ORDER FOR SUPPLIES OR SERVICES

PAGE 1 OF 33

1 CONTRACT/PURCH ORDER/ AGREEMENT NO	2 DELIVERY ORDER/ CALL NO	3 DATE OF ORDER/CALL (YYYYMMMDD)	4 REQ / PURCH REQUEST NO	5 PRIORITY
W81XWH-16-D-0009	W81XWH20F0253	2020 Jun 15	0011505652	

6. ISSUED BY CODE W81XWH
USA MED RESEARCH ACQ ACTIVITY
820 CHANDLER ST
FORT DETRICK MD 21702-5014

7. ADMINISTERED BY *(if other than 6)* CODE
SEE ITEM 6

8. DELIVERY FOB
[X] DESTINATION
[ ] OTHER
(See Schedule if other)

9. CONTRACTOR CODE 3KJL6 FACILITY
NAME AND ADDRESS
INBIOS INTERNATIONAL INC
(b) (6)
307 WESTLAKE AVE N STE 300
SEATTLE WA 98109-5235

10 DELIVER TO FOB POINT BY (Date) *(YYYYMMMDD)*
SEE SCHEDULE

11. MARK IF BUSINESS IS
[ ] SMALL
[ ] SMALL DISADVANTAGED
[ ] WOMEN-OWNED

12 DISCOUNT TERMS
Net 30 Days

13. MAIL INVOICES TO THE ADDRESS IN BLOCK
See Item 15

14. SHIP TO CODE W23RYX
USA MED RESEARCH MAT CMD
(b) (6)
1430 VETERANS DRIVE
FORT DETRICK MD 21702-5009

15. PAYMENT WILL BE MADE BY CODE HQ0490
DFAS-INDY VP GFEBS
8899 E 56TH STREET
INDIANAPOLIS IN 46249-3800

MARK ALL PACKAGES AND PAPERS WITH IDENTIFICATION NUMBERS IN BLOCKS 1 AND 2.

16. TYPE OF ORDER			
	DELIVERY/ CALL	X	This delivery order/call is issued on another Government agency or in accordance with and subject to terms and conditions of above numbered contract
	PURCHASE		Reference your quote dated Furnish the following on terms specified herein REF:

ACCEPTANCE. THE CONTRACTOR HEREBY ACCEPTS THE OFFER REPRESENTED BY THE NUMBERED PURCHASE ORDER AS IT MAY PREVIOUSLY HAVE BEEN OR IS NOW MODIFIED, SUBJECT TO ALL OF THE TERMS AND CONDITIONS SET FORTH, AND AGREES TO PERFORM THE SAME.

NAME OF CONTRACTOR | SIGNATURE | TYPED NAME AND TITLE | DATE SIGNED (YYYYMMMDD)

[ ] If this box is marked, supplier must sign Acceptance and return the following number of copies

17. ACCOUNTING AND APPROPRIATION DATA/ LOCAL USE
See Schedule

18. ITEM NO.	19. SCHEDULE OF SUPPLIES/ SERVICES	20. QUANTITY ORDERED/ ACCEPTED*	21. UNIT	22. UNIT PRICE	23. AMOUNT
	SEE SCHEDULE				

** If quantity accepted by the Government is same as quantity ordered, indicate by X. If different, enter actual quantity accepted below quantity ordered and encircle.*

24. UNITED STATES OF AMERICA
TEL: (301) 619-2779
EMAIL: patrick.k.harris11.civ@mail.mil
BY: PATRICK K HARRIS CONT (b) (6)

25. TOTAL $2,478,537.50
26. DIFFERENCES

27a. QUANTITY IN COLUMN 20 HAS BEEN
[ ] INSPECTED [ ] RECEIVED [ ] ACCEPTED, AND CONFORMS TO THE CONTRACT EXCEPT AS NOTED

b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE | c. DATE (YYYYMMMDD) | d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE

f. TELEPHONE NUMBER | g. E-MAIL ADDRESS

36. I certify this account is correct and proper for payment.
a. DATE (YYYYMMMDD) | b. SIGNATURE AND TITLE OF CERTIFYING OFFICER

28. SHIP NO. | 29. DO VOUCHER NO. | 30. INITIALS

[ ] PARTIAL [ ] FINAL

31. PAYMENT
[ ] COMPLETE [ ] PARTIAL [ ] FINAL

32. PAID BY

33. AMOUNT VERIFIED CORRECT FOR

34. CHECK NUMBER

35. BILL OF LADING NO.

37. RECEIVED AT	38. RECEIVED BY	39. DATE RECEIVED (YYYYMMMDD)	40. TOTAL CONTAINERS	41. S/R ACCOUNT NO	42. S/R VOUCHER NO.

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001		1	Job		$(b) (4) NTE

FDA EUA Antigen Detection FDA Fast Track
CPFF
FDA EUA Antigen Detection- FDA Fast Track; Serology assay optimization as described in the Statement of Work.
FOB: Destination
PURCHASE REQUEST NUMBER: 0011505652
PSC CD: AJ53

ESTIMATED COST	$(b) (4)
FIXED FEE	$(b) (4)
TOTAL EST COST + FEE	$(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101					$0.00

Funding
CPFF
Funding Only
PURCHASE REQUEST NUMBER: 0011505652

ESTIMATED COST	$0.00
FIXED FEE	$0.00
TOTAL EST COST + FEE	$0.00

ACRN AA $(b) (4)
CIN: GFEBS001150565200001

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002		1	Job		$(b) (4) NTE

Base Task - Other Direct Costs (ODCs)
COST
Base Task - Other Direct Costs (ODCs) as described in the Statement of Work.
FOB: Destination
PSC CD: AJ53

ESTIMATED COST	$(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000201					$0.00

Funding Only
COST
Funding ONly
PURCHASE REQUEST NUMBER: 0011505652

ESTIMATED COST $0.00

ACRN AA $(b) (4)
CIN: GFEBS001150565200002

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003		1	Job		$(b) (4) NTE
OPTION					

Optional Task 1 - FDA 510(k) Antigen
CPFF
Optional Task 1 - FDA 510(k) Clearance and CLIA Waiver for Antigen as described in the Statement of Work.

FOB: Destination
PSC CD: AJ53

ESTIMATED COST $(b) (4)
FIXED FEE $(b) (4)
TOTAL EST COST + FEE $(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004		1	Job		$(b) (4) NTE
OPTION					

Opt Task 1 - Other Direct Costs (ODCs)
COST
Optional Task 1 - Other Direct Costs (ODCs) as described in the Statement of Work.
FOB: Destination
PSC CD: AJ53

ESTIMATED COST $(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0005		1	Job		$(b) (4) NTE
OPTION	Optional Task 2 - FDA 510(k)- Serology CPFF Optional Task 2 - FDA 510(k) Clearance and CLIA Waiver for Serology as described in the Statement of Work. FOB: Destination PSC CD: AJ53				

ESTIMATED COST	$(b) (4)
FIXED FEE	$(b) (4)
TOTAL EST COST + FEE	$(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0006		1	Job		$(b) (4) NTE
OPTION	Opt Task 2 - Other Direct Costs (ODCs) COST Optional Task 2 - Other Direct Costs (ODCs) as described in the Statement of Work. FOB: Destination PSC CD: AJ53				

ESTIMATED COST	$(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0007		1	Job	$(b) (4)	$(b) (4)
	Contractor Manpower Reporting FFP Contractor Manpower Reporting as described in the Statement of Work. FOB: Destination PSC CD: AJ53				

NET AMT	$(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000701					$0.00
	Funding Only FFP Funding Only PURCHASE REQUEST NUMBER: 0011505652				
				NET AMT	$0.00
	ACRN AA CIN: GFEBS001150565200003				$(b) (4)

Section C - Descriptions and Specifications

STATEMENT OF WORK

STATEMENT OF WORK
IDIQ Contract Number: W81XWH-16-D-0009
Task Order: W81XWH-20-F-0253
Offeror: InBios International, Inc.
Technical Contact: (b) (6)

DEVELOPMENT AND FDA CLEARANCE OF RAPID DIAGNOSTIC TESTS TO DETECT BIOMARKERS OF SARS-COV-2 INFECTION

Contractual Statement of Work
Submitted on May 1, 2020

This Task Order will be focused on the development, design controls, production, and analytical studies and clinical trials required for FDA authorization or clearance of rapid human diagnostic Component Assays for SARS-CoV-2 infection, the causative agent of COVID-19. The task order Statement of Work encompasses all development, manufacturing, regulatory, and quality control activities required to achieve Key Performance parameter (KPPs) and FDA authorization and clearance.

Overall Objectives and Scope

The overall goal of this task order is to obtain FDA authorization and/or clearance for hand-held Immunochromatographic Tests (ICTs) detecting several biomarkers corresponding to severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2) infection that have the ability to enhance differential diagnosis through all stages of infection - early, late, and convalescent infection by direct antigen and serology detection.

The ICTs will be simple, easy-to-use devices designed to detect SARS-CoV-2-specific analytes in small volumes of human samples that can be collected in Clinical Laboratory Improvement Amendments (CLIA)-waiver settings. The SCoV-2 *Detect*™ IgM/IgG rapid test will detect IgM and IgG antibodies to SARS-CoV-2 in fingerprick blood, venous whole blood and serum samples. The SCoV-2 Ag *Detect*™ Rapid Tests will detect SARS-CoV-2 antigens in respiratory specimens collected from acute patients. The ICTs will produce results within 15-30 minutes from sample collection and the lateral flow test strip shelf life will be ≥18 months at room temperature.

Option 1: FDA EUA for SCoV-2 Ag *Detect*™ Rapid Test
The objective of this option is to develop and obtain Emergency Use Authorization (EUA) for SCoV-2 Ag Detect, a point-of-care (POC) diagnostic test to identify persons infected with SARS-CoV-2, the causative agent of COVID-19. The assay will detect virus particles in respiratory specimens (including nasopharyngeal swab samples) from patients who meet COVID-19 clinical and/or epidemiological criteria.
Anticipated period of performance: May, 10 2020 – September 30, 2020

Option 2: FDA clearance and CLIA waiver for SCoV-2 Ag *Detect*™ Rapid Test
After obtaining Emergency Use Authorization (EUA) for SCoV-2 Ag *Detect*™ Rapid Test, InBios will pursue *de novo*/510(k) submissions for SCoV-2 Ag *Detect*™ Rapid Test. CLIA waiver submission will be pursued in parallel.
Anticipated period of performance: October, 1 2020 – September 30, 2022

Option 3: FDA clearance and CLIA waiver for SCoV-2 *Detect*™ IgM/IgG Rapid Test
The objective of this option is to develop and obtain FDA clearance and CLIA waiver for SCoV-2 *Detect*™ IgM/IgG Rapid Test, a lateral flow serodiagnostic test designed to identify persons infected with SARS-CoV-2 using serum and whole blood, including fingerprick blood. SCoV-2 *Detect*™ IgM/IgG Rapid Test is designed to detect the human biomarkers IgM and IgG to SARS-CoV-2 in point-of-care settings. Rapid serological tests are needed to quickly and easily identify symptomatic and high-risk asymptomatic individuals who can be carriers

responsible for a large percentage of person-to-person transmission.
Anticipated period of performance: July 1 2020, - March 31, 2022

The scope of work for this task order includes optimization and finalization of SCoV-2 *Detect*™ Rapid Test assay designs, production of kits, conducting analytical and clinical performance studies for regulatory submissions clearance, regulatory communication with FDA including submissions, and following all necessary design and quality controls for SCoV-2 *Detect*™ Rapid Tests. TO#0004 will cover all activities required to ensure high performance throughout the task order including project management, subcontractor management, risk analysis, and quality assurance and control activities,

STATEMENT OF WORK

DEVELOPMENT AND FDA CLEARANCE OF RAPID DIAGNOSTIC TESTS TO DETECT BIOMARKERS OF SARS-COV-2 INFECTION

Task 1. Development of SCoV-2 Ag *Detect*™ Rapid Test

1.1. Option 1: Emergency Use Authorization (EUA) for SCoV-2 Ag *Detect*™

1.1.1. Regulatory

InBios shall develop and manufacture SCoV-2 Ag *Detect*™ kit, an easy-to-use rapid lateral flow immunoassay for identification of persons infected with severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2), the causative agent of COVID-19. InBios will initially seek Emergency Use Authorization (EUA) for SCoV-2 Ag *Detect*™.

1.1.1.1. Pre-EUA FDA communication. FDA has issued an EUA interactive review template for antigen-based tests for 2019 Novel Coronavirus. The studies for inclusion in an EUA submission package include limit of detection (LOD), inclusivity, cross-reactivity, microbial and endogenous interference studies, specimen stability, matrix equivalency, hook effect, and clinical evaluation. InBios will continue to seek and follow FDA guidance during the ongoing pre-EUA interactive review period.

1.1.1.2. EUA submission. The EUA submission package will follow the EUA template and include a proposed intended use statement, study performance data, and a draft package insert. After submission, InBios will work with the FDA during the interactive review period until EUA is obtained.

1.1.2. Development of SCoV-2 Ag *Detect*™ Kit design.

InBios shall develop lateral flow immunoassay prototypes for SARS-CoV-2 antigen detection towards EUA submission.

1.1.2.1. Generate anti-SARS-CoV-2 antibodies. InBios shall generate antibody reagents to specifically and sensitively bind and detect SARS-CoV-2 antigens. We will first focus on antibodies to (b) (4) InBios has immunized a number of animals with (b) (4) including mice, rabbits, and (b) (4) generation of monoclonal antibodies, polyclonal antibodies, and (b) (4), respectively. InBios is also working with a number of collaborators to generate and acquire/license some of the antibody reagents.
Additional antigens may be be acquired or cloned and purified for immunization, if deemed necessary. All antigenic targets may also be used in task 1.1.2.8.

1.1.2.2. Screening of developed SARS-CoV-2 antibodies. The antibodies from immunized animals will be screened and selected for affinity to SARS-CoV-2 antigens. Screening methods such as ELISAs and our proprietary SmartShot system, for identifying and characterizing promising SARS-CoV-2 antibodies, will be deployed. The antibodies will also be sequenced for potential generation of chimeras to enhance binding activity or assay performance.

Our proprietary imaging sensor-based SmartShot system will be used to select antibodies based on binding affinity and complementarity to one another. We will also use the SmartShot system to test for possible interference if we combine antibodies against multiple targets into a single test line. The highest performing antibody pairs will be used to develop and optimize rapid test prototypes.

1.1.2.3. Antibody purification. Selected antibodies shall be purified initially at a small scale for evaluation in the SCoV-2 Ag *Detect*™ prototype. Once promising antibodies are identified, three lots of purified antibodies shall be purified to ensure lot-to-lot consistency prior to design freeze. ELISA methods will be developed to qualify purified antibodies and ensure lot-to-lot consistency prior to incorporation into the SCoV-2 Ag *Detect*™ prototype.

