EX-10.1 2 exhibit101to3q20orm.htm EX-10.1

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS *OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30O*	1. REQUISITION NUMBER 5763920	PAGE OF 1 / 34

2. CONTRACT NO. 75N92020C00009	3. AWARD/ EFFECTIVE DATE	4. ORDER NUMBER.	1 5. SOLICITATION NUMBER	6 . SOLICITATION ISSUE DATE
7. FOR SOLICITATION INFORMATION CALL:	a. NAME LINDA SMITH	b. TELEPHONE NUMBERT *(No collect calls)* +1 301 827-7741	8. OFFER DUE DATE/LOCAL TIME	

9. ISSUED BY CODE	NHLBI	10. THIS ACQUISITION IS x UNRESTRICTED OR ☐ SET ASIDE: % FOR: ☐ SMALL BUSINESS ☐ WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED ☐ HUBZONE SMALL SMALL BUSINESS PROGRAM NAICS: 334516 BUSINESS ☐ EDWOSB ☐ SERVICE-DISABLED ☐ 8(A) VETERAN-OWNED SIZE STANDARD: 1,000 SMALL BUSINESS
National Institutes of Health National Heart, Lung, and Blood Institute Bethesda, MD 20892-7511		

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED x SEE SCHEDULE	12. DISCOUNT TERMS	☐ 13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	13b.RATING 14. METHOD OF SOLICITATION ☐ RFQ ☐ IFB ☐ RFP
15 DELIVER TO CODE TDP, BTHOFF Two Democracy Plaza, Bethesda Off C 2 Democracy Plaza 6707 Democracy Blvd Bethesda MD 20817		CODE TDP, BTHOFF National Institutes of Health National Institute of Biomedical Imaging and Bioengineering Bethesda, MD 20892-7511	NIBIB
17a. CONTRACTOR/ OFFEROR CODE FLUIDIGM CORPORATION:1157584 2 TOWER PLACE SUITE 2000 SOUTH SAN FRANCISCO CA 940801826 TELEPHONE NO. -	FACILITY CODE	18a. PAYMENT WILL BE MADE BY CODE Approved By, NHLBI Branch A Invoice Paid By: NIH Commercial Accounts Br 2115 East Jefferson St, MSC 8500 Room 4B-432 Bethesda, MD 20892-8500	NHLBI INV-BR-A
17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER		18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED ☐ SEE ADDENDUM	

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21 QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
1	NIBID: 75N92020C00009 Rapid Acceleration of Diagnostics (RADx) Program: Tech Project # 6114 Fluidigm - Advanta Dx SARS-CoV-2 RT-PCR Assay for Saliva Period of Performance: 07/30/2020 to 07/29/2021 Stage 1 - Test Verification Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Continued ... (Use Reverse and!or Attach Additional Sheets as Necessary)			[***]	

25. ACCOUNTING AND APPROPRIATION DATA

26. TOTAL AWARD AMOUNT *(For Govt. Use Only)*
$12,151,000.00

☐ 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED

X 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA X ARE X ARE NOT ATTACHED

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

☐ 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.	☐ 29. AWARD OF CONTRACT: OFFER DATED . YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:
30a. SIGNATURE OF OFFEROR/CONTRACTOR /s/ S. Christopher Linthwaite	1 16B. UNITED STATES OF AMERICA (*SIGNATURE OFCONTRACTING OFFICER)* /s/ Roxane S. Burkett -S Digitally signed by Roxane S. Burkett -S Date: 2020.07.30 077:36:45 -04'00'
30b. NAME AND TITLE OF SIGNER *(Type or print)* S. Christopher Linthwaite, President and CEO)	30C. DATE SIGNED 7/29/2020
31b. NAME OF CONTRACTING OFFICER *(Type or print)* ROxANE S. BURKETT	31c. DATE SIGNED

AUTHORIZED FOR LOCAL REPRODUCTION STANDARD FORM 1449 (REV. 2/2012)3)
PREVIOUS EDITION IS NOT USABLE Prescribed by GSA - FAR (48 CFR) 53.212

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
2	Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: 08/08/2020 Stage 1A - Design Review Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: 09/12/2020				[***]

32a. QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED ☐ INSPECTED ☐ ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED:

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	32c. DAT	32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE
2e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE		32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE
		32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE

33. SHIP NUMB PARTIAL FINAL	34. VOUCHER NUMBER	35. AMOUNT VERIFIED CORRECT	36. PAYMENT COMPLETE PARTIAL FINAL	37. CHECK NUMBER
38. S/R ACCOUNT NUMBER	39. S/R VOUCHER NUMBER	40. PAID BY		

41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT		42a. RECEIVED *BY (Print)*	
41b. SIGNATURE AND TITLE OF CERTIFYING OFFICERFFI	41c. DATE	42b. RECEIVED *AT (Locatiion)*	
		42c. DATE REC*'D (YY!MM!/DD)*	42d. TOTAL CONTAINEERS

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES

This Letter Contract forms a preliminary understanding between Fluidigm Corporation and the National Institutes of Health (NIH) and is issued as a result of the Rapid Acceleration of Diagnostics Advanced Technology Platforms (RADx-ATP) to increase the testing capacity of high throughput labs by scaling up late stage testing platforms for detecting SARS-CoV-2, the virus that causes COVID-19. Issuance of this Letter Contract authorizes the Contractor to immediately begin the activities necessary to perform the requirements as identified in the Statement of Objectives covering the full range of activities needed to increase capacity and optimize throughput necessary to distribute a viable product to the public.

The scope of work executed under this contract, includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled up capacity to the U.S. public. Fluidigm technology to support this effort will be to scale up the Integrated Fluidic Circuit (IFC) and completion of the multiplex assay development system for rapid acceleration of testing.

This Letter Contract has been issued based on the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the Point of Care Teachnology Research Network (POCTRN) application review process. The Contractor's inability to meet the requirements as defined within this Letter Contract and proposed within the POCTRN application process may result in the termination of the Letter Contract in accordance with the termination clauses contained herein.

ARTICLE B.2. PRICES

a. The total Firm Fixed Price (FFP) amount for this Letter Contract is $12,151,000.

Payment Schedule *[See complete breakdown in Deliverable Schedule]*	
Milestone	**Amount**
Stage 1 – Test Verification	[***]
Stage 1A – Design Review	[***]
Total	**$12,151,000**

ARTICLE B.3. ADVANCE UNDERSTANDINGS

a. The parties acknowledge and agree that the situation around COVID-19 is highly dynamic, evolving rapidly, and subject to significant uncertainty. The Letter Contract is being executed on an expedited timeline to meet an urgent and compelling government need without the benefit of prior negotiation. Thus, the parties will negotiate in good faith to ensure that the definitized contract reflects an appropriate allocation of risk and responsibility and that it is consistent with the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through Letter Contract issuance. Until the Performance Work Statement (PWS) is finalized the Statement of Objective (SOO) will govern.

b. The parties anticipate that the definitive contract resulting from this Letter Contract will include a

negotiated firm fixed price not to exceed $36,834,000. The amount of funding provided for this Letter Contract is stated in Article B.2 avove, the contractor shall not incur costs in excess of this amount.

c. Commercial Item Status: The services provided by the Contractor under the Letter Contract and any definitized contract constitute commercial item services, and the terms of any definitized contract will reflect that understanding.

d. Performance Work Statement: The parties will negotiate the Performance Work Statement in the process of contract definitization to fairly reflect the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between application submission through letter contract issuance.

e. HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.

f. The parties agree prior to negotiate further the terms of milestone payments to include in the definitized contract. In the negotiation, the parties will consider terms addressing liquidation of milestone payments.

g. Successful performance under this contract requires the Contractor obtain and maintain an Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA); the Contractor shall copy us on all FDA correspondence related to the project, including email communications to and from the FDA. The FDA EUA services provided under this Letter Contract constitute a commercial service to detect SARS-CoV-2.

h. Fair Pricing: The Rapid Acceleration of Diagnostics (RADx) application review process determined the cost per test is competitive with the current market price. The Contractor must comply with applicable federal law to ensure that prices to consumers are offered at fair market rate and at a rate consistent with the objective to increase and improve testing in the United States and its territories.

i. In accordance with the goals of the RADx program, the tests produced under this contract are to be sold within the U.S. and its territories; provided, however, that, to the extent there is insufficient demand within the U.S. and its territories for the tests produced up to the additional manufacturing capacity funded by NIH and then available (as described in the Schedule of Deliverables), contractor will be permitted to sell such tests outside the U.S. and its territories. The factors, process and mechanism to determine whether contractor has insufficient demand for the tests up to the then-available capacity will be determined in the definitive contract.

j. Sharing Data and Reports: The Contractor will be required to provide data and reports (e.g., manufacturing, supply chain, production rates), which NIH will use to evaluate completion or achievement of milestones, progress toward deliverables, and compliance with the requirements of this Letter Contract. NIH may use the data to coordinate with other U.S. Government Agencies to accelerate development and deployment of innovative COVID-19 diagnostic tests, and ensure effective stewardship of federal funds. Sharing data within the federal government enables NIH to discuss the project's challenges and progress with federal agencies offering scientific, manufacturing, and logistics expertise. To ensure that innovations are available to the public as quickly as possible, NIH will leverage

established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, and the Department of Defense, and partnerships with State agencies to propel technologies developed by RADx into widespread use.

k. Contractor Facilities: The contractor shall certify that they will maintain their Facility and Equipment in satisfactory operating condition, as required to enable the contractor to perform the deliverables and achieve the milestones in accordance with the Statement of Objectives and all other applicable laws, regulations, rules or orders. Routine repairs, preventive maintenance, and service contracts for the Facility and Equipment shall be arranged by contractor at no additional cost to the Government.

l. FAR 52.212-4 (l), the Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

m. Letter Contract Termination: In accordance with FAR 52.212-4(m), the Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

n. Security and Privacy of Protected Health Information (PHI) processed under this contract: The Contractor , shall meet the definition of either a Covered Entity or Business Associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The contractor shall therefore comply with the HIPAA regulatory standards set forth in the Code of Federal Regulations (CFR) 45 C.F.R. Part 160, Part 162, and Part 164. To the extent that the Contractor engages subcontractors or other Business Associates to provide services under this Contract, and such Subcontractors or Business Associates will receive or create protected health information (PHI) on behalf of the contractor, the contractor shall obtain satisfactory assurances from its business associate that the business associate will appropriately safeguard the protected health information. The satisfactory assurances must be in writing, whether in the form of a contract or other agreement between the Contractor and the business associate. In the event of a suspected or known security or privacy breach, in addition to following the procedures set forth in 45 C.F.R. Part 164, the contractor shall also immediately notify the NIH via the Contracting Officer (CO)and the Contracting Officer's Representative (COR).

o. The parties agree to address HHS Information Security and Privacy Requirements, as applicable, during definitization of the contract.

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF OBJECTIVES

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Objectives, dated July 27, 2020, set forth in SECTION J – List of Attachments, attached hereto and made a part of this Leter Contract. Work to be performed shall be consistent with the application and preliminary work file submitted by the Contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through Letter Contract issuance.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format only. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

Reporting requirements TBD.
Placeholder: De-identified data for NIH research database

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional instructions or specifications applicable to this contract other than the delivery instructions contained herein.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized Contracting Officer's Representative (COR) will perform inspection and acceptance of deliverables to be performed and the milestones to be achieved.
b. Inspection and acceptance will be performed as identified in the contract requirements.

SECTION F - DELIVERIES OR PERFORMANCE ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of the contract is anticipated to be July 30, 2020 through July 29, 2021.

ARTICLE F.2. DELIVERIES

Satisfactory performance shall be deemed to occur upon performance of the work described in the Statement of Objectives Article in SECTION C of this Letter Contract and upon notice and acceptance by the Contracting Officer, or the duly authorized representative, in accordance with the stated deliverables schedule.
The deliverables or documentation there of shall be submitted to the Contracting Officer or designated Contracting Officer Representative (COR).

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER (CO)

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

Name: Roxane Burkett
Telephone: 301-827-7535
Email: burkettr@nih.nhlbi.gov

The Contracting Officer is the only person with authority to act as agent of the Government under this task order. Only the Contracting Officer has authority to:

1) direct or negotiate any changes in the statement of work;
2) modify or extend the period of performance;
3) change the delivery schedule;
4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract;
5) otherwise change any terms and conditions of this contract; or
6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract.

All correspondence (including invoices) that proposes or otherwise involves waivers, deviations, or modifications to requirement shall be provided to the CO issuing the task order and the COR supporting the CO.

ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) is anticipated to represent the Government for the purpose of this contract:

Olga Hartman, PhD
Telephone: 443-350-7696
Email: olga.hartman.civ@mail.mil

The COR is responsible for:

(1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;
(2) interpreting the Statement of Objectives and any other technical performance requirements;
(3) performing technical evaluation as required;
(4) performing technical inspections and acceptances required by this Letter Contract; and
(5) assisting in the resolution of technical problems encountered during performance.

The Government may unilaterally change the COR designation.

ARTICLE G.3. PRIMARY PROGRAM MANAGER

The Primary Program Manager specified in this task order is considered to be essential to work performance. At least 30 days prior to any changes to the individual listed below to other programs or task orders (or as soon as reasonably possible, if an individual must be replaced, for example, as a result of

leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the change request (including proposed substitutions for primary program manager) to permit evaluation by the Government of the impact on performance under this task order. The Contractor shall not replace any primary program manager without the written consent of the Contracting Officer. The Government may modify the task order to add or delete primary program manager at the request of the contractor or Government. In no case shall the individual's effort exceed 100% across all task orders.

[***]
[***]

ARTICLE G.4. INVOICE SUBMISSION

In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all task order payment requests:

a. The Contract Title is: "Rapid Acceleration of Diagnostics (RADx) Program: Tech Project # 6114 Fluidigm – Advanta Dx SARS-CoV-2 RT-PCR Assay for Saliva"
b. The Contract Line Items are defined within the Section 20. Schedule of Supplies/Services of the Standard Form 1449.
c. Invoice Instructions are attached and made part of this task order. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.
   a. One copy of the invoice shall be submitted to the approving official at the following email addresses:

      NHLBI Branch B Central Mailbox (NHLBIContractsBranchB@mail.nih.gov)

      NIH centralized invoice email box: invoicing@nih.gov

2. E-Mail: The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.
3. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests (invoices):
   a. Name of the Office of Acquisitions. The Office of Acquisitions for this task order is **NHLBI**.
   b. Central Point of Distribution. For the purpose of this Task Order, the Central Point of Distribution is **NHLBI Branch B Invoices**.
   c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is*

assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.] If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

e. Invoice Matching Option. This Task Order requires a **two-way** match.

f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

g. PRISM/NBS Line Item Number and associated PRISM/NBS Line Item Period of Performance (see SF 1449, Attachment #2).

