SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS

OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, AND 30

1. REQUISITION NUMBER	PAGE 1 OF 67
0011560875-0001	

2. CONTRACT NO.	3. AWARD/EFFECTIVE DATE	4. ORDER NUMBER	5. SOLICITATION NUMBER	6. SOLICITATION ISSUE DATE
W911QY21C0012	09-Nov-2020			

7. FOR SOLICITATION INFORMATION CALL:	a. NAME	b. TELEPHONE NUMBER *(No Collect Calls)*	8. OFFER DUE DATE/LOCAL TIME

9. ISSUED BY CODE W911QY

W6QK ACC-APG NATICK DIVISION
BLDG 1 GENERAL GREENE AVENUE
NATICK MA 01760-5011

TEL:
FAX (b) (6)

10. THIS ACQUISITION IS

- [X] UNRESTRICTED OR [ ] SET ASIDE: _____ % FOR:
- [ ] SMALL BUSINESS
- [ ] WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM
- [ ] HUBZONE SMALL BUSINESS
- [ ] EDWOSB
- NAICS: 541380
- [ ] SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS
- [ ] 8(A)
- SIZE STANDARD: (b) (4)

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED	12. DISCOUNT TERMS	13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	13b. RATING / 14. METHOD OF SOLICITATION
[ ] SEE SCHEDULE	Net 30 Days	[ ]	[ ] RFQ [ ] IFB [ ] RFP

15. DELIVER TO	CODE	16. ADMINISTERED BY	CODE
SEE SCHEDULE		**SEE ITEM 9**	

17a. CONTRACTOR/ OFFEROR CODE 1CD10 FACILITY CODE 1CD10

MICROBIOLOGICS, INC.
(b) (6)
200 COOPER AVE N
SAINT CLOUD MN 56303-4452

TELEPHONE NO (b) (6)

[ ] 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

18a. PAYMENT WILL BE MADE BY CODE HQ0490

DEFENSE FINANCE AND ACCOUNTING SERVICE
DFAS- NDY VP GFEBS
8899 E 56TH STREET
INDIANAPOLIS IN 46249-3800

18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a. UNLESS BLOCK BELOW IS CHECKED [X] SEE ADDENDUM

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/ SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	SEE SCHEDULE				

25. ACCOUNTING AND APPROPRIATION DATA	26. TOTAL AWARD AMOUNT (For Govt. Use Only)
See Schedule	(b) (4)

[ ] 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1. 52.212-4. FAR 52.212-3. 52.212-5 ARE ATTACHED. ADDENDA [ ] ARE [ ] ARE NOT ATTACHED

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

[X] 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.

REF: Commercial Solutions Proposal

[ ] 29. AWARD OF CONTRACT: REF. OFFER DATED 08-Oct-2020 . YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS: SEE SCHEDULE

30a. SIGNATURE OF OFFEROR/CONTRACTOR	31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER)
	(b) (6)

30b. NAME AND TITLE OF SIGNER *(TYPE OR PRINT)*	30c. DATE SIGNED	31b. NAME OF CONTRACTING OFFICER *(TYPE OR PRINT)*	31c. DATE SIGNED
		(b) (6) TEL: (b) (6) EMAIL: (b) (6)	09-Nov-2020

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS (CONTINUED)

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/ SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	SEE SCHEDULE				

32a. QUANTITY IN COLUMN 21 HAS BEEN

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

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE	32c. DATE	32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE	32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE
	32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE

33. SHIP NUMBER ☐ PARTIAL ☐ FINAL	34. VOUCHER NUMBER	35. AMOUNT VERIFIED CORRECT FOR	36. PAYMENT ☐ COMPLETE ☐ PARTIAL ☐ FINAL	37. CHECK NUMBER

38. S/R ACCOUNT NUMBER	39. S/R VOUCHER NUMBER	40. PAID BY

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

Section SF 1449 - CONTINUATION SHEET

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

Technlology Transfer of Wild Type Assay
FFP
The contractor shall Technology Transfer (TT) the validated WT virus neutralization (VN) assay and demonstrate method equivalence. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020.
FOB: Destination
PSC CD: Q301

NET AMT $(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101					(b) (4)

ACRN AA @ $(b) (4)
FFP
PURCHASE REQUEST NUMBER: 0011560875-0001

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156087500001

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002		1	Each	(b) (4)	(b) (4)

Technology Transfer of Reporter VN Assay
FFP
The contractor shall Technology Transfer (TT) the qualified reporter VN assay and subsequent validation. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020.
FOB: Destination
PSC CD: Q301

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000201					(b) (4)

ACRN AA @ (b) (4)
FFP
PURCHASE REQUEST NUMBER: 0011560875-0001

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156087500002

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003		1,000	Each	(b) (4)	(b) (4)

Initial Assay Sample Testing
FFP
The contractor shall test 500 samples using of the wild type validated assay and 500 samples using of the validated reporter virus type assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020.
FOB: Destination
PSC CD: Q301

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000301					(b) (4)

ACRN AA @ (b) (4)
FFP
PURCHASE REQUEST NUMBER: 0011560875-0001

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156087500003

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004		1	Each	(b) (4)	(b) (4)

Drug Master File (DMF) WT Assay
FFP
The contractor provide a Drug Master File (DMF) WT virus neutralization VN assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020.
FOB: Destination
PSC CD: Q301

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000401					(b) (4)

ACRN AA @ (b) (4)
FFP
PURCHASE REQUEST NUMBER: 0011560875-0001

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156087500004

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0005		1	Each	(b) (4)	(b) (4)

Drug Master File (DMF) Reporter VN Assay
FFP
The contractor provide a Drug Master File (DMF) reporter VN assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020.
FOB: Destination
PSC CD: Q301

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000501					(b) (4)

ACRN AA @ (b) (4)
FFP
PURCHASE REQUEST NUMBER: 0011560875-0001

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156087500005

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1001		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 1 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 2 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1003		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 3 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1004		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 4 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1005		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 5 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1006		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 6 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1007		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 7 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1008		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 8 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1009		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 9 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				
				NET AMT	(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1010		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 10 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				
				NET AMT	(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1011		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 11 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1012		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 12 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1013		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 13 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1014		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 14 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1015		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 15 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1016		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 16 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1017		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 17 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1018		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 18 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1019		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 19 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1020		1,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 1,000 Samples FFP Option 20 - Testing of 1,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1021		2,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 2,000 Samples FFP Option 21 - Testing of 2,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1022		2,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 2,000 Samples FFP Option 22 - Testing of 2,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1023		2,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 2,000 Samples FFP Option 23 - Testing of 2,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1024		2,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 2,000 Samples FFP Option 24 - Testing of 2,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1025		2,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 2,000 Samples FFP Option 25 - Testing of 2,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1026		2,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 2,000 Samples FFP Option 26 - Testing of 2,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1027		2,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 2,000 Samples FFP Option 27 - Testing of 2,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1028		2,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 2,000 Samples FFP Option 28 - Testing of 2,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1029		2,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 2,000 Samples FFP Option 29 - Testing of 2,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1030		2,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 2,000 Samples FFP Option 30 - Testing of 2,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1031		5,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 5,000 Samples FFP Option 31 - Testing of 5,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1032		5,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 5,000 Samples FFP Option 32 - Testing of 5,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1033		5,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 5,000 Samples FFP Option 33 - Testing of 5,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1034		5,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 5,000 Samples FFP Option 34 - Testing of 5,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1035		5,000	Each	(b) (4)	(b) (4)
OPTION	Testing of 5,000 Samples FFP Option 35 - Testing of 5,000 clinical trial samples using one of the validated assay. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020. FOB: Destination PSC CD: Q301				

NET AMT (b) (4)

ADDENDUM: The following pages hereby supplements FAR 52.212-4

SOW For COVID-19 Immune Assay Implementation and Serum Testing Services
Title of Project: Establishment of high throughput neutralization assay laboratory capability for COVID-19 and testing of human serum samples

1. Introduction

An outbreak of respiratory disease caused by a novel coronavirus was first detected in China in late 2019 and has now spread worldwide, including the United States (US). The virus has been named Severe Acute Respiratory Disease Coronavirus-2 (SARS-CoV-2) and causes Coronavirus Disease 2019 (COVID-19). On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO), declared the outbreak a "Public Health Emergency of International Concern" (PHEIC). On January 31, the US Department of Health and Human Services Secretary (HHS), Alex M. Azar II, declared a Public Health Emergency for the US to aid the nation's healthcare community in responding to COVID-19. On March 11, WHO publicly declared COVID-19 as a pandemic. On March 13, the President of the United States declared the COVID-19 outbreak a national emergency. The US Government (USG) has identified COVID-19 vaccine candidates (prototypes) that are progressing rapidly through advanced research and development activities. A joint HHS and Department of Defense (DOD) leadership team named Operation Warp Speed (OWS) is charged with development of COVID-19 vaccines and other medical countermeasures.

This procurement action is aimed at providing additional laboratory assay capacity sites for analysis of serum samples collected from subjects enrolled in COVID-19 vaccine clinical trials. Serum samples are tested to ascertain the ability of the vaccine to induce an immune response. Studies have shown that serum antibodies directed against viral spike (S) that block infection of target cells can be readily detected by Virus Neutralization (VN) assays. The USG has supported development of two VN assays at two organizations herein designates as "assay developer laboratory (ADL)" and seeks to transfer this assay technology to a new facility per this solicitation.

The FDA published guidance Development and Licensure of Vaccines to Prevent COVID-19 (6/30/2020) for manufacturers developing COVID-19 vaccines. The guidance document states: "There are currently no accepted surrogate endpoints that are reasonably likely to predict clinical benefit of a COVID-19 vaccine" (1). Use of new vaccines will require an Emergency Use Authorization or a BLA approval based on direct evidence of vaccine safety and efficacy in protecting humans from SARS-CoV-2 infection and/or clinical disease. The ultimate goal of this project is to provide serologic data to support establishment of a correlate of protection. The latter would facilitate

expanded use of approved COVID-19 vaccines and accelerated approvals of additional vaccines.