1.1.2.4. Finalization of antibodies based on their reactivity in lateral flow immunoassay format. We will optimize the assay format by identifying which antibodies perform best as capture vs. detection reagents. Antibody pairs will be tested by both striping on membrane (capture system) and conjugating to gold nanoparticles (detection system). Selecting the right combination of antibodies as detection and capture reagents is critical to the development of a sensitive lateral flow assay. We will optimize assay sensitivity and functionality by iteratively testing combinations of sample and conjugate pads, gold conjugation conditions, blocking reagents, assay assembly methods, and other assay components.

1.1.2.5. Test and optimize gold conjugation conditions. Gold conjugation parameters such as pH, the concentration of antibody/OD gold, and the inclusion of blocking reagents conjugation shall be tested and optimized.

1.1.2.6. Identify and optimize blocking reagents to maximize assay specificity. In-house and commercial blockers shall be assessed for their ability to block non-specific reactivity. The concentration and formulation of blockers shall be optimized to maximize assay specificity without significantly compromising assay reactivity.

1.1.2.7. Design and test cassette. A cassette shall be selected from our in-house design library or newly designed. 3D-printed prototypes will be tested for specimen flow and clearance. Finalizing a cassette design will require multiple iterations of modification of the cassette and testing using serum and whole blood specimens. Injection-molded plastic cassettes will be manufactured once a cassette design is decided upon.

1.1.2.8. Development of positive and negative controls. The FDA will require external positive and negative controls to be provided with the SCoV-2 Ag *Detect*™ kit. Controls shall be developed using developed antigens from task 1.1.2.1.

1.1.2.9. Evaluate preliminary assay performance. During assay development, the rapid test will be evaluated and optimized using respiratory samples spiked with purified recombinant proteins internally or with *in vitro* grown virus with known titers externally (b) (4) (b) (4) Respiratory samples positive for other diseases may be used to initially test assay cross-reactivity. In parallel, we will identify respiratory samples from confirmed COVID-19 positive patients through collaborators and/or commercial suppliers for additional studies. Based on internal and external evaluation, a prototype device shall be chosen for execution of EUA studies with the goal of submitting for FDA EUA clearance.

1.1.3. Manufacture SCoV-2 Ag *Detect*™ Rapid Test for EUA studies

The Design Plan for the SCoV-2 Ag *Detect*™ Rapid Test will outline the design inputs and plans for process development, design transfer and manufacturing, and performance studies. SCoV-2 Ag *Detect*™ Rapid Tests shall be manufactured for EUA studies by the InBios manufacturing team.

1.1.3.1. Establish QC panels and test procedures. A QC panel containing antigens spiked into commercially available respiratory samples will be used to monitor assay development and for QC of the initial production lots. We will explore the use of (b) (4) with known copies/ml spiked into respiratory samples. Negative samples will include normal NP swab samples and potentially samples spiked with unrelated (b) (4)

1.1.3.2. SCoV-2 Ag *Detect*™ Rapid Test manufacture for EUA studies. We will manufacture pilot lot of SCoV-2 Ag *Detect*™ Rapid Test for execution of performance studies for EUA submission.

Standard operating procedures will be drafted for SCoV-2 Ag *Detect*™ Rapid Test production.

1.1.4. Conduct performance studies for EUA submission

All analytical and clinical studies will be conducted following guidance from FDA. Study protocols shall be finalized based on FDA guidance in the interactive EUA template. Final study protocols shall be documented in the Design History File (DHF).

1.1.4.1. Analytical sensitivity/LoD: The LoD will determined using SARS-CoV-2 purified antigens or (b) (4) into respiratory specimen samples. We will explore the use inactivated SARS-CoV-2 for additional studies if the LoD study supports that the inactivation process did not impact the assay LoD.

1.1.4.2. Cross-reactivity: Samples for cross-reactivity studies will include (b) (4) spiked into respiratory specimens. The full list of specimens to be tested in the cross-reactivity study will be confirmed with FDA.

1.1.4.3. Inclusivity: We will evaluate the ability of the SCov-2 Ag *Detect*™ assay to detect available SARS-CoV-2 isolates.

1.1.4.4. Specimen stability: A specimen stability study will be conducted to support specimen stability claims. A fresh/frozen and/or freeze/thaw study may be needed to support the use of frozen specimens in the clinical evaluation study.

1.1.4.5. Hook Effect: A hook effect study will be used to determine if a false negative can result when very high levels of antigen are present in a sample.

1.1.4.6. Interfering substances: Interfering substances study will be used to determine if microbes or substances present in blood products will result in false positive or false negative results.

1.1.4.7. Clinical evaluation: Due to limited access to clinical specimens, we propose to perform part of the clinical evaluation study using (b) (4) into individual respiratory samples. Positive and negative percent agreement are expected to be ≥ 90%.

1.1.4.8. EUA study data analysis and report writing. EUA study data shall be analyzed in accordance with study protocols. Reports shall be written to summarize study design and results and shall be documented in the DHF.

1.2. Option 2: FDA market authorization for SCoV-2 Ag *Detect*™

1.2.1. Regulatory

After obtaining Emergency Use Authorization (EUA) for SCoV-2 Ag *Detect*™, InBios will pursue *de novo*/510(k) submission for SCoV-2 Ag *Detect*™. CLIA waiver submission will be pursued concurrently. InBios shall seek FDA guidance during the design phase via FDA pre-submission program.

1.2.1.1. Prepare and submit pre-submission to FDA. InBios shall continue to interact with the FDA to seek guidance for a regulatory strategy for FDA clearance and CLIA waiver of the SCoV-2 Ag *Detect*™ assay. A pre-submission package will be submitted to obtain guidance on data required for de novo/510(k) clearance. The pre-submission package shall be focused on clarifying product intended use statement, the regulatory pathway, and protocols for bench and clinical performance studies that will be required for market authorization.

1.2.1.2. Prepare and submit *de novo*/510(k) package. InBios shall follow the regulatory guidance gained during the pre-submission process. Preparation of the *de novo*/510(k) submission package shall begin when analytical and clinical performance data analyses are complete, and study results meet the design specifications.

1.2.1.3. Prepare and submit CLIA waiver package. InBios shall follow the regulatory guidance gained during the pre-submission process to submit an application for CLIA waiver.

1.2.2. Finalize device design for market authorization (*de novo*/510(k) submission)

InBios shall build on the EUA SCov-2 Ag *Detect*™ device design. If warranted, InBios will optimize the lateral flow immunoassay design based on the outcomes of the EUA performance studies. Assay parameters that may be modified include the cassette design, optimizing formulation of blocking reagents, inclusion of additional SARS-CoV-2 target antigens, or optimizing gold conjugation conditions.

1.2.2.1. Perform further testing and selection of SARS-CoV-2 antibodies in lateral flow immune-assay format, **if warranted**. Additional promising antibodies, or antigenic detection targets, shall be incorporated and tested in the LFI format to determine whether they improve reactivity of the SCoV-2 Ag *Detecf*™ prototype.

1.2.2.2. Optimize assay specifications and formulations based on EUA study performnace. If warranted based on EUA study performance and other performance evaluations, SCov-2 Ag *Detecf*™ assay parameters may be optimized to enhance assay performance for FDA clearance. This may include investigations into gold conjugation conditions; identifying, formulating, and optimizing additional blocking reagents, adding stabilizers to the assay components for extended shelf life, cassette modifications, or modifying pad treatment formulations and buffers.

1.2.2.3. Finalize positive and negative control formulations and preliminary stability studies. The positive and negative control formulations shall be finalized. We shall begin accelerated and real-time stability studies prior to design freeze. Control formulations shall be stable at room temperature for ≥18 months.

1.2.2.4. Complete stability testing of final SCoV-2 Ag *Detecf*™ prototype. Final SCoV-2 Ag *Detecf*™ prototype shall be tested in preliminary accelerated and real-time stability experiments. The target shelf-life for the SCoV-2 Ag *Detecf*™ device is at least 18 months at room temperature.

1.2.2.5. Evaluate assay performance of final SCoV-2 Ag *Detecf*™ prototype. During the final assay development, the rapid test will be evaluated using respiratory samples spiked with purified recombinant proteins internally or with (b) (4) externally (b) (4) n parallel, respiratory samples from confirmed COVID-19 positive patients acquired through collaborators and/or commercial suppliers will be tested. Respiratory samples positive for other diseases will be used to initially test assay cross-reactivity. Based on the results and internal evaluations, InBios will select a final prototype to move forward with design freeze, cGMP manufacture, and FDA *de novo*/510(k) submission studies.

1.2.3. Process Development and Scale Up

Once optimized procedures are developed for the production of all reagents, InBios shall initiate the scale-up of reagents to ensure a steady supply of reagents is available for the manufacture of SCoV-2 Ag *Detecf*™ Rapid Test kits. Production procedures will be updated and/or finalized during the scale-up and process development will be finalized.

1.2.3.1. Optimization and scale-up of hybridomas for antibody production. We shall scale-up and optimize procedures for the production of the selected antibodies. Scaled up cell culture techniques shall be used to ensure an efficient process is in place for generating antibodies.

1.2.3.2. Optimization and scale up of antibody purifications. We shall optimize procedures for purification and long-term storage of the selected antibodies. Purified antibodies may be dialyzed into optimized buffer conditions prior to storage. Three lots of each antibody shall be produced using the final purification procedure to ensure a repeatable process is in place.

1.2.3.3. Scale up antibody-gold conjugation. The optimized gold conjugation conditions from task 1.2.2.2 shall be scaled-up to produce large lots for incorporation into the ICTs.

1.2.3.4. Identify sources for kit accessories as needed. Raw material specification documents shall be in place for all vendor-acquired kit accessories.

1.2.3.5. Draft product insert. Once an assay procedure is identifed, a product insert shall be drafted for use in performance studies and for eventual FDA submission. The final product insert shall describe: 1) intended use, 2) description of device, 3) description of kit contents, 4) instructions for device use, 5) algorithm for results interpretation, 6) quality control guidance, 7) precaution statements, 8) device performance characteristics and 9) possible use limitations.

1.2.3.6. Development of QC panels. A QC Panel will be developed to monitor cGMP manufacturing and lot to lot variability. Panel members shall include SARS-CoV-2 antigen-spiked specimens close to the limit of detection. Antigen stability shall be assessed to ensure QC panel stability. New panel members shall be generated after determining antigen concentration using validated

methods. QC panel members shall made in natural or simulated respiratory specimens, which may potentially be spiked with any cross-reactive or false positive antigens.

1.2.4. Design Transfer

InBios has extensive knowledge and experience in design transfer of devices from R&D to manufacturing and cGMP manufacturing. This knowledge base shall be applied to the transfer of the SCoV-2 Ag *Detect*™ assay to GMP manufacturing. Production standard operating procedures updated during the scale-up and process development will be finalized.

1.2.4.1. Finalize documentation for manufacturing SCoV-2 Ag *Detect*™ rapid tests. InBios will finalize all documentation required for the spray, gold conjugation, lamination, assembly, and quality control of the SCoV-2 Ag *Detect*™ rapid tests prior to cGMP manufacture.

1.2.4.2. Finalize raw material specification. Raw material specification documents will be completed for each raw material that is incorporated into the SCoV-2 Ag *Detect*™ rapid tests kit.

1.2.4.3. Complete Design Transfer, Part 1. Prior to cGMP manufacture of SCoV-2 Ag *Detect*™ rapid test kits for performance studies, Part 1 of a documented design transfer process as outlined in InBios document SOP-0035 shall take place.

1.2.4.4. Complete Design Transfer, Part 2. The Design Transfer, Part 2 will take place prior to FDA submission after all performance study data is collected and the design team ensures the design outputs meet the design input criteria.

1.2.5. GMP Manufacturing

Upon completion design transfer, InBios shall initiate manufacturing of SCoV-2 Ag *Detect*™ kits under cGMP.

1.2.5.1. Draft device master record and product specifications. After all manufacturing documents are written, we shall draft product specifications and establish a Device Master Record (DMR) containing a list of all documents required for the manufacture of SCoV-2 Ag *Detect*™.

1.2.5.2. cGMP manufacturing. Once the SCoV-2 Ag *Detect*™ design is frozen and transferred from R&D to manufacturing, we shall manufacture at least three test kit lots under cGMP. InBios will manufacture lots of SCoV-2 Ag *Detect*™ rapid tests for process validation, in-house studies, and clinical evaluation studies as per FDA pre-submission feedback under cGMP. Device History Records will be generated for each lot of SCoV-2 Ag *Detect*™ rapid tests produced. The QC panel shall be used to demonstrate lot-to-lot consistency for the three lots of SCoV-2 Ag *Detect*™ assays.

1.2.6. Studies for *de novo*/510(k) and CLIA waiver submission

With FDA guidance, we shall execute the necessary SCoV-2 Ag *Detect*™ performance studies required for regulatory submission. Studies will be conducted using kits produced under cGMP.

1.2.6.1. Bench studies. FDA will require a number of laboratory product performance data to support SCoV-2 Ag *Detect*™ regulatory submission and clearance. We shall conduct pre-submission communications with the FDA (1.2.1.1.) to establish details of bench studies to be performed. Testing shall be performed according to the instructions provided in the package insert. It is anticipated additional studies, such as flex studies shall be required for CLIA waiver. All data shall be analyzed and submitted as reports which will be included in the de novo submission package.

1.2.6.1.1. Draft bench study protocols. Study protocols shall be drafted prior to submitting an FDA pre-submission supplement to gain FDA guidance.

1.2.6.1.2. Finalize protocols for in-house studies as per pre-submission feedback from FDA. We shall gain pre-submission feedback from the FDA before finalizing in-house study protocols. All study protocols will be finalized prior to execution.

1.2.6.1.3. Acquire reagents needed for bench studies. We shall obtain specimens and reagents required to complete the bench studies. These reagents will be obtained from collaborators or purchased from commercial vendors or collaborators. We will establish

agreements with subcontractors to conduct analytical studies requiring Biosafety Level 3 capbilities (which InBios does not have).

1.2.6.1.4. Perform bench studies in accordance with the final study protocols. The studies required for FDA clearance and CLIA waiver submission will likely include: Limit of Detection study, Inclusivity/analytical reactivity study, Exclusivity/analytical specificity study, Interfering substances/Microbial Interference, Flex studies, Specimen stability studies, and a multi-site Reproducibility study. Operators shall be trained on protocols prior to study execution. Data will be filed in the DHF.

1.2.6.1.4.1. Identify sites for reproducibility studies and execute subcontracting agreements, as necessary for testing. Subcontracting agreements shall be executed prior to testing at external sites.

1.2.6.1.5. Perform accelerated stability testing at high elevated temperature with GMP kit lots. The stability study shall compare tests that have undergone accelerated aging to a control group and to expected values. These studies are conducted to establish shelf life of the SCoV-2 Ag *Detect*™ kit.

1.2.6.1.6. Perform stability studies. An accelerated stability study shall compare tests that have undergone accelerated aging to a control group and to expected values. Real-time stability studies shall directly compare tests that have undergone real-time aging to a control group and to expected values. The SCoV-2 Ag *Detect*™ Rapid Test kit target shelf life is at least 18 months at room temperature.

1.2.6.1.7. Perform Shipping studies (including heat stress and cold stress). Shipping studies shall be performed to characterize the packaging strength and reagent stability of the SCoV-2 Ag *Detect*™ kit.