(d) Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.

SECTION H - ADDITONAL CONTRACT CLAUSES

ARTICLE H.1. CONFIDENTIALITY OF 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 Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor 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. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination

from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ARTICLE H.2. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institutes of Health, Department of Health and Human Services, under Contract No: 75N92020C00009."

ARTICLE H.3. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The website to file a complaint on-line is: http://oig.hhs.gov/fraud/hotline/ and the mailing address is:

US Department of Health and Human Services Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489 Washington, D.C. 20026

PART II - CONTRACT CLAUSES SECTION I - CONTRACT CLAUSES
Selections will be made by the Contracting Officer during definitization

ARTICLE I.1. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FAR Clause 52.212-3 Offeror Representations and Certifications – Commercial Items (Jun 2020)
a. FAR Clause 52.212-4 Contract Terms and Conditions – Commercial Items (Oct 2018)
b. FAR Clause 52.203-13, Contractor Code of Business Ethics and Conduct (October 2015)
c. FAR Clause 52.204-2, Security Requirements (August 1996).
d. FAR Clause 52.204-9, Personal Identity Verification of Contractor Personnel (January 2011).
e. FAR Clause 52.204-13, System for Award Management Maintenance
f. FAR Clause 52.204-18 Commercial and Government Entity Code Maintenance (July 2016)
g. FAR Clause 52.204-23 Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities

h. FAR Clause 52.209-10, Prohibition on Contracting With Inverted Domestic Corporations(November 2015).
i. FAR Clause 52.222-4, Contract Work Hours and Safety Standards - Overtime Compensation -General (May 2014).
j. FAR Clause 52.222-29, Notification of Visa Denial (April 2015).
k. FAR Clause 52.223-15, Energy Efficiency in Energy-Consuming Products (December 2007).
l. FAR Clause 52.224-1, Privacy Act Notification (April 1984).
m. FAR Clause 52.224-2, Privacy Act (April 1984).
n. FAR Clause 52.227-1, Aughorization and Consent (Jun 2020).
o. FAR Clause 52.227-3 Patent Indemnity (Apr 1984).
p. FAR Claus 52.227-11 Patent Rights-Ownership by the Contractor (May 2014).
q. FAR Clause 52.227-14, Rights in Data - General (May 2014).
r. FAR Clause 52.227-14, Rights in Data - General (May 2014) Alternate II (Dec 2007).
s. FAR Clause 52.232-40, Providing Accelerated Payments to Small Business Subcontractors (Dec 2013)

ARTICLE I.3. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during definitization. This contract incorporates the following clauses in full text.

1. FAR 52.216-23 - EXECUTION AND COMMENCMENT OF WORK (APR 1984)

The Contractor shall indicate acceptance of this letter contract by signing One Copy of the contract and returning them to the Contracting Officer not later than July 29, 2020 at 4:00 p.m. Eastern. Upon acceptance by both parties, the Contractor shall proceed with performance of the work, including purchase of necessary materials.

2. FAR 52.216-24 - LIMITATION OF GOVERNMENT LIABILITY (APR 1984)

(a) In performing this contract, the Contractor is not authorized to make expenditures or incur obligations exceeding $12,151,000 dollars.

(b) The maximum amount for which the Government shall be liable if this contract is terminated is $12,151,000 dollars.

3. FAR 52.216-25 - CONTRACT DEFINITIZATION (OCT 2010)

(a) A Firm Fixed Price (FFP) definitive contract is contemplated. The Contractor agrees to begin promptly negotiating with the Contracting Officer the terms of a definitive contract that will include (1) all clauses required by the Federal Acquisition Regulation (FAR) on the date of execution of the letter contract, (2) all clauses required by law on the date of execution of the definitive contract, and (3) any other mutually agreeable clauses, terms, and conditions. The Contractor agrees to submit a Firm Fixed Price proposal, including data other than certified cost or pricing data, and certified cost or pricing data, in accordance with FAR 15.408, Table 15-2, supporting its proposal.

(b) The schedule for definitizing this contract is as follows:
Estimated date for start of negotiations: 8/3/2020
Target date for definitization: 9/25/2020

Definitization Schedule	Date
Statement of Work Review	7/27/2020

Issuance of Letter Contract	7/30/2020
Letter Contract Post Award Kick Off meeting	7/31/2020
Contractor Price Proposal Submittal	8/5/2020
Business and Technical Review	8/12/2020
Negotiations Start	8/13/2020
Request Budget and Price Breakdown	9/7/2020
Definitization of Letter Contract	9/25/2020

(c) If agreement on a definitive contract to supersede this letter contract is not reached by the target date in paragraph (b) of this section, or within any extension of it granted by the Contracting Officer, the Contracting Officer may, with the approval of the head of the contracting activity, determine a reasonable price or fee in accordance with subpart 15.4 and part 31 of the FAR, subject to Contractor appeal as provided in the Disputes clause. In any event, the Contractor shall proceed with completion of the contract, subject only to the Limitation of Government Liability clause.

(1) After the Contracting Officer's determination of price or fee, the contract shall be governed by-

(i) All clauses required by the FAR on the date of execution of this letter contract for either fixed-price or cost-reimbursement contracts, as determined by the Contracting Officer under this paragraph (c);

(ii) All clauses required by law as of the date of the Contracting Officer's determination; and

(iii) Any other clauses, terms, and conditions mutually agreed upon.

(2) To the extent consistent with paragraph (c)(1) of this section, all clauses, terms, and conditions included in this letter contract shall continue in effect, except those that by their nature apply only to a letter contract.

4. FAR Clause 52.204-21, Basic Safeguarding of Covered Contractor Information Systems **(Jun 2016)**

(a) Definitions. As used in this clause–

Covered contractor information system means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

Federal contract information means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public websites) or simple transactional information, such as necessary to process payments.

Information means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

Information system means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

Safeguarding means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements and procedures.

(1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

(iii) Verify and control/limit connections to and use of external information systems.

(iv) Control information posted or processed on publicly accessible information systems.

(v) Identify information system users, processes acting on behalf of users, or devices.

(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

(xii) Identify, report, and correct information and information system flaws in a timely manner.

(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.

(xiv) Update malicious code protection mechanisms when new releases are available.

(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) Other requirements. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)

5. **FAR 52.214-5** Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items **(Jul 2020)**

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).

(5) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).

(6) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items. Selections will be made by the Contracting Officer during definitization:

__ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (June 2020), with *Alternate I* (Oct 1995) (41U.S.C.4704 and 10 U.S.C. 2402).
__ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (Jun 2020) (41 U.S.C. 3509)).
__ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)
__ (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (Jun 2020) (Pub. L. 109-282) (31 U.S.C. 6101 note).
__ (5) [Reserved].
__ (6) 52.204-14, Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Jun 2020) (31 U.S.C. 6101 note).
__ (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Oct 2018) (41 U.S.C. 2313).
__ (10) [Reserved].
__ (11) (i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (Mar 2020) (15 U.S.C. 657a).
__ (ii) Alternate I (Mar 2020) of 52.219-3.
__ (12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Mar 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
__ (ii) Alternate I (Mar 2020) of 52.219-4.
__ (13) [Reserved]
__ (14) (i) 52.219-6, Notice of Total Small Business Set-Aside (Mar 2020) of 52.219-6 (15 U.S.C. 644).
__ (ii) Alternate I (Mar 2020) of 52.219-6 .
__ (15) (i) 52.219-7, Notice of Partial Small Business Set-Aside (Mar 2020) (15 U.S.C. 644).
__ (ii) Alternate I (Mar 2020) of 52.219-7.
__ (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).
__ (17) (i) 52.219-9, Small Business Subcontracting Plan (Jun 2020) (15 U.S.C. 637(d)(4)).
__ (ii) Alternate I (Nov 2016) of 52.219-9.
__ (iii) Alternate II (Nov 2016) of 52.219-9.
__ (iv)Alternate III (Jun 2020) of 52.219-9.
__ (v)Alternate IV (Jun 2020) of 52.219-9
__ (18) (i) 52.219-13, Notice of Set-Aside of Orders (Mar 2020) (15 U.S.C. 644(r)).
__ (ii) Alternate I (Mar 2020) of 52.219-13.
__ (19) 52.219-14, Limitations on Subcontracting (Mar 2020) (15 U.S.C. 637(a)(14)).
__ (20) 52.219-16, Liquidated Damages-Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
__ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Mar

2020) (15 U.S.C. 657f).

__ (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (May 2020) (15 U.S.C. 632(a)(2)).
__ (ii) Alternate I (MAR 2020) of 52.219-28.
__ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Mar 2020) (15 U.S.C. 637(m)).
__ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Mar2020) (15 U.S.C. 637(m)).
__ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (Mar 2020)(15 U.S.C. 644(r)).
__ (26) 52.219-33, Nonmanufacturer Rule (Mar 2020) (15U.S.C. 637(a)(17)).
__ (27) 52.222-3, Convict Labor (Jun 2003) (E.O.11755).
__ (28) 52.222-19, Child Labor- Cooperation with Authorities and Remedies (Jan2020) (E.O.13126)
__ (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
__ (30) (i) 52.222-26, Equal Opportunity (Sep 2016) (E.O.11246).
__ (ii) Alternate I (Feb 1999) of 52.222-26.
__ (31) (i) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C. 4212).
__ (ii) Alternate I (Jul 2014) of 52.222-35.
__ (32) (i) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C. 793).
__ (ii) Alternate I (Jul 2014) of 52.222-36.
__ (33) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).
__ (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
__ (35) (i) 52.222-50, Combating Trafficking in Persons (Jan 2019) (22 U.S.C. chapter 78 and E.O. 13627).
__ (ii) Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
__ (36) 52.222-54, Employment Eligibility Verification (Oct 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)
__ (37) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
__ (ii) Alternate I (May 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
__ (38) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).
__ (39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).
__ (40) (i) 52.223-13, Acquisition of EPEAT®-Registered Imaging Equipment (Jun 2014) (E.O.s 13423 and 13514).
__ (ii) Alternate I (Oct 2015) of 52.223-13.
__ (41) (i) 52.223-14, Acquisition of EPEAT®-Registered Televisions (Jun 2014) (E.O.s 13423 and 13514).
__ (ii) Alternate I (Jun2014) of 52.223-14.
__ (42) 52.223-15, Energy Efficiency in Energy-Consuming Products (May 2020) (42 U.S.C. 8259b).

__ (43) (i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (Oct 2015) (E.O.s 13423 and 13514).
__ (ii) Alternate I (Jun 2014) of 52.223-16.
_ (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020) (E.O. 13513).
__ (45) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).
__ (46) 52.223-21, Foams (Jun2016) (E.O. 13693).
__ (47) (i) 52.224-3 Privacy Training (Jan 2017) (5 U.S.C. 552 a).
__ (ii) Alternate I (Jan 2017) of 52.224-3.
__ (48) 52.225-1, Buy American-Supplies (May 2014) (41 U.S.C. chapter 83).
__ (49) (i) 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act (May 2014) (41 U.S.C.chapter83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.
__ (ii) Alternate I (May 2014) of 52.225-3.
__ (iii) Alternate II (May 2014) of 52.225-3.
__ (iv) Alternate III (May 2014) of 52.225-3.
__ (50) 52.225-5, Trade Agreements (Oct 2019) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).
__ (51) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
__ (52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302Note).
__ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov2007) (42 U.S.C. 5150).
__ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov2007) (42 U.S.C. 5150).
__ (55) 52.229-12, Tax on Certain Foreign Procurements (Jun 2020).
__ (56) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
__ (57) 52.232-30, Installment Payments for Commercial Items (Jan2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)_ (58) 52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct2018) (31 U.S.C. 3332).
__ (59) 52.232-34, Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).
__ (60) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).
__ (61) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).
__ (62) 52.242-5, Payments to Small Business Subcontractors (Jan 2017) (15 U.S.C. 637(d)(13)).
__ (63) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).
__ (ii) Alternate I (Apr 2003) of 52.247-64.
__ (iii) Alternate II (Feb 2006) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:
__ (1) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter67).
__ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (May

2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
__ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (Aug 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
__ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (May 2014) (29U.S.C.206 and 41 U.S.C. chapter 67).
__ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) (41 U.S.C. chapter 67).
__ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) (41 U.S.C. chapter 67).
__ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).
__ (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
__ (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this contract, and does not contain the clause at 52.215-2, Audit and Records-Negotiation.
(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-
(i) 52.203-13, Contractor Code of Business Ethics and Conduct (Jun 2020) (41 U.S.C. 3509).
(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(iii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).
(iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).
(v) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
(vi) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
(vii) 52.222-26, Equal Opportunity (Sep 2015) (E.O.11246).
(viii) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C. 4212).
(ix) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C. 793).
(x) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).
(xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.
(xii) 52.222-41, Service Contract Labor Standards (Aug2018) (41 U.S.C. chapter 67).
(xiii) (A) 52.222-50, Combating Trafficking in Persons (Jan 2019) (22 U.S.C. chapter 78 and E.O 13627).
(B) Alternate I (Mar2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
(xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May2014) (41 U.S.C. chapter 67).
(xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May2014) (41 U.S.C. chapter 67).
(xvi) 52.222-54, Employment Eligibility Verification (Oct 2015) (E.O. 12989).
(xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).
(xviii) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
(xix) (A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).
(B) Alternate I (Jan 2017) of 52.224-3.
(xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
(xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
(xxii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J LIST OF ATTACHMENTS

1. Statement of Objectives
    i. Appendix 1: Contract Deliverables

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.

Statement of Objectives

Program Title: Rapid Acceleration of Diagnostics (RADx) – Tech
Project Title: Rapid Acceleration of Diagnostics (RADx) Program: Tech Project # 6114 Fluidigm – Advanta Dx SARS-CoV-2RT-PCR Assay for Saliva
Agency: National Institute of Biomedical Imaging and Bioengineering (NIBIB) / National Institutes of Health (NIH)

1. Background

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) has a requirement for proposals to provide up to $500 million across multiple projects to rapidly produce innovative SARS-CoV-2 diagnostic tests that will assist the public's safe return to normal activities. Rapid Acceleration of Diagnostics (RADx), is a fast-track technology development program that leverages the National Institutes of Health (NIH) Point-of- Care Technology Research Network (POCTRN). RADx will support novel solutions that build the U.S. capacity for SARS-CoV-2 testing up to 100-fold above what is achievable with standard approaches. RADx is structured to deliver innovative testing strategies to the public as soon as late summer 2020 and is an accelerated and comprehensive multi-pronged effort by NIH to make SARS-CoV-2 testing readily available to every American.

2. Purpose and Objectives

NIBIB is providing substantial support to accelerate the development, validation, and commercialization of innovative point-of-care and home-based tests, as well as improvements to clinical laboratory tests, that can directly detect SARS-CoV-2, the virus that causes COVID-19. NIBIB will support the full range of product development including commercialization and product distribution. The ultimate goal of the RADx program
– across multiple projects/contracts – is to make millions of tests per week available to the American public, particularly those most vulnerable to and/or disproportionately impacted by COVID-19, in the late summer of 2020, and having even more tests available in time for the 2020–2021 flu season.