2. Scope

The program goals are twofold: 1. Technology transfer of two VN assays to a Biosafety Level 3 (BSL3) laboratory other than the ADL in compliance with GLP (Contract Base period). The first transfer will include transfer of a high throughput validated neutralization assay and subsequent method equivalence demonstration meeting FDA requirements for Phase 3 sample testing; the second will include technology transfer of a qualified live virus reporter assay for subsequent validation meeting FDA requirements for Phase 3 sample testing. 2. Test serum samples from human subjects enrolled in clinical trials of COVID-19 vaccines using the new validated assay in compliance with GLP.

3. Regulatory compliance

The offeror is expected to comply with GLP Standards (2).

The neutralization assays must be conducted with live SARS-CoV-2 virus; therefore, laboratory testing must be conducted in a BSL-3 environment (3). The offeror's facility must demonstrate appropriate permits for the operation of the laboratory facilities in compliance with BSL-3 as described in CDC Guidelines. The offeror should describe the safety procedures and provide assurances regarding Facility Safety Plan, CDC guidelines, and the appropriate SOPs and institutional biosafety requirements for handing live SARS-COV-2.

Given that the test results for human sera collected as part of a clinical trial are part of a BLA submission to the FDA, the organization must be prepared to provide the necessary supporting quality systems documentation to the sponsor company for inclusion in the regulatory filing or in the course of quality audits (4,5). These supporting quality systems along with assay validation reports and other supporting documentation are required for GLP compliance and should be documented in the drug master file (DMF) or other negotiated means. The contractor is expected to participate in an External Quality Assurance scheme to assess continued ability to perform tests correctly.

A facility audit will be conducted.

4. Statement of Objectives

The objective of this project is the establishment of a high throughput wild type and reporter SARS-CoV-2 virus neutralization assays for COVID-19 for use in testing serum samples from human subjects enrolled in clinical trials of COVID-19 vaccines in compliance with GLP.

Operation Warp Speed (OWS) has supported development of two VN assays at organizations herein designated as "assay developer laboratory (ADL)". The ADL will develop the assays using two virus platforms - a live wild type (WT) virus and a live reporter virus for transfer to the new facility. The WT virus is the clinical SARS-CoV-2 isolate WA1 strain isolated from the first US COVID-19 patient identified in Washington State and the reporter virus has a bioluminescent luciferase gene inserted to generate a recombinant SARS-CoV-2 virus strain. The WT virus assay will be transferred in a validated state; the reporter virus assay will be transferred in a qualified state.

After contract award, the offeror is expected to submit a protocol (in coordination with the ADL) to technology transfer the previously validated WT VN assay to quantify SARS-CoV-2 neutralizing antibodies in human sera using VERO E6 cells and subsequently perform method equivalence. The offeror will use a panel of COVID-19 convalescent and COVID-19 vaccine recipient samples to demonstrate method equivalence relative to the performance characteristics at the ADL (4). The VN assay follows traditional protocols, with a serum sample that is serially diluted and then incubated with a known amount of virus (neutralization step). For the WT VN assay, a cell monolayer is then inoculated with the sample/virus mix and incubated for approximately 24 hours prior to acetone fixation and immunoenzymatic detection of SARS-COV-2 N protein expression (in situ N-ELISA). The VN assay median endpoint titer is reported as the reciprocal of the highest dilution at which the input virus is neutralized ELISA OD units below an established threshold). The assay will be considered fully transferred only once the FDA has reviewed and concurred with tech transfer acceptability through review of documentation submitted to a DMF or

through other negotiated means.

Conversely, the reporter VN assay relies on a luminescence readout. This assay will be transferred in a qualified state and the receiving lab will be required to validate the assay. Assay validation will be considered complete only once the FDA has reviewed and concurred with validation report acceptability through review of documentation submitted to a DMF or through other negotiated means.

Details of the protocol for both the assays will be provided by the ADL in the course of jointly preparing the technology transfer protocol package.

- Base Period: Technology Transfer of validated and qualified OWS neutralization assays, subsequent method equivalency demonstration and validation, and sample testing of 1000 clinical trial samples inclusive of a an equivalency convalescent serum panel
- Options 1-20: Sample testing of 1000 clinical trial specimens
- Options 21-30 : Sample testing of 2000 clinical trial specimens
- Options 31-35: Sample testing of 5000 clinical trial specimens

The proposal's basic framework should include the following specific tasks:

Base Period (CLIN 0001-CLIN 005): Technology Transfer of one validated and one qualified OWS VN assay. After contract award, the offeror will host an audit and should provide a project plan (in coordination with ADL) that describes the approach to 1) technology transfer the validated WT virus assay and demonstrate method equivalence with a panel of test serum samples provided by the USG and 2) technology transfer the qualified reporter virus assay and subsequently validate the assay. Offerors are encouraged to describe their testing workflow in detail to include the use of robotic systems in order to increase sample throughput. Assay validation and overall readiness to test Phase 3 samples from the clinical trials includes FDA concurrence with the assay documentation submitted to the DMF

CLIN0001: Technology transfer the validated WT VN assay.

o Technology transfer package (documentation from ADL) will include the following:

(i) An assay specific SOP for WT VN assay
(ii) A validation protocol designed to evaluate precision, dilutional linearity, limit of detection, limit of quantification, selectivity (matrix effects), and specificity as appropriate. The validation protocol shall include a statistical analysis plan.
(iii) Serum equivalence panel (see 5. Critical reagents)
(iv) A validation report

o The offeror shall provide:

i. A proof-of-concept data report on assay performance conducted prior to assay validation or equivalence execution, capturing, at a minimum, a demonstration of precision with two samples tested over three days.
ii. Technology transfer assay protocol to demonstrate method equivalence (in coordination with the ADL)
iii. Submission of the technology transfer protocol to the FDA DMFs
iv. Execute the technology transfer assay protocol
v. A draft and final technology transfer report
vi. Copies of FDA's concurrence with WT VN assay equivalence testing indicating readiness to initiate Phase 3 clinical trial sample testing

CLIN0002: Technology transfer the qualified reporter VN assay and subsequent validation

o Technology transfer package (documentation from ADL) will include the following:

(i) An assay specific SOP for live reporter VN assay
(ii) A qualification protocol designed to evaluate precision, dilutional linearity, limit of detection, limit of quantification, selectivity (matrix effects), and specificity as appropriate. The qualification protocol shall include a statistical analysis plan.
(iii) Serum equivalence panel (see 5. Critical reagents)
(iv) A qualification report.

- The offeror shall provide:

(i) A draft and final validation protocol
(ii) A Validation Report
(iii) Submission of the validation report to the FDA DMF
(iv) Copies of FDA's concurrence with validation report indicating readiness to initiate Phase 3 clinical trial sample testing

CLIN0003: Testing of 1000 clinical trial specimens using the validated assays. (500 samples for WT and 500 samples for live virus reporter) The offeror shall provide:

- The proposed sample testing turnaround time when operating at full capacity for extended periods
- The offeror should provide a sample management plan that describes in substantial detail the procedures for serum sample accessioning, handling, safety and integrity (including power failures and other risks), with auditable tracking systems throughout the chain of custody.
- The offeror should provide a data management plan describing the information technology infrastructure to receive the serum samples data and demonstrate data integrity, accuracy and security thought the life cycle of the sample and completion of the project.

CLIN0004: Drug Master File (DMF) WT Neutralization VN Assay

CLIN0005: Drug Master File (DMF) Reporter VN Assay

Contract Options (Options 1-35) : Testing of clinical trial samples using one of the validated
CLIN 1001-1020 Option 1-20: Testing of 1,000 clinical trial samples using one of the validated assay
CLIN 1021-1030 Option 21-30: Testing of 2,000 clinical trial samples using one of the validated assay
CLIN 1031-1035 Option 31-35: Testing of 5,000 clinical trial samples using one of the validated assay

5. Critical reagents

The USG will provide certain reagents (e.g. SARS-CoV-2 virus seed) and a panel of 18 human serum samples to assay equivalence between different sites executing the same assay. This panel comprises 15 COVID-19 convalescent samples (equally distributed among samples with low, medium and high antibody titers) with certified titers and 3 negative controls.

6. Capacity

Minimum 1000 samples /week. The maximum capacity within the accepted proposal is expected to be 1,000 samples for the WT VN assay and 2000 for the reporter VN assay tested every seven days. Testing under options that are exercised will be IAW the accepted proposals stated capacities.

7. Period of Performance

The Base Period of Performance (POP): The proposed OWS VN assay capacity must be available for use in full no later than February 15 2021(after FDA concurrence with the tech transfer and equivalence report). The total proposed duration of this work is 12 months from award.

8. Personnel and Place of performance

The proposal should describe the key personnel and provide CVs to document training and experience for the project as well as the overall staffing plan for the proposed activities.

The facilities where the work will be conducted as well as supporting activities should be described in sufficient detail to support assessment of fitness for purpose.

9. Deliverables

The following deliverables would be provided by the offeror. The following proposed deliverable schedule is of critical importance to the USG.

General Deliverables

a) PERIODIC TELECONFERENCES (Biweekly or as negotiated)

1) Draft bulleted agenda provided 48 hours prior to teleconference.
2) Meeting minutes provided 3 business days after teleconference.

b) COMMUNICATION MANAGEMENT PLAN

1) Outlines communications goals and strategies for the task order. Template will be provided.

c) MONTHLY REPORTS

1) Reports shall describe progress of meeting contract milestones- overall project assessment, problems encountered and recommended solutions. The USG will receive information on the Tech transfer results/report, testing status, number of samples processed, and number samples that are outstanding
2) Reports shall detail the planned progress and actual progress during the period covered, explaining occurrences of any differences and corrective steps/actions planned if behind schedule. Deviation reporting should occur in real time.
3) Reports shall detail estimated invoice submissions/acceptance dates, and a narrative of the percentage of work completed.
4) Reports shall include an updated Gantt.

d) DRAFT FINAL REPORT

1) A final report shall be provided for USG review and comment. The report shall summarize all work conducted during the period of performance and provide all results (include specific items required in the report).

e) FINAL REPORT

1) The final report shall address USG comments regarding the draft report.