1.2.6.1.8. Bench study data analysis and report writing. Data analysis for all bench studies will take place according to the finalized protocols. Reports for all bench studies shall be written and placed into the DHF. SCoV-2 Ag *Detect*™ bench study reports will be included in the for FDA submission package.

1.2.6.2. Clinical performance studies. We plan to start clinical studies using cGMP kits as per FDA pre-submission feedback (1.2.1.1). InBios shall initiate a teaming agreement with a Contract Research Organization (CRO) to implement clinical studies.

1.2.6.2.1. Draft clinical study protocols. Study protocols shall be created with engagement from the CRO. A reference standard shall be agreed upon with feedback from FDA.

1.2.6.2.2. Finalize protocols as per FDA pre-submission feedback. The clinical study protocol shall be finalized based on FDA pre-submission feedback and will approved by InBios and the CRO.

1.2.6.2.3. Site selection; establish subcontractor agreements with clinical sites. Appropriate clinical sites shall be identified for conducting the clinical evaluation studies. Subcontractor agreements shall be established between InBios and field sites. It is anticipated the clinical studies will be conducted at at least 3 locations.

1.2.6.2.4. Clinical study protocol and study document approval from appropriate IRBs and HRPO. The finalized clinical study protocol, consent documents, and any other required documentation will be submitted to the appropriate IRBs and HRPO. Any required changes will be incorporated prior to IRB/HRPO approval.

1.2.6.2.5. Conduct study initiation, train operators at test sites. The CRO shall conduct onboard training at clinical testing sites. Operators shall be trained on how to use the test kits and electronic data management system, and how to properly conduct the study prior to study initiation.

1.2.6.2.6. Clinical testing at field sites and confirmatory testing. Testing at field sites should take place after all IRB/HRPO approvals are obtained. Clinical evaluation studies will proceed in accordance with the final clinical study protocol.

1.2.6.2.7. Site closeouts, data analysis, report writing. The CRO shall conduct a closeout session after the conclusion of clinical trials. This will include spot-checking records to make sure data transfer and recording are correct, overseeing disposal of leftover materials, and spot-checking that patients enrolled in studies met inclusion criteria. A report of the

clinical trial data and analysis shall be written for *de novo*/510(k) submission.

Task 2. FDA 510(k) clearance of SCoV-2 *Detect*™ IgM/IgG Rapid Test

2.1. Option 3: FDA market authorization for SCoV-2 *Detect*™ IgM/IgG Rapid Test

InBios shall finalize assay design for SCoV-2 *Detect*™ IgM/IgG Rapid Test, an easy-to-use rapid lateral flow immunoassay for identification human IgM and IgG antibodies against SARS-CoV-2 in blood specimens. Process development and cGMP manufacture of SCoV-2 *Detect*™ IgM/IgG Rapid Test will occur after design transfer. Performance studies for regulatory submission will be conducted based on FDA guidance obtained during the pre-submission process.

2.1.1. Regulatory

After obtaining Emergency Use Authorization (EUA) for SCoV-2 *Detect*™ IgM/IgG Rapid Test (anticipated June 2020), InBios will pursue *de novo*/510(k) submission for SCoV-2 *Detect*™ IgM/IgG Rapid Test. InBios shall seek FDA guidance via the FDA pre-submission program.

2.1.1.1. Prepare and submit pre-submission supplement to FDA. InBios will submit a pre-submission package to FDA to obtain guidance on studies required for FDA clearance and CLIA waiver application. The pre-submission package will include a draft intended use statement, proposed regulatory pathway, device description, specific questions, and draft analytical and clinical study protocols.

2.1.1.2. Prepare and submit *de novo*/510(k) package. InBios shall follow the regulatory guidance gained during the pre-submission process. Preparation of the *de novo*/510(k) submission package shall begin when analytical and clinical performance data analyses are complete, and study results meet the design specifications.

2.1.1.3. Prepare and submit CLIA waiver package. InBios shall follow the regulatory guidance gained during the pre-submission process to submit an application for CLIA waiver.

2.1.2. Finalize device design for FDA clearance and CLIA waiver application

InBios shall build on the EUA SCoV-2 *Detect*™ IgM/IgG Rapid Test device design. If warranted, InBios will optimize the lateral flow immunoassay design based on the outcomes of the EUA performance studies. Assay parameters that may be modified include the cassette design, optimizing formulation of blocking reagents, inclusion of additional SARS-CoV-2 target antigens, optimizing gold conjugation buffers.

2.1.2.1. Perform further testing and selection of SARS-CoV-2 antigens in lateral flow immune-assay format, **if warranted**. Additional promising antigens shall be expressed, purified, and incorporated in the LFI format to determine whether they improve reactivity of the SCoV-2 *Detect*™ IgM/IgG prototypes without compromising assay specificity.

2.1.2.2. Optimize assay specifications and formulations based on EUA study performnace. If warranted based on EUA study performance and other performance evaluations, SCov-2 *Detect*™ IgM/IgG assay parameters may be optimized to enhance assay performance for FDA clearance. This may include investigations into gold conjugation conditions; identifying, formulating, and optimizing additional blocking reagents, adding stabilizers to the assay components for extended shelf life, cassette modifications, or modifying pad treatment formulations and buffers.

2.1.2.3. Finalize positive and negative control formulations and preliminary stability studies. Due to a lack of consistent supply of disease serum for positive control, InBios shall explore the production of human chimeric antibodies for use as artificial positive controls. Artificial positive control formulations will be finalized prior to beginning accelerated and real-time stability studies. Control formulations shall be stable at room temperature for ≥18 months.

2.1.2.4. Complete stability testing of final SCoV-2 *Detect*™ IgM/IgG Rapid Test prototype. The SCoV-2 *Detect*™ IgM/IgG Rapid Test prototype shall be tested in preliminary accelerated and real-time stability experiments. The target shelf-life for the SCoV-2 *Detect*™ IgM/IgG Rapid Test is at least 18 months at room temperature.

2.1.2.5. Evaluate assay performance of SCoV-2 *Detect*™ IgM/IgG Rapid Test prototype. During the

final assay optimization phase, the rapid test will be evaluated using a panel of well-characterized known COVID-positive and negative specimens to ensure robust assay performance prior to design freeze. The final assay design shall be tested using whole blood specimens prior to design freeze.

2.1.3. Process Development and Scale-Up

Once optimized procedures are developed for the production of all reagents, InBios shall initiate the scale-up of reagents to ensure a steady supply of reagents is available for the manufacture of SCoV-2 *Detect*™ IgM/IgG Rapid Test kits.

2.1.3.1. Optimization and scale-up of SARS-CoV-2 antigen production. We shall scale-up and optimize procedures for the cell culture and expression of the selected antigens. Stable cell lines of all cellular expression systems will be pursued. Scaled up cell culture techniques shall be used to ensure an efficient process is in place for generating antigens.

2.1.3.2. Optimization and scale up of SARs-CoV-2 antigen purification. We shall optimize procedures to purify the selected antigens. We shall investigate techniques to scale up antigen purification. Three lots of each antigen shall be produced using the final purification procedure to ensure a repeatable process is in place. Antigens will be qualified prior to incorporation into the rapid test.

2.1.3.3. Scale up gold conjugation. The optimized gold conjugation conditions from task 2.1.2.2 shall be scaled-up to produce large lots of detection reagents.

2.1.3.4. Identify sources for kit accessories as needed. Raw material specification documents shall be in place for all vendor-acquired kit accessories.

2.1.3.5. Draft product insert. Once an assay procedure is identifed, a product insert shall be drafted for use in performance studies and for eventual FDA submission. The final product insert shall describe: 1) intended use, 2) description of device, 3) description of kit contents, 4) instructions for device use, 5) algorithm for results interpretation, 6) quality control guidance, 7) precaution statements, 8) device performance characteristics and 9) possible use limitations.

2.1.3.6. Development of QC panels. A QC Panel will be developed to monitor cGMP manufacturing and lot to lot variability. Panel members shall include specimens confirmed positive and negative for anti-SARS-CoV-2 IgM and IgG. QC panel members shall include normal human and whole blood specimens, and potentially any cross-reactive or false positive specimens.

2.1.4. Design Transfer

InBios has extensive knowledge and experience in design transfer of devices from R&D to manufacturing and cGMP manufacturing. This knowledge base shall be applied to the transfer of the SCoV-2 *Detect*™ IgM/IgG Rapid Test to GMP manufacturing.

2.1.4.1. Finalize documentation for manufacturing SCoV-2 *Detect*™ IgM/IgG Rapid Tests. InBios will finalize all documentation required for the spray, gold conjugation, lamination, assembly, and quality control of the SCoV-2 *Detect*™ IgM/IgG Rapid Test prior to cGMP manufacture.

2.1.4.2. Finalize raw material specification. Raw material specification documents will be completed for each raw material that is incorporated into the SCoV-2 *Detect*™ IgM/IgG Rapid Test kit.

2.1.4.3. Complete Design Transfer, Part 1. Prior to cGMP manufacture of SCoV-2 *Detect*™ IgM/IgG Rapid Tests for performance studies, Part 1 of a documented design transfer process as outlined in InBios document SOP-0035 shall take place.

2.1.4.4. Complete Design Transfer, Part 2. The Design Transfer, Part 2 will take place prior to FDA submission after all performance study data is collected and the design team ensures the design outputs meet the design input criteria.

2.1.5. GMP Manufacturing

Upon completion design transfer, InBios shall initiate manufacturing of SCoV-2 *Detect*™ IgM/IgG Rapid Test kits under cGMP.

2.1.5.1. Draft device master record and product specifications. After all manufacturing documents are

written, we shall draft product specifications and establish a Device Master Record (DMR) containing a list of all documents required for the manufacture of SCoV-2 *Detect*™ IgM/IgG Rapid Test kits.

2.1.5.2. cGMP manufacturing. Once the SCoV-2 *Detect*™ IgM/IgG Rapid Test design is frozen and transferred from R&D to manufacturing, we shall manufacture at least three test kit lots under cGMP. InBios will begin manufacturing lots of SCoV-2 *Detect*™ IgM/IgG Rapid Tests for process validation, in-house studies, and field studies as per FDA pre-submission feedback under cGMP. Device History Records will be generated for each lot of SCoV-2 *Detect*™ IgM/IgG Rapid Test kits produced. The QC panel shall be used to demonstrate lot-to-lot consistency for the three lots of SCoV-2 *Detect*™ IgM/IgG Rapid Tests.

2.1.6. Studies for *de novo*/510(k) and CLIA waiver submission

After obtaining FDA guidance, we shall execute the necessary performance studies required for regulatory submission of SCoV-2 *Detect*™ IgM/IgG Rapid Tests. Studies will be conducted using kits produced under cGMP.

2.1.6.1. Bench studies. FDA will require a number of laboratory product performance data to support SCoV-2 *Detect*™ IgM/IgG Rapid Tests regulatory clearance and CLIA waiver application. We shall conduct pre-submission communications with the FDA (2.1.1.1.) to establish details of bench studies to be performed. All data shall be analyzed and submitted as reports which will be included in the regulatory submission package.

2.1.6.1.1. Draft bench study protocols. Study protocols shall be drafted prior to submitting an FDA pre-submission package to gain FDA guidance.

2.1.6.1.2. Finalize protocols for in-house studies. FDA feedback obtained during the pre-submission process will be incorporated into the study protocols prior to finalization. Protocols will be finalized prior to study execution.

2.1.6.1.3. Acquire reagents needed for bench studies. We shall obtain specimens and reagents required to complete the bench studies. These reagents will be obtained from collaborators or purchased from commercial vendors.

2.1.6.1.4. Perform bench studies in accordance with the final study protocols. The studies required for FDA clearance and CLIA waiver submission will likely include: Limit of detection/matrix comparison study, IgM/IgG specificity study, cross-reactivity study, interfering substances studies, flex studies, specimen stability studies, and a multi-site reproducibility study. Operators shall be trained on protocols prior to study execution. Data will be filed in the DHF.

2.1.6.1.4.1. Identify sites for reproducibility studies and execute subcontracting agreements, as necessary for testing. Subcontracting agreements shall be executed prior to reproducibility testing at external sites.

2.1.6.1.5. Perform stability testing. An accelerated stability study shall compare tests that have undergone accelerated aging to a control group and to expected values. Real-time stability studies shall directly compare tests that have undergone real-time aging to a control group and to expected values. The SCoV-2 *Detect*™ IgM/IgG Rapid Test kit target shelf life is at least 18 months at room temperature.

2.1.6.1.6. Perform Shipping studies (including heat stress and cold stress). Shipping studies shall be performed to characterize the packaging strength and reagent stability of the SCoV-2 *Detect*™ IgM/IgG Rapid Test kit.

2.1.6.1.7. Bench study data analysis and report writing. Data analysis for all bench studies will take place according to the finalized protocols. Reports for all bench studies outlined above shall be written and placed into the DHF. SCoV-2 *Detect*™ IgM/IgG Rapid Test bench studies report will be written completed for FDA *de novo*/510(k) submission.

2.1.6.2. Clinical performance studies. We plan to start clinical studies using cGMP kits as per FDA pre-submission feedback (2.1.1.1.). InBios shall initiate a teaming agreement with a Contract Research Organization (CRO) to implement clinical studies.

2.2.6.2.1. Draft clinical study protocols. Study protocols shall be created with engagement from

the CRO. A reference standard shall be agreed upon with feedback from FDA.

2.2.6.2.2. Finalize protocols as per FDA pre-submission feedback. The clinical study protocol shall be finalized based on FDA pre-submission feedback and will approved by InBios and the CRO.

2.2.6.2.3. Site selection; establish subcontractor agreements with clinical sites. Appropriate clinical sites shall be identified for conducting the clinical evaluation studies. Subcontractor agreements shall be established between InBios and field sites. It is anticipated the clinical studies will be conducted at at least 3 locations.

2.2.6.2.4. Clinical study protocol and study document approval from appropriate IRBs and HRPO. The finalized clinical study protocol, consent documents, and any other required documentation will be submitted to the appropriate IRBs and HRPO. Any required changes will be incorporated prior to IRB/HRPO approval.

2.2.6.2.5. Conduct study initiation, train operators at test sites. The CRO shall conduct onboard training at clinical testing sites. Operators shall be trained on how to use the test kits and electronic data management system, and how to properly conduct the study prior to study initiation.

2.2.6.2.6. Clinical testing at field sites and confirmatory testing. Testing at field sites should take place after all IRB/HRPO approvals are obtained. Clinical evaluation studies will proceed in accordance with the final clinical study protocol.

2.2.6.2.7. Site closeouts, data analysis, report writing. The CRO shall conduct a closeout session after the conclusion of clinical trials. This will include spot-checking records to make sure data transfer and recording are correct, overseeing disposal of leftover materials, and spot-checking that patients enrolled in studies met inclusion criteria. A report of the clinical trial data and analysis shall be written for *de novo*/510(k) submission.

Task 3. Project management

3.1. Establish and maintain an Integrated Master Schedule (IMS). InBios shall maintain an IMS that provides accurate and timely schedule and performance information throughout the lifecycle of the effort.