To meet the accelerated timelines, RADx has assembled a national network of expert technical, clinical, manufacturing, and regulatory advisors who will provide individualized assistance for project development and commercialization. Funding for projects selected for this program will be dependent on successfully meeting aggressive project milestones. Through the POCTRN grants, NIBIB provides financial and in-kind support to accelerate the entire product life-cycle, from design to market, for projects that meet milestones successfully. To ensure that innovations are available to the public as quickly as possible, NIH will leverage established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, the Department of Defense, as well as commercial and private entities to propel technologies developed by RADx into widespread use.

The RADx program will consider innovations at all stages of readiness to circumvent current limitations to SARS-CoV-2 testing capacity, including:

- Early stage: transformative innovations based on novel testing strategies that have potential for major scale up
- Mid stage: technologies using novel testing strategies that have demonstrated capability but need further validation, regulatory approval, and scale up
- Advanced stage (RADx ATP): modification and optimization of existing SARS-CoV-2 testing approaches, including clinical laboratory tests, that can dramatically increase testing capacity. Note: This arm of the RADx program is addressed under separate Acquisition Plan.

Design features might include technical innovations that:

- Improve analytical performance, e.g., sensitivity, specificity, dynamic range, limit of detection, reliability, accuracy, speed (time to test result) and throughput
- Enhance operational performance through, e.g., development of a patient- and user-friendly design, use of alternative sampling strategies (e.g., saliva, exhaled breath), integration with mobile-devices, designs for home-based use or strategies to overcome bottlenecks with current testing approaches
- Improve access and reduce the cost of testing.

3. Scope

RADx-Tech is a two-phase program. All applications undergo an intensive week-long risk assessment by a panel of expert technical, clinical, manufacturing, and regulatory advisors. If the proposed technology meets viability metrics, projects may be selected to enter phase one.

Phase one, performed under separate funding mechanism, consists of an accelerated research and development program in which the awardee receives both financial support and in-kind services through RADx grant funding. This outcome of this work is a fully instantiated technology ready for clinical validation, regulatory authorization, production and commercialization.

Phase two, or Work Package 2, of the program, executed under this contract, includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled up capacity to the U.S. public.

4. Performance Objectives (Required Results)

A. Contract recipients have completed major research and development efforts and are focused in phase two on completion of required clinical validation, preparation of regulatory submissions, scale-up of production capabilities, and preparation for full commercialization of their product – a testing technology. Every contract will encompass similar expectations and milestones concerned with:
   1. meeting regulatory requirements, resulting in regulatory authorization for sale and use of the test;
   2. instantiation of agreed-upon production capacity;
   3. meeting agreed-upon production goals; and
   4. implementation of an agreed-upon commercial strategy to bring the test to market in a timeframe that will impact the COVID-19 pandemic as soon as possible.

B. Contract funding in phase two is structured in order to reduce risk to the Government, and is dependent on achievement of specific milestones in the Schedule of Deliverables, according to the Payment Schedule.

C. The contractor must use a SARS-Cov-2 test with FDA EUA (or will have EUA near the time of award), indicating a combination of sensitivity, specificity, and usability appropriate to the intended use according to FDA and/or CDC guidance, as applicable.

D. The contractor must make the product available for a confidential independent regulatory/validation assessment. The independent assessor will be selected by the Government and specified in the contract.

E. The contractor must provide a risk mitigation plan for each identified risk and update and inform

NIH on any changes/newly identified risks in an ongoing manner.

5. Contract Type

The contract type is Firm Fixed Price.

6. Place of Performance

Place of Performance will be at the contractor's site(s).

7. Period of Performance

The period of performance of the contract is anticipated to be July 30, 2020 through July 29, 2021.

8. Deliverables/Delivery Schedule

See the attached Appendix 1: Schedule of Deliverables.

9. Other Requirements

A. The contractor must meet regularly (at least weekly) with NIH officials to update on progress toward deliverables; anticipated and ongoing issues and problems; and timelines for deliverable completion. When guided by NIH officials, the contractor must be willing to collaborate and cooperate under reasonable confidentiality terms with external organizations as needed to meet the contract goals in a manner which will not infringe contractor commercial or intellectual property rights.

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.

No.	Objective Defined	Milestone Defined	Deliverable	Success Criteria	Est. Deliverable Due Date	Stage
1	[***]	[***]	[***]	[***]	[***]	1
2	[***]	[***]	[***]	[***]	[***]	2
3	[***]	[***]	[***]	[***]	[***]	3
4	[***]	[***]	[***]	[***]	[***]	3
5	[***]	[***]	[***]	[***]	[***]	4
6	[***]	[***]	[***]	[***]	[***]	4
7	[***]	[***]	[***]	[***]	[***]	5
8	[***]	[***]	[***]	[***]	[***]	5

SubTasks

No.	Objective Defined	Milestone Defined	Deliverable	Success Criteria	Est. Deliverable Due Date	Stage
A	[***]	[***]	[***]	[***]	[***]	1A
B **	[***]	[***]	[***]	[***]	[***]	1A
C	[***]	[***]	[***]	[***]	[***]	2A

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT	1. CONTRACT ID CODE	PAGE OF PAGES
		1 / 34

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00001	09/25/2020	5830960	

6. ISSUED BY CODE	NHLBI	7. ADMINISTERED BY *(If other than item 6)* CODE	NIBIB
National Institutes of Health National Heart, Lung, and Blood Institute Bethesda, MD 20892-7511		National Institutes of Health National Institute of Biomedical Imaging and Bioengineering Bethesda, MD 20892-7511	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		9A. AMENDMENT OF SOLICITATION NO.
FLUIDIGM CORPORATION:1157584 2 TOWER PLACE SUITE 2000 SOUTH SAN FRANCISCO CA 940801826	(x)	
		9B. DATED *(SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. 75N92020C00009
		10B. *(SEE ITEM 13)* 07/30/2020
CODE / FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

12. ACCOUNTING AND APPROPRIATION DATA *(If required)* Net Increase: $21,865,056.00

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	OTHER *(Specify type of modification and authority)* FAR 52.216-25 — Contract Definitization

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

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

TITLE: RADx Tech Project # 6114 Fluidigm Corporation, Inc. "Advanta Dx SARS—CoV-2 RT—PCR Assay for Saliva"

PURPOSE: To definitize the letter contract.
Delivery Location Code: TDP, BTHOFF
Two Democracy Plaza, Bethesda Off C
2 Democracy Plaza
6707 Democracy Blvd
Bethesda MD 20817 US

Continued …

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*			16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*		
Andrew Quong, Chief Science Officer			ROXANE S. BURKETT		
15B. CONTRACTOR/OFFEROR	Digitally signed by Andrew Quong Date: 2020.09.28 13:10:54 -07'00'	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	Digitally signed by Roxane S. Burkett -S Date: 2020.09.28 17:34:18 -04'00'	16C. DATE SIGNED
/s/ Andrew Quong			/s/ Roxane S. Burkett -S		
(Signature of person authorized to sign)			*(Signature of Contracting Office!)*		

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED 75N92020C00009/P00001	PAGE OF 2 / 34

NAME OF OFFEROR OR CONTRACTOR

FLUIDIGM CORPORATION:1157584

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Payment: Approved By, NHLBI Branch A Invoice Paid By: NIH Commercial Accounts Br 2115 East Jefferson St, MSC 8500 Room 4B-432 Bethesda, MD 20892-8500 Period of Performance: [***] Add Item 3 as follows:				
3	Operation established - Phase I Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***] Add Item 4 as follows:				[***]
4	Submit FDA EUA Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***] Add Item 5 as follows:				[***]
5	Clinical Samples Obligated Amount: [***] Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***] Add Item 6 as follows:				[***]
6	Facility Construction Initiated Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Continued ...				[***]

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***]				
	Add Item 7 as follows:				
7	Additional Production Lines Initiated Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***]				[***]
	Add Item 8 as follows:				
8	Full production capacity on all 3 lines. Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***]				[***]

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.

PART I – THE SCHEDULE

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES

This contract is part of the Rapid Acceleration of Diagnostics (RADx) Tech program which is structured to deliver innovative testing strategies to the public and is an accelerated and comprehensive multi-pronged effort by NIH to make SARS-CoV-2 testing readily available to every American. The scope of work executed under this contract includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled-up capacity to the U.S. public. Fluidigm technology to support this effort will be to scale up the Integrated Fluidic Circuit (IFC) and completion of the multiplex assay development system for rapid acceleration of testing.

ARTICLE B.2. PRICES

a. The total Firm Fixed Price (FFP) amount for this contract is $34,016,056.

Prism Line Item	**Milestone**	**Description**	**Date**	**Amount**
1	1	**Stage 1 Test Verification - [***]**	[***]	[***]
2	A1	**Stage 1A- Design Review - [***]**	[***]	[***]
3	2	**Operation established - Phase I - [***]**	[***]	[***]
4	A2	**Submit FDA EUA -** [***]	[***]	[***]
5	A3	**Clinical samples –** [***]	[***]	[***]
6	3	**Facility Construction Initiated -** [***]	[***]	[***]
7	4	**Additional Production Lines Initiated** - [***]	[***]	[***]

8	5	**Full production capacity on all 3 lines - [***]**	[***]	[***]
	Total			**$34,016,056**

ARTICLE B.3. ADVANCE UNDERSTANDINGS

a. Commercial Item Status: The services provided by the Contractor under this definitized contract constitutes commercial item services.

b. HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.

c. Liquidated Damages – Milestone-Based Payments
If the Contractor fails to deliver the supplies or perform the services within the time specified in this contract, and fails to cure within the time specified by the Government and the Government terminates this contract in whole or in part for cause, the Contractor shall, in place of actual damages, pay to the Government liquidated damages in the amount of 33% of the amount(s) already disbursed to date under the contract. Any liquidated damaged owed by the Contractor shall be paid to the Government no later than 6 months from the date of termination.

The Contractor will not be charged with liquidated damages when the delay in delivery or performance is beyond the control and without the fault or negligence of the Contractor as defined in FAR Clause 52.212-4, Contract Terms and Conditions-Commercial Items, incorporated in this contract.

d. Successful performance under this contract requires the Contractor obtain and maintain an Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA); the Contractor shall copy us on all FDA correspondence related to the project, including email communications to and from the FDA. The FDA EUA services provided under this Contract constitute a commercial service to detect SARS-CoV-2.

e. Fair Pricing: The Rapid Acceleration of Diagnostics (RADx) application review process determined the cost per test is competitive with the current market price. The Contractor must comply with applicable federal law to ensure that prices to consumers are offered at fair market rate and at a rate consistent with the objective to increase and improve testing in the United States.

f. Security and Privacy of Protected Health Information (PHI) processed under this contract: In the event the Contractor meets the definition of either a Covered Entity or Business Associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Contractor shall comply with the HIPAA regulatory standards set forth in the Code of Federal Regulations (CFR) 45 C.F.R. Part 160, Part 162, and Part 164. To the extent that the Contractor engages subcontractors or other Business Associates to provide services under this Contract, and such Subcontractors or Business Associates will receive or create protected health information (PHI) on behalf of the contractor, the contractor shall obtain satisfactory assurances from its business associate that the business associate will appropriately safeguard the protected health information. The satisfactory assurances must be in writing, whether in the form of a contract or other agreement between the Contractor and the business associate. In the event of a suspected or known security or privacy breach, in addition to following the procedures set forth in 45 C.F.R. Part 164, the contractor shall also immediately notify the NIH via the Contracting Officer (CO)and the Contracting Officer's Representative (COR).

g. Sharing Data and Reports: The Contractor will be required to provide data and reports (e.g., manufacturing, supply chain, production rates), which NIH will use to evaluate completion or achievement of milestones, progress toward deliverables, and compliance with the requirements of this contract. NIH may use the data to coordinate with other U.S. Government Agencies to accelerate development and deployment of innovative COVID-19 diagnostic tests, and ensure effective stewardship of federal funds. The reports and data shall not be disclosed outside of the U.S. Government. Sharing data within the federal government enables NIH to discuss the project's challenges and progress with federal agencies offering scientific, manufacturing, and logistics expertise. To ensure that innovations are available to the public as quickly as possible, NIH will leverage established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, and the Department of Defense, and partnerships with State agencies to propel technologies developed by RADx into widespread use.

h. Contractor Facilities: The contractor shall certify that they will maintain their Facility and Equipment in satisfactory operating condition, as required to enable the contractor to perform the deliverables and achieve the milestones in accordance with the Statement of Objectives and all other applicable laws, regulations, rules or orders. Routine repairs, preventive maintenance, and service contracts for the Facility and Equipment beyond that accounted for in the contract shall be arranged by contractor at no additional cost to the Government.

i. The novel coronavirus (COVID-19) pandemic has introduced new cybersecurity risks both at the NIH and across the globe. NIH and NIBIB recognize that that the high profile nature of the RADx response may attract the attention of highly motivated malicious actors and want vendors to understand that the risks are real and there is a strong interest in protecting the valued work being conducted through these contracts. NIH and NIBIB are asking vendors to consider their current security posture and to make all reasonable efforts to protect their environment, Information technology, and the products that are being produced. NIST Special Publication 800-171 can be a useful tool or measuring stick to understand your current security posture as it relates to government computer security standards. Templates can be found at https://csrc.nist.gov/publications/detail/sp/800-171/rev-2/final .

j. Contract Termination: In accordance with FAR 52.212-4 (l) Termination for the Government's convenience. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work.

Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

k. Contract Termination: In accordance with FAR 52.212-4(m), the Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

l. Any imported materials must be FDA-approved for use in the U.S.

m. In accordance with the goals of the RADx program, during the Period of Performance (as defined below) the tests manufactured under this contract are to be sold within the U.S. and its territories; provided, however, that, to the extent there is insufficient demand within the U.S. and its territories for the tests produced up to the additional manufacturing capacity funded by NIH and then available (as described in the Schedule of Deliverables), contractor will be permitted to sell such tests outside the U.S. and its territories. The factors, process and mechanism to determine whether contractor has insufficient demand for the tests up to the then-available capacity will be determined on a case by case basis and with approval of the Contracting Officer.

n. Purchase of clinical samples is permited under this contract and identified as a separate line item. If samples are not purchased this line item will not be billed against and therefore deobligated from the contract.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF OBJECTIVES

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Objectives, dated July 27, 2020 and the Performance Work Statement (PWS) dated August 31, 2020, set forth in SECTION J – List of Attachments, attached hereto and made a part of this Contract. Work to be performed shall be consistent with the application and preliminary work file submitted by the Contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through contract award.