Technical deliverables

Del. #	Deliverable Description	Due Date
1	Host a facility Audit	2 weeks from award
2	Procurement of critical reagents and equipment; Proof-of-concept data report, as described under CLIN001	6 weeks after contract award
3	Assay technology transfer protocol for WT virus (in coordination with ADL and BARDA)	2 weeks from receipt of WT VN assay technology transfer package (documentation from ADL) as described under CLIN001

4	Validation protocol for reporter virus assay(in coordination with ADL and BARDA)	2 weeks from receipt of reporter VN assay technology transfer package (documentation from ADL) as described under CLIN002
5	Establishment of DMF(s)	2 weeks from contract award
6	Submission of technology transfer protocol (WT assay) and validation protocol (Reporter assay) to DMF(s)	5 weeks from receipt of technology transfer package (documentation from ADL)
7	Draft technology transfer Report for WT virus assay	6 weeks from DMF submission of the technology transfer protocol
8	Final technology transfer Report for WT virus assay and submission to DMF	1 week from draft technology transfer report
9	Copy of FDA concurrence on WT virus assay readiness for Phase 3 sample testing	Not applicable (dependent on FDA)
10	Draft validation report for the reporter virus assay	8 weeks from DMF submission of the validation protocol
11	Final validation report for the reporter virus assay and submission to DMF	1 week from draft validation report
12	FDA concurrence on reporter virus assay readiness for Phase 3 sample testing	Not applicable (dependent on FDA)
13	Testing batch of sera samples (1,000)	3 weeks from sample receipt
14	Testing batch of 1,000 sera samples per option (Option 1-20)	3 weeks from sample receipt
15	Testing batch of 2,000 sera samples per option (Option 21-30)	4 weeks from sample receipt
16	Testing batch of 5,000 sera samples per option (Option 31-35)	6 weeks from sample receipt

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE

0001	POP 09-NOV-2020 TO 08-NOV-2021	N/A	BARDA (b) (6) BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024 (b) (6) FOB: Destination	W56XNH
000101	N/A	N/A	N/A	N/A
0002	POP 09-NOV-2020 TO 08-NOV-2021	N/A	BARDA (b) (6) BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024 (b) (6) FOB: Destination	W56XNH
000201	N/A	N/A	N/A	N/A
0003	POP 09-NOV-2020 TO 08-NOV-2021	N/A	BARDA (b) (6) BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024 (b) (6) FOB: Destination	W56XNH
000301	N/A	N/A	N/A	N/A
0004	POP 09-NOV-2020 TO 08-NOV-2021	N/A	BARDA (b) (6) BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024 (b) (6) FOB: Destination	W56XNH
000401	N/A	N/A	N/A	N/A
0005	POP 09-NOV-2020 TO 08-NOV-2021	N/A	BARDA (b) (6) BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024 (b) (6) FOB: Destination	W56XNH
000501	N/A	N/A	N/A	N/A

1001	POP 09-NOV-2020 TO 08-NOV-2021	N/A	BARDA (b) (6) BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024 (b) (6) FOB: Destination	W56XNH
1002	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1003	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1004	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1005	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1006	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1007	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1008	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1009	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1010	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1011	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1012	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1013	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1014	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1015	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1016	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH

1017	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1018	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1019	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1020	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1021	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1022	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1023	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1024	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1025	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1026	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1027	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1028	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1029	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1030	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1031	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1032	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1033	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
1034	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH

1035	POP 09-NOV-2020 TO 08-NOV-2021	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH

DELIVERY OR PERFORMANCE

F.1. Technical Deliverables

Technical Deliverables	Begin Date	End Date	Deadlines that effect Overall Project Timeline
Award of Project	11/9/2020	11/16/2020	*Deadline of 11/16/2020 for Award of project to keep described schedule
Facility Audit	11/17/2020	11/30/2020	
Procurement of critical reagents and equipment. Begin Installation Activities	11/17/2020	12/7/2020	
Complete Installations (IQOQPQ etc.) & Receive all materials	12/8/2020	12/21/2020	
Receipt of tech. Transfer Package	11/9/2020	11/16/2020	*Deadline of 11/16/2020 for receipt of tech. transfer package to keep described schedule
Receive virus stock, cells, and other reagents for the tech transfer	11/17/2020	11/23/2020	*Deadline of 11/23/2020 for ADL to send materials required for tech. transfer activities to keep described schedule
Expand Provided Cells to Generate Master Cell Bank	11/24/2020	12/4/2020	
Complete Qualification of Master Cell Bank	12/5/2020	12/11/2020	
Expand Provided Virus Stock to complete Master Virus Bank	11/24/2020	12/7/2020	
Complete Qualification of Virus Master Bank	12/8/2020	12/14/2020	
Hire Any Identified Additional Staff Desired	11/17/2020	12/7/2020	
Complete typical Onboarding Process	12/8/2020	12/7/2020	
Complete any Assay Specific Training for Additional Staff	12/8/2020	1/6/2021	
Work with ADL to Understand Assay Being Transferred	11/17/2020	11/23/2020	*Deadline of 11/16/2020 for ADL to send tech transfer package which includes previous optimization/Development protocols
CLIN001-Perform proof of concept. 2 Samples tested over 3 days. Materials provided by ADL/USG	11/24/2020	12/14/2020	

Issue Proof of Concept data report to ADL/USG	12/28/2020	12/28/2020	
Complete and Issue Tech Transfer Protocol for assay	11/24/2020	12/7/2020	
Execute Tech Transfer Protocol	12/22/2020	1/13/2021	
Complete & Issue Final Tech Transfer Report	1/28/2021	2/3/2021	
Establishment of DMF with FDA	11/17/2020	11/30/2020	
Submission of Tech. Transfer protocol for WT assay to DMF	12/1/2020	12/21/2020	
Draft tech. transfer report for WT virus	12/22/2020	2/3/2021	
Final tech. transfer report for WT virus submission to DMF	2/4/2021	2/10/2021	
Work with ADL to identify Critical Assay Specifics	11/17/2020	11/23/2020	*Deadline of 11/16/2020 for ADL to send tech transfer package which includes previous optimization/Development protocols
Identification of Equipment Differences and Bridging of materials	11/24/2020	11/30/2020	
Determination of Appropriate Validation methods for Identified items	12/1/2020	12/14/2020	
Assay Validation Protocol Completed and Issued	12/15/2020	12/21/2020	
Execute Assay Validation Protocol	12/22/2020	2/10/2021	
Complete & Issue Validation Report	2/11/2021	2/17/2021	
Submission of tech validation protocol for reporter assay to DMF	12/1/2020	12/21/2020	
Draft validation report for reporter virus	12/22/2020	2/17/2021	
Final validation report for reporter virus submission to DMF	2/18/2021	2/24/2021	
Receive First 1000 samples	2/25/2021	2/25/2021	
Initiate Test of first 1000 Samples Sent	2/26/2021	3/18/2021	

F.2. Supply Chain Resiliency Plan: The contractor shall develop and submit within 30 calendar days of contract award, a comprehensive Supply Chain Resiliency Program that provides identification and reporting of critical components associated with the secure supply of. cells, virus, and assay positive and negative controls. The USG will supply reagents associated with technology transfer but the organization is expected to subsequently produce and procure their own critical reagents.

a) A critical component is defined as any material that is essential to the assay t or the testing services associated with this contract. Included in the definition are cell banks and virus seed stocks NOT included in the definition are facility and capital equipment.

A clear example of a critical component is one where a sole supplier is utilized.

The contractor shall identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award.

a) Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.
b) The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries.

The contractor shall articulate in the plan, the methodology for inventory control, , scheduling processes and ordering mechanisms, as part of those agreed deliveries.

a) lead times shall be understood and communicated to the Contracting Officer or the Contracting Officer's Representative as necessary.
b) Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items should include the following information:

a) Critical Material
b) Vendor
c) Supplier, Manufacturing / Distribution Location
d) Supplier Lead Time
e) Shelf Life
f) Transportation / Shipping restrictions

The CO and COR reserve the right to request un-redacted copies of technical documents, during the period of performance, for distribution within the Government. Documents shall be provided within ten (10) days after CO issues the request. The Contractor may arrange for additional time if deemed necessary, and agreed to by the CO.

F.3. Product Development Source Material and Manufacturing Reports and Projections: The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States.
F.4. Contractor Locations: The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.

Contractor will submit Work Locations Report:

- Within 5 business days of contract award
- Within 30 business days after a substantive location or capabilities change
- Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO

F.5. Access and General Protection/Security Policy and Procedures: This standard language text is applicable to ALL employees working on critical information related to Operation Warp Speed (OWS), and to those with an area of performance within a Government controlled installation, facility or area. Employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The performer also shall provide all information required for background checks necessary to access critical information related to OWS, and to meet Government installation

access requirements to be accomplished by installation Director of Emergency Services or Security Office. The workforce must comply with all personnel identity verification requirements as directed by the Government and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the security status of OWS change the Government may require changes in performer security matters or processes. In addition to the industry standards for employment background checks, The Contractor must be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States Government.

F.6. Operational Security (OPSEC): The performer shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90)-calendar-days of project award to be reviewed and approved by the responsible Government OPSEC officer. This plan will be submitted to the COR for coordination of approvals. This SOP/Plan will include identifying the critical information related to this contract, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

F.7. Security Plan: The contractor shall develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan shall establish security practices and procedures that demonstrate how the contractor will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing, and shall be delivered to the Government within 30 calendar days of award. The contractor shall also ensure all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, comply with all Government security requirements and prime contractor security plans.

a) The Government will review in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within (10) calendar days after receipt of the comments.
b) The Security Plan shall include a timeline for compliance of all the required security measures outlined by the Government.
c) Upon completion of initiating all security measures, the Contractor shall supply to the Contracting Officer a letter certifying compliance to the elements outlined in the Final Security Plan.