3.2. Establish and maintain risk management system. InBios shall devise and update a Risk Management Plan and Risk Management Master File in accordance with InBios Standard Operating Procedure SOP-0089 Risk Management Policy.

3.3. Establish and maintain a regularly scheduled joint Government IPT / project team meeting. InBios shall participate in regular teleconferences and/or additional face-to-face prescheduled meetings to discuss status, issues, and path forward; thus, providing a general update of the project and enabling real-time Government feedback on progress.

3.4. Submit monthly technical reports (MTR) to the COR. InBios shall report regularly on the status of the development, testing, and manufacture of the SCoV-2 *Detect*™ Rapid Tests.

3.5. Obtain sufficient rights to technical data, strains, analytes, isolates, etc. as necessary to ensure market sustainability of the device.

3.6. Develop and maintain a management and quality system and Management and Quality Plan (MQP) describing the processes, procedures, and methods used to manage the necessary activities required to achieve the Government's requirement.

3.6.1. Design Plan. InBios shall write a Design Plan, which shall include a timeline for developmental activities, design input, pre-set acceptance criteria, performance studies required for regulatory clearance, and a plan for the design transfer and manufacture of SCoV-2 *Detect*™ Rapid Tests.

3.6.2. Design controls. As required by 21 CFR 820.30, InBios shall maintain a design controls and a design history file (DHF). Design review meetings shall be held to cover the following project milestones: Review Design Plan, Risk Analysis and Mitigation, Prototype selection, Design Transfer, Initiate bench studies, Review bench studies results/reports, Initiate clinical studies, Review clinical studies results/statistical analysis, Design Verification, FDA submission, and Design Validation

DELIVERABLE TABLE

Item	Title	Description	Distribute to	Initial	Frequency Contractor Performs	AQL / Frequency
Deliverable 1	Work Breakdown Structure (WBS)	Will be to a depth and breadth necessary to accurately describe the Offeror's proposed effort	COR	At the time of TO proposal	Review/update upon TO Modification	At the time of proposal review
Deliverable 2	Integrated Master Schedule (IMS)	Will indicate task progress, percent completion, schedule slippage. Issues and questions from the IMS shall be discussed at the monthly teleconference. The IMS shall be structured to correlate with the Work Breakdown Structure (WBS) and shall contain planned events, milestones, accomplishments, and activities from contract award to the completion of the contract.	COR	Within 30 days of TO award.	Review/update every three (3) months throughout PoP	Quarterly
Deliverable 3	Program Progress, Status, Management Reports	Indicated that progress of the work, status of the program, and of the assigned tasks. The report shall include cost incurred, report planned monthly costs (spend plan), and information relating to existing or potential problem areas, and proposed action(s) to resolve the problem(s).	COR	The 15th of the month following the reporting month.	Throughout PoP	Monthly
Deliverable 4	Program Incident Reports	The contractor shall report any incident that could result is more than a three (3) month delay in schedule and/or a 5% increase in cost estimate at contract completion.	COR	Notification within one (1) of incident and a written summary within two (2) weeks of identification to include resolution.	Monthly	Monthly

Deliverable 5	Annual Program Review	The Contractor will host at least one onsite program review with the Government. The content of the briefing shall include but is not limited to the following: completed tasks within the year, highlights of completed tasks, summary of results from studies, schedule updates, summary of results from completed studies, risks/issues, and funding execution.	COR	Annually	Annually	Annually
Deliverable 6	Risk Management Plan	Provide a risk management plan identifying project risk in all areas of the project, including cost, schedule, and performance risks. The Plan shall characterize each identifiable risk as to probability of occurrence, severity if realized, and mitigation strategy(ies) that will be employed to mitigate or eliminate each identified risk. The Plan will be a living document; issues and questions from the risk management plan should be discussed at each monthly teleconference.	COR	Within 30 days of TO award	Review/update annually throughout PoP	Annually
Deliverable 7	Regulatory Strategy Plan	Detailing engagement with and licensure by FDA; should include details of EUA and/or 510(k) filing path(s) and all regulatory actions necessary to achieve FDA clearance.	COR	Within 30 days of TO award	Review/update annually throughout PoP	Annually
Deliverable 8	Quality Plan	Describes the contractor management steps to ensure that all activities of the project are managed in a sound, reasonable way to achieve the Government's objectives and that all deliverables produced are acceptable prior to delivery to the Government. Shall demonstrate that a corporate quality management system is in place and identified the roles and responsibilities of contractor and subcontractor(s). Under this Quality Plan, the contractor will allow the Government or its designee to audit the contractor and/or its subcontractor(s) for regulatory compliance and quality assurance purposes. The Quality Plan is a living document.	COR	Within 30 days of TO award	Review/update annually throughout PoP.	Annually

Deliverable 9	FDA Communications and Study Reports	Data package shall contain copies of all communications with the U.S. FDA, including all submissions, amendments, periodic reports, and materials supporting meetings with the FDA. The data package shall also contain FDA initiated correspondence, to include meeting minutes, requests for additional information, etc. All FDA communications shall be submitted in accordance with the FDA guidance to industry. The Government shall be included in all discussions with the FDA and shall be given sufficient advance notice for these discussions.	COR	Copies will be sent to the Government at the same time they are sent to the US FDA; communications received from the FDA shall be sent within three (3) days of receipt.	Throughout PoP	Per occurrence
Deliverable 10	Product Issue Summary Report(s)	Summarizing incidents related to product development, manufacturing, testing and evaluation or any other issue related to the product.	COR	Throughout PoP within three (3) business days of issue occurrence.	Throughout PoP	Per occurrence
Deliverable 11	Technical Data Package (TDP)	Prepare and maintain currency of a Technical Data Package that includes all necessary documentation and technical data and reports collected and prepared during the development effort funded by the Government. Shall include all necessary documentation and data for the Government, or its designee, to continue the development or production of the product. The Contractor shall provide copies of the TDP content within seven (7) business days of the Government's request. The TDP shall be transferred to the Government immediately if at any time, the Contractor defaults or fails to remedy said default.	COR	Within 30 days of TO award	Review/update annually throughout PoP.	Annually

Deliverable 12	Full Clinical Study Protocol	FDA approved protocol to conduct a full clinical study to evaluate product sensitivity and specificity	COR	Within five (5) days of receiving FDA approval; protocol amendments to be provided at the same time they are sent to the US FDA.	Throughout PoP	Per occurrence

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
000101	N/A	N/A	N/A	N/A
0002	Destination	Government	Destination	Government
000201	N/A	N/A	N/A	N/A
0003	Destination	Government	Destination	Government
0004	Destination	Government	Destination	Government
0005	Destination	Government	Destination	Government
0006	Destination	Government	Destination	Government
0007	Destination	Government	Destination	Government
000701	N/A	N/A	N/A	N/A

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	POP 15-JUN-2020 TO 30-SEP-2022	N/A	USA MED RESEARCH MAT CMD (b) (6) 1430 VETERANS DRIVE FORT DETRICK MD 21702-5009 (b) (6) FOB: Destination	W23RYX
000101	N/A	N/A	N/A	N/A
0002	POP 15-JUN-2020 TO 30-SEP-2022	N/A	USA MED RESEARCH MAT CMD (b) (6) 1430 VETERANS DRIVE FORT DETRICK MD 21702-5009 (b) (6) FOB: Destination	W23RYX
000201	N/A	N/A	N/A	N/A
0003	POP 15-JUN-2020 TO 30-SEP-2022	N/A	USA MED RESEARCH MAT CMD (b) (6) 1430 VETERANS DRIVE FORT DETRICK MD 21702-5009 (b) (6) FOB: Destination	W23RYX
0004	POP 15-JUN-2020 TO 30-SEP-2022	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W23RYX
0005	POP 15-JUN-2020 TO 30-SEP-2022	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W23RYX
0006	POP 15-JUN-2020 TO 30-SEP-2022	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W23RYX
0007	POP 15-JUN-2020 TO 30-SEP-2022	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W23RYX
000701	N/A	N/A	N/A	N/A

Section G - Contract Administration Data

PAYMENT INSTRUCTIONS
PGI 204.7108 Payment instructions.
The contracting officer shall insert the payment instructions at the table found at the link below:
https://www.acq.osd.mil/dpap/dars/pgi/pgi_htm/current/PGI204_71.htm#payment_instructions

ACCOUNTING AND APPROPRIATION DATA

AA: 097202020210130000184105525202 55 R.0038743.3.2.2 6100.9000021001
COST CODE: A97CJ
AMOUNT: $(b) (4)

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	000101	GFEBS001150565200001	$(b) (4)
	000201	GFEBS001150565200002	$(b) (4)
	000701	GFEBS001150565200003	$(b) (4)

CLAUSES INCORPORATED BY FULL TEXT

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

(a) Definitions. As used in this clause—

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

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

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

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

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

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

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

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

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

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

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

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

Invoice as a 'Cost Voucher'

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

(ii) For fixed price line items—

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

_____

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

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

_____

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

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

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

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

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

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

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

Routing Data Table*

Field Name in WAWF	*Data to be entered in WAWF*
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W81XWH
Admin DoDAAC**	W81XWH
Inspect By DoDAAC	HAA480
Ship To Code	NA
Ship From Code	NA
Mark For Code	NA
Service Approver (DoDAAC)	W806YH
Service Acceptor (DoDAAC)	W806YH
Accept at Other DoDAAC	NA
LPO DoDAAC	NA
DCAA Auditor DoDAAC	HAA480
Other DoDAAC(s)	NA

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

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

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

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

(g) WAWF point of contact.

(b) (6) [redacted]

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

_____

(Contracting Officer: Insert applicable information or "Not applicable.")

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

(End of clause)

Section H - Special Contract Requirements

REGULATORY RIGHTS

REGULATORY RIGHTS IN EVENT OF PRODUCT DEVELOPMENT FAILURES

This contract includes research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. It is expected that this contract will result in the FDA clearance and commercialization of the SCoV-2 Ag *Detect*™ Rapid Test or the "Technology". The Contractor will be the sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) that controls the research under this contract. As the sponsor of the Regulatory Application to FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application. This provision protects the return on research and development investment made by the U.S. Army Medical Research and Development Command (USAMRDC) in the event of certain regulatory product development failures related to the Technology.

The Contractor agrees to the following:

a. Contractor will, within three (3) business days of receipt, provide USAMRDC with all communications and summaries thereof, both formal and informal, to or from FDA regarding the Technology and ensure that USAMRDC representatives are given advance notice of and are invited to participate with at least two (2) representatives in any formal or informal sponsor meetings with FDA;

b. If this contract/task order is terminated for nonperformance or the Contractor fails to commercially market the regulated technology within three years after the FDA issues approval or clearance, the Contractor, upon the request of the Government:

(i) shall transfer possession, ownership and sponsorship or holdership of any Regulatory Application (including any associated expedited review designation, priority review voucher, or marketing exclusivity eligibility or award), regulatory correspondence, and supporting regulatory information related to the Technology to USAMRMC or its designee;
(ii) shall inform FDA of the transfer of sponsorship or holdership of the Regulatory Application transferred under section (c)(i) above.

c. The terms of this provision and its derivative obligations:
(i) will be included in any license, sale or transfer by the Contractor to a third party of any intellectual property covered by section (b) above.
(ii) will survive the acquisition or merger of the Contractor by or with any third party.
(iii) will be included in any subcontracts relating to the development of the Technology.
(iv) will survive the expiration of this contract.

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.243-2 Alt V	Changes--Cost-Reimbursement (Aug 1987) - Alternate V	APR 1984
252.204-7018	Prohibition on the Acquisition of Covered Defense Telecommunications Equipment or Services	DEC 2019

CLAUSES INCORPORATED BY FULL TEXT

52.216-7 ALLOWABLE COST AND PAYMENT (AUG 2018)

(a) Invoicing.

(1) The Government will make payments to the Contractor when requested as work progresses, but (except for small business concerns) not more often than once every 2 weeks, in amounts determined to be allowable by the Contracting Officer in accordance with Federal Acquisition Regulation (FAR) subpart 31.2 in effect on the date of this contract and the terms of this contract. The Contractor may submit to an authorized representative of the Contracting Officer, in such form and reasonable detail as the representative may require, an invoice or voucher supported by a statement of the claimed allowable cost for performing this contract.

(2) Contract financing payments are not subject to the interest penalty provisions of the Prompt Payment Act. Interim payments made prior to the final payment under the contract are contract financing payments, except interim payments if this contract contains Alternate I to the clause at 52.232-25.

(3) The designated payment office will make interim payments for contract financing on the **30th** day after the designated billing office receives a proper payment request.

In the event that the Government requires an audit or other review of a specific payment request to ensure compliance with the terms and conditions of the contract, the designated payment office is not compelled to make payment by the specified due date.

(b) Reimbursing costs. (1) For the purpose of reimbursing allowable costs (except as provided in subparagraph (b)(2) of the clause, with respect to pension, deferred profit sharing, and employee stock ownership plan contributions), the term "costs" includes only--

(i) Those recorded costs that, at the time of the request for reimbursement, the Contractor has paid by cash, check, or other form of actual payment for items or services purchased directly for the contract;

(ii) When the Contractor is not delinquent in paying costs of contract performance in the ordinary course of business, costs incurred, but not necessarily paid, for--

(A) Supplies and services purchased directly for the contract and associated financing payments to subcontractors, provided payments determined due will be made--

(1) In accordance with the terms and conditions of a subcontract or invoice; and

(2) Ordinarily within 30 days of the submission of the Contractor's payment request to the Government;

(B) Materials issued from the Contractor's inventory and placed in the production process for use on the contract;

(C) Direct labor;

(D) Direct travel;

(E) Other direct in-house costs; and

(F) Properly allocable and allowable indirect costs, as shown in the records maintained by the Contractor for purposes of obtaining reimbursement under Government contracts; and

(iii) The amount of financing payments that have been paid by cash, check, or other forms of payment to subcontractors.

(2) Accrued costs of Contractor contributions under employee pension plans shall be excluded until actually paid unless--

(i) The Contractor's practice is to make contributions to the retirement fund quarterly or more frequently; and

(ii) The contribution does not remain unpaid 30 days after the end of the applicable quarter or shorter payment period (any contribution remaining unpaid shall be excluded from the Contractor's indirect costs for payment purposes).

(3) Notwithstanding the audit and adjustment of invoices or vouchers under paragraph (g) of this clause, allowable indirect costs under this contract shall be obtained by applying indirect cost rates established in accordance with paragraph (d) of this clause.

(4) Any statements in specifications or other documents incorporated in this contract by reference designating performance of services or furnishing of materials at the Contractor's expense or at no cost to the Government shall be disregarded for purposes of cost-reimbursement under this clause.

(c) Small business concerns. A small business concern may receive more frequent payments than every 2 weeks.

(d) Final indirect cost rates. (1) Final annual indirect cost rates and the appropriate bases shall be established in accordance with Subpart 42.7 of the Federal Acquisition Regulation (FAR) in effect for the period covered by the indirect cost rate proposal.