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and would be competitively harmful if publicly disclosed.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format only. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

The following reporting requirements shall be submitted electronically to the Contracting Officer and Contracting Officer's Representative in accordance with the due dates specified below:

Item No.	Reporting Requirements	Due Date
1	Bi-weekly Production Status Report – to include the following: • current plant production capacity and output on a per-week basis, • a breakdown of capacity and output on a per-line/per week basis, • a description of any issues/problems encountered with plans for solution/mitigation (e.g., delays in meeting deliverables, supply chain issues, design/validation issues, etc.) • sales reporting to include the name and kind of organization, as well as the number of IFCs sold to that organization during the reporting period. Sales reports may be submitted in every other bi-weekly report (i.e. monthly).	[***]
2	Final Report - Summary of salient results of the entire contract period, including number of lines built, production capacity over time, production output over time, and a summary of the sales reports. It shall include evidence of sustained production at capacity levels or higher assuming demand has not decreased.	[***]

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional instructions or specifications applicable to this contract other than the delivery instructions contained herein.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized Contracting Officer's Representative (COR) will perform inspection and acceptance of deliverables to be performed and the milestones to be achieved.

b. Inspection and acceptance will be performed utilizing the success criteria outlined in the deliverable schedule.

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of the contract is [***].

ARTICLE F.2. DELIVERIES

Satisfactory performance shall be deemed to occur upon performance of the work described in the Statement of Objectives Article in SECTION C of this Contract and upon notice and acceptance by the Contracting Officer, or the duly authorized representative, in accordance with the stated deliverables schedule as listed in the Performance Work Statement (PWS) (See Attachment 2).

The deliverables or documentation shall be submitted to the Contracting Officer and designated Contracting Officer Representative (COR) by email.

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER (CO)

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

Name: Roxane Burkett
Telephone: 301.827.7535
Email: burkettr@nhlbi.nih.gov

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to:

1) direct or negotiate any changes in the Statement of Objectives or Performance Work Statement;
2) modify or extend the period of performance;
3) change the deliverables or milestones schedule;
4) authorize reimbursement to the Contractor for any costs incurred during the performance of this Contract;
5) otherwise change any terms and conditions of this Contract;

All correspondence (including invoices) that proposes or otherwise involves waivers, deviations, or modifications to requirement shall be provided to the CO issuing this Contract and the COR supporting the CO.

ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) is anticipated to represent the Government for the purpose of this contract:

Olga Hartman, PhD
Telephone: 443-350-7696
Email: olga.hartman.civ@mail.mil

The COR is responsible for:

(1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;
(2) interpreting the Statement of Objectives and any other technical performance requirements;
(3) performing technical evaluation as required;
(4) performing technical inspections and acceptances required by this Contract; and
(5) assisting in the resolution of technical problems encountered during performance.

The Government may unilaterally change the COR designation.

ARTICLE G.3. PRIMARY PROGRAM MANAGER

The Primary Program Manager specified in this contract is considered to be essential to work performance. At least 30 days prior to any changes to the individual listed below to other programs or contracts (or as soon as reasonably possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the change request (including proposed substitutions for primary program manager) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not replace any primary program manager without the written consent of the Contracting Officer. The Government may modify the contract to add or delete primary program manager at the request of the Contractor or Government. In no case shall the individual's effort exceed 100% across all contracts.

[***]
[***]

ARTICLE G.4. INVOICE SUBMISSION

In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all contract payment requests:

a. The Contract Title is: RADx Tech Fluidigm 6114 – "Advanta Dx SARS-CoV-2 RT-PCR Assay for Saliva"
b. The Contract Line Items are defined within the Section 20. Schedule of Supplies/Services of the Standard Form 1449.
c. Invoice Instructions are attached and made part of this Contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.
   1. Payment requests shall be submitted to the offices identified below. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in this Contract or requested by the Contracting Officer.

a. One copy of the invoice shall be submitted to the approving official at the following email addresses:

NHLBI Branch B Central Mailbox (NHLBIContractsBranchB@mail.nih.gov)

NIH centralized invoice email box: invoicing@nih.gov

2. E-Mail: The Contractor shall submit an electronic copy of the payment request to the approving official. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.
3. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests (invoices):
   a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is **NHLBI**.
   b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is **NHLBI Branch B Invoices**.
   c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
   d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
   e. Invoice Matching Option. This Contract requires a **two-way** match.
   f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.
   g. PRISM/NBS Line Item Number and associated PRISM/NBS Line Item Period of Performance (see Section B – PRICES/OPTION).

d. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.

SECTION H - ADDITONAL CONTRACT CLAUSES

ARTICLE H.1. CONFIDENTIALITY OF 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 Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this Contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the Contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this Contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor 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. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ARTICLE H.2. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this Contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N92020C0009."

In addition to acknowledging NIH funding, the Contractor shall refer any media inquiries relating to the role of the US Government in their contract to the COR within one day for a response.

ARTICLE H.3. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The website to file a complaint on-line is: http://oig.hhs.gov/fraud/hotline/ and the mailing address is:

US Department of Health and Human Services Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489 Washington, D.C. 20026

ARTICLE H.4. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-74 (December 2015)

a. Pursuant to Section 508 of the Rehabilitation Act of 1973(29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the "Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at http://www.hhs.gov/web/508 . The complete text of Section 508 Final Provisions can be accessed at http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards .

b. The Section 508 accessibility standards applicable to this contract or order are identified below. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

c. The Section 508 accessibility standards applicable to this contract are:
   - 300 – Functional Performance Requirements
   - 500 – Software Standards General
   - 600 – Support Services & Documentation Standards
   - WCAG Level A Requirements
   - WCAG Level AA Requirements

d. In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS Web site: (http://www.hhs.gov/web/508). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

e. If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at http://www.hhs.gov/web/508 . If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(End of clause)

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text.

1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

a. FAR Clause 52.202-1 Definitions
b. FAR Clause 52.203-6 Restrictions on Subcontractor Sales to the Government.
   i. Alternate I 52.203-6
c. FAR Clause 52.203-13, Contractor Code of Business Ethics and Conduct (October 2015)
d. FAR Clause 52.203-17 Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights.
e. FAR Clause 52.204-9, Personal Identity Verification of Contractor Personnel (January 2011).
f. FAR Clause 52.204-13, System for Award Management Maintenance
g. FAR Clause 52.204-18 Commercial and Government Entity Code Maintenance (July 2016)
h. FAR Clause 52.204-23 Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
i. FAR Clause 52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services of Equipment (Aug 2020)
j. FAR Clause 52.209-10, Prohibition on Contracting With Inverted Domestic Corporations(November 2015).
k. FAR Provision 52.212-3, Offeror Representations and Certifications – Commercial Items (Jun 2020)
l. FAR Clause 52.212-4 Contract Terms and Conditions – Commercial Items (Oct 2018)
m. FAR Clause 52.222-4, Contract Work Hours and Safety Standards - Overtime Compensation -General (May 2014).
n. FAR Clause 52.222-29, Notification of Visa Denial (April 2015).
o. FAR Clause 52.223-15, Energy Efficiency in Energy-Consuming Products (December 2007).

p. FAR Clause 52.227-11 Patent Rights-Ownership by the Contractor
q. FAR Clause 52.227-14, Rights in Data - General (May 2014).
r. FAR Clause 52.227-14, Rights in Data - General (May 2014) Alternate II (Dec 2007).
s. FAR Clause 52.232-40, Providing Accelerated Payments to Small Business Subcontractors

2. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER CLAUSES:

a. HHSAR Clause 352.227-70, Publications and Publicity

ARTICLE I.2. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

This contract incorporates the following clauses in full text.

i. FAR Clause 52.204-21, Basic Safeguarding of Covered Contractor Information Systems (Jun 2016)

(a) Definitions. As used in this clause–

Covered contractor information system means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

Federal contract information means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public websites) or simple transactional information, such as necessary to process payments.

Information means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

Information system means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

Safeguarding means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements and procedures.

(1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall

include, at a minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

(iii) Verify and control/limit connections to and use of external information systems.

(iv) Control information posted or processed on publicly accessible information systems.

(v) Identify information system users, processes acting on behalf of users, or devices.

(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

(xii) Identify, report, and correct information and information system flaws in a timely manner.

(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.

(xiv) Update malicious code protection mechanisms when new releases are available.

(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) Other requirements. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive

Order 13556.

(c) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)

ii. FAR 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items (Aug 2020)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).

(5) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).

(6) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:
[*Contracting Officer check as appropriate*.] –

_X_ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (June 2020), with *Alternate I* (Oct 1995) (41U.S.C.4704 and 10 U.S.C. 2402).
_X_ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (Jun 2020) (41 U.S.C. 3509)).
__ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)

_X_ (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (Jun 2020) (Pub. L. 109-282) (31 U.S.C. 6101 note).
__ (5) [Reserved].
_X_ (6) 52.204-14, Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).
_X_ (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Jun 2020) (31 U.S.C. 6101 note).
_X_ (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Oct 2018) (41 U.S.C. 2313).
__ (10) [Reserved].
__ (11) (i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (Mar 2020) (15 U.S.C. 657a).
__ (ii) Alternate I (Mar 2020) of 52.219-3.
__ (12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Mar 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
__ (ii) Alternate I (Mar 2020) of 52.219-4.
__ (13) [Reserved]
__ (14) (i) 52.219-6, Notice of Total Small Business Set-Aside (Mar 2020) of 52.219-6 (15 U.S.C. 644).
__ (ii) Alternate I (Mar 2020) of 52.219-6 .
__ (15) (i) 52.219-7, Notice of Partial Small Business Set-Aside (Mar 2020) (15 U.S.C. 644).
__ (ii) Alternate I (Mar 2020) of 52.219-7.
_X_ (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).
__ (17) (i) 52.219-9, Small Business Subcontracting Plan (Jun 2020) (15 U.S.C. 637(d)(4)).
__ (ii) Alternate I (Nov 2016) of 52.219-9.
__ (iii) Alternate II (Nov 2016) of 52.219-9.
__ (iv)Alternate III (Jun 2020) of 52.219-9.
__ (v)Alternate IV (Jun 2020) of 52.219-9
__ (18) (i) 52.219-13, Notice of Set-Aside of Orders (Mar 2020) (15 U.S.C. 644(r)).
__ (ii) Alternate I (Mar 2020) of 52.219-13.
__ (19) 52.219-14, Limitations on Subcontracting (Mar 2020) (15 U.S.C. 637(a)(14)).
__ (20) 52.219-16, Liquidated Damages-Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
__ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Mar 2020) (15 U.S.C. 657f).
__ (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (May 2020) (15 U.S.C. 632(a)(2)).
__ (ii) Alternate I (MAR 2020) of 52.219-28.
__ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Mar 2020) (15 U.S.C. 637(m)).
__ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Mar2020) (15 U.S.C. 637(m)).
__ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (Mar 2020)(15 U.S.C.

644(r)).
__ (26) 52.219-33, Nonmanufacturer Rule (Mar 2020) (15U.S.C. 637(a)(17)).
_X_ (27) 52.222-3, Convict Labor (Jun 2003) (E.O.11755).
_X_ (28) 52.222-19, Child Labor- Cooperation with Authorities and Remedies (Jan2020) (E.O.13126)
_X_ (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
_X_ (30) (i) 52.222-26, Equal Opportunity (Sep 2016) (E.O.11246).
__ (ii) Alternate I (Feb 1999) of 52.222-26.
__ (31) (i) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C. 4212).
__ (ii) Alternate I (Jul 2014) of 52.222-35.
__ (32) (i) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C. 793).
__ (ii) Alternate I (Jul 2014) of 52.222-36.
__ (33) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).
_X_ (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
_X_ (35) (i) 52.222-50, Combating Trafficking in Persons (Jan 2019) (22 U.S.C. chapter 78 and E.O. 13627).
__ (ii) Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
__ (36) 52.222-54, Employment Eligibility Verification (Oct 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)
__ (37) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
__ (ii) Alternate I (May 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
__ (38) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).
__ (39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).
__ (40) (i) 52.223-13, Acquisition of EPEAT®-Registered Imaging Equipment (Jun 2014) (E.O.s 13423 and 13514).
__ (ii) Alternate I (Oct 2015) of 52.223-13.
__ (41) (i) 52.223-14, Acquisition of EPEAT®-Registered Televisions (Jun 2014) (E.O.s 13423 and 13514).
__ (ii) Alternate I (Jun2014) of 52.223-14.
__ (42) 52.223-15, Energy Efficiency in Energy-Consuming Products (May 2020) (42 U.S.C. 8259b).
__ (43) (i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (Oct 2015) (E.O.s 13423 and 13514).
__ (ii) Alternate I (Jun 2014) of 52.223-16.
_X_ (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020) (E.O. 13513).
__ (45) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).
__ (46) 52.223-21, Foams (Jun2016) (E.O. 13693).
_ (47) (i) 52.224-3 Privacy Training (Jan 2017) (5 U.S.C. 552 a).
__ (ii) Alternate I (Jan 2017) of 52.224-3.
__ (48) 52.225-1, Buy American-Supplies (May 2014) (41 U.S.C. chapter 83).