At a minimum, the Final Security Plan shall address the following items:

Security Requirements:

1. Facility Security Plan Description: As part of the partner facility's overall security program, the contractor shall submit a written security plan with their proposal to the Government for review and approval by Government security subject matter experts. The performance of work under the contract will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:	
Security Administration	organization chart and responsibilities written security risk assessment for site threat levels with identification matrix (High, Medium, or Low) enhanced security procedures during elevated threats liaison procedures with law enforcement annual employee security education and training program
Personnel Security	policies and procedures candidate recruitment process background investigations process employment suitability policy employee access determination rules of behavior/ conduct termination procedures non-disclosure agreements

Physical Security Policies and Procedures	internal/external access control protective services identification/badging
	employee and visitor access controls parking areas and access control perimeter fencing/barriers product shipping, receiving and transport security procedures facility security lighting restricted areas signage intrusion detection systems alarm monitoring/response closed circuit television product storage security other control measures as identified
Information Security	identification and marking of sensitive information access control storage of information document control procedures retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	intrusion detection and prevention systems threat identification employee training (initial and annual) encryption systems identification of sensitive information/media password policy (max days 90) lock screen time out policy (minimum time 20 minutes) removable media policy laptop policy removal of IT assets for domestic/foreign travel access control and determination VPN procedures WiFi and Bluetooth disabled when not in use system document control system backup system disaster recovery incident response system audit procedures property accountability
2. Site Security Master Plan Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.	
3. Site Threat / Vulnerability / Risk Assessment Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.	
4. Physical Security Description:	

Closed Circuit Television (CCTV) Monitoring	a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored.
	CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. Video recordings must be maintained for a minimum of 30 days. CCTV surveillance system must be on emergency power backup. CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. Video recordings must be maintained for a minimum of 30 days. CCTV surveillance system must be on emergency power backup.
Facility Lighting	Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. Lighting must have emergency power backup. Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	Must have CCTV coverage and an electronic access control system. Must have procedures in place to control access and movement of drivers picking up or delivering shipments. Must identify drivers picking up Government products by government issued photo identification.
Access Control	Must have an electronic intrusion detection system with centralized monitoring. Responses to alarms must be immediate and documented in writing. Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.). The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of 12 months. Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company. Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. Should have written procedures to prevent employee piggybacking access to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. Must have a written manual key accountability and inventory process. Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Identification	Should issue company photo identification to all employees. Photo identification should be displayed above the waist anytime the employee is on company property. Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.

Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces	Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces Operations	Must have in-service training program. Must have Use of Force Continuum. Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer). Must have Standing Post Orders. Must wear distinct uniform identifying them as securityofficers.
5. Security Operations Description:	
Information Sharing	Establish formal liaison with law enforcement. Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented. Implement procedures for receiving and disseminating threat information.
Training	Conduct new employee security awareness training. Conduct and maintain records of annual security awareness training.
Security Management	Designate a knowledgeable security professional to manage the security of the facility. Ensure subcontractor compliance with all Government security requirements.
6. Personnel Security Description:	
Records Checks	Verification of social security number, date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, sex offender registry, credit check based upon position within the company; motor vehicle records check as appropriate; and local/national criminal history search.
Hiring and Retention Standards	Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures. Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.
7. Information Security Description:	
Physical Document Control	Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate governmentmarkings. Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents must be destroyed using approved destruction measures (i.e., shredders/approved third party vendors / pulverizing / incinerating).
8. Information Technology & Cybersecurity Description:	

Identity Management	Physical devices and systems within the organization are inventoried and accounted for annually. Organizational cybersecurity policy is established and communicated. Asset vulnerabilities are identified and documented.
	Cyber threat intelligence is received from information sharing forums and sources. Threats, vulnerabilities, likelihoods, and impacts are used to determine risk. Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes. Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals' security and privacy risks and other organizational risks)
Access Control	Limit information system access to authorized users. Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. Limit physical access to information systems, equipment, and server rooms with electronic access controls. Limit access to/ verify access to use of external information systems.
Training	Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months. Ensure the actions of individual information system users can be uniquely traced to those users. Update malicious code mechanisms when new releases are available. Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.
Configuration Management	Establish and enforce security configuration settings. Implement sub networks for publically accessible system components that are physically or logically separated from internal networks.
Contingency Planning	a) Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.
Incident Response	Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually.
Media and Information Protection	Protect information system media, both paper and digital. Limit access to information on information systems media to authorized users. Sanitize and destroy media no longer in use. Control the use of removable media through technology or policy.

Physical and Environmental Protection	Limit access to information systems, equipment, and the respective operating environments to authorized individuals. Intrusion detection and prevention system employed on IT networks. Protect the physical and support infrastructure for all information systems. Protect information systems against environmental hazards. Escort visitors and monitor visitor activity.
Network Protection	Employ intrusion prevention and detection technology with immediate analysis capabilities.

9. Transportation Security Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	Drivers must be vetted in accordance with Government Personnel Security Requirements. Drivers must be trained on specific security and emergency procedures. Drivers must be equipped with backup communications. Driver identity must be 100 percent confirmed before the pick-up of any Government product. Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency. Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.
Transport Routes	Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.

Product Security	Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed. Tamper resistant seals must be verified as "secure" after the product is placed in the transport vehicle. Government products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented. Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.
10. Security Reporting Requirements Description: The partner facility shall notify the Government Security Team within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.	
11. Security Audits Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and subcontractor.	

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
000301	N/A	N/A	N/A	N/A
0004	Destination	Government	Destination	Government
000401	N/A	N/A	N/A	N/A
0005	Destination	Government	Destination	Government
000501	N/A	N/A	N/A	N/A
1001	Destination	Government	Destination	Government
1002	Destination	Government	Destination	Government
1003	Destination	Government	Destination	Government
1004	Destination	Government	Destination	Government
1005	Destination	Government	Destination	Government
1006	Destination	Government	Destination	Government
1007	Destination	Government	Destination	Government
1008	Destination	Government	Destination	Government
1009	Destination	Government	Destination	Government
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1033	Destination	Government	Destination	Government
1034	Destination	Government	Destination	Government
1035	Destination	Government	Destination	Government

CONTRACT ADMINISTRATION

Government Contract Administration:

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

Contracting Officer:

(b) (6)
[redacted]
Bldg 1, General Greene Avenue Natick, MA 01760-5011

Procurement Specialist:

(b) (6)
[redacted]
Bldg 1, General Greene Avenue Natick, MA 01760-5011

Procurement Specialist:

(b) (6)
[redacted]
Bldg 1, General Greene Avenue Natick, MA 01760-5011

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

Government Technical Points of Contact:

Contracting Officers Representative (COR):

(b) (6)
Health Scientist
Influenza and Emerging Diseases Division
Biomedical Advanced Research and Development Authority (BARDA)/HHS/ASPR
200 C St SW,Washington, DC 20515
Email: (b) (6)
Office: (b) (6)
Cell: (b) (6)

Technical Point of Contact:

(b) (6)
Biologist, Influenza and Emerging Diseases Division
Biomedical Advanced Research and Development Authority (BARDA)/HHS/ASPR
Email: (b) (6)
Office: (b) (6)
Cell: (b) (6)

Quality Assurance Point of Contact:

(b) (6)
Title:Senior Regulatory Affairs Analyst
Email(b) (6)
Office:U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES |O'Neill Federal Office Building I Washington, DC 20024
Phone: (b) (6)

Contractor's Contract Administration

Technical Point of Contact:

(b) (6)
Senior Scientist
Email: (b) (6)
Office: (b) (6)
Cell: (b) (6)

Administrative Point of Contact:

(b) (6)
Vice President (b) (6)
Email: (b) (6)
Office: (b) (6)
Cell: (b) (6)

Contractor's Past Performance Point of Contact (POC):

Annual contract past performance evaluations will be performed by the government. The offeror shall identify a Point of Contact (POC) to participate in these on-line evaluations. This individual is required to register in the Contractor Performance Assessment Reporting System (CPARS @ http://www.cpars.csd.disa.mil) and respond to the government evaluations in a timely manner. The contractor POC responsible for this action is:

(b) (6)
Vice President (b) (6)
Email: (b) (6)
Office: (b) (6)

Cell: (b) (6)

Notifications of Revisions and Changes:

Notification of revision or changes to names or email addresses will be provided by official correspondence from the PCO/ACO or office of the PCO/ACO in lieu of a contract modification. This does not apply to any such revisions or changes in the event this contract includes a key personnel clause.

ACCOUNTING AND APPROPRIATION DATA

AA: 021202020212040000664643255 S.0074658.5.11.1 6100.9000021001
COST CODE: A5XAH
AMOUNT: (b) (4)

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	000101	GFEBS001156087500001	(b) (4)
	000201	GFEBS001156087500002	(b) (4)
	000301	GFEBS001156087500003	(b) (4)
	000401	GFEBS001156087500004	(b) (4)
	000501	GFEBS001156087500005	(b) (4)

TERMS AND CONDITIONS

SPECIAL CONTRACT REQUIREMENTS

H.1. Contractor's Organization: The contractor's organization shall be established with authority to effectively accomplish the objectives of the Statement of Work. This organization shall become effective upon award of the contract and its integrity shall be maintained for the duration of the contract effort.

H.1. Key Personnel: Any key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) calendar days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the contractorshall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractoris terminated for cause or separates from the contractorvoluntarily with less than thirty (30) calendar-day notice, the contractorshall provide the maximum notice practicable under the circumstances. The contractorshall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

The following individuals are determined to be key personnel:

- (b) (6), Ph.D., Senior Scientist
- (b) (6) Production Control and Operations Manager
- (b) (6) Executive Director, Experimental Biology and Regulatory Affairs
- (b) (6), General Manager for Microbiologics

H.1.1. Substitution of Key Personnel: The contractoragrees to assign to the contract those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the contract. No substitutions shall be made except in accordance with this guidance. All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the contracting officer to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The contracting officer or authorized representative

H.2. Disclosure of Information: Performance under this contract may require the contractor to access non public data and information proprietary to a government agency, another government contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the government or others. Neither the Contractor, nor contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by government personnel or upon written approval of the CO in accordance with OWS or other government policies and/or guidance. The contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

The contractor shall comply with all government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a contractor employee, or other appropriate redress. Neither the contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

H.3. Publication and Publicity: The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the government.