(2)(i) The Contractor shall submit an adequate final indirect cost rate proposal to the Contracting Officer (or cognizant Federal agency official) and auditor within the 6-month period following the expiration of each of its fiscal years. Reasonable extensions, for exceptional circumstances only, may be requested in writing by the Contractor and granted in writing by the Contracting Officer. The Contractor shall support its proposal with adequate supporting data.

(ii) The proposed rates shall be based on the Contractor's actual cost experience for that period. The appropriate Government representative and the Contractor shall establish the final indirect cost rates as promptly as practical after receipt of the Contractor's proposal.

(iii) An adequate indirect cost rate proposal shall include the following data unless otherwise specified by the cognizant Federal agency official:

(A) Summary of all claimed indirect expense rates, including pool, base, and calculated indirect rate.

(B) General and Administrative expenses (final indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts).

(C) Overhead expenses (final indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts) for each final indirect cost pool.

(D) Occupancy expenses (intermediate indirect cost pool). Schedule of claimed expenses by element of cost as identified in accounting records (Chart of Accounts) and expense reallocation to final indirect cost pools.

(E) Claimed allocation bases, by element of cost, used to distribute indirect costs.

(F) Facilities capital cost of money factors computation.

(G) Reconciliation of books of account (i.e., General Ledger) and claimed direct costs by major cost element.

(H) Schedule of direct costs by contract and subcontract and indirect expense applied at claimed rates, as well as a subsidiary schedule of Government participation percentages in each of the allocation base amounts.

(I) Schedule of cumulative direct and indirect costs claimed and billed by contract and subcontract.

(J) Subcontract information. Listing of subcontracts awarded to companies for which the contractor is the prime or upper-tier contractor (include prime and subcontract numbers; subcontract value and award type; amount claimed during the fiscal year; and the subcontractor name, address, and point of contact information).

(K) Summary of each time-and-materials and labor-hour contract information, including labor categories, labor rates, hours, and amounts; direct materials; other direct costs; and, indirect expense applied at claimed rates.

(L) Reconciliation of total payroll per IRS form 941 to total labor costs distribution.

(M) Listing of decisions/agreements/approvals and description of accounting/organizational changes.

(N) Certificate of final indirect costs (see 52.242-4,
Certification of Final Indirect Costs).

(O) Contract closing information for contracts physically completed in this fiscal year (include contract number, period of performance, contract ceiling amounts, contract fee computations, level of effort, and indicate if the contract is ready to close).

(iv) The following supplemental information is not required to determine if a proposal is adequate, but may be required during the audit process:

(A) Comparative analysis of indirect expense pools detailed by account to prior fiscal year and budgetary data.

(B) General organizational information and limitation on allowability of compensation for certain contractor personnel. See 31.205-6(p). Additional salary reference information is available at https://www.whitehouse.gov/wp-content/uploads/2017/11/ContractorCompensationCapContractsAwardedBeforeJune24.pdf and https://www.whitehouse.gov/wp-content/uploads/2017/11/ContractorCompensationCapContractsAwardedafterJune24.pdf.

(C) Identification of prime contracts under which the contractor performs as a subcontractor.

(D) Description of accounting system (excludes contractors required to submit a CAS Disclosure Statement or contractors where the description of the accounting system has not changed from the previous year's submission).

(E) Procedures for identifying and excluding unallowable costs from the costs claimed and billed (excludes contractors where the procedures have not changed from the previous year's submission).

(F) Certified financial statements and other financial data (e.g., trial balance, compilation, review, etc.).

(G) Management letter from outside CPAs concerning any internal control weaknesses.

(H) Actions that have been and/or will be implemented to correct the weaknesses described in the management letter from subparagraph G) of this section.

(I) List of all internal audit reports issued since the last disclosure of internal audit reports to the Government.

(J) Annual internal audit plan of scheduled audits to be performed in the fiscal year when the final indirect cost rate submission is made.

(K) Federal and State income tax returns.

(L) Securities and Exchange Commission 10-K annual report.

(M) Minutes from board of directors meetings.

(N) Listing of delay claims and termination claims submitted which contain costs relating to the subject fiscal year.

(O) Contract briefings, which generally include a synopsis of all pertinent contract provisions, such as: Contract type, contract amount, product or service(s) to be provided, contract performance period, rate ceilings, advance approval requirements, pre-contract cost allowability limitations, and billing limitations.

(v) The Contractor shall update the billings on all contracts to reflect the final settled rates and update the schedule of cumulative direct and indirect costs claimed and billed, as required in paragraph (d)(2)(iii)(I) of this section, within 60 days after settlement of final indirect cost rates.

(3) The Contractor and the appropriate Government representative shall execute a written understanding setting forth the final indirect cost rates. The understanding shall specify (i) the agreed-upon final annual indirect cost rates, (ii) the bases to which the rates apply, (iii) the periods for which the rates apply, (iv) any specific indirect cost items treated as direct costs in the settlement, and (v) the affected contract and/or subcontract, identifying any with advance agreements or special terms and the applicable rates. The understanding shall not change any monetary ceiling, contract obligation, or specific cost allowance or disallowance provided for in this contract. The understanding is incorporated into this contract upon execution.

(4) Failure by the parties to agree on a final annual indirect cost rate shall be a dispute within the meaning of the Disputes clause.

(5) Within 120 days (or longer period if approved in writing by the Contracting Officer) after settlement of the final annual indirect cost rates for all years of a physically complete contract, the Contractor shall submit a completion invoice or voucher to reflect the settled amounts and rates. The completion invoice or voucher shall include settled subcontract amounts and rates. The prime contractor is responsible for settling subcontractor amounts and rates included in the completion invoice or voucher and providing status of subcontractor audits to the contracting officer upon request.

(6)(i) If the Contractor fails to submit a completion invoice or voucher within the time specified in paragraph (d)(5) of this clause, the Contracting Officer may--

(A) Determine the amounts due to the Contractor under the contract; and

(B) Record this determination in a unilateral modification to the contract.

(ii) This determination constitutes the final decision of the Contracting Officer in accordance with the Disputes clause.

(e) Billing rates. Until final annual indirect cost rates are established for any period, the Government shall reimburse the Contractor at billing rates established by the Contracting Officer or by an authorized representative (the cognizant auditor), subject to adjustment when the final rates are established. These billing rates--

(1) Shall be the anticipated final rates; and

(2) May be prospectively or retroactively revised by mutual agreement, at either party's request, to prevent substantial overpayment or underpayment.

(f) Quick-closeout procedures. Quick-closeout procedures are applicable when the conditions in FAR 42.708(a) are satisfied.

(g) Audit. At any time or times before final payment, the Contracting Officer may have the Contractor's invoices or vouchers and statements of cost audited. Any payment may be (1) Reduced by amounts found by the Contracting Officer not to constitute allowable costs or (2) Adjusted for prior overpayments or underpayments.

(h) Final payment. (1) Upon approval of a completion invoice or voucher submitted by the Contractor in accordance with paragraph (d)(5) of this clause, and upon the Contractor's compliance with all terms of this contract, the Government shall promptly pay any balance of allowable costs and that part of the fee (if any) not previously paid.

(2) The Contractor shall pay to the Government any refunds, rebates, credits, or other amounts (including interest, if any) accruing to or received by the Contractor or any assignee under this contract, to the extent that those amounts are properly allocable to costs for which the Contractor has been reimbursed by the Government. Reasonable expenses incurred by the Contractor for securing refunds, rebates, credits, or other amounts shall be allowable costs if approved by the Contracting Officer. Before final payment under this contract, the Contractor and each assignee whose assignment is in effect at the time of final payment shall execute and deliver--

(i) An assignment to the Government, in form and substance satisfactory to the Contracting Officer, of refunds, rebates, credits, or other amounts (including interest, if any) properly allocable to costs for which the Contractor has been reimbursed by the Government under this contract; and

(ii) A release discharging the Government, its officers, agents, and employees from all liabilities, obligations, and claims arising out of or under this contract, except--

(A) Specified claims stated in exact amounts, or in estimated amounts when the exact amounts are not known;

(B) Claims (including reasonable incidental expenses) based upon liabilities of the Contractor to third parties arising out of the performance of this contract; provided, that the claims are not known to the Contractor on the date of the execution of the release, and that the Contractor gives notice of the claims in writing to the Contracting Officer within 6 years following the release date or notice of final payment date, whichever is earlier; and

(C) Claims for reimbursement of costs, including reasonable incidental expenses, incurred by the Contractor under the patent clauses of this contract, excluding, however, any expenses arising from the Contractor's indemnification of the Government against patent liability.

(End of clause)

52.244-2 SUBCONTRACTS (OCT 2010)

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

Approved purchasing system means a Contractor's purchasing system that has been reviewed and approved in accordance with Part 44 of the Federal Acquisition Regulation (FAR).

Consent to subcontract means the Contracting Officer's written consent for the Contractor to enter into a particular subcontract.

Subcontract means any contract, as defined in FAR Subpart 2.1, entered into by a subcontractor to furnish supplies or services for performance of the prime contract or a subcontract. It includes, but is not limited to, purchase orders, and changes and modifications to purchase orders.

(b) When this clause is included in a fixed-price type contract, consent to subcontract is required only on unpriced contract actions (including unpriced modifications or unpriced delivery orders), and only if required in accordance with paragraph (c) or (d) of this clause.

(c) If the Contractor does not have an approved purchasing system, consent to subcontract is required for any subcontract that—

(1) Is of the cost-reimbursement, time-and-materials, or labor-hour type; or

(2) Is fixed-price and exceeds—

(i) For a contract awarded by the Department of Defense, the Coast Guard, or the National Aeronautics and Space Administration, the greater of the simplified acquisition threshold or 5 percent of the total estimated cost of the contract; or

(ii) For a contract awarded by a civilian agency other than the Coast Guard and the National Aeronautics and Space Administration, either the simplified acquisition threshold or 5 percent of the total estimated cost of the contract.

(d) If the Contractor has an approved purchasing system, the Contractor nevertheless shall obtain the Contracting Officer’s written consent before placing the following subcontracts:

(e)(1) The Contractor shall notify the Contracting Officer reasonably in advance of placing any subcontract or modification thereof for which consent is required under paragraph (b), (c), or (d) of this clause, including the following information:

(i) A description of the supplies or services to be subcontracted.

(ii) Identification of the type of subcontract to be used.

(iii) Identification of the proposed subcontractor.

(iv) The proposed subcontract price.

(v) The subcontractor’s current, complete, and accurate certified cost or pricing data and Certificate of Current Cost or Pricing Data, if required by other contract provisions.

(vi) The subcontractor’s Disclosure Statement or Certificate relating to Cost Accounting Standards when such data are required by other provisions of this contract.

(vii) A negotiation memorandum reflecting—

(A) The principal elements of the subcontract price negotiations;

(B) The most significant considerations controlling establishment of initial or revised prices;

(C) The reason certified cost or pricing data were or were not required;

(D) The extent, if any, to which the Contractor did not rely on the subcontractor's certified cost or pricing data in determining
the price objective and in negotiating the final price;

(E) The extent to which it was recognized in the negotiation that the subcontractor's certified cost or pricing data were not accurate, complete, or current; the action taken by the Contractor and the subcontractor; and the effect of any such defective data on the total price negotiated;

(F) The reasons for any significant difference between the Contractor's price objective and the price negotiated; and

(G) A complete explanation of the incentive fee or profit plan when incentives are used. The explanation shall identify each critical performance element, management decisions used to quantify each incentive element, reasons for the incentives, and a summary of all trade-off possibilities considered.

(2) The Contractor is not required to notify the Contracting Officer in advance of entering into any subcontract for which consent is not required under paragraph (c), (d), or (e) of this clause.

(f) Unless the consent or approval specifically provides otherwise, neither consent by the Contracting Officer to any subcontract nor approval of the Contractor's purchasing system shall constitute a determination—

(1) Of the acceptability of any subcontract terms or conditions;

(2) Of the allowability of any cost under this contract; or

(3) To relieve the Contractor of any responsibility for performing this contract.

(g) No subcontract or modification thereof placed under this contract shall provide for payment on a cost-plus-a-percentage-of-cost basis, and any fee payable under cost-reimbursement type subcontracts shall not exceed the fee limitations in FAR 15.404-4(c)(4)(i).

(h) The Contractor shall give the Contracting Officer immediate written notice of any action or suit filed and prompt notice of any claim made against the Contractor by any subcontractor or vendor that, in the opinion of the Contractor, may result in litigation related in any way to this contract, with respect to which the Contractor may be entitled to reimbursement from the Government.

(i) The Government reserves the right to review the Contractor's purchasing system as set forth in FAR Subpart 44.3.

(j) Paragraphs (c) and (e) of this clause do not apply to the following subcontracts, which were evaluated during negotiations:

Subcontractors listed in original proposal

(End of clause)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
	1 19

2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00001	06-Nov-2020	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
USA MED RESEARCH ACQ ACTIVITY 820 CHANDLER ST FORT DETRICK MD 21702-5014	W81XWH	See Item 6	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
INBIOS NTERNATIONAL NC (b) (6) 307 WESTLAKE AVE N STE 300 SEATTLE WA 98109-5235		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W81XWH20F0253
	X	10B. DATED (SEE ITEM 13) 15-Jun-2020
CODE 3KJL6	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 Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

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

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
FAR 52.243-2 Alt V and FAR 52.217-9

☐ D. 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.)

Modification Control Number: jdiggs212

The Purpose of this Modification is to:

a) Exercise Optional Task CLINs 0003, 0004, 0005, and 0006.
b) Increase CLIN 0005 for the within scope change to add additional clinical site.
c) Provide funding to CLINs 0003, 0004, 0005, and 0006.
d) Update incremental funding schedule; See Summary of Changes for details.
e) All other terms and conditions remain unchanged.

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

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) PATRICK K HARRIS / CONTRACTING OFFICER TEL: (301) 619-2779 EMAIL: patrick.k.harris11.civ@mail.mil	
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY (b) (6)	16C. DATE SIGNED 06-Nov-2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by $(b) (4) from $(b) (4) to $(b) (4)

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0003
The option status has changed from Option to Option Exercised.

CLIN 0004
The option status has changed from Option to Option Exercised.

CLIN 0005
The estimated/max cost has increased by $(b) (4) from $(b) (4) to $(b) (4)
The option status has changed from Option to Option Exercised.
The total cost of this line item has increased by $(b) (4) from $(b) (4) to $(b) (4)

CLIN 0006
The option status has changed from Option to Option Exercised.

