to exceed 120 days pending receipt of such instructions. Storage shall be at no additional cost to the Government unless otherwise noted in the Agreement. The Government, upon written notice to

the Awardee, may abandon any Government Property in place, at which time all obligations of the Government regarding such Government Property shall cease.

**Awardee Liability for Government Property.** “Loss of Government Property” means the loss, damage or destruction to Government Property reducing the Government’s expected economic benefits of the property and includes loss of accountability but does not include planned and purposeful destructive testing, obsolescence, reasonable wear and tear or manufacturing defects. THE AWARDEE SHALL BE LIABLE FOR LOSS OF GOVERNMENT PROPERTY IN AWARDEE’S POSSESSION, EXCEPT WHEN ANY ONE OF THE FOLLOWING APPLIES:

(I) OTAO GRANTS RELIEF OF RESPONSIBILITY AND LIABILITY FOR LOSS OF THE PARTICULAR GOVERNMENT PROPERTY; (II) GOVERNMENT PROPERTY IS DELIVERED OR SHIPPED UNDER THE GOVERNMENT’S INSTRUCTIONS AND SHIPPERS; OR (III) GOVERNMENT PROPERTY IS DISPOSED OF IN ACCORDANCE WITH THE GOVERNMENT’S DIRECTIONS.

## Section E - Inspection and Acceptance

## INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	N/A	N/A	N/A	Government
0002	N/A	N/A	N/A	Government
0003	N/A	N/A	N/A	Government
0004	N/A	N/A	N/A	Government

## Section F - Deliveries or Performance

## DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	08-APR-2021	1	JPM MEDICAL JPM CBRN MEDICAL 1564 FREEDMAN DRIVE FORT DETRICK, MD MD 21702 240-675-3192 FOB: Origin (Shipping Point)	W56XNH
0002	11-MAR-2021	6,000,000	(SAME AS PREVIOUS LOCATION) FOB: Origin (Shipping Point)	W56XNH
0003	11-MAR-2021	30,000	(SAME AS PREVIOUS LOCATION) FOB: Origin (Shipping Point)	W56XNH
0004	11-MAR-2021	60,000	(SAME AS PREVIOUS LOCATION) FOB: Origin (Shipping Point)	W56XNH

Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

AA: 0212020202120400000664643255      S.0074658.5.22      6100.9000021001  
COST CODE: A5XAH  
AMOUNT: \$480,916,636.62

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	0001	GFEB001156060100001	(b) (4)
	0002	GFEB001156060100002	(b) (4)
	0003	GFEB001156060100003	(b) (4)
	0004	GFEB001156060100004	(b) (4)