(a) Unless otherwise specified in this contract, the contractor may "NOT" publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.

(b) Unless authorized in writing by the CO, the contractor shall "NOT" display government logos including Operating Division or Staff Division logos on any publications.

(c) The contractor shall "NOT" reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies government approval or endorsement of the product(s) or service(s) provided.

(d) The contractor shall include this language, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the government whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part by the U.S. government under Contract No. "W911QY-21-C- 0012". The US government is authorized to reproduce and distribute reprints for governmental purposes notwithstanding any

copyright notation thereon.

H.4. Confidentiality of Information:

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

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

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

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

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

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

All above requirements MUST be passed to all Sub-contractors.

H.5. Organizational Conflicts of Interest: Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.

The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractor‘s performance of this contract, as well as the creation of any unfair competitive advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

The contractor shall notify the Contracting Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the contractor shall promptly submit a plan to the Contracting Officer to either avoid or mitigate any such OCI. The Contracting Officer will have sole discretion in accepting the Contractor‘s mitigation plan. In the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the contractor from participating in contract requirements related to OCI.

Whenever performance of this contract provides access to another Contractor's proprietary information, the contractor shall enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors' offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within fifteen (15) calendar days of execution.

H.6. Institutional Responsibility Regarding Investigator Conflicts of Interest: The Institution (includes any Contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under government contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=45:1.0.1.1.51

As required by 45 CFR Part 94, the Institution shall, at a minimum:

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;

2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or

3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and

2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any government funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.

c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the government funded research.

d. Require that each Investigator who is planning to participate in the government funded research disclose to

the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for government funded research. Require that each Investigator who is participating in the government funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to government funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to government funded research when the Institution, thorough its designated official(s), reasonably determines that the significant financial interest: Could be affected by the government funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the government funded research.

f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).

g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).

h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Contractors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the government funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the government funded research project.

The Contracting Officer and/or government may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the government funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that government funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

H.7. All special requirements list in Section H shall be included or added into any subcontract awarded by the contractor. Additionally all required contract clauses must flow down to any and all subcontracts award by the contractor.

CLAUSES INCORPORATED BY REFERENCE

52.204-7	System for Award Management	OCT 2018
52.204-13	System for Award Management Maintenance	OCT 2018
52.204-21	Basic Safeguarding of Covered Contractor Information Systems	JUN 2016
52.204-24	Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment.	AUG 2020
52.204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.	AUG 2020
52.212-3 Alt I	Offeror Representations and Certifications--Commercial Items (AUG 2020) Alternate I	OCT 2014
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	DEC 2013
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	SEP 2011
252.204-7012	Safeguarding Covered Defense Information and Cyber Incident Reporting	DEC 2019
252.211-7003	Item Unique Identification and Valuation	MAR 2016
52.227-11	Patent Rights--Ownership By The Contractor	MAY 2014
252.227-7013	Rights in Technical Data--Noncommercial Items	FEB 2014
252.227-7015	Technical Data--Commercial Items	FEB 2014
252.227-7039	Patents--Reporting Of Subject Inventions	APR 1990
252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	DEC 2018
252.232-7010	Levies on Contract Payments	DEC 2006
252.244-7000	Subcontracts for Commercial Items	JUN 2013

CLAUSES INCORPORATED BY FULL TEXT

52.204-14 SERVICE CONTRACT REPORTING REQUIREMENTS (OCT 2016)

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

(b) The Contractor shall report, in accordance with paragraphs (c) and (d) of this clause, annually by October 31, for services performed under this contract during the preceding Government fiscal year (October 1-September 30).

(c) The Contractor shall report the following information:

(1) Contract number and, as applicable, order number.

(2) The total dollar amount invoiced for services performed during the previous Government fiscal year under the contract.

(3) The number of Contractor direct labor hours expended on the services performed during the previous Government fiscal year.

(4) Data reported by subcontractors under paragraph (f) of this clause.

(d) The information required in paragraph (c) of this clause shall be submitted via the internet at www.sam.gov. (See SAM User Guide). If the Contractor fails to submit the report in a timely manner, the contracting officer will exercise appropriate contractual remedies. In addition, the Contracting Officer will make the Contractor's failure to comply with the reporting requirements a part of the Contractor's performance information under FAR subpart 42.15.

(e) Agencies will review Contractor reported information for reasonableness and consistency with available contract information. In the event the agency believes that revisions to the Contractor reported information are warranted, the agency will notify the Contractor no later than November 15. By November 30, the Contractor shall revise the report, or document its rationale for the agency.

(f)(1) The Contractor shall require each first-tier subcontractor providing services under this contract, with subcontract(s) each valued at or above the thresholds set forth in 4.1703(a)(2), to provide the following detailed information to the Contractor in sufficient time to submit the report:

(i) Subcontract number (including subcontractor name and unique entity identifier); and

(ii) The number of first-tier subcontractor direct-labor hours expended on the services performed during the previous Government fiscal year.

(2) The Contractor shall advise the subcontractor that the information will be made available to the public as required by section 743 of Division C of the Consolidated Appropriations Act, 2010.

(End of clause)

52.212-4 CONTRACT TERMS AND CONDITIONS-- COMMERCIAL ITEMS (OCT 2018)

(a) Inspection/Acceptance. The Contractor shall only tender for acceptance those items that conform to the requirements of this contract. The Government reserves the right to inspect or test any supplies or services that have been tendered for acceptance. The Government may require repair or replacement of nonconforming supplies or reperformance of nonconforming services at no increase in contract price. If repair/replacement or reperformance will not correct the defects or is not possible, the Government may seek an equitable price reduction or adequate consideration for acceptance of nonconforming supplies or services. The Government must exercise its post-acceptance rights (1) within a reasonable time after the defect was discovered or should have been discovered; and (2) before any substantial change occurs in the condition of the item, unless the change is due to the defect in the item.

(b) Assignment. The Contractor or its assignee may assign its rights to receive payment due as a result of performance of this contract to a bank, trust company, or other financing institution, including any Federal lending agency in accordance with the Assignment of Claims Act (31 U.S.C. 3727). However, when a third party makes payment (e.g., use of the Governmentwide commercial purchase card), the Contractor may not assign its rights to receive payment under this contract.

(c) Changes. Changes in the terms and conditions of this contract may be made only by written agreement of the parties.

(d) Disputes. This contract is subject to 41 U.S.C. chapter 71, Contract Disputes", as amended (41 U.S.C. 601-613). Failure of the parties to this contract to reach agreement on any request for equitable adjustment, claim, appeal or action arising under or relating to this contract shall be a dispute to be resolved in accordance with the clause at FAR 52.233-1, Disputes, which is incorporated herein by reference. The Contractor shall proceed diligently with performance of this contract, pending final resolution of any dispute arising under the contract.

(e) Definitions. The clause at FAR 52.202-1, Definitions, is incorporated herein by reference.

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

(g) Invoice.

(1) The Contractor shall submit an original invoice and three copies (or electronic invoice, if authorized) to the address designated in the contract to receive invoices. An invoice must include--

(i) Name and address of the Contractor;

(ii) Invoice date and number;

(iii) Contract number, line item number and, if applicable, the order number;

(iv) Description, quantity, unit of measure, unit price and extended price of the items delivered;

(v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on Government bill of lading;

(vi) Terms of any discount for prompt payment offered;

(vii) Name and address of official to whom payment is to be sent;

(viii) Name, title, and phone number of person to notify in event of defective invoice; and

(ix) Taxpayer Identification Number (TIN). The Contractor shall include its TIN on the invoice only if required elsewhere in this contract.

(x) Electronic funds transfer (EFT) banking information.

(A) The Contractor shall include EFT banking information on the invoice only if required elsewhere in this contract.

(B) If EFT banking information is not required to be on the invoice, in order for the invoice to be a proper invoice, the Contractor shall have submitted correct EFT banking information in accordance with the applicable solicitation provision, contract clause (e.g., 52.232-33, Payment by Electronic Funds Transfer—System for Award Management, or 52.232-34, Payment by Electronic
Funds Transfer--Other Than System for Award Management), or applicable agency procedures.

(C) EFT banking information is not required if the Government waived the requirement to pay by EFT.

(2) Invoices will be handled in accordance with the Prompt Payment Act (31 U.S.C. 3903) and Office of Management and Budget (OMB) prompt payment regulations at 5 CFR part 1315.

(h) Patent indemnity. The Contractor shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of the performance of this contract, provided the Contractor is reasonably notified of such claims and proceedings.

(i) Payment.--

(1) Items accepted. Payment shall be made for items accepted by the Government that have been delivered to the delivery destinations set forth in this contract.

(2) Prompt payment. The Government will make payment in accordance with the Prompt Payment Act (31 U.S.C. 3903) and prompt payment regulations at 5 CFR part 1315.

(3) Electronic Funds Transfer (EFT). If the Government makes payment by EFT, see 52.212-5(b) for the appropriate EFT clause.

(4) Discount. In connection with any discount offered for early payment, time shall be computed from the date of the invoice. For the purpose of computing the discount earned, payment shall be considered to have been made on the date which appears on the payment check or the specified payment date if an electronic funds transfer payment is made.

(5) Overpayments. If the Contractor becomes aware of a duplicate contract financing or invoice payment or that the Government has otherwise overpaid on a contract financing or invoice payment, the Contractor shall--

(i) Remit the overpayment amount to the payment office cited in the contract along with a description of the overpayment including the--

(A) Circumstances of the overpayment (e.g., duplicate payment, erroneous payment, liquidation errors, date(s) of overpayment);

(B) Affected contract number and delivery order number, if applicable;

(C) Affected line item or subline item, if applicable; and

(D) Contractor point of contact.