SUBCLIN 000301 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000301					$0.00
	Funding Only				
	CPFF				
	Funding Only				
	PURCHASE REQUEST NUMBER: 0011568334				
				ESTIMATED COST	$0.00
				FIXED FEE	$0.00
				TOTAL EST COST + FEE	$0.00
	ACRN AB				$(b) (4)
	CIN: GFEBS001156833400001				

SUBCLIN 000401 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000401					$0.00
	Funding				
	COST				
	Funding				
	PURCHASE REQUEST NUMBER: 0011568334				
				ESTIMATED COST	$0.00
	ACRN AB				$(b) (4)
	CIN: GFEBS001156833400002				

SUBCLIN 000501 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000501					$0.00
	Funding				
	CPFF				
	Funding				
	PURCHASE REQUEST NUMBER: 0011568334				
				ESTIMATED COST	$0.00
				FIXED FEE	$0.00
				TOTAL EST COST + FEE	$0.00
	ACRN AB				$(b) (4)
	CIN: GFEBS001156833400003				

SUBCLIN 000601 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000601					$0.00
	Funding				
	COST				
	Funding				
	PURCHASE REQUEST NUMBER: 0011568334				
				ESTIMATED COST	$0.00
	ACRN AB				$(b) (4)
	CIN: GFEBS001156833400004				

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been added by full text:

SOW-10-13-20

VOLUME II(B) – TECHNICAL VOLUME ATTACHMENTS
STATEMENT OF WORK

Contract Number: W81XWH-16-D-0009 (TO#4)

Offeror: InBios International, Inc.

Technical Contact: (b) (6) [redacted]

DEVELOPMENT AND FDA CLEARANCE OF RAPID DIAGNOSTIC TESTS TO DETECT BIOMARKERS OF SARS-COV-2 INFECTION

Contractual Statement of Work

Submitted on May 1, 2020
Revised SOW: October 13, 2020

This Task Order will be focused on the development, design controls, production, and analytical studies and clinical trials required for FDA authorization or clearance of rapid human diagnostic Component Assays for SARS-CoV-2 infection, the causative agent of COVID-19. The task order Statement of Work encompasses all development, manufacturing, regulatory, and quality control activities required to achieve Key Performance parameter (KPPs) and FDA authorization and clearance.

Overall Objectives and Scope

The overall goal of this task order is to obtain FDA authorization and/or clearance for hand-held Immunochromatographic Tests (ICTs) detecting several biomarkers corresponding to severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2) infection that have the ability to enhance differential diagnosis through all stages of infection - early, late, and convalescent infection by direct antigen and serology detection.

The ICTs will be simple, easy-to-use devices designed to detect SARS-CoV-2-specific analytes in small volumes of human samples that can be collected in Clinical Laboratory Improvement Amendments (CLIA)-waiver settings. The SCoV-2 *Detect*™ IgM/IgG rapid test will detect IgM and IgG antibodies to SARS-CoV-2 in fingerprick blood, venous whole blood and serum samples. The SCoV-2 Ag *Detect*™ Rapid Tests will detect SARS-CoV-2 antigens in respiratory specimens collected from acute patients. The ICTs will produce results within 15-30 minutes from sample collection and the lateral flow test strip shelf life will be ≥18 months at room temperature.

Option 1: FDA EUA for SCoV-2 Ag *Detect*™ Rapid Test
The objective of this option is to develop and obtain Emergency Use Authorization (EUA) for SCoV-2 Ag Detect, a point-of-care (POC) diagnostic test to identify persons infected with SARS-CoV-2, the causative agent of COVID-19. The assay will detect virus particles in respiratory specimens (including nasopharyngeal swab samples) from patients who meet COVID-19 clinical and/or epidemiological criteria.
Anticipated period of performance: May, 10 2020 – September 30, 2020

Option 2: FDA clearance and CLIA waiver for SCoV-2 Ag *Detect*™ Rapid Test
After obtaining Emergency Use Authorization (EUA) for SCoV-2 Ag *Detect*™ Rapid Test, InBios will pursue *de novo*/510(k) submissions for SCoV-2 Ag *Detect*™ Rapid Test. CLIA waiver submission will be pursued in parallel.
Anticipated period of performance: October, 1 2020 – September 30, 2022

Option 3: Clinical studies for FDA EUA POC claim for SCoV-2 *Detect*™ IgM/IgG Rapid Test
The objective of this option is to carry out performance studies at two clinical test sites required to obtain FDA EUA with a POC claim for SCoV-2 *Detect*™ IgM/IgG Rapid Test.

Anticipated period of performance: October, 16 2020 – March 30, 2021

Option 4: FDA clearance and CLIA waiver for SCoV-2 *Detect*™ IgM/IgG Rapid Test
The objective of this option is to develop and obtain FDA clearance and CLIA waiver for SCoV-2 *Detect*™ IgM/IgG Rapid Test, a lateral flow serodiagnostic test designed to identify persons infected with SARS-CoV-2 using serum and whole blood, including fingerprick blood. SCoV-2 *Detect*™ IgM/IgG Rapid Test is designed to detect the human biomarkers IgM and IgG to SARS-CoV-2 in point-of-care settings. Rapid serological tests are needed to quickly and easily identify symptomatic and high-risk asymptomatic individuals who can be carriers responsible for a large percentage of person-to-person transmission.
Anticipated period of performance: July 1 2020, - March 31, 2022

The scope of work for this task order includes optimization and finalization of SCoV-2 *Detect*™ Rapid Test assay designs, production of kits, conducting analytical and clinical performance studies for regulatory submissions clearance, regulatory communication with FDA including submissions, and following all necessary design and quality controls for SCoV-2 *Detect*™ Rapid Tests. TO#0004 will cover all activities required to ensure high performance throughout the task order including project management, subcontractor management, risk analysis, and quality assurance and control activities,

STATEMENT OF WORK (TASK ORDER 0004)

DEVELOPMENT AND FDA CLEARANCE OF RAPID DIAGNOSTIC TESTS TO DETECT BIOMARKERS OF SARS-COV-2 INFECTION

Task 1. Development of SCoV-2 Ag *Detect*™ Rapid Test

1.1. Option 1: Emergency Use Authorization (EUA) for SCoV-2 Ag *Detect*™

1.1.1. Regulatory
InBios shall develop and manufacture SCoV-2 Ag *Detect*™ kit, an easy-to-use rapid lateral flow immunoassay for identification of persons infected with severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2), the causative agent of COVID-19. InBios will initially seek Emergency Use Authorization (EUA) for SCoV-2 Ag *Detect*™.

1.1.1.1. Pre-EUA FDA communication. FDA has issued an EUA interactive review template for antigen-based tests for 2019 Novel Coronavirus. The studies for inclusion in an EUA submission package include limit of detection (LOD), inclusivity, cross-reactivity, microbial and endogenous interference studies, specimen stability, matrix equivalency, hook effect, and clinical evaluation. InBios will continue to seek and follow FDA guidance during the ongoing pre-EUA interactive review period.

1.1.1.2. EUA submission. The EUA submission package will follow the EUA template and include a proposed intended use statement, study performance data, and a draft package insert. After submission, InBios will work with the FDA during the interactive review period until EUA is obtained.

1.1.2. Development of SCoV-2 Ag *Detect*™ Kit design.
InBios shall develop lateral flow immunoassay prototypes for SARS-CoV-2 antigen detection towards EUA submission.

1.1.2.1. Generate anti-SARS-CoV-2 antibodies. InBios shall generate antibody reagents to specifically and sensitively bind and detect SARS-CoV-2 antigens. We will first focus on antibodies to (b) (4) including mice, rabbits, and alpacas for generation of monoclonal antibodies, polyclonal antibodies, (b) (4), respectively. InBios is also working with a number of collaborators to

generate and acquire/license some of the antibody reagents.
Additional antigens may be be acquired or cloned and purified for immunization, if deemed necessary. All antigenic targets may also be used in task 1.1.2.8.

1.1.2.2. Screening of developed SARS-CoV-2 antibodies. The antibodies from immunized animals will be screened and selected for affinity to SARS-CoV-2 antigens. Screening methods such as ELISAs and our proprietary SmartShot system, for identifying and characterizing promising SARS-CoV-2 antibodies, will be deployed. The antibodies will also be sequenced for potential generation of chimeras to enhance binding activity or assay performance.
Our proprietary imaging sensor-based SmartShot system will be used to select antibodies based on binding affinity and complementarity to one another. We will also use the SmartShot system to test for possible interference if we combine antibodies against multiple targets into a single test line. The highest performing antibody pairs will be used to develop and optimize rapid test prototypes.

1.1.2.3. Antibody purification. Selected antibodies shall be purified initially at a small scale for evaluation in the SCoV-2 Ag *Detect*™ prototype. Once promising antibodies are identified, three lots of purified antibodies shall be purified to ensure lot-to-lot consistency prior to design freeze. ELISA methods will be developed to qualify purified antibodies and ensure lot-to-lot consistency prior to incorporation into the SCoV-2 Ag *Detect*™ prototype.

1.1.2.4. Finalization of antibodies based on their reactivity in lateral flow immunoassay format. We will optimize the assay format by identifying which antibodies perform best as capture vs. detection reagents. Antibody pairs will be tested by both striping on membrane (capture system) and conjugating to gold nanoparticles (detection system). Selecting the right combination of antibodies as detection and capture reagents is critical to the development of a sensitive lateral flow assay. We will optimize assay sensitivity and functionality by iteratively testing combinations of sample and conjugate pads, gold conjugation conditions, blocking reagents, assay assembly methods, and other assay components.

1.1.2.5. Test and optimize gold conjugation conditions. Gold conjugation parameters such as pH, the concentration of antibody/OD gold, and the inclusion of blocking reagents conjugation shall be tested and optimized.

1.1.2.6. Identify and optimize blocking reagents to maximize assay specificity. In-house and commercial blockers shall be assessed for their ability to block non-specific reactivity. The concentration and formulation of blockers shall be optimized to maximize assay specificity without significantly compromising assay reactivity.

1.1.2.7. Design and test cassette. A cassette shall be selected from our in-house design library or newly designed. 3D-printed prototypes will be tested for specimen flow and clearance. Finalizing a cassette design will require multiple iterations of modification of the cassette and testing using serum and whole blood specimens. Injection-molded plastic cassettes will be manufactured once a cassette design is decided upon.

1.1.2.8. Development of positive and negative controls. The FDA will require external positive and negative controls to be provided with the SCoV-2 Ag *Detect*™ kit. Controls shall be developed using developed antigens from task 1.1.2.1.

1.1.2.9. Evaluate preliminary assay performance. During assay development, the rapid test will be evaluated and optimized using respiratory samples spiked with purified recombinant proteins internally or with *in vitro* grown virus with known titers externally (b) (4) (b) (4). Respiratory samples positive for other diseases may be used to initially test assay cross-reactivity. In parallel, we will identify respiratory samples from confirmed COVID-19 positive patients through collaborators and/or commercial suppliers for additional studies. Based on internal and external evaluation, a prototype device shall be chosen for execution of EUA studies with the goal of submitting for FDA EUA clearance.

1.1.3. Manufacture SCoV-2 Ag *Detect*™ Rapid Test for EUA studies

The Design Plan for the SCoV-2 Ag *Detect*™ Rapid Test will outline the design inputs and plans for process development, design transfer and manufacturing, and performance studies. SCoV-2 Ag *Detect*™ Rapid Tests shall be manufactured for EUA studies by the InBios manufacturing team.

1.1.3.1. Establish QC panels and test procedures. A QC panel containing antigens spiked into commercially available respiratory samples will be used to monitor assay development and for QC of the initial production lots. We will explore the use of (b) (4) (b) (4) piked into respiratory samples. Negative samples will include normal NP swab samples and potentially samples (b) (4)

1.1.3.2. SCoV-2 Ag *Detect*™ Rapid Test manufacture for EUA studies. We will manufacture pilot lot of SCoV-2 Ag *Detect*™ Rapid Test for execution of performance studies for EUA submission. Standard operating procedures will be drafted for SCoV-2 Ag *Detect*™ Rapid Test production.

1.1.4. Conduct performance studies for EUA submission

All analytical and clinical studies will be conducted following guidance from FDA. Study protocols shall be finalized based on FDA guidance in the interactive EUA template. Final study protocols shall be documented in the Design History File (DHF).

1.1.4.1. Analytical sensitivity/LoD: The LoD will determined using SARS-CoV-2 purified antigens or *in vitro* grown SARS-CoV-2 virus spiked into respiratory specimen samples. We will explore the use inactivated SARS-CoV-2 for additional studies if the LoD study supports that the inactivation process did not impact the assay LoD.

1.1.4.2. Cross-reactivity: Samples for cross-reactivity studies will include (b) (4) into respiratory specimens. The full list of specimens to be tested in the cross-reactivity study will be confirmed with FDA.

1.1.4.3. Inclusivity: We will evaluate the ability of the SCov-2 Ag *Detect*™ assay to detect available SARS-CoV-2 isolates.

1.1.4.4. Specimen stability: A specimen stability study will be conducted to support specimen stability claims. A fresh/frozen and/or freeze/thaw study may be needed to support the use of frozen specimens in the clinical evaluation study.

1.1.4.5. Hook Effect: A hook effect study will be used to determine if a false negative can result when very high levels of antigen are present in a sample.

1.1.4.6. Interfering substances: Interfering substances study will be used to determine if microbes or substances present in blood products will result in false positive or false negative results.

1.1.4.7. Clinical evaluation: Due to limited access to clinical specimens, we propose to perform part of the clinical evaluation study using different (b) (4) (b) (4) Positive and negative percent agreement are expected to be ≥ 90%.

1.1.4.8. EUA study data analysis and report writing. EUA study data shall be analyzed in accordance with study protocols. Reports shall be written to summarize study design and results and shall be documented in the DHF.

1.2. Option 2: FDA market authorization for SCoV-2 Ag *Detect*™

1.2.1. Regulatory

After obtaining Emergency Use Authorization (EUA) for SCoV-2 Ag *Detect*™, InBios will pursue *de novo*/510(k) submission for SCoV-2 Ag *Detect*™. CLIA waiver submission will be pursued concurrently. InBios shall seek FDA guidance during the design phase via FDA pre-submission program.

1.2.1.1. Prepare and submit pre-submission to FDA. InBios shall continue to interact with the FDA to seek guidance for a regulatory strategy for FDA clearance and CLIA waiver of the SCoV-2 Ag *Detect*™ assay. A pre-submission package will be submitted to obtain guidance on data required for de novo/510(k) clearance. The pre-submission package shall be focused on clarifying product intended use statement, the regulatory pathway, and protocols for bench and clinical performance studies that will be required for market authorization.

1.2.1.2. Prepare and submit *de novo*/510(k) package. InBios shall follow the regulatory guidance gained during the pre-submission process. Preparation of the *de novo*/510(k) submission package shall begin when analytical and clinical performance data analyses are complete, and study results meet the design specifications.

1.2.1.3. Prepare and submit CLIA waiver package. InBios shall follow the regulatory guidance gained during the pre-submission process to submit an application for CLIA waiver.

1.2.2. Finalize device design for market authorization (*de novo*/510(k) submission)

InBios shall build on the EUA SCov-2 Ag *Detecf*™ device design. If warranted, InBios will optimize the lateral flow immunoassay design based on the outcomes of the EUA performance studies. Assay parameters that may be modified include the cassette design, optimizing formulation of blocking reagents, inclusion of additional SARS-CoV-2 target antigens, or optimizing gold conjugation conditions.

1.2.2.1. Perform further testing and selection of SARS-CoV-2 antibodies in lateral flow immune-assay format, **if warranted**. Additional promising antibodies, or antigenic detection targets, shall be incorporated and tested in the LFI format to determine whether they improve reactivity of the SCoV-2 Ag *Detecf*™ prototype.