__ (49) (i) 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act (May 2014) (41 U.S.C.chapter83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.
__ (ii) Alternate I (May 2014) of 52.225-3.
__ (iii) Alternate II (May 2014) of 52.225-3.
__ (iv) Alternate III (May 2014) of 52.225-3.
__ (50) 52.225-5, Trade Agreements (Oct 2019) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).
_X_ (51) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
__ (52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302Note).
__ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov2007) (42 U.S.C. 5150).
__ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov2007) (42 U.S.C. 5150).
__ (55) 52.229-12, Tax on Certain Foreign Procurements (Jun 2020).
__ (56) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
__ (57) 52.232-30, Installment Payments for Commercial Items (Jan2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
_X_ (58) 52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct2018) (31 U.S.C. 3332).
__ (59) 52.232-34, Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).
__ (60) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).
__ (61) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).
_X_ (62) 52.242-5, Payments to Small Business Subcontractors (Jan 2017) (15 U.S.C. 637(d)(13)).
__ (63) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).
__ (ii) Alternate I (Apr 2003) of 52.247-64.
__ (iii) Alternate II (Feb 2006) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:
[*Contracting Officer check as appropriate.*]
__ (1) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter67).
__ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
__ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (Aug 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
__ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (May 2014) (29U.S.C.206 and 41 U.S.C. chapter 67).
__ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May

2014) (41 U.S.C. chapter 67).
__ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) (41 U.S.C. chapter 67).
__ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).
__ (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
__ (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this contract, and does not contain the clause at 52.215-2, Audit and Records-Negotiation.
(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-
(i) 52.203-13, Contractor Code of Business Ethics and Conduct (Jun 2020) (41 U.S.C. 3509).
(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).
(iii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).
(iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).
(v) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in

FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
(vi) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
(vii) 52.222-26, Equal Opportunity (Sep 2015) (E.O.11246).
(viii) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C. 4212).
(ix) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C. 793).
(x) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).
(xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.
(xii) 52.222-41, Service Contract Labor Standards (Aug2018) (41 U.S.C. chapter 67).
(xiii) (A) 52.222-50, Combating Trafficking in Persons (Jan 2019) (22 U.S.C. chapter 78 and E.O 13627).
(B) Alternate I (Mar2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
(xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May2014) (41 U.S.C. chapter 67).
(xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May2014) (41 U.S.C. chapter 67).
(xvi) 52.222-54, Employment Eligibility Verification (Oct 2015) (E.O. 12989).
(xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).
(xviii) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
(xix) (A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).
(B) Alternate I (Jan 2017) of 52.224-3.
(xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
(xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
(xxii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

a. Statement of Objectives
b. Performance Work Statement
Appendix 1: Cost-Price Quote
Appendix 2: Quality Assurance Surveillance Plan (QASP)

EX-10.1 2 exhibit10110q1q2021ng.htm EX-10.1

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE	PAGE OF PAGES
				1 / 4

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00002	See Block 16C	5942874	

6. ISSUED BY CODE	NHLBI	7. ADMINISTERED BY *(If other than item 6)* CODE	NIBIB
National Institutes of Health National Heart, Lung, and Blood Institute Bethesda, MD 20892-7511		National Institutes of Health National Institute of Biomedical Imaging and Bioengineering Bethesda, MD 20892-7511	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		9A. AMENDMENT OF SOLICITATION NO.
FLUIDIGM CORPORATION:1157584 2 TOWER PLACE SUITE 2000 SOUTH SAN FRANCISCO CA 940801826		9B. DATED *(SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. 75N92020C00009
		10B. DATED *(SEE ITEM 13)* 07/30/2020
CODE FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

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

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
x	OTHER *(Specify type of modification and authority)* FAR 52.243-1 - Changes-Fixed Price (August 1987)

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

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

The purpose of this Modification is to amend "Article B.2 Prices" by canceling and de-obligating funds from Lines #4, 5, 7 and 8 and to add new Lines #9 through #18 and to amend "Article G.2" to update the Contracting Officer's Representative (COR); and to attach the revised Performance Work Statement and deliverable schedule.

All other terms and conditions of this contract remain the same.
Delivery Location Code: TDP, BTHOFF
Two Democracy Plaza, Bethesda Off C
2 Democracy Plaza
6707 Democracy Blvd
Bethesda MD 20817 US
Continued …

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*			16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*		
Andrew Quong, CSO			ROXANE S. BURKETT		
15B. CONTRACTOR/OFFEROR	Digitally signed by Andrew Quong Date: 2021.02.18 22:16:38 -08'00'	15C. DATE SIGNED	1 16B. UNITED STATES OF AMERICA	Digitally signed by Roxane S. Burkett -S Date: 2021.02.19 07:46:34 -05'00'	16C. DATE SIGNED
/s/ Andrew Quong			/s/ Roxane S. Burkett -S		
(Signature of person authorized to sign)		2/18/21	*(Signature of Contracting Office!)*		

NSN 7540-01-152-8070 STANDARD FORM 30 (REV. 10-83)
Previous edition unusable Prescribed by GSA

FAR (48 CFR) 53.243

NAME OF OFFEROR OR CONTRACTOR
FLUIDIGM CORPORATION:1157584

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Payment: Approved By, NHLBI Branch A Invoice Paid By: NIH Commercial Accounts Br 2115 East Jefferson St, MSC 8500 Room 4B-432 Bethesda, MD 20892-8500 Period of Performance: [***] Cancel Item 4 in its entirety. Cancel Item 5 in its entirety. Cancel Item 7 in its entirety. Cancel Item 8 in its entirety. Add Item 9 as follows:				
9	[***] Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***] Add Item 10 as follows:				[***]
10	[***] Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***] Add Item 11 as follows:				[***]
11	[***] Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Continued...				[***]

NAME OF OFFEROR OR CONTRACTOR
FLUIDIGM CORPORATION:1157584

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***] Add Item 12 as follows:				
12	[***] Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***] Add Item 13 as follows:				[***]
13	[***] Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***] Add Item 14 as follows:				[***]
14	[***] Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***] Add Item 15 as follows:				[***]
15	[***] Continued...				[***]

NAME OF OFFEROR OR CONTRACTOR
FLUIDIGM CORPORATION:1157584

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***] Add Item 16 as follows::				
16	[***] Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***] Add Item 17 as follows:				[***]
17	[***] Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***] Add Item 18 as follows:				[***]
18	[***] Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: [***]				[***]

BEGINNING WITH THE EFFECTIVE DATE OF THIS MODIFICATION, THE GOVERNMENT AND THE CONTRACTOR MUTUALLY AGREE AS FOLLOWS:

ARTICLE B.2. PRICES shall be amended by canceling and de-obligating lines 4, 5, 7 and 8 and to add the flowing lines, 9 through 18, below and shall read as follows:

ARTICLE B.2. PRICES

a. The total Firm Fixed Price (FFP) amount for this contract is $34,016,056.

Prism Line Item	Milestone	**Invoice Line Item** - description	Date	Amount
9	4	**Equipment Procurement, Construction, Initiation of Installation - [***]**	[***]	[***]
10	5	**Equipment Installation - [***]**	[***]	[***]
11	6	**Performance Qualification - [***]**	[***]	[***]
12	A2	Design Lock - [***]	[***]	[***]
13	A3	Clinical Studies - [***]	[***]	[***]
14	A4	**Submit EUA to FDA - [***]**	[***]	[***]
15	A5	Clinical Samples - [***]	[***]	[***]
16	7a	Full Production Capacity on Line 2 - [***]	[***]	[***]
17	7b	Full Production Capacity on Line 3 - [***]	[***]	[***]
18	8	**Final Report - [***]**	[***]	[***]
			Total	**$34,016,056**

ARTICLE C.1. STATEMENT OF OBJECTIVES shall be amended and read as follows:
Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Objectives, dated July 27, 2020 and the Performance Work Statement (PWS) dated January 19, 2021, set forth in SECTION J – List of Attachments, attached hereto and made a part of this Contract. Work to be performed shall be consistent with the application and preliminary work file submitted by the Contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through contract award.

ARTICLE C.2. REPORTING REQUIREMENTS shall be amended and read as follows:
All reports required herein shall be submitted in electronic format only. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

The following reporting requirements shall be submitted electronically to the Contracting Officer and Contracting Officer's Representative in accordance with the due dates specified below:

Item No.	Reporting Requirements	Due Date
1	Bi-weekly Production Status Report – to include the following: • current plant production capacity and output on a per-week basis, • a breakdown of capacity and output on a per-line/per week basis, • a description of any issues/problems encountered with plans for solution/mitigation (e.g., delays in meeting deliverables, supply chain issues, design/validation issues, etc.) • sales reporting to include the name and kind of organization, as well as the number of IFCs sold to that organization during the reporting period. Sales reports may be submitted in every other bi-weekly report (i.e. monthly).	[***]
2	Final Report - Summary of salient results of the entire contract period, including number of lines built, production capacity over time, production output over time, and a summary of the sales reports. It shall include evidence of sustained production at capacity levels or higher assuming demand has not decreased.	[***]

ARTICLE F.1. PERIOD OF PERFORMANCE shall be amended and read as follows:
The period of performance of the contract is **[***].**

ARTICLE F.2. DELIVERIES shall be amended and read as follows:
Satisfactory performance shall be deemed to occur upon performance of the work described in the Statement of Objectives Article in SECTION C of this Contract and upon notice and acceptance by the Contracting Officer, or the duly authorized representative, in accordance with the stated deliverables schedule as listed in the Performance Work Statement (PWS) dated January 19, 2021 (See Attachment 2).

The deliverables or documentation shall be submitted to the Contracting Officer and designated Contracting Officer Representative (COR) by email.

ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR) shall be amended and read as follows:

The following Contracting Officer's Representative (COR) is anticipated to represent the Government for the purpose of this contract:

Matthew Sanders
301.480.1863
matthew.sanders@nih.gov

The COR is responsible for:
(1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements.
(2) interpreting the Statement of Objectives and any other technical performance requirements.
(3) performing technical evaluation as required.
(4) performing technical inspections and acceptances required by this Contract; and
(5) assisting in the resolution of technical problems encountered during performance.

The Government may unilaterally change the COR designation.

SECTION J - LIST OF ATTACHMENTS shall be amended and read as follows:

1. Statement of Objectives
2. Performance Work Statement dated January 19, 2021
   Appendix 1: Cost-Price Quote
   Appendix 2: Quality Assurance Surveillance Plan (QASP)

All other terms and conditions of the contract remain the same.

RADx #6114
Fluidigm Corporation
Letter Contract number: 75N92020C00009

Performance Work Statement

PWS Title: Rapid Acceleration of Diagnostics (RADx) Program: Tech Project # 6114 Fluidigm – Advanta Dx SARS-CoV-2 RT-PCR Assay for Saliva

1.0 Background

Fluidigm has developed a diagnostic molecular test for the qualitative detection of SARS-CoV-2 in saliva specimens under FDA Emergency Use Authorization (EUA). The Advanta™ Dx SARS-CoV-2 RT-PCR Assay is a qPCR-based test that, by taking advantage of Fluidigm's proprietary microfluidics technology and Juno™ and Biomark™ HD systems, enables high throughput and scalable testing of saliva samples from patients suspected of COVID-19 (coronavirus) infection. Featuring extraction-free sample processing, a modular workflow and large batch-sample size, the Advanta Dx SARS-CoV-2 RT-PCR Assay aims to meet the RADx goal of enhance laboratory SARS-CoV-2 testing capacity.

Fluidigm's BioMark HD microfluidics platform addresses the massive demand for SARS-CoV-2PCR testing- combining speed, minimal cost, and massive throughput unparalleled in the industry. Further advantages include flexibility to rapidly integrate new mutational markers or increase panel size to include additional infectious agents. This platform works with all clinical sample types.

Our solution leverages Advanta™ Dx SARS-CoV-2 RT-PCR Assay submitted for an EUA, and two assays under development that can change the landscape for detection. This assay allows for up to 6000 samples per day on a single system. Additional assays address different needs in testing, throughput, specificity and sensitivity.

Our technology offers significant advantages overcoming many supply chain barriers and provides a robust platform for scale up of testing for SARS-CoV-2.

Fluidigm has been able to detect both N1 and N2 SARS-CoV-2 targets across all samples provided by Washington University, including the lowest dilution (10 cp/ul). Highlights from that work are the detection of:

- 10 copies in the reaction using 4 ul of saliva sample
- 1.x copies in the reaction using 1 ul of saliva sample
- Across all dilution buffer and RNase inhibitor conditions

Of the amplification chemistries tested, optimum results were obtained from the FLDM 1-Step RT-PCR Master Mix, 2.5 hour 1-step RT-PCR protocol.

2.0 Objectives

The baseline technology provided in Fluidigm's EUA filing allows for performing 6000 tests per day on each Biomark HD system and Fluidigm currently has the ability to manufacture approximately 50,000 tests per day. The rate limiting component is the Integrated Fluidic Circuit (IFC), which is the microfluidic chip that is required for running the assay. The two types of IFCs described herein are the 192.24 IFC which is used in the current Advanta™ Dx SARS-CoV-2 RT-PCR Assay under EUA, and cartridge-based solution IFC which is the basis for a simplified workflow. Each 192.24 IFC has the capacity to run 192 tests and each cartridge-based solution IFC has the capacity to run 96 tests. This project has two major

deliverables: 1) to increase manufacturing capacity of IFCs and to develop and 2) to manufacture a cartridge-based solution that will simplify the workflow and increase the likelihood of sales and deployment of the COVID tests to a broader customer base.

The cartridge-based solution incorporates two independent reactions necessary to process the sample into the same chip to simplify the overall workflow. Compared to the 192.24 IFC approach, each individual sample in the cartridge-based solution increases the number of reaction chambers in the microfluidic chip. Thus, the overall sample capacity of the chip is reduced as there is more chemistry being performed on chip. As a result, switching to the production of the cartridge will result in a simplified workflow but lower volume of tests because it has half the sample capacity of the 192.24 IFC.

The cartridge-based solution requires the redevelopment of the assay to include on IFC Reverse Transcription and a solid-phase bead-based capture of the target nucleic acid sequences. This solid-phase bead-based capture is a novel addition which is a departure from the EUA for the Advanta Dx SARS-CoV-2 assay. Therefore, the full development of the cartridge-based assay will require a new clinical study and EUA submission.

The limiting factor to Fluidigm provided testing is the manufacture of the IFCs. This is because the Fluidigm test does not require extraction, and only nano-liters of reagents are used for each PCR reaction. Scale up for IFC production will occur in Fluidigm's Singapore facility by first maximizing production in the existing manufacturing line which will increase production capacity to 12,000 IFCs per month from the current 7,000 per month. Simultaneously, Fluidigm will add two additional manufacturing lines to the Singapore facility which will ultimately provide manufacturing capacity of 36,000 IFCs per month. The investment into the capital equipment to construct additional manufacturing lines and expand the production of the IFCs can be leveraged to produce the cartridge-based solution. The cartridge-based solution requires a new process and molds but uses the existing equipment.

3.0 Scope

Fluidigm will deploy a complete testing solution using a saliva based, extraction free, viral detection assay for broad distribution. This section describes the scope of work for RADx 6114.

Currently Fluidigm has the capability to deliver testing capacity of approximately 50,000 tests/day. The cartridge-based solution will deliver testing capacity of up to 115,200 tests/day by Q3 2021.

The Contractor shall accomplish the following milestones in the stages outlined below:

- Stage 1: Test Verification
  - Deliver 1plex tests to Verification Core at Emory University
  - Provide final report from the Verification Core
- Stage 2: Scale Up
  - Increase production capacity of Line 1 with 24/7 operation
- Stage 3: Scale Up and Facility Construction
  - Increase production capacity of Line 1 to full scale
  - Begin construction of facility to build two additional production lines

- Stage 4: Quality Systems, Equipment and Performance Qualification
  - Expansion of Quality Control (QC) systems
  - Equipment procurement, delivery, and initiation of installation
- Stage 5: Achieve Full Production Capacity
  - Capital equipment installed, qualified, and validated for two additional production lines
  - Demonstrate full IFC production capacity on all three production lines
  - Full production capacity for cartridge-based solution on 1 line

The Contractor shall accomplish the following milestones which have been defined by subtasks

- Stage A1: Multi-plex design finalized
  - Determine final design for barcoding solution and the requirements for the clinical study
- Stage A2: Cartridge-based solution design finalized
  - Determine final design for the cartridge-based solution and the requirements for the clinical study
- Stage A3 - A5: Clinical/FDA studies and EUA Submission
  - Complete clinical studies required for EUA Submission
  - Submission of EUA for cartridge-based solution
  - Purchase of clinical samples if applicable

4.0 Tasks

Tasks to be completed by the Contractor are divided into three main objectives:

1) Maximizing throughput on the existing manufacturing line to 12k IFCs per month

2) Addition of two manufacturing lines in the Singapore facility

3) Simplifying the workflow of the current RT-PCR assay by developing the cartridge-based solution.