(ii) Provide a copy of the remittance and supporting documentation to the Contracting Officer.

(6) Interest.

(i) All amounts that become payable by the Contractor to the Government under this contract shall bear simple interest from the date due until paid unless paid within 30 days of becoming due. The interest rate shall be the interest rate established by the Secretary of the Treasury as provided in 41 U.S.C.
7109, which is applicable to the period in which the amount becomes due, as provided in (i)(6)(v) of this clause, and then at the rate applicable for each six-month period as fixed by the Secretary until the amount is paid.

(ii) The Government may issue a demand for payment to the Contractor upon finding a debt is due under the contract.

(iii) Final decisions. The Contracting Officer will issue a final decision as required by 33.211 if--

(A) The Contracting Officer and the Contractor are unable to reach agreement on the existence or amount of a debt within 30 days;

(B) The Contractor fails to liquidate a debt previously demanded by the Contracting Officer within the timeline specified in the demand for payment unless the amounts were not repaid because the Contractor has requested an installment payment agreement; or

(C) The Contractor requests a deferment of collection on a debt previously demanded by the Contracting Officer (see 32.607-2).

(iv) If a demand for payment was previously issued for the debt, the demand for payment included in the final decision shall identify the same due date as the original demand for payment.

(v) Amounts shall be due at the earliest of the following dates:

(A) The date fixed under this contract.

(B) The date of the first written demand for payment, including any demand for payment resulting from a default termination.

(vi) The interest charge shall be computed for the actual number of calendar days involved beginning on the due date and ending on--

(A) The date on which the designated office receives payment from the Contractor;

(B) The date of issuance of a Government check to the Contractor from which an amount otherwise payable has been withheld as a credit against the contract debt; or

(C) The date on which an amount withheld and applied to the contract debt would otherwise have become payable to the Contractor.

(vii) The interest charge made under this clause may be reduced under the procedures prescribed in 32.608-2 of the Federal Acquisition Regulation in effect on the date of this contract.

(j) Risk of loss. Unless the contract specifically provides otherwise, risk of loss or damage to the supplies provided under this contract shall remain with the Contractor until, and shall pass to the Government upon:

(1) Delivery of the supplies to a carrier, if transportation is f.o.b. origin; or

(2) Delivery of the supplies to the Government at the destination specified in the contract, if transportation is f.o.b. destination.

(k) Taxes. The contract price includes all applicable Federal, State, and local taxes and duties.

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

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

(n) Title. Unless specified elsewhere in this contract, title to items furnished under this contract shall pass to the Government upon acceptance, regardless of when or where the Government takes physical possession.

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

(p) Limitation of liability. Except as otherwise provided by an express warranty, the Contractor will not be liable to the Government for consequential damages resulting from any defect or deficiencies in accepted items.

(q) Other compliances. The Contractor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations applicable to its performance under this contract.

(r) Compliance with laws unique to Government contracts. The Contractor agrees to comply with 31 U.S.C. 1352 relating to limitations on the use of appropriated funds to influence certain Federal contracts; 18 U.S.C. 431 relating to officials not to benefit; 40 U.S.C. chapter 37, Contract Work Hours and Safety Standards; 41 U.S.C. chapter 87, Kickbacks; 41 U.S.C. 4712 and 10 U.S.C. 2409 relating to whistleblower protections; 49 U.S.C. 40118, Fly American; and 41 U.S.C. chapter 21 relating to procurement integrity.

(s) Order of precedence. Any inconsistencies in this solicitation or contract shall be resolved by giving precedence in the following order: (1) the schedule of supplies/services; (2) The Assignments, Disputes, Payments, Invoice, Other Compliances, Compliance with Laws Unique to Government Contracts, and Unauthorized Obligations paragraphs of this clause; (3) the clause at 52.212-5; (4) addenda to this solicitation or contract, including any license agreements for computer software; (5) solicitation provisions if this is a solicitation; (6) other paragraphs of this clause; (7) the Standard Form 1449; (8) other documents, exhibits, and attachments; and (9) the specification.

(t) Reserved.

(u) Unauthorized Obligations.

(1) Except as stated in paragraph (u)(2) of this clause, when any supply or service acquired under this contract is subject to any End User License Agreement (EULA), Terms of Service (TOS), or similar legal instrument or agreement, that includes any clause requiring the Government to indemnify the Contractor or any person or entity for damages, costs, fees, or any other loss or liability that would create an Anti-Deficiency Act violation (31 U.S.C. 1341), the following shall govern:

(i) Any such clause is unenforceable against the Government.

(ii) Neither the Government nor any Government authorized end user shall be deemed to have agreed to such clause by virtue of it appearing in the EULA, TOS, or similar legal instrument or agreement. If the EULA, TOS, or similar legal instrument or agreement is invoked through an ``I agree" click box or other comparable mechanism (e.g., ``click-wrap" or ``browse-wrap" agreements), execution does not bind the Government or any Government authorized end user to such clause.

(iii) Any such clause is deemed to be stricken from the EULA, TOS, or similar legal instrument or agreement.

(2) Paragraph (u)(1) of this clause does not apply to indemnification by the Government that is expressly authorized by statute and specifically authorized under applicable agency regulations and procedures.

(v) Incorporation by reference. The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

(End of Clause)

52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS--COMMERCIAL ITEMS (AUG 2020)

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

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

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

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

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

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

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

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

XX (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (JUN 2020), with Alternate I (Oct 1995) (41 U.S.C. 4704 and 10 U.S.C. 2402).

XX (2) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509).

____ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (JUN 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)

XX (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (JUN 2020) (Pub. L. 109-282) (31 U.S.C. 6101 note).

___ (5) [Reserved]

XX (6) 52.204-14, Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

____ (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C).

XX (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (JUN 2020) (31 U.S.C. 6101 note).

XX (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (OCT 2018) (41 U.S.C. 2313).

____ (10) [Reserved]

____ (11)(i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (MAR 2020) (15 U.S.C. 657a).

____ (ii) Alternate I (MAR 2020) of 52.219-3.

____ (12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (MAR 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).

____ (ii) Alternate I (MAR 2020) of 52.219-4.

____ (13) [Reserved]

XX (14)(i) 52.219-6, Notice of Total Small Business Set-Aside (MAR 2020) (15 U.S.C. 644).

____ (ii) Alternate I (MAR 2020) of 52.219-6.

____ (15)(i) 52.219-7, Notice of Partial Small Business Set-Aside (MAR 2020) (15 U.S.C. 644).

____ (ii) Alternate I (MAR 2020) of 52.219-7.

____ (16) 52.219-8, Utilization of Small Business Concerns (OCT 2018) (15 U.S.C. 637(d)(2) and (3)).

____ (17)(i) 52.219-9, Small Business Subcontracting Plan (JUN 2020) (15 U.S.C. 637(d)(4)).

____ (ii) Alternate I (NOV 2016) of 52.219-9.

____ (iii) Alternate II (NOV 2016) of 52.219-9.

____ (iv) Alternate III (JUN 2020) of 52.219-9.

____ (v) Alternate IV (JUN 2020) of 52.219-9.

____ (18) (i) 52.219-13, Notice of Set-Aside of Orders (MAR 2020) (15 U.S.C. 644(r)).

____ (ii) Alternate I (MAR 2020) of 52.219-13.

____ (19) 52.219-14, Limitations on Subcontracting (MAR 2020) (15 U.S.C. 637(a)(14)).

____ (20) 52.219-16, Liquidated Damages—Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).

____ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (MAR 2020) (15 U.S.C. 657f).

____ (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (MAY 2020) (15 U.S.C. 632(a)(2)).

____ (ii) Alternate I (MAR 2020) of 52.219-28.

____ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business (EDWOSB) Concerns (MAR 2020) (15 U.S.C. 637(m)).

____ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (MAR 2020) (15 U.S.C. 637(m)).
____ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (MAR 2020) (15 U.S.C. 644(r)).

____ (26) 52.219-33, Nonmanufacturer Rule (MAR 2020) (15 U.S.C. 637(a)(17)).

XX (27) 52.222-3, Convict Labor (JUN 2003) (E.O. 11755).

XX(28) 52.222-19, Child Labor--Cooperation with Authorities and Remedies (JAN 2020) (E.O. 13126).

XX (29) 52.222-21, Prohibition of Segregated Facilities (APR 2015).

XX (30)(i) 52.222-26, Equal Opportunity (SEPT 2016) (E.O. 11246).

____ (ii) Alternate I (FEB 1999) of 52.222-26.

XX (31)(i) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).

____ (ii) Alternate I (JUL 2014) of 52.222-35.

XX (32)(i) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).

____ (ii) Alternate I (JUL 2014) of 52.222-36.

XX (33) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).

XX (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496).

XX (35)(i) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O. 13627).

____ (ii) Alternate I (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

XX (36) 52.222-54, Employment Eligibility Verification (OCT 2015). (E. O. 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)

____ (37)(i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA–Designated Items (MAY 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

____ (ii) Alternate I (MAY 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

____ (38) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (JUN 2016) (E.O. 13693).

____ (39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (JUN 2016) (E.O. 13693).

_____ (40) (i) 52.223-13, Acquisition of EPEAT® Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).

_____ (ii) Alternate I (OCT 2015) of 52.223-13.

_____ (41)(i) 52.223-14, Acquisition of EPEAT® Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).

_____ (ii) Alternate I (JUN 2014) of 52.223-14.

____ (42) 52.223-15, Energy Efficiency in Energy-Consuming Products (MAY 2020) (42 U.S.C. 8259b).

____ (43)(i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (OCT 2015) (E.O.s 13423 and 13514).

____ (ii) Alternate I (JUN 2014) of 52.223-16.

XX (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (JUN 2020) (E.O. 13513).