1.2.2.2. Optimize assay specifications and formulations based on EUA study performnace. If warranted based on EUA study performance and other performance evaluations, SCov-2 Ag *Detecf*™ assay parameters may be optimized to enhance assay performance for FDA clearance. This may include investigations into gold conjugation conditions; identifying, formulating, and optimizing additional blocking reagents, adding stabilizers to the assay components for extended shelf life, cassette modifications, or modifying pad treatment formulations and buffers.

1.2.2.3. Finalize positive and negative control formulations and preliminary stability studies. The positive and negative control formulations shall be finalized. We shall begin accelerated and real-time stability studies prior to design freeze. Control formulations shall be stable at room temperature for ≥18 months.

1.2.2.4. Complete stability testing of final SCoV-2 Ag *Detecf*™ prototype. Final SCoV-2 Ag *Detecf*™ prototype shall be tested in preliminary accelerated and real-time stability experiments. The target shelf-life for the SCoV-2 Ag *Detecf*™ device is at least 18 months at room temperature.

1.2.2.5. Evaluate assay performance of final SCoV-2 Ag *Detecf*™ prototype. During the final assay development, the rapid test will be evaluated using respiratory samples spiked with purified recombinant proteins internally or (b) (4) (b) (4) In parallel, respiratory samples from confirmed COVID-19 positive patients acquired through collaborators and/or commercial suppliers will be tested. Respiratory samples positive for other diseases will be used to initially test assay cross-reactivity. Based on the results and internal evaluations, InBios will select a final prototype to move forward with design freeze, cGMP manufacture, and FDA *de novo*/510(k) submission studies.

1.2.3. Process Development and Scale Up

Once optimized procedures are developed for the production of all reagents, InBios shall initiate the scale-up of reagents to ensure a steady supply of reagents is available for the manufacture of SCoV-2 Ag *Detecf*™ Rapid Test kits. Production procedures will be updated and/or finalized during the scale-up and process development will be finalized.

1.2.3.1. Optimization and scale-up of hybridomas for antibody production. We shall scale-up and optimize procedures for the production of the selected antibodies. Scaled up cell culture techniques shall be used to ensure an efficient process is in place for generating antibodies.

1.2.3.2. Optimization and scale up of antibody purifications. We shall optimize procedures for purification and long-term storage of the selected antibodies. Purified antibodies may be dialyzed into optimized buffer conditions prior to storage. Three lots of each antibody shall be produced using the final purification procedure to ensure a repeatable process is in place.

1.2.3.3. Scale up antibody-gold conjugation. The optimized gold conjugation conditions from task 1.2.2.2 shall be scaled-up to produce large lots for incorporation into the ICTs.

1.2.3.4. Identify sources for kit accessories as needed. Raw material specification documents shall be in place for all vendor-acquired kit accessories.

1.2.3.5. Draft product insert. Once an assay procedure is identifed, a product insert shall be drafted for

use in performance studies and for eventual FDA submission. The final product insert shall describe: 1) intended use, 2) description of device, 3) description of kit contents, 4) instructions for device use, 5) algorithm for results interpretation, 6) quality control guidance, 7) precaution statements, 8) device performance characteristics and 9) possible use limitations.

1.2.3.6. Development of QC panels. A QC Panel will be developed to monitor cGMP manufacturing and lot to lot variability. Panel members shall include SARS-CoV-2 antigen-spiked specimens close to the limit of detection. Antigen stability shall be assessed to ensure QC panel stability. New panel members shall be generated after determining antigen concentration using validated methods. QC panel members shall made in (b) (4) which may potentially be spiked with any (b) (4)

1.2.4. Design Transfer

InBios has extensive knowledge and experience in design transfer of devices from R&D to manufacturing and cGMP manufacturing. This knowledge base shall be applied to the transfer of the SCoV-2 Ag *Detect*™ assay to GMP manufacturing. Production standard operating procedures updated during the scale-up and process development will be finalized.

1.2.4.1. Finalize documentation for manufacturing SCoV-2 Ag *Detect*™ rapid tests. InBios will finalize all documentation required for the spray, gold conjugation, lamination, assembly, and quality control of the SCoV-2 Ag *Detect*™ rapid tests prior to cGMP manufacture.

1.2.4.2. Finalize raw material specification. Raw material specification documents will be completed for each raw material that is incorporated into the SCoV-2 Ag *Detect*™ rapid tests kit.

1.2.4.3. Complete Design Transfer, Part 1. Prior to cGMP manufacture of SCoV-2 Ag *Detect*™ rapid test kits for performance studies, Part 1 of a documented design transfer process as outlined in InBios document SOP-0035 shall take place.

1.2.4.4. Complete Design Transfer, Part 2. The Design Transfer, Part 2 will take place prior to FDA submission after all performance study data is collected and the design team ensures the design outputs meet the design input criteria.

1.2.5. GMP Manufacturing

Upon completion design transfer, InBios shall initiate manufacturing of SCoV-2 Ag *Detect*™ kits under cGMP.

1.2.5.1. Draft device master record and product specifications. After all manufacturing documents are written, we shall draft product specifications and establish a Device Master Record (DMR) containing a list of all documents required for the manufacture of SCoV-2 Ag *Detect*™.

1.2.5.2. cGMP manufacturing. Once the SCoV-2 Ag *Detect*™ design is frozen and transferred from R&D to manufacturing, we shall manufacture at least three test kit lots under cGMP. InBios will manufacture lots of SCoV-2 Ag *Detect*™ rapid tests for process validation, in-house studies, and clinical evaluation studies as per FDA pre-submission feedback under cGMP. Device History Records will be generated for each lot of SCoV-2 Ag *Detect*™ rapid tests produced. The QC panel shall be used to demonstrate lot-to-lot consistency for the three lots of SCoV-2 Ag *Detect*™ assays.

1.2.6. Studies for *de novo*/510(k) and CLIA waiver submission

With FDA guidance, we shall execute the necessary SCoV-2 Ag *Detect*™ performance studies required for regulatory submission. Studies will be conducted using kits produced under cGMP.

1.2.6.1. Bench studies. FDA will require a number of laboratory product performance data to support SCoV-2 Ag *Detect*™ regulatory submission and clearance. We shall conduct pre-submission communications with the FDA (1.2.1.1.) to establish details of bench studies to be performed. Testing shall be performed according to the instructions provided in the package insert. It is anticipated additional studies, such as flex studies shall be required for CLIA waiver. All data shall be analyzed and submitted as reports which will be included in the de novo submission package.

1.2.6.1.1. Draft bench study protocols. Study protocols shall be drafted prior to submitting an FDA pre-submission supplement to gain FDA guidance.

1.2.6.1.2. Finalize protocols for in-house studies as per pre-submission feedback from FDA. We shall gain pre-submission feedback from the FDA before finalizing in-house study protocols. All study protocols will be finalized prior to execution.

1.2.6.1.3. Acquire reagents needed for bench studies. We shall obtain specimens and reagents required to complete the bench studies. These reagents will be obtained from collaborators or purchased from commercial vendors or collaborators. We will establish agreements with subcontractors to conduct analytical studies requiring Biosafety Level 3 capbilities (which InBios does not have).

1.2.6.1.4. Perform bench studies in accordance with the final study protocols. The studies required for FDA clearance and CLIA waiver submission will likely include: Limit of Detection study, Inclusivity/analytical reactivity study, Exclusivity/analytical specificity study, Interfering substances/Microbial Interference, Flex studies, Specimen stability studies, and a multi-site Reproducibility study. Operators shall be trained on protocols prior to study execution. Data will be filed in the DHF.

1.2.6.1.4.1. Identify sites for reproducibility studies and execute subcontracting agreements, as necessary for testing. Subcontracting agreements shall be executed prior to testing at external sites.

1.2.6.1.5. Perform accelerated stability testing at high elevated temperature with GMP kit lots. The stability study shall compare tests that have undergone accelerated aging to a control group and to expected values. These studies are conducted to establish shelf life of the SCoV-2 Ag *Detect*™ kit.

1.2.6.1.6. Perform stability studies. An accelerated stability study shall compare tests that have undergone accelerated aging to a control group and to expected values. Real-time stability studies shall directly compare tests that have undergone real-time aging to a control group and to expected values. The SCoV-2 Ag *Detect*™ Rapid Test kit target shelf life is at least 18 months at room temperature.

1.2.6.1.7. Perform Shipping studies (including heat stress and cold stress). Shipping studies shall be performed to characterize the packaging strength and reagent stability of the SCoV-2 Ag *Detect*™ kit.

1.2.6.1.8. Bench study data analysis and report writing. Data analysis for all bench studies will take place according to the finalized protocols. Reports for all bench studies shall be written and placed into the DHF. SCoV-2 Ag *Detect*™ bench study reports will be included in the for FDA submission package.

1.2.6.2. Clinical performance studies. We plan to start clinical studies using cGMP kits as per FDA pre-submission feedback (1.2.1.1). InBios shall initiate a teaming agreement with a Contract Research Organization (CRO) to implement clinical studies.

1.2.6.2.1. Draft clinical study protocols. Study protocols shall be created with engagement from the CRO. A reference standard shall be agreed upon with feedback from FDA.

1.2.6.2.2. Finalize protocols as per FDA pre-submission feedback. The clinical study protocol shall be finalized based on FDA pre-submission feedback and will approved by InBios and the CRO.

1.2.6.2.3. Site selection; establish subcontractor agreements with clinical sites. Appropriate clinical sites shall be identified for conducting the clinical evaluation studies. Subcontractor agreements shall be established between InBios and field sites. It is anticipated the clinical studies will be conducted at at least 3 locations.

1.2.6.2.4. Clinical study protocol and study document approval from appropriate IRBs and HRPO. The finalized clinical study protocol, consent documents, and any other required documentation will be submitted to the appropriate IRBs and HRPO. Any required changes will be incorporated prior to IRB/HRPO approval.

1.2.6.2.5. Conduct study initiation, train operators at test sites. The CRO shall conduct onboard training at clinical testing sites. Operators shall be trained on how to use the test kits and electronic data management system, and how to properly conduct the study prior to

study initiation.

1.2.6.2.6. Clinical testing at field sites and confirmatory testing. Testing at field sites should take place after all IRB/HRPO approvals are obtained. Clinical evaluation studies will proceed in accordance with the final clinical study protocol.

1.2.6.2.7. Site closeouts, data analysis, report writing. The CRO shall conduct a closeout session after the conclusion of clinical trials. This will include spot-checking records to make sure data transfer and recording are correct, overseeing disposal of leftover materials, and spot-checking that patients enrolled in studies met inclusion criteria. A report of the clinical trial data and analysis shall be written for *de novo*/510(k) submission.

Task 2. Clinical studies for FDA EUA of SCoV-2 *Detect*™ IgM/IgG Rapid Test

2.1 Option 3: Clinical studies for FDA EUA point-of-care claim for SCoV-2 *Detect*™ IgM/IgG Rapid Test

InBios shall execute clinical studies at two different POC test settings to support the FDA EUA POC claim for SCoV-2 *Detect*™ IgM/IgG Rapid Test, an easy-to-use rapid lateral flow immunoassay for identification human IgM and IgG antibodies against SARS-CoV-2 in blood specimens.

2.1.1. Clinical study protocol and study document approval from appropriate IRBs and HRPO. The finalized clinical study protocol, consent documents, and any other required documentation will be submitted to the appropriate IRBs and HRPO. Any required changes will be incorporated prior to IRB/HRPO approval.

2.1.2. Conduct study initiation, train operators at test sites. InBios shall conduct onboard training at clinical testing sites. Operators shall be trained on how to properly conduct the study, including the required study documentation, prior to study initiation.

2.1.3. Clinical testing at field sites and confirmatory testing. Testing at POC clinical test sites shall take place after all IRB/HRPO approvals are obtained. Clinical evaluation studies will proceed in accordance with the final clinical study protocol.

2.1.4. Site closeouts, data analysis, report writing. InBios shall conduct a closeout session after the conclusion of clinical trials. This will include spot-checking records to make sure data transfer and recording are correct, overseeing disposal of leftover materials, and spot-checking that patients enrolled in studies met inclusion criteria. A report of the clinical trial data and analysis shall be written for EUA submission.

Task 3. FDA 510(k) clearance of SCoV-2 *Detect*™ IgM/IgG Rapid Test

3.1 Option 4: FDA market authorization for SCoV-2 *Detect*™ IgM/IgG Rapid Test

InBios shall finalize assay design for SCoV-2 *Detect*™ IgM/IgG Rapid Test. Process development and cGMP manufacture of SCoV-2 *Detect*™ IgM/IgG Rapid Test will occur after design transfer. Performance studies for regulatory submission will be conducted based on FDA guidance obtained during the pre-submission process.

3.1.1. Regulatory

After obtaining Emergency Use Authorization (EUA) for SCoV-2 *Detect*™ IgM/IgG Rapid Test (anticipated June 2020), InBios will pursue *de novo*/510(k) submission for SCoV-2 *Detect*™ IgM/IgG Rapid Test. InBios shall seek FDA guidance via the FDA pre-submission program.

3.1.1.1. Prepare and submit pre-submission supplement to FDA. InBios will submit a pre-submission package to FDA to obtain guidance on studies required for FDA clearance and CLIA waiver application. The pre-submission package will include a draft intended use statement, proposed regulatory pathway, device description, specific questions, and draft analytical and clinical study protocols.

3.1.1.2. Prepare and submit *de novo*/510(k) package. InBios shall follow the regulatory guidance

gained during the pre-submission process. Preparation of the *de novo*/510(k) submission package shall begin when analytical and clinical performance data analyses are complete, and study results meet the design specifications.

3.1.1.3. Prepare and submit CLIA waiver package. InBios shall follow the regulatory guidance gained during the pre-submission process to submit an application for CLIA waiver.

3.1.2. Finalize device design for FDA clearance and CLIA waiver application

InBios shall build on the EUA SCoV-2 *Detect*™ IgM/IgG Rapid Test device design. If warranted, InBios will optimize the lateral flow immunoassay design based on the outcomes of the EUA performance studies. Assay parameters that may be modified include the cassette design, optimizing formulation of blocking reagents, inclusion of additional SARS-CoV-2 target antigens, optimizing gold conjugation buffers.

3.1.2.1. Perform further testing and selection of SARS-CoV-2 antigens in lateral flow immune-assay format, **if warranted**. Additional promising antigens shall be expressed, purified, and incorporated in the LFI format to determine whether they improve reactivity of the SCoV-2 *Detect*™ IgM/IgG prototypes without compromising assay specificity.

3.1.2.2. Optimize assay specifications and formulations based on EUA study performnace. If warranted based on EUA study performance and other performance evaluations, SCov-2 *Detect*™ IgM/IgG assay parameters may be optimized to enhance assay performance for FDA clearance. This may include investigations into gold conjugation conditions; identifying, formulating, and optimizing additional blocking reagents, adding stabilizers to the assay components for extended shelf life, cassette modifications, or modifying pad treatment formulations and buffers.