Progress on the tasks will be included in the project workstream tracker. Updates will be provided to the COR and RADx program personnel in the weekly meetings.

5.0 Deliverables

Deliverables for the PWS include deliverables outlined in the final Statement of Objectives, and reports which shall be paired with the agreed upon Payment Schedule.

The list of milestones and deliverables for the PWS is available in Appendix 1: Cost-Price Quote.

6.0 Quality Assurance

The Contractor shall ensure that all deliverables are reviewed and edited to ensure that documents are free of typographical, grammatical and technical errors. The Contracting Officer Representative (COR), shall have final authority over the format, style, editing and content of all deliverables. Further, the contractor will be responsible for ensuring that final documents incorporate all comments, modifications, and editing recommended by the COR.

7.0 Quality Assurance Surveillance Plan (QASP)

The QASP is attached as Appendix 2. Additional quality assurance processes are included in the attached file: Fluidigm Corporate Quality Manual.

8.0 Period of Performance

The period of performance is as follows:

Base Period	[***]

9.0 Appendices

Appendix 1: Cost-Price Quote

Appendix 2: QASP

10.0 Additional Documents

Fluidigm Corporate Quality Manual

RADx #6114
Fluidigm Corporation
Letter Contract number: 75N92020C00009

QUALITY ASSURANCE SURVEILLANCE PLAN
(QASP)

PWS Appendix 2

1 INTRODUCTION

This quality assurance surveillance plan (QASP) is pursuant to the milestone deliverables attached to the Performance Work Statement (PWS) entitled Rapid Acceleration of Diagnostics (RADx) Program: Tech Project # 6114 Fluidigm – Advanta Dx SARS-CoV-2 RT-PCR Assay for Saliva. This plan sets forth the procedures and guidelines the RADx-Tech Contracting Officers and Contracting Officer's Representatives (CORs) will use in ensuring the required performance standards or service levels are achieved by the contractor.

1.1 Purpose

1.1.1 The purpose of the QASP is to describe the systematic methods used to monitor performance and to identify the required documentation and the resources to be employed. The QASP provides a means for evaluating whether the contractor is meeting the performance standards/quality levels identified in the PWS and the contractor's quality control plan (QCP), and to ensure that the government pays only for the level of services received.

1.1.2 This QASP defines the roles and responsibilities of all members of the integrated project team (IPT), identifies the performance objectives, defines the methodologies used to monitor and evaluate the contractor's performance, describes quality assurance documentation requirements, and describes the analysis of quality assurance monitoring results.

1.2 Performance Management Approach

1.2.1 The PWS structures the acquisition around "what" service or quality level is required, as opposed to "how" the contractor should perform the work (i.e., results, not compliance). This QASP will define the performance management approach taken by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to monitor and manage the contractor's performance to ensure the expected outcomes or performance objectives communicated in the PWS are achieved. Performance management rests on developing a capability to review and analyze information generated through performance assessment. The ability to make decisions based on the analysis of performance data is the cornerstone of performance management; this analysis yields information that indicates whether expected outcomes for the project are being achieved by the contractor.

1.2.2 Performance management represents a significant shift from the more traditional quality assurance (QA) concepts in several ways. Performance management focuses on assessing whether outcomes are being achieved and to what extent. This approach migrates away from scrutiny of compliance with the processes and practices used to achieve the outcome. A performance-based approach enables the contractor to play a large role in how the work is performed, as long as the proposed processes are within the stated constraints. The only exceptions to process reviews are those required by law (federal, state, and local) and compelling business situations, such as safety and health. A "results" focus provides the contractor flexibility to continuously improve and innovate over the course of the contract as long as the critical outcomes expected are being achieved and/or the desired performance levels are being met.

1.3 Performance Management Strategy

1.3.1 The contractor is responsible for the quality of all work performed. The contractor measures that quality through the contractor's own quality control (QC) program. QC is work output, not workers, and therefore includes all work performed under this contract regardless of whether the work is performed by contractor employees or by subcontractors. The contractor's quality control program (QCP) will set forth the staffing and procedures for self-inspecting the quality, timeliness, responsiveness, customer satisfaction, and other performance requirements in the PWS. The contractor will develop and implement a performance management system with processes to assess and report its performance to the designated government representative. The contractor's QCP will set forth the staffing and procedures for self-inspecting the quality, timeliness, responsiveness, customer satisfaction, and other performance requirements in the PWS. This QASP enables the government to take advantage of the contractor's QC program.

1.3.2 The government representatives will monitor performance and review performance reports/milestone deliverables furnished by the contractor. If a milestone deliverable is delayed, the contractor will be responsible for reporting the reason and providing an updated schedule.

2 ROLES AND RESPONSIBILITIES

2.1 The Contracting Officer

The Contracting Officer (CO) is responsible for monitoring contract compliance, contract administration, and cost control and for resolving any differences between the observations documented by the Contracting Officer's Representative (COR). The CO will designate one full-time COR as the government authority for performance management. The number of additional representatives serving as technical inspectors depends on the complexity of the services measured, as well as the contractor's performance, and must be identified and designated by the CO.

2.2 The Contracting Officer's Representative

The Contracting Officer's Representative (COR) is designated in writing by the CO to act as his or her authorized representative to assist in administering a contract. COR limitations are contained in the written appointment letter. The COR is responsible for technical administration of the project and ensures proper government surveillance of the contractor's performance. The COR is not empowered to make any contractual commitments or to authorize any contractual changes on the government's behalf. Any changes that the contractor deems may affect contract price, terms, or conditions shall be referred to the CO for action. The COR will have the responsibility for completing QA monitoring forms used to document the inspection and evaluation of the contractor's work performance. Government surveillance may occur under the inspection of services clause for any service relating to the contract.

3 IDENTIFICATION OF REQUIRED PERFORMANCE STANDARDS/QUALITY LEVELS

The required milestone deliverables are included in the PWS. If the contractor meets the milestone deliverable, it will be paid the representative milestone payment agreed on in the contract. If the contractor does not meet the milestone deliverable, the milestone payment will be delayed, and it will put the future milestone payments at risk.

4 METHODOLOGIES TO MONITOR PERFORMANCE

4.1 Surveillance Techniques

In an effort to minimize the performance management burden, simplified surveillance methods shall be used by the government to evaluate contractor performance when appropriate. The primary methods of surveillance are:

- 100% Inspection – As determined appropriate, the COR shall review the generated documentation and enter summary results into the Surveillance Activity Checklist.

4.2 Acceptable Performance Levels

Milestone payments will be issued upon meeting milestone deliverables.

5 QUALITY ASSURANCE DOCUMENTATION

5.1 Monitoring Form

The government's QA surveillance, accomplished by the COR, will be reported using the monitoring form in Attachment 1. The form will document the government's assessment of the contractor's performance under the contract to ensure that the required results are being achieved.

5.1.1 The COR and CO will retain a copy of all completed QA surveillance forms.

6 ANALYSIS OF QUALITY ASSURANCE ASSESSMENT

6.1 Determining Performance

6.1.1 Government shall use the monitoring methods cited to determine whether the milestone deliverables have been met. If the contractor has not met milestone deliverable, it may be asked to develop a corrective action plan to show how and by what date it intends to meet the milestone deliverable. Failure to meet the milestone deliverable may result in a delay of the milestone payment and may put future milestone payments at risk.

6.2 Reporting

6.2.1 At the end of each contract month, the COR will prepare a written report summarizing the overall results of the quality assurance surveillance of the contractor's performance. This written report will become part of the QA documentation. It will enable the government to demonstrate whether the contractor is meeting the stated objectives.

6.3 Reviews and Resolution

6.3.1 The COR may require the contractor's project manager, or a designated alternate, to meet with the CO and other government IPT personnel as deemed necessary to discuss performance evaluation. The COR will define a frequency of in-depth reviews with the contractor, including appropriate self-assessments by the contractor; however, if the need arises, the contractor will meet with the COR as often as required or per the contractor's request. The agenda of the reviews may include:

- Weekly performance assessment data and trend analysis;
- Issues and concerns of both parties;

- Projected outlook for upcoming months and progress against expected trends, including a corrective action plan analysis;
- Recommendations for improved efficiency and/or effectiveness;
- Issues arising from the performance monitoring processes.

The COR and the CO must coordinate and communicate with the contractor to resolve issues and concerns regarding marginal or unacceptable performance.

6.4 Performance Requirements

For performance requirements, see Milestone table in Cost Price Quote (Performance Work Statement, Appendix 1)

ATTACHMENT 1: SAMPLE QUALITY ASSURANCE MONITORING FORM

SERVICE: _____

_____

_____

_____

_____

SURVEY PERIOD: _____

SURVEILLANCE METHOD (Check):

Random Sampling 100% Inspection Periodic Inspection Customer Complaint

LEVEL OF SURVEILLANCE (Check):

Monthly Quarterly As needed

PERCENTAGE OF ITEMS SAMPLED DURING SURVEY PERIOD: _____ %

ANALYSIS OF RESULTS:

Observed Service Provider Performance Measurement Rate: _____%

Service Provider's Performance (Check): Meets Standards

Does Not Meet Standards

Narrative of Performance During Survey Period: _____

_____

_____

_____

_____

PREPARED BY: _____ **DATE:** _____

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FRQFHUQV H[FHHGV WKH DSSOLFDEOH WKUHVKROG VSHFLÀHG LQ) $ 5 ¬ D RQ WKH GDWH RI VXEFRQWUDFWDZ DUG WKH
VXEFRQWUDFWRUP XVWLQFOXGH ¬ -LQ ORZ HUWLHUVXEFRQWUDFWV WKDWRIIHUVXEFRQWUDFWLQJ RSSRUWXQLWLHV

YL¬ 3 URKLELWLRQ RI 6 HJUHJDWHG) DFLOLWLHV¬$ SU

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YLLL¬ (TXDO2 SSRUWXQLW\ IRU9 HWHUDQV¬- XQ ¬ -8 6 & ¬

L[¬ (TXDO2 SSRUWXQLW\ IRU: RUNHUV Z LWK ' LVDELOLWLHV¬- XQ ¬ -8 6 & ¬

[¬ (P SOR\ P HQW5 HSRUWV RQ 9 HWHUDQV¬- XQ ¬ -8 6 & ¬

[L¬ 1 RWLÀFDWLRQ RI (P SOR\ HH 5 LJKWV 8 QGHUWKH 1 DWLRQDO/ DERU5 HODWLRQV $ FW' HF ¬(2
) ORZ GRZ Q UHTXLUHG LQ DFFRUGDQFH Z LWK SDUDJUDSK I RI) $ 5 FODXVH ¬

[LL¬ 6 HUYLFH & RQWUDFW/ DERU6 WDQGDUGV $ XJ -8 6 & -FKDSWHU¬

[LLL¬$ ¬ & RP EDWLQJ 7UDIÀFNLQJ LQ 3 HUVRQV¬- DQ ¬ -8 6 & -FKDSWHU¬ -DQG (2

%-$ OWHUQDWH , 0 DU RI¬ ¬ -8 6 & -FKDSWHU¬ -DQG (2 ¬

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& DOLEUDWLRQ RU5 HSDLURI & HUWDLQ (TXLSP HQW5 HTXLUHP HQWV 0 D\ -8 6 & -FKDSWHU¬

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6 HUYLFHV 5 HTXLUHP HQWV¬0 D\ ¬ -8 6 & -FKDSWHU¬

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[YLL¬ 0 LQLP XP : DJHV 8 QGHU([HFXWLYH 2 UGHU ¬' HF

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[L[¬$ ¬ 3 ULYDF\ 7UDLQLQJ - DQ -8 6 & ¬ D

%-$ OWHUQDWH ,¬- DQ -RI¬

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[[L¬ 3 URP RWLQJ ([FHVV) RRG ' RQDWLRQ WR 1 RQSURÀW2 UJDQL]DWLRQV¬- XQ ¬ -8 6 & ¬) ORZ
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DGGLWLRQDOFODXVHV QHFHVVDU\ WR VDWLVI\ LWV FRQWUDFWXDOREOLJDWLRQV

(QG RI FODXVH

RADx Proposal Modifications: 1/15/2021				
Date	Milestone	Deliverable	Amount	Prism Line item #
[***]	[***]	[***]	[***]	1
[***]	[***]	[***]	[***]	2
[***]	[***]	[***]	[***]	3
[***]	[***]	[***]	[***]	6
[***]	[***]	[***]	[***]	9
[***]	[***]	[***]	[***]	10
[***]	[***]	[***]	[***]	11
[***]	[***]	[***]	[***]	12
[***]	[***]	[***]	[***]	13
[***]	[***]	[***]	[***]	14
[***]	[***]	[***]	[***]	15
[***]	[***]	[***]	[***]	16
[***]	[***]	[***]	[***]	17
[***]	[***]	[***]	[***]	

		Total	$34,016,056

Exhibit 10.1

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE OF PAGES
			1 / 10

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00003	See Block 16C		

6. ISSUED BY CODE	NHLBI	7. ADMINISTERED BY *(If other than item 6)* CODE	NIBIB
National Institutes of Health National Heart, Lung, and Blood Institute Bethesda, MD 20892-7511		National Institutes of Health National Institute of Biomedical Imaging and Bioengineering Bethesda, MD 20892-7511	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		
FLUIDIGM CORPORATION:1157584 2 TOWER PLACE SUITE 2000 SOUTH SAN FRANCISCO CA 940801826	(x)	9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED *(SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. 75N92020C00009
		10B. DATED *(SEE ITEM 13)* 07/30/2020
CODE FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

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

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
X	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	OTHER *(Specify type of modification and authority)*

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

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

The purpose of this Modification is to amend "Article B.2 Prices" and to attach the revised Performance Work Statement and deliverable schedule with updated milestones for A2, A3 and A4.

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All other terms and conditions of this contract remain the same.