____ (45) 52.223-20, Aerosols (JUN 2016) (E.O. 13693).

____ (46) 52.223-21, Foams (JUN 2016) (E.O. 13693).

____ (47)(i) 52.224-3, Privacy Training (JAN 2017) (5 U.S.C. 552a).

____ (ii) Alternate I (JAN 2017) of 52.224-3.

____ (48) 52.225-1, Buy American--Supplies (MAY 2014) (41 U.S.C. chapter 83).

____ (49) (i) 52.225-3, Buy American--Free Trade Agreements--Israeli Trade Act (MAY 2014) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

_____ (ii) Alternate I (MAY 2014) of 52.225-3.

_____ (iii) Alternate II (MAY 2014) of 52.225-3.

_____ (iv) Alternate III (MAY 2014) of 52.225-3.

XX (50) 52.225-5, Trade Agreements (OCT 2019) 19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).

XX (51) 52.225-13, Restrictions on Certain Foreign Purchases (JUN 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

____ (52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (OCT 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

____ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (NOV 2007) (42 U.S.C. 5150

____ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (NOV 2007) (42 U.S.C. 5150).

____ (55) 52.229-12, Tax on Certain Foreign Procurements (JUN 2020).

XX (56) 52.232-29, Terms for Financing of Purchases of Commercial Items (FEB 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

____ (57) 52.232-30, Installment Payments for Commercial Items (JAN 2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

____ (58) 52.232-33, Payment by Electronic Funds Transfer—System for Award Management (OCT 2018) (31 U.S.C. 3332).

____ (59) 52.232-34, Payment by Electronic Funds Transfer—Other than System for Award Management (JUL 2013) (31 U.S.C. 3332).

XX (60) 52.232-36, Payment by Third Party (MAY 2014) (31 U.S.C. 3332).

____ (61) 52.239-1, Privacy or Security Safeguards (AUG 1996) (5 U.S.C. 552a).

____ (62) 52.242-5, Payments to Small Business Subcontractors (JAN 2017)(15 U.S.C. 637(d)(13)).

____ (63)(i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (FEB 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).

____ (ii) Alternate I (APR 2003) of 52.247-64.

____ (iii) Alternate II (FEB 2006) of 52.247-64.

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

XX (1) 52.222-41, Service Contract Labor Standards (AUG 2018) (41 U.S.C. chapter 67).

XX (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (MAY 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

_____ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (Multiple Year and Option Contracts) (AUG 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

_____ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (MAY 2014) (29 U.S.C 206 and 41 U.S.C. chapter 67).

_____ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (MAY 2014) (41 U.S.C. chapter 67).

_____ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (MAY 2014) (41 U.S.C. chapter 67).

XX(7) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2015) (E.O. 13658).

XX (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).

_____ (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (JUN 2020) (42 U.S.C. 1792).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this contract, and does not contain the clause at 52.215-2, Audit and Records--Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

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

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

(e) (1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1)in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509).

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

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

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

(v) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(vi) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

(vii) 52.222-26, Equal Opportunity (Sep 2016) (E.O. 11246).

(viii) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).

(ix) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).

(x) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).

(xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.

(xii) 52.222-41, Service Contract Labor Standards (Aug 2018), (41 U.S.C. chapter 67).

(xiii) _____ (A) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O. 13627).

_____ (B) Alternate I (March 2, 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
(xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (May 2014) (41 U.S.C. chapter 67.)

(xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (May 2014) (41 U.S.C. chapter 67)

(xvi) 52.222-54, Employment Eligibility Verification (Oct 2015) (E. O. 12989).

(xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015) (E.O. 13658).

(xviii) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

(xix) (A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).

(B) Alternate I (Jan 2017) of 52.224-3.

(xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

(xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations. (JUN 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xxii) 52.247-64, Preference for Privately-Owned U.S. Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

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

(End of clause)

52.217-8 OPTION TO EXTEND SERVICES (NOV 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within period of performance listed in the option CLINS.

(End of clause)

52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within any time during the period of performance listed within the option CLINS; provided that the Government gives the Contractor a

preliminary written notice of its intent to extend at least 2 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed twenty four months.
(End of clause)

52.246-15 CERTIFICATE OF CONFORMANCE (APR 1984)

(a) When authorized in writing by the cognizant Contract Administration Office (CAO), the Contractor shall ship with a Certificate of Conformance any supplies for which the contract would otherwise require inspection at source. In no case shall the Government's right to inspect supplies under the inspection provisions of this contract be prejudiced. Shipments of such supplies will not be made under this contract until use of the Certificate of Conformance has been authorized in writing by the CAO, or inspection and acceptance have occurred.

(b) The Contractor's signed certificate shall be attached to or included on the top copy of the inspection or receiving report distributed to the payment office or attached to the CAO copy when contract administration (Block 10 of the DD Form 250) is performed by the Defense Contract Administration Services. In addition, a copy of the signed certificate shall also be attached to or entered on copies of the inspection or receiving report accompanying the shipment.

(c) The Government has the right to reject defective supplies or services within a reasonable time after delivery by written notification to the Contractor. The Contractor shall in such event promptly replace, correct, or repair the rejected supplies or services at the Contractor's expense.

(d) The certificate shall read as follows:

"I certify that on _____ [insert date], the ____ [insert Contractor's name] furnished the supplies or services called for by Contract No._____ via ____ [Carrier] on _____[identify the bill of lading or shipping document] in accordance with all applicable requirements. I further certify that the supplies or services are of the quality specified and conform in all respects with the contract requirements, including specifications, drawings, preservation, packaging, packing, marking requirements, and physical item identification (part number), and are in the quantity shown on this or on the attached acceptance document."

Date of Execution: _____

Signature: _____

Title: _____

(End of clause)

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

(a) Definitions. As used in this clause—

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) For fixed price line items—

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

Receiving Report (DD 250) Destination Inspection / Destination Acceptance /Inspection and Acceptance at place of destination

(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.

Invoice as 2-in-1 (FP Services Only – No DD250 Required)

(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	(b) (4)
Issue By DoDAAC	
Admin DoDAAC**	
Inspect By DoDAAC	
Ship To Code	
Ship From Code	
Mark For Code	
Service Approver (DoDAAC)	
Service Acceptor (DoDAAC)	
Accept at Other DoDAAC	
LPO DoDAAC	
DCAA Auditor DoDAAC	
Other DoDAAC(s)	

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

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

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

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

(g) WAWF point of contact.

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

Name	Email	Phone	Job Title
(b) (6)			JPEO WAWF Acceptor
(b) (6)			COR/Acceptor
(b) (6)			Contracting Officer

(b) (6)	[redacted]	[redacted]	Contract Specialist
(b) (6)	[redacted]	[redacted]	Contract Specialist

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

(End of clause)

ATTACHMENTS & REFERENCES

Attachments:

Attachmnet 0001: Reference list

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 31

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00001	18-Mar-2021	SEE SCHEDULE	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	See Item 6	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
MICROBIOLOGICS, INC. (b) (6) 200 COOPER AVE N SAINT CLOUD MN 56303-4452		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY21C0012
	X	10B. DATED (SEE ITEM 13) 09-Nov-2020

CODE 1CD10	FACILITY CODE 1CD10

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:
Mutual Agreement of the Parties, FAR 43.103(a)(3)

☐ 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: (b) (6)
ACTION OBLIGATION AMOUNT: (b) (4)

The purpose of this modification is to:
1.) Add CLINS 0006-0010 to continue the Technology Transfer of a validated WT Virus Neutralization (VN) assay and to demonstrate method equivalence as a result of the delays with the ADL validating the assay with approval from the FDA. The new CLINS also cover the government change from a GLP requirement to GCLP as well as the costs associated with the security audit.
2.) The sample testing unit prices have been reduced to remove costs that are tied to the Technology Transfer and are required prior to sample testing.

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

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
	(b) (6) TEL: (b) (6) EMAIL: (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
_____ (Signature of person authorized to sign)		BY (b) (6) (Signature of Contracting Officer)	18-Mar-2021

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 1449 - CONTINUATION SHEET

SOLICITATION/CONTRACT FORM

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

SUPPLIES OR SERVICES AND PRICES

CLIN 0003
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1001
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1002
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1003
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1004
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1005
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1006

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1007

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1008

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1009

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1010

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1011

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1012

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4).

CLIN 1013

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1014

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1015

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1016
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1017
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4) .
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1018
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1019
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4) .
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1020
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1021
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4) .
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1022
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4) .
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1023
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1024
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4) .

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

CLIN 1025

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1026

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4) .
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1027

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1028

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1029

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1030

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by $(b) (4) from (b) (4) to (b) (4) .

CLIN 1031

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1032

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1033

The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1034
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 1035
The unit price amount has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) to (b) (4)

CLIN 0006 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0006		1	Each	(b) (4)	(b) (4)

Technlology Transfer of Wild Type Assay
FFP
The contractor shall Technology Transfer (TT) the validated WT virus neutralization (VN) assay and demonstrate method equivalence. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020.
FOB: Destination
PSC CD: Q301

NET AMT (b) (4)

SUBCLIN 000601 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000601					(b) (4)

ACRN AA @ (b) (4)
FFP
PURCHASE REQUEST NUMBER: 0011560875-0002

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156087500006

CLIN 0007 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0007		1	Each	(b) (4)	(b) (4)

Technlology Transfer of Wild Type Assay
FFP
The contractor shall Technology Transfer (TT) the validated WT virus neutralization (VN) assay and demonstrate method equivalence. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020.
FOB: Destination
PSC CD: Q301

NET AMT (b) (4)

SUBCLIN 000701 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000701					(b) (4)

ACRN AA @ (b) (4)
FFP
PURCHASE REQUEST NUMBER: 0011560875-0002

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156087500007

CLIN 0008 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0008		1	Each	(b) (4)	(b) (4)

Technlology Transfer of Wild Type Assay
FFP
The contractor shall Technology Transfer (TT) the validated WT virus neutralization (VN) assay and demonstrate method equivalence. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020.
FOB: Destination
PSC CD: Q301

NET AMT (b) (4)

SUBCLIN 000801 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000801					(b) (4)