3.1.2.3. Finalize positive and negative control formulations and preliminary stability studies. Due to a lack of consistent supply of disease serum for positive control, InBios shall explore the production of human chimeric antibodies for use as artificial positive controls. Artificial positive control formulations will be finalized prior to beginning accelerated and real-time stability studies. Control formulations shall be stable at room temperature for ≥18 months.

3.1.2.4. Complete stability testing of final SCoV-2 *Detect*™ IgM/IgG Rapid Test prototype. The SCoV-2 *Detect*™ IgM/IgG Rapid Test prototype shall be tested in preliminary accelerated and real-time stability experiments. The target shelf-life for the SCoV-2 *Detect*™ IgM/IgG Rapid Test is at least 18 months at room temperature.

3.1.2.5. Evaluate assay performance of SCoV-2 *Detect*™ IgM/IgG Rapid Test prototype. During the final assay optimization phase, the rapid test will be evaluated [redacted] performance prior to design [redacted] The final assay design shall be tested using whole blood specimens prior to design freeze.

3.1.3. Process Development and Scale-Up

Once optimized procedures are developed for the production of all reagents, InBios shall initiate the scale-up of reagents to ensure a steady supply of reagents is available for the manufacture of SCoV-2 *Detect*™ IgM/IgG Rapid Test kits.

3.1.3.1. Optimization and scale-up of SARS-CoV-2 antigen production. We shall scale-up and optimize procedures for the cell culture and expression of the selected antigens. Stable cell lines of all cellular expression systems will be pursued. Scaled up cell culture techniques shall be used to ensure an efficient process is in place for generating antigens.

3.1.3.2. Optimization and scale up of SARs-CoV-2 antigen purification. We shall optimize procedures to purify the selected antigens. We shall investigate techniques to scale up antigen purification. Three lots of each antigen shall be produced using the final purification procedure to ensure a repeatable process is in place. Antigens will be qualified prior to incorporation into the rapid test.

3.1.3.3. Scale up gold conjugation. The optimized gold conjugation conditions from task 2.1.2.2 shall be scaled-up to produce large lots of detection reagents.

3.1.3.4. Identify sources for kit accessories as needed. Raw material specification documents shall be

in place for all vendor-acquired kit accessories.

3.1.3.5. Draft product insert. Once an assay procedure is identifed, a product insert shall be drafted for use in performance studies and for eventual FDA submission. The final product insert shall describe: 1) intended use, 2) description of device, 3) description of kit contents, 4) instructions for device use, 5) algorithm for results interpretation, 6) quality control guidance, 7) precaution statements, 8) device performance characteristics and 9) possible use limitations.

3.1.3.6. Development of QC panels. A QC Panel will be developed to monitor cGMP manufacturing and lot to lot variability. Panel members shall include specimens [redacted] (b) (4) [redacted] QC [redacted] (b) (4) [redacted] and whole blood specimens, and potentially any cross-reactive or false positive specimens.

3.1.4. Design Transfer

InBios has extensive knowledge and experience in design transfer of devices from R&D to manufacturing and cGMP manufacturing. This knowledge base shall be applied to the transfer of the SCoV-2 *Detect*™ IgM/IgG Rapid Test to GMP manufacturing.

3.1.4.1. Finalize documentation for manufacturing SCoV-2 *Detect*™ IgM/IgG Rapid Tests. InBios will finalize all documentation required for the spray, gold conjugation, lamination, assembly, and quality control of the SCoV-2 *Detect*™ IgM/IgG Rapid Test prior to cGMP manufacture.

3.1.4.2. Finalize raw material specification. Raw material specification documents will be completed for each raw material that is incorporated into the SCoV-2 *Detect*™ IgM/IgG Rapid Test kit.

3.1.4.3. Complete Design Transfer, Part 1. Prior to cGMP manufacture of SCoV-2 *Detect*™ IgM/IgG Rapid Tests for performance studies, Part 1 of a documented design transfer process as outlined in InBios document SOP-0035 shall take place.

3.1.4.4. Complete Design Transfer, Part 2. The Design Transfer, Part 2 will take place prior to FDA submission after all performance study data is collected and the design team ensures the design outputs meet the design input criteria.

3.1.5. GMP Manufacturing

Upon completion design transfer, InBios shall initiate manufacturing of SCoV-2 *Detect*™ IgM/IgG Rapid Test kits under cGMP.

3.1.5.1. Draft device master record and product specifications. After all manufacturing documents are written, we shall draft product specifications and establish a Device Master Record (DMR) containing a list of all documents required for the manufacture of SCoV-2 *Detect*™ IgM/IgG Rapid Test kits.

3.1.5.2. cGMP manufacturing. Once the SCoV-2 *Detect*™ IgM/IgG Rapid Test design is frozen and transferred from R&D to manufacturing, we shall manufacture at least three test kit lots under cGMP. InBios will begin manufacturing lots of SCoV-2 *Detect*™ IgM/IgG Rapid Tests for process validation, in-house studies, and field studies as per FDA pre-submission feedback under cGMP. Device History Records will be generated for each lot of SCoV-2 *Detect*™ IgM/IgG Rapid Test kits produced. The QC panel shall be used to demonstrate lot-to-lot consistency for the three lots of SCoV-2 *Detect*™ IgM/IgG Rapid Tests.

3.1.6. Studies for *de novo*/510(k) and CLIA waiver submission

After obtaining FDA guidance, we shall execute the necessary performance studies required for regulatory submission of SCoV-2 *Detect*™ IgM/IgG Rapid Tests. Studies will be conducted using kits produced under cGMP.

3.1.6.1. Bench studies. FDA will require a number of laboratory product performance data to support SCoV-2 *Detect*™ IgM/IgG Rapid Tests regulatory clearance and CLIA waiver application. We shall conduct pre-submission communications with the FDA (2.1.1.1.) to establish details of bench studies to be performed. All data shall be analyzed and submitted as reports which will be included in the regulatory submission package.

3.1.6.1.1. Draft bench study protocols. Study protocols shall be drafted prior to submitting an FDA

pre-submission package to gain FDA guidance.

3.1.6.1.2. Finalize protocols for in-house studies. FDA feedback obtained during the pre-submission process will be incorporated into the study protocols prior to finalization. Protocols will be finalized prior to study execution.

3.1.6.1.3. Acquire reagents needed for bench studies. We shall obtain specimens and reagents required to complete the bench studies. These reagents will be obtained from collaborators or purchased from commercial vendors.

3.1.6.1.4. Perform bench studies in accordance with the final study protocols. The studies required for FDA clearance and CLIA waiver submission will likely include: Limit of detection/matrix comparison study, IgM/IgG specificity study, cross-reactivity study, interfering substances studies, flex studies, specimen stability studies, and a multi-site reproducibility study. Operators shall be trained on protocols prior to study execution. Data will be filed in the DHF.

3.1.6.1.4.1. Identify sites for reproducibility studies and execute subcontracting agreements, as necessary for testing. Subcontracting agreements shall be executed prior to reproducibility testing at external sites.

3.1.6.1.5. Perform stability testing. An accelerated stability study shall compare tests that have undergone accelerated aging to a control group and to expected values. Real-time stability studies shall directly compare tests that have undergone real-time aging to a control group and to expected values. The SCoV-2 *Detect*™ IgM/IgG Rapid Test kit target shelf life is at least 18 months at room temperature.

3.1.6.1.6. Perform Shipping studies (including heat stress and cold stress). Shipping studies shall be performed to characterize the packaging strength and reagent stability of the SCoV-2 *Detect*™ IgM/IgG Rapid Test kit.

3.1.6.1.7. Bench study data analysis and report writing. Data analysis for all bench studies will take place according to the finalized protocols. Reports for all bench studies outlined above shall be written and placed into the DHF. SCoV-2 *Detect*™ IgM/IgG Rapid Test bench studies report will be written completed for FDA *de novo*/510(k) submission.

3.1.6.2. Clinical performance studies. We plan to start clinical studies using cGMP kits as per FDA pre-submission feedback (2.1.1.1.). InBios shall initiate a teaming agreement with a Contract Research Organization (CRO) to implement clinical studies.

4.2.6.2.1. Draft clinical study protocols. Study protocols shall be created with engagement from the CRO. A reference standard shall be agreed upon with feedback from FDA.

4.2.6.2.2. Finalize protocols as per FDA pre-submission feedback. The clinical study protocol shall be finalized based on FDA pre-submission feedback and will approved by InBios and the CRO.

4.2.6.2.3. Site selection; establish subcontractor agreements with clinical sites. Appropriate clinical sites shall be identified for conducting the clinical evaluation studies. Subcontractor agreements shall be established between InBios and field sites. It is anticipated the clinical studies will be conducted at at least 3 locations.

4.2.6.2.4. Clinical study protocol and study document approval from appropriate IRBs and HRPO. The finalized clinical study protocol, consent documents, and any other required documentation will be submitted to the appropriate IRBs and HRPO. Any required changes will be incorporated prior to IRB/HRPO approval.

4.2.6.2.5. Conduct study initiation, train operators at test sites. The CRO shall conduct onboard training at clinical testing sites. Operators shall be trained on how to use the test kits and electronic data management system, and how to properly conduct the study prior to study initiation.

4.2.6.2.6. Clinical testing at field sites and confirmatory testing. Testing at field sites should take place after all IRB/HRPO approvals are obtained. Clinical evaluation studies will proceed in accordance with the final clinical study protocol.

4.2.6.2.7. Site closeouts, data analysis, report writing. The CRO shall conduct a closeout session after the conclusion of clinical trials. This will include spot-checking records to make sure data transfer and recording are correct, overseeing disposal of leftover materials,

and spot-checking that patients enrolled in studies met inclusion criteria. A report of the clinical trial data and analysis shall be written for *de novo*/510(k) submission.

Task 4. Project management

4.1. Establish and maintain an Integrated Master Schedule (IMS). InBios shall maintain an IMS that provides accurate and timely schedule and performance information throughout the lifecycle of the effort.
4.2. Establish and maintain risk management system. InBios shall devise and update a Risk Management Plan and Risk Management Master File in accordance with InBios Standard Operating Procedure SOP-0089 Risk Management Policy.
4.3. Establish and maintain a regularly scheduled joint Government IPT / project team meeting. InBios shall participate in regular teleconferences and/or additional face-to-face prescheduled meetings to discuss status, issues, and path forward; thus, providing a general update of the project and enabling real-time Government feedback on progress.
4.4. Submit monthly technical reports (MTR) to the COR. InBios shall report regularly on the status of the development, testing, and manufacture of the SCoV-2 *Detect*™ Rapid Tests.
4.5. Obtain sufficient rights to technical data, strains, analytes, isolates, etc. as necessary to ensure market sustainability of the device.
4.6. Develop and maintain a management and quality system and Management and Quality Plan (MQP) describing the processes, procedures, and methods used to manage the necessary activities required to achieve the Government's requirement.
    4.6.1. Design Plan. InBios shall write a Design Plan, which shall include a timeline for developmental activities, design input, pre-set acceptance criteria, performance studies required for regulatory clearance, and a plan for the design transfer and manufacture of SCoV-2 *Detect*™ Rapid Tests.
    4.6.2. Design controls. As required by 21 CFR 820.30, InBios shall maintain a design controls and a design history file (DHF). Design review meetings shall be held to cover the following project milestones: Review Design Plan, Risk Analysis and Mitigation, Prototype selection, Design Transfer, Initiate bench studies, Review bench studies results/reports, Initiate clinical studies, Review clinical studies results/statistical analysis, Design Verification, FDA submission, and Design Validation

The following have been deleted:
STATEMENT OF WORK

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000301:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for SUBCLIN 000401:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for SUBCLIN 000501:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY

N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for SUBCLIN 000601:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION F - DELIVERIES OR PERFORMANCE

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

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 15-JUN-2020 TO 30-SEP-2022	N/A	USA MED RESEARCH MAT CMD (b) (6) [redacted] 1430 VETERANS DRIVE FORT DETRICK MD 21702-5009 (b) (6) [redacted] FOB: Destination	W23RYX

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 06-NOV-2020 TO 30-SEP-2022	N/A	USA MED RESEARCH MAT CMD (b) (6) [redacted] 1430 VETERANS DRIVE FORT DETRICK MD 21702-5009 (b) (6) [redacted] FOB: Destination	W23RYX

The following Delivery Schedule item for CLIN 0004 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 15-JUN-2020 TO 30-SEP-2022	N/A	USA MED RESEARCH MAT CMD (b) (6) [redacted] 1430 VETERANS DRIVE FORT DETRICK MD 21702-5009 (b) (6) [redacted] FOB: Destination	W23RYX

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE

POP 06-NOV-2020 TO 30-SEP-2022	N/A	USA MED RESEARCH MAT CMD (b) (6) 1430 VETERANS DRIVE FORT DETRICK MD 21702-5009 (b) (6) FOB: Destination	W23RYX

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

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 15-JUN-2020 TO 30-SEP-2022	N/A	USA MED RESEARCH MAT CMD (b) (6) 1430 VETERANS DRIVE FORT DETRICK MD 21702-5009 (b) (6) FOB: Destination	W23RYX

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 06-NOV-2020 TO 30-SEP-2022	N/A	USA MED RESEARCH MAT CMD (b) (6) 1430 VETERANS DRIVE FORT DETRICK MD 21702-5009 (b) (6) FOB: Destination	W23RYX

The following Delivery Schedule item for CLIN 0006 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 15-JUN-2020 TO 30-SEP-2022	N/A	USA MED RESEARCH MAT CMD (b) (6) 1430 VETERANS DRIVE FORT DETRICK MD 21702-5009 (b) (4), (b) (6) FOB: Destination	W23RYX

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE

POP 06-NOV-2020 TO 30-SEP-2022	N/A	USA MED RESEARCH MAT CMD (b) (6) 1430 VETERANS DRIVE FORT DETRICK MD 21702-5009 (b) (6) FOB: Destination	W23RYX

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $(b) (4) from $(b) (4) to $(b) (4)

SUBCLIN 000301:
Funding on SUBCLIN 000301 is initiated as follows:

ACRN: AB

CIN: GFEBS001156833400001

Acctng Data: 021202120222040000664643255 R.0004145.3.35 6100.9000021001

Increase: $(b) (4)

Total: $(b) (4)

Cost Code: A97CJ

SUBCLIN 000401:
Funding on SUBCLIN 000401 is initiated as follows:

ACRN: AB

CIN: GFEBS001156833400002

Acctng Data: 021202120222040000664643255 R.0004145.3.35 6100.9000021001

Increase: $(b) (4)

Total: $(b) (4)

Cost Code: A97CJ

SUBCLIN 000501:
Funding on SUBCLIN 000501 is initiated as follows:

ACRN: AB

CIN: GFEBS001156833400003

Acctng Data: 021202120222040000664643255 R.0004145.3.35 6100.9000021001

Increase: $(b) (4)

Total: $(b) (4)

Cost Code: A97CJ

SUBCLIN 000601:
Funding on SUBCLIN 000601 is initiated as follows:

ACRN: AB

CIN: GFEBS001156833400004

Acctng Data: 021202120222040000664643255 R.0004145.3.35 6100.9000021001

Increase: $(b) (4)

Total: $(b) (4)

Cost Code: A97CJ

(End of Summary of Changes)