Discount Terms: PROMPT PAY

Continued …

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*			16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*		
Andrew Quong, CSO			ROXANE S. BURKETT		
15B. CONTRACTOR/OFFEROR	Digitally signed by Andrew Quong Date: 2021.05.06 16:30:07 -07'00'	15C. DATE SIGNED	1 16B. UNITED STATES OF AMERICA	Digitally signed by Roxane S. Burkett -S Date: 2021.05.10 11:06:41 -04'00'	16C. DATE SIGNED
/s/ Andrew Quong			/s/ Roxane S. Burkett -S		
(Signature of person authorized to sign)			*(Signature of Contracting Officer)*		

STANDARD FORM 30 (REV. 11/2016)
Previous edition unusable Prescribed by GSA FAR (48 CFR) 53.243

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

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NAME OF OFFEROR OR CONTRACTOR
FLUIDIGM CORPORATION:1157584

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Payment: Approved By, NHLBI Branch A Invoice Paid By: NIH Commercial Accounts Br 2115 East Jefferson St, MSC 8500 Room 4B-432 Bethesda, MD 20892-8500 Period of Performance: [***] Change Item 12 to read as follows (amount shown is the obligated amount) :				
12	[***] Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING				[***]
	Change Item 13 to read as follows (amount shown is the obligated amount) :				
13	[***] Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING				[***]
	Change Item 14 to read as follows (amount shown is the obligated amount) :				
14	[***] Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING				[***]

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

BEGINNING WITH THE EFFECTIVE DATE OF THIS MODIFICATION, THE GOVERNMENT AND THE CONTRACTOR MUTUALLY AGREE AS FOLLOWS:

ARTICLE B.2. PRICES shall be amended by updating the milestone dates for A2, A3 and A4:

ARTICLE B.2. PRICES

a. The total Firm Fixed Price (FFP) amount for this contract is $34,016,056.

Prism Line Item	Milestone	**Invoice Line Item** - description	Date	Amount
9	4	**Equipment Procurement, Construction, Initiation of Installation - [***]**	[***]	[***]
10	5	**Equipment Installation - [***]**	[***]	[***]
11	6	**Performance Qualification - [***]**	[***]	[***]
12	A2	**Design Lock - [***]**	[***]	[***]
13	A3	**Clinical Studies - [***]**	[***]	[***]
14	A4	**Submit EUA to FDA - [***]**	[***]	[***]
15	A5	**Clinical Samples - [***]**	[***]	[***]
16	7a	**Full Production Capacity on Line 2 - [***]**	[***]	[***]
17	7b	**Full Production Capacity on Line 3 - [***]**	[***]	[***]
18	8	**Final Report - [***]**	[***]	[***]
			Total	**$34,016,056**

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

MODIFICATION OF CONTRACT CONTINUATION PAGE
Contract No. 75N92020C00009
Modification P0003

ARTICLE C.1. STATEMENT OF OBJECTIVES shall be amended and read as follows:
Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Objectives, dated July 27, 2020 and the Performance Work Statement (PWS) dated January 19, 2021, set forth in SECTION J – List of Attachments, attached hereto and made a part of this Contract. Work to be performed shall be consistent with the application and preliminary work file submitted by the Contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through contract award.

ARTICLE C.2. REPORTING REQUIREMENTS shall be amended and read as follows:
All reports required herein shall be submitted in electronic format only. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

The following reporting requirements shall be submitted electronically to the Contracting Officer and Contracting Officer's Representative in accordance with the due dates specified below:

Item No.	Reporting Requirements	Due Date
1	Bi-weekly Production Status Report – to include the following: • current plant production capacity and output on a per-week basis, • a breakdown of capacity and output on a per-line/per week basis, • a description of any issues/problems encountered with plans for solution/mitigation (e.g., delays in meeting deliverables, supply chain issues, design/validation issues, etc.) • sales reporting to include the name and kind of organization, as well as the number of IFCs sold to that organization during the reporting period. Sales reports may be submitted in every other bi-weekly report (i.e. monthly).	[***]
2	Final Report - Summary of salient results of the entire contract period, including number of lines built, production capacity over time, production output over time, and a summary of the sales reports. It shall include evidence of sustained production at capacity levels or higher assuming demand has not decreased.	[***]

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

MODIFICATION OF CONTRACT CONTINUATION PAGE
Contract No. 75N92020C00009
Modification P0003

ARTICLE F.1. PERIOD OF PERFORMANCE shall be amended and read as follows:
The period of performance of the contract is **[***].**

ARTICLE F.2. DELIVERIES shall be amended and read as follows:
Satisfactory performance shall be deemed to occur upon performance of the work described in the Statement of Objectives Article in SECTION C of this Contract and upon notice and acceptance by the Contracting Officer, or the duly authorized representative, in accordance with the stated deliverables schedule as listed in the Performance Work Statement (PWS) dated January 19, 2021 (See Attachment 2).

The deliverables or documentation shall be submitted to the Contracting Officer and designated Contracting Officer Representative (COR) by email.

SECTION J - LIST OF ATTACHMENTS shall be amended and read as follows:

1. Performance Work Statement dated January 19, 2021
   Appendix 1: Cost-Price Quote

All other terms and conditions of the contract remain the same.

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

RADx #6114
Fluidigm Corporation
Letter Contract number: 75N92020C00009

Performance Work Statement

PWS Title: Rapid Acceleration of Diagnostics (RADx) Program: Tech Project # 6114 Fluidigm – Advanta Dx SARS-CoV-2 RT-PCR Assay for Saliva

1.0 Background

Fluidigm has developed a diagnostic molecular test for the qualitative detection of SARS-CoV-2 in saliva specimens under FDA Emergency Use Authorization (EUA). The Advanta™ Dx SARS-CoV-2 RT-PCR Assay is a qPCR-based test that, by taking advantage of Fluidigm's proprietary microfluidics technology and Juno™ and Biomark™ HD systems, enables high throughput and scalable testing of saliva samples from patients suspected of COVID-19 (coronavirus) infection. Featuring extraction-free sample processing, a modular workflow and large batch-sample size, the Advanta Dx SARS-CoV-2 RT-PCR Assay aims to meet the RADx goal of enhance laboratory SARS-CoV-2 testing capacity.

Fluidigm's BioMark HD microfluidics platform addresses the massive demand for SARS-CoV-2PCR testing- combining speed, minimal cost, and massive throughput unparalleled in the industry. Further advantages include flexibility to rapidly integrate new mutational markers or increase panel size to include additional infectious agents. This platform works with all clinical sample types.

Our solution leverages Advanta™ Dx SARS-CoV-2 RT-PCR Assay submitted for an EUA, and two assays under development that can change the landscape for detection. This assay allows for up to 6000 samples per day on a single system. Additional assays address different needs in testing, throughput, specificity and sensitivity.

Our technology offers significant advantages overcoming many supply chain barriers and provides a robust platform for scale up of testing for SARS-CoV-2.

Fluidigm has been able to detect both N1 and N2 SARS-CoV-2 targets across all samples provided by Washington University, including the lowest dilution (10 cp/ul). Highlights from that work are the detection of:

- 10 copies in the reaction using 4 ul of saliva sample
- 1.x copies in the reaction using 1 ul of saliva sample
- Across all dilution buffer and RNase inhibitor conditions

Of the amplification chemistries tested, optimum results were obtained from the FLDM 1-Step RT-PCR Master Mix, 2.5 hour 1-step RT-PCR protocol.

2.0 Objectives

The baseline technology provided in Fluidigm's EUA filing allows for performing 6000 tests per day on each Biomark HD system and Fluidigm currently has the ability to manufacture approximately 50,000 tests per day. The rate limiting component is the Integrated Fluidic Circuit (IFC), which is the microfluidic chip that is required for running the assay. The two types of IFCs described herein are the 192.24 IFC which is used in the current Advanta™ Dx SARS-CoV-2 RT-PCR Assay under EUA, and cartridge-based solution IFC which is the basis for a simplified workflow. Each 192.24 IFC has the capacity to run 192 tests and each cartridge-based solution IFC has the capacity to run 96 tests. This project has

two major deliverables: 1) to increase manufacturing capacity of IFCs and to develop and 2) to manufacture a cartridge-based solution that will simplify the workflow and increase the likelihood of sales and deployment of the COVID tests to a broader customer base.

The cartridge-based solution incorporates two independent reactions necessary to process the sample into the same chip to simplify the overall workflow. Compared to the 192.24 IFC approach, each individual sample in the cartridge-based solution increases the number of reaction chambers in the microfluidic chip. Thus, the overall sample capacity of the chip is reduced as there is more chemistry being performed on chip. As a result, switching to the production of the cartridge will result in a simplified workflow but lower volume of tests because it has half the sample capacity of the 192.24 IFC.

The cartridge-based solution requires the redevelopment of the assay to include on IFC Reverse Transcription and a solid-phase bead-based capture of the target nucleic acid sequences. This solid-phase bead-based capture is a novel addition which is a departure from the EUA for the Advanta Dx SARS-CoV-2 assay. Therefore, the full development of the cartridge-based assay will require a new clinical study and EUA submission.

The limiting factor to Fluidigm provided testing is the manufacture of the IFCs. This is because the Fluidigm test does not require extraction, and only nano-liters of reagents are used for each PCR reaction. Scale up for IFC production will occur in Fluidigm's Singapore facility by first maximizing production in the existing manufacturing line which will increase production capacity to 12,000 IFCs per month from the current 7,000 per month. Simultaneously, Fluidigm will add two additional manufacturing lines to the Singapore facility which will ultimately provide manufacturing capacity of 36,000 IFCs per month. The investment into the capital equipment to construct additional manufacturing lines and expand the production of the IFCs can be leveraged to produce the cartridge-based solution. The cartridge-based solution requires a new process and molds but uses the existing equipment.

3.0 Scope

Fluidigm will deploy a complete testing solution using a saliva based, extraction free, viral detection assay for broad distribution. This section describes the scope of work for RADx 6114.

Currently Fluidigm has the capability to deliver testing capacity of approximately 50,000 tests/day. The cartridge-based solution will deliver testing capacity of up to 115,200 tests/day by Q3 2021.

The Contractor shall accomplish the following milestones in the stages outlined below:

- Stage 1: Test Verification
  - Deliver 1plex tests to Verification Core at Emory University
  - Provide final report from the Verification Core
- Stage 2: Scale Up
  - Increase production capacity of Line 1 with 24/7 operation
- Stage 3: Scale Up and Facility Construction
  - Increase production capacity of Line 1 to full scale
  - Begin construction of facility to build two additional production lines

- Stage 4: Quality Systems, Equipment and Performance Qualification
  - Expansion of Quality Control (QC) systems
  - Equipment procurement, delivery, and initiation of installation
- Stage 5: Achieve Full Production Capacity
  - Capital equipment installed, qualified, and validated for two additional production lines
  - Demonstrate full IFC production capacity on all three production lines
  - Full production capacity for cartridge-based solution on 1 line

The Contractor shall accomplish the following milestones which have been defined by subtasks

- Stage A1: Multi-plex design finalized
  - Determine final design for barcoding solution and the requirements for the clinical study
- Stage A2: Cartridge-based solution design finalized
  - Determine final design for the cartridge-based solution and the requirements for the clinical study
- Stage A3 - A5: Clinical/FDA studies and EUA Submission
  - Complete clinical studies required for EUA Submission
  - Submission of EUA for cartridge-based solution
  - Purchase of clinical samples if applicable

4.0 Tasks

Tasks to be completed by the Contractor are divided into three main objectives:

1) Maximizing throughput on the existing manufacturing line to 12k IFCs per month

2) Addition of two manufacturing lines in the Singapore facility

3) Simplifying the workflow of the current RT-PCR assay by developing the cartridge-based solution.

Progress on the tasks will be included in the project workstream tracker. Updates will be provided to the COR and RADx program personnel in the weekly meetings.

5.0 Deliverables

Deliverables for the PWS include deliverables outlined in the final Statement of Objectives, and reports which shall be paired with the agreed upon Payment Schedule.

The list of milestones and deliverables for the PWS is available in Appendix 1: Cost-Price Quote.

6.0 Quality Assurance

The Contractor shall ensure that all deliverables are reviewed and edited to ensure that documents are free of typographical, grammatical and technical errors. The Contracting Officer Representative (COR), shall have final authority over the format, style, editing and content of all deliverables. Further, the contractor will be responsible for ensuring that final documents incorporate all comments, modifications, and editing recommended by the COR.

7.0 Quality Assurance Surveillance Plan (QASP)

The QASP is attached as Appendix 2. Additional quality assurance processes are included in the attached file: Fluidigm Corporate Quality Manual.

8.0 Period of Performance

The period of performance is as follows:

Base Period	[***]

9.0 Appendices

Appendix 1: Cost-Price Quote

Appendix 2: QASP

10.0 Additional Documents

Fluidigm Corporate Quality Manual

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

RADx Proposal Modifications: 1/15/2021				
Date	Milestone	Deliverable	Amount	Prism Line Item #
[***]	[***]	[***]	[***]	1
[***]	[***]	[***]	[***]	2
[***]	[***]	[***]	[***]	3
[***]	[***]	[***]	[***]	6
[***]	[***]	[***]	[***]	9
[***]	[***]	[***]	[***]	10
[***]	[***]	[***]	[***]	11
[***]	[***]	[***]	[***]	12
[***]	[***]	[***]	[***]	13
[***]	[***]	[***]	[***]	14
[***]	[***]	[***]	[***]	15
[***]	[***]	[***]	[***]	16
[***]	[***]	[***]	[***]	17
[***]	[***]	[***]	[***]	

				18
		Total	**$34,016,056**	

Exhibit 10.1

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AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE	PAGE OF PAGES
				1 / 6

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00004	See Block 16C		

6. ISSUED BY CODE	NHLBI	7. ADMINISTERED BY *(If other than Item 6)* CODE	NIBIB
National Institutes of Health National Heart, Lung, and Blood Institute Bethesda, MD 20892-7511		National Institutes of Health National Institute of Biomedical Imaging and Bioengineering Bethesda, MD 20892-7511	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		
FLUIDIGM CORPORATION:1157584 2 TOWER PLACE SUITE 2000 SOUTH SAN FRANCISCO CA 940801826	(x)	9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED *(SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. 75N92020C00009
		10B. DATED *(SEE ITEM 13)* 07/30/2020
CODE FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

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

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

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	OTHER *(Specify type of modification and authority)* FAR 52.243-1 Changes-Fixed Price (August 1987)

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

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

The purpose of this Modification is to extend the Period of Performance of this contract and to amend "Article B.2 Prices" and to attached the revised Performance Work Statement and deliverable schedule with updated milestones for A2, A3, A4, 7b and 8.

The Period of Performance has changed from July 30, 2020 to September 30, 2021 to July 30, 2021 to December 30, 2021.