ACRN AA @ (b) (4)
FFP
PURCHASE REQUEST NUMBER: 0011560875-0002

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156087500008

CLIN 0009 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0009		1	Each	(b) (4)	(b) (4)

Technlology Transfer of Wild Type Assay
FFP
The contractor shall Technology Transfer (TT) the validated WT virus neutralization (VN) assay and demonstrate method equivalence. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020.
FOB: Destination
PSC CD: Q301

NET AMT (b) (4)

SUBCLIN 000901 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000901					(b) (4)

ACRN AA @ (b) (4)
FFP
PURCHASE REQUEST NUMBER: 0011560875-0002

NET AMT

ACRN AA (b) (4)
CIN: GFEBS001156087500009

CLIN 0010 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0010		1	Each	(b) (4)	(b) (4)

Technlology Transfer of Wild Type Assay
FFP
The contractor shall Technology Transfer (TT) the validated WT virus neutralization (VN) assay and demonstrate method equivalence. All required work shall be IAW the SOW and Commercial Solution Proposal titled "COMMERCIAL SOLUTIONS PROPOSAL: CSO AOI W911QY-20-S-C001-A002", dated November 9, 2020.
FOB: Destination
PSC CD: Q301

NET AMT (b) (4)

SUBCLIN 001001 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
001001					(b) (4)

ACRN AA @ (b) (4)
FFP
PURCHASE REQUEST NUMBER: 0011560875-0002

NET AMT (b) (4)

ACRN AA (b) (4)
CIN: GFEBS001156087500010

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:

AA: 02120202021204000000664643255 S.0074658.5.11.1 6100.9000021001 A5XAH (CIN GFEBS001156087500003) was decreased by (b) (4) from (b) (4) to (b) (4)

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

ACRN: AA

CIN: GFEBS001156087500006

Acctng Data: 021202020212040000066464325 5 S.0074658.5.11.1 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

SUBCLIN 000701:
Funding on SUBCLIN 000701 is initiated as follows:

ACRN: AA

CIN: GFEBS001156087500007

Acctng Data: 021202020212040000066464325 5 S.0074658.5.11.1 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

SUBCLIN 000801:
Funding on SUBCLIN 000801 is initiated as follows:

ACRN: AA

CIN: GFEBS001156087500008

Acctng Data: 021202020212040000066464325 5 S.0074658.5.11.1 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

SUBCLIN 000901:
Funding on SUBCLIN 000901 is initiated as follows:

ACRN: AA

CIN: GFEBS001156087500009

Acctng Data: 021202020212040000066464325 5 S.0074658.5.11.1 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

SUBCLIN 001001:
Funding on SUBCLIN 001001 is initiated as follows:

ACRN: AA

CIN: GFEBS001156087500010

Acctng Data: 021202020212040000066464325 5 S.0074658.5.11.1 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

DELIVERIES AND PERFORMANCE

The following Delivery Schedule for CLIN 0006 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAR-2021 TO 08-NOV-2021	N/A	BARDA (b) (6) BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024 (b) (6) FOB: Destination	W56XNH

The following Delivery Schedule for CLIN 0007 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAR-2021 TO 08-NOV-2021	N/A	BARDA (b) (6) BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024 (b) (6) FOB: Destination	W56XNH

The following Delivery Schedule for CLIN 0008 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE

POP 19-MAR-2021 TO 08-NOV-2021	N/A	BARDA (b) (6) BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024 (b) (6) FOB: Destination	W56XNH

The following Delivery Schedule for CLIN 0009 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAR-2021 TO 08-NOV-2021	N/A	BARDA (b) (6) BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024 (b) (6) FOB: Destination	W56XNH

The following Delivery Schedule for CLIN 0010 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 19-MAR-2021 TO 08-NOV-2021	N/A	BARDA (b) (6) BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT AUTH 200 C STREET, SW WASHINGTON DC 20024 (b) (6) FOB: Destination	W56XNH

INSPECTION AND ACCEPTANCE

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

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

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

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

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

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

The following Acceptance/Inspection Schedule was added for SUBCLIN 000701:

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

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

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

The following Acceptance/Inspection Schedule was added for SUBCLIN 000801:

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

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

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

The following Acceptance/Inspection Schedule was added for SUBCLIN 000901:

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

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

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

The following Acceptance/Inspection Schedule was added for SUBCLIN 001001:

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

The following have been modified:

ADDENDUM: The following pages hereby supplements FAR 52.212-4

SOW For COVID-19 Immune Assay Implementation and Serum Testing Services
Title of Project: Establishment of high throughput neutralization assay laboratory capability for COVID-19 and testing of human serum samples

1. Introduction

An outbreak of respiratory disease caused by a novel coronavirus was first detected in China in late 2019 and has now spread worldwide, including the United States (US). The virus has been named Severe Acute Respiratory Disease Coronavirus-2 (SARS-CoV-2) and causes Coronavirus Disease 2019 (COVID-19). On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO), declared the outbreak a "Public Health Emergency of International Concern" (PHEIC). On January 31, the US Department of

Health and Human Services Secretary (HHS), Alex M. Azar II, declared a Public Health Emergency for the US to aid the nation's healthcare community in responding to COVID-19. On March 11, WHO publicly declared COVID-19 as a pandemic. On March 13, the President of the United States declared the COVID-19 outbreak a national emergency. The US Government (USG) has identified COVID-19 vaccine candidates (prototypes) that are progressing rapidly through advanced research and development activities. A joint HHS and Department of Defense (DOD) leadership team named Operation Warp Speed (OWS) is charged with development of COVID-19 vaccines and other medical countermeasures.

This procurement action is aimed at providing additional laboratory assay capacity sites for analysis of serum samples collected from subjects enrolled in COVID-19 vaccine clinical trials. Serum samples are tested to ascertain the ability of the vaccine to induce an immune response. Studies have shown that serum antibodies directed against viral spike (S) that block infection of target cells can be readily detected by Virus Neutralization (VN) assays. The USG has supported development of two VN assays at two organizations herein designates as "assay developer laboratory (ADL)" and seeks to transfer this assay technology to a new facility per this solicitation.

The FDA published guidance Development and Licensure of Vaccines to Prevent COVID-19 (6/30/2020) for manufacturers developing COVID-19 vaccines. The guidance document states: "There are currently no accepted surrogate endpoints that are reasonably likely to predict clinical benefit of a COVID-19 vaccine" (1). Use of new vaccines will require an Emergency Use Authorization or a BLA approval based on direct evidence of vaccine safety and efficacy in protecting humans from SARS-CoV-2 infection and/or clinical disease. The ultimate goal of this project is to provide serologic data to support establishment of a correlate of protection. The latter would facilitate expanded use of approved COVID-19 vaccines and accelerated approvals of additional vaccines.

2. Scope

The program goals are twofold: 1. Technology transfer of two VN assays to a Biosafety Level 3 (BSL3) laboratory other than the ADL in compliance with GCLP (Contract Base period). The first transfer will include transfer of a high throughput validated neutralization assay and subsequent method equivalence demonstration meeting FDA requirements for Phase 3 sample testing; the second will include technology transfer of a qualified live virus reporter assay for subsequent validation meeting FDA requirements for Phase 3 sample testing. 2. Test serum samples from human subjects enrolled in clinical trials of COVID-19 vaccines using the new validated assay in compliance with GCLP.

3. Regulatory compliance

The offeror is expected to comply with GCLP Standards (2).

The neutralization assays must be conducted with live SARS-CoV-2 virus; therefore, laboratory testing must be conducted in a BSL-3 environment (3). The offeror's facility must demonstrate appropriate permits for the operation of the laboratory facilities in compliance with BSL-3 as described in CDC Guidelines. The offeror should describe the safety procedures and provide assurances regarding Facility Safety Plan, CDC guidelines, and the appropriate SOPs and institutional biosafety requirements for handing live SARS-COV-2.

Given that the test results for human sera collected as part of a clinical trial are part of a BLA submission to the FDA, the organization must be prepared to provide the necessary supporting quality systems documentation to the sponsor company for inclusion in the regulatory filing or in the course of quality audits (4,5). These supporting quality systems along with assay validation reports and other supporting documentation are required for GCLP compliance and should be documented in the drug master file (DMF) or other negotiated means. The contractor is expected to participate in an External Quality Assurance scheme to assess continued ability to perform tests correctly.

A facility audit will be conducted.

4. Statement of Objectives

The objective of this project is the establishment of a high throughput wild type and reporter SARS-CoV-2 virus

neutralization assays for COVID-19 for use in testing serum samples from human subjects enrolled in clinical trials of COVID-19 vaccines in compliance with GCLP.

Operation Warp Speed (OWS) has supported development of two VN assays at organizations herein designated as "assay developer laboratory (ADL)". The ADL will develop the assays using two virus platforms - a live wild type (WT) virus and a live reporter virus for transfer to the new facility. The WT virus is the clinical SARS-CoV-2 isolate WA1 strain isolated from the first US COVID-19 patient identified in Washington State and the reporter virus has a bioluminescent luciferase gene inserted to generate a recombinant SARS-CoV-2 virus strain. The WT virus assay will be transferred in a validated state; the reporter virus assay will be transferred in a qualified state.

After contract award, the offeror is expected to submit a protocol (in coordination with the ADL) to technology transfer the previously validated WT VN assay to quantify SARS-CoV-2 neutralizing antibodies in human sera using VERO E6 cells and subsequently perform method equivalence. The offeror will use a panel of COVID-19 convalescent and COVID-19 vaccine recipient samples to demonstrate method equivalence relative to the performance characteristics at the ADL (4). The VN assay follows traditional protocols, with a serum sample that is serially diluted and then incubated with a known amount of virus (neutralization step). For the WT VN assay, a cell monolayer is then inoculated with the sample/virus mix and incubated for approximately 24 hours prior to acetone fixation and immunoenzymatic detection of SARS-COV-2 N protein expression (in situ N-ELISA). The VN assay median endpoint titer is reported as the reciprocal of the highest dilution at which the input virus is neutralized