All other terms and conditions of this contract remain the same.
Discount Terms: PROMPT PAY

Continued …

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

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
Andrew Quong, CSO		ROXANE S. BURKETT	
15B. CONTRACTOR/OFFEROR Digitally signed by Andrew Quong /s/ Andrew Quong *(Signature of person authorized to sign)*	15C. DATE SIGNED 09/28/2021	16B. UNITED STATES OF AMERICA Digitally signed by Roxane S. Burkett -S /s/ Roxane S. Burkett -S *(Signature of Contracting Officer)*	16C. DATE SIGNED 09/29/2021

STANDARD FORM 30 (REV. 11/2016)
Previous edition unusable Prescribed by GSA FAR (48 CFR) 53.243

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

ITEM NO. (A)	
	Payment: Approved By, NHLBI Branch A Invoice Paid By: NIH Commercial Accounts Br 2115 East Jefferson St, MSC 8500 Room 4B-432 Bethesda, MD 20892-8500 Period of Performance: [***] Change Item 12 to read as follows (amount shown is the obligated amount) :
12	[***] Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Change Item 13 to read as follows (amount shown is the obligated amount) :
13	[***] Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Project Data: 151201.2020.300.COVID-19.DIAG.HN81 NIBIB OD OFFICE OF THE DIRECTOR.25235 ALL OTHER NON-FED SERVCS.02/17/2021 Accounting Info: 08039820200DAD.2021.83.8100.EM81000000C.E.C4400.40 6.COVD.25235.61000001.9999.9999.9999 Funded: [***]

Continued...

NAME OF OFFEROR OR CONTRACTOR

FLUIDIGM CORPORATION:1157584

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Change Item 14 to read as follows (amount shown is the obligated amount) :				
14	[***] Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Project Data: 151201.2020.300.COVID-19.DIAG.HN81 NIBIB OD OFFICE OF THE DIRECTOR.25235 ALL OTHER NON-FED SERVCS.02/17/2021 Accounting Info: 08039820200DAD.2021.83.8100.EM81000000C.E.C4400.406.COVD.25235.61000001.9999.9999.9999 Funded: [***} Change Item 17 to read as follows (amount shown is the obligated amount) :				[***]
17	[***] Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Project Data: 151201.2020.300.COVID-19.DIAG.HN81 NIBIB OD OFFICE OF THE DIRECTOR.25235 ALL OTHER NON-FED SERVCS.02/17/2021 Accounting Info: 08039820200DAD.2021.83.8100.EM81000000C.E.C4400.406.COVD.25235.61000001.9999.9999.9999 Funded: [***] Change Item 18 to read as follows (amount shown is the obligated amount) :				[***]
18	[***] Obligated Amount: [***] Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Continued ...				[***]

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

NAME OF OFFEROR OR CONTRACTOR

FLUIDIGM CORPORATION:1157584

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Product/Service Description: MEDICAL- LABORATORY TESTING Project Data: 151201.2020.300.COVID-19.DIAG.HN81 NIBIB OD OFFICE OF THE DIRECTOR.25235 ALL OTHER NON-FED SERVCS.02/17/2021 Accounting Info: 08039820200DAD.2021.83.8100.EM81000000C.E.C4400.406.COVD.25235.61000001.9999.9999.9999 Funded: [***]				

BEGINNING WITH THE EFFECTIVE DATE OF THIS MODIFICATION, THE GOVERNMENT AND THE CONTRACTOR MUTUALLY AGREE AS FOLLOWS:

ARTICLE B.2. PRICES shall be amended by updating the milestone dates for A2, A3, A4, 7B and 8:

ARTICLE B.2. PRICES

a. The total Firm Fixed Price (FFP) amount for this contract is $34,016,056.

Prism Line Item	Milestone	**Invoice Line Item** - description	Date	Amount
9	4	**Equipment Procurement, Construction, Initiation of Installation - [***]**	[***]	[***]
10	5	**Equipment Installation - [***]**	[***]	[***]
11	6	**Performance Qualification - [***]**	[***]	[***]
12	A2	**Design Lock - [***]**	[***]	[***]
13	A3	**Clinical Studies - [***]**	[***]	[***]
14	A4	**Submit EUA to FDA - [***]**	[***]	[***]
15	A5	**Clinical Samples - [***]**	[***]	[***]
16	7a	**Full Production Capacity on Line 2 - [***]**	[***]	[***]
17	7b	**Full Production Capacity on Line 3 - [***]**	[***]	[***]
18	8	**Final Report - [***]**	[***]	[***]
			Total	**$34,016,056**

ARTICLE C.1. STATEMENT OF OBJECTIVES shall be amended and read as follows:
Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Objectives, dated July 27, 2020 and the Performance Work Statement (PWS) dated January 19, 2021, set forth in SECTION J – List of Attachments, attached hereto and made a part of this Contract. Work to be performed shall be consistent with the application and preliminary work file submitted by the Contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through contract award.

ARTICLE C.2. REPORTING REQUIREMENTS shall be amended and read as follows:
All reports required herein shall be submitted in electronic format only. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

The following reporting requirements shall be submitted electronically to the Contracting Officer and Contracting Officer's Representative in accordance with the due dates specified below:

Item No.	Reporting Requirements	Due Date
1	Bi-weekly Production Status Report – to include the following: • current plant production capacity and output on a per-week basis, • a breakdown of capacity and output on a per-line/per week basis, • a description of any issues/problems encountered with plans for solution/mitigation (e.g., delays in meeting deliverables, supply chain issues, design/validation issues, etc.) • sales reporting to include the name and kind of organization, as well as the number of IFCs sold to that organization during the reporting period. Sales reports may be submitted in every other bi-weekly report (i.e. monthly).	[***]
2	Final Report - Summary of salient results of the entire contract period, including number of lines built, production capacity over time, production output over time, and a summary of the sales reports. It shall include evidence of sustained production at capacity levels or higher assuming demand has not decreased.	[***]

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MODIFICATION OF CONTRACT CONTINUATION PAGE
Contract No. 75N92020C00009
Modification P0004

ARTICLE F.1. PERIOD OF PERFORMANCE shall be amended and read as follows:
The period of performance of the contract is **[***].**

ARTICLE F.2. DELIVERIES shall be amended and read as follows:
Satisfactory performance shall be deemed to occur upon performance of the work described in the Statement of Objectives Article in SECTION C of this Contract and upon notice and acceptance by the Contracting Officer, or the duly authorized representative, in accordance with the stated deliverables schedule as listed in the Performance Work Statement (PWS) dated January 19, 2021 (See Attachment 2).

The deliverables or documentation shall be submitted to the Contracting Officer and designated Contracting Officer Representative (COR) by email.

SECTION J - LIST OF ATTACHMENTS shall be amended and read as follows:

1. Performance Work Statement dated January 19, 2021
   Appendix 1: Cost-Price Quote

All other terms and conditions of the contract remain the same.

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

RADx #6114
Fluidigm Corporation
Letter Contract number: 75N92020C00009

Performance Work Statement

PWS Title: Rapid Acceleration of Diagnostics (RADx) Program: Tech Project # 6114 Fluidigm – Advanta Dx SARS-CoV-2 RT-PCR Assay for Saliva

1.0 Background

Fluidigm has developed a diagnostic molecular test for the qualitative detection of SARS-CoV-2 in saliva specimens under FDA Emergency Use Authorization (EUA). The Advanta™ Dx SARS-CoV-2 RT-PCR Assay is a qPCR-based test that, by taking advantage of Fluidigm's proprietary microfluidics technology and Juno™ and Biomark™ HD systems, enables high throughput and scalable testing of saliva samples from patients suspected of COVID-19 (coronavirus) infection. Featuring extraction-free sample processing, a modular workflow and large batch-sample size, the Advanta Dx SARS-CoV-2 RT-PCR Assay aims to meet the RADx goal of enhance laboratory SARS-CoV-2 testing capacity.

Fluidigm's BioMark HD microfluidics platform addresses the massive demand for SARS-CoV-2PCR testing- combining speed, minimal cost, and massive throughput unparalleled in the industry. Further advantages include flexibility to rapidly integrate new mutational markers or increase panel size to include additional infectious agents. This platform works with all clinical sample types.

Our solution leverages Advanta™ Dx SARS-CoV-2 RT-PCR Assay submitted for an EUA, and two assays under development that can change the landscape for detection. This assay allows for up to 6000 samples per day on a single system. Additional assays address different needs in testing, throughput, specificity and sensitivity.

Our technology offers significant advantages overcoming many supply chain barriers and provides a robust platform for scale up of testing for SARS-CoV-2.

Fluidigm has been able to detect both N1 and N2 SARS-CoV-2 targets across all samples provided by Washington University, including the lowest dilution (10 cp/ul). Highlights from that work are the detection of:

- 10 copies in the reaction using 4 ul of saliva sample
- 1.x copies in the reaction using 1 ul of saliva sample
- Across all dilution buffer and RNase inhibitor conditions

Of the amplification chemistries tested, optimum results were obtained from the FLDM 1-Step RT-PCR Master Mix, 2.5 hour 1-step RT-PCR protocol.

2.0 Objectives

The baseline technology provided in Fluidigm's EUA filing allows for performing 6000 tests per day on each Biomark HD system and Fluidigm currently has the ability to manufacture approximately 50,000 tests per day. The rate limiting component is the Integrated Fluidic Circuit (IFC), which is the microfluidic chip that is required for running the assay. The two types of IFCs described herein are the 192.24 IFC which is used in the current Advanta™ Dx SARS-CoV-2 RT-PCR Assay under EUA, and a cartridge-based solution IFC which is the basis for a simplified workflow. Each 192.24 IFC has the capacity to run 192 tests and each cartridge-based solution IFC has the capacity to run 96 tests. This project has

two major deliverables: 1) to increase manufacturing capacity of IFCs and to develop and 2) to manufacture a cartridge-based solution that will simplify the workflow and increase the likelihood of sales and deployment of the COVID tests to a broader customer base.

The cartridge-based solution incorporates two independent reactions necessary to process the sample into the same chip to simplify the overall workflow. Compared to the 192.24 IFC approach, each individual sample in the cartridge-based solution increases the number of reaction chambers in the microfluidic chip. Thus, the overall sample capacity of the chip is reduced as there is more chemistry being performed on chip. As a result, switching to the production of the cartridge will result in a simplified workflow but lower volume of tests because it has half the sample capacity of the 192.24 IFC. Furthermore, the cartridge IFC will require more time for both manufacturing and quality control compared to the 192.24 IFC. While the expected initial production capacity is expected to be lower than the established 192.24 IFC production capacity, Fluidigm historically demonstrated that on average, IFC yield can be expected to increase from pilot phase to maturity (3 quarter) by approximately 20%.

The cartridge-based solution requires the redevelopment of the assay to include the use of extracted RNA from nasal pharyngeal (NP) samples as input. The addition of RNA extraction to the assay workflow is a departure from the EUA for the Advanta Dx SARS-CoV-2 assay. Therefore, the full development of the cartridge-based assay will require a new clinical study and new EUA submission. This cartridge-based assay complements the Advanta Dx SARS-CoV2 assay by providing an NP-based test in addition to the saliva-based test already on market.

The limiting factor to Fluidigm provided testing is the manufacture of the IFCs. This is because the Advanta Dx SARS-CoV2 assay does not require extraction, and only nano-liters of reagents are used for each PCR reaction. Scale up for IFC production will occur in Fluidigm's Singapore facility by first maximizing production in the existing manufacturing line which will increase production capacity to 12,000 IFCs per month from the current 7,000 per month. Simultaneously, Fluidigm will add two additional manufacturing lines to the Singapore facility which will ultimately provide manufacturing capacity of 36,000 IFCs per month. The investment into the capital equipment to construct additional manufacturing lines and expand the production of the IFCs can be leveraged to produce the cartridge-based solution. The cartridge-based solution requires a new process and molds but uses the existing equipment.

3.0 Scope

Fluidigm will deploy the Advanta Dx SARS-CoV2 assay, a complete testing solution using a saliva based, extraction free, viral detection assay for broad distribution. Fluidigm will also develop an NP extracted RNA based viral detection assay. This section describes the scope of work for RADx 6114.

Currently Fluidigm has the capability to deliver testing capacity of approximately 50,000 tests/day. The cartridge-based solution will deliver testing capacity of up to 115,200 tests/day by Q3 2021.

The Contractor shall accomplish the following milestones in the stages outlined below:

- Stage 1: Test Verification
    - Deliver 1plex tests to Verification Core at Emory University
    - Provide final report from the Verification Core

- Stage 2: Scale Up
  - Increase production capacity of Line 1 with 24/7 operation
- Stage 3: Scale Up and Facility Construction
  - Increase production capacity of Line 1 to full scale
  - Begin construction of facility to build two additional production lines
- Stage 4: Quality Systems, Equipment and Performance Qualification
  - Expansion of Quality Control (QC) systems
  - Equipment procurement, delivery, and initiation of installation
- Stage 5: Achieve Full Production Capacity
  - Capital equipment installed, qualified, and validated for two additional production lines
  - Demonstrate full IFC production capacity on all three production lines
    - 192.24 IFC production on Line 1 (see Stage 2 Scale Up)
    - 192.24 IFC production on Line 2
    - Cartridge IFC production on Line 3

The Contractor shall accomplish the following milestones which have been defined by subtasks

- Stage A1: Multi-plex design finalized
  - Determine final design for barcoding solution and the requirements for the clinical study
- Stage A2: Cartridge-based solution design finalized
  - Determine final design for the cartridge-based solution and the requirements for the clinical study
- Stage A3 - A5: Clinical/FDA studies and EUA Submission
  - Complete clinical studies required for EUA Submission
  - Submission of EUA for cartridge-based solution
  - Purchase of clinical samples if applicable

4.0 Tasks

Tasks to be completed by the Contractor are divided into three main objectives:

1) Maximizing throughput on the existing manufacturing line to 12k IFCs per month

2) Addition of two manufacturing lines in the Singapore facility

3) Simplifying the workflow of the current RT-PCR assay by developing the cartridge-based solution.

Progress on the tasks will be included in the project workstream tracker. Updates will be provided to the COR and RADx program personnel in the weekly meetings.

5.0 Deliverables

Deliverables for the PWS include deliverables outlined in the final Statement of Objectives, and reports which shall be paired with the agreed upon Payment Schedule.

The list of milestones and deliverables for the PWS is available in Appendix 1: Cost-Price Quote.

6.0 Quality Assurance

The Contractor shall ensure that all deliverables are reviewed and edited to ensure that documents are free of typographical, grammatical, and technical errors. The Contracting Officer Representative (COR), shall have final authority over the format, style, editing, and content of all deliverables. Further, the contractor will be responsible for ensuring that final documents incorporate all comments, modifications, and editing recommended by the COR.

7.0 Quality Assurance Surveillance Plan (QASP)

The QASP is attached as Appendix 2. Additional quality assurance processes are included in the attached file: Fluidigm Corporate Quality Manual.

8.0 Period of Performance

The period of performance is as follows:

Base Period	[***]

9.0 Appendices

Appendix 1: Cost-Price Quote

Appendix 2: QASP

10.0 Additional Documents

Fluidigm Corporate Quality Manual

Certain identified information marked with [***] has been excluded from this exhibit because it is not material and is of the type that the registrant treats as private and confidential.

			RADx Proposal Modifications: 6
Date	Milestone	Deliverable	Amount
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
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[***]	[***]	[***]	[***]
		Total	**$34,016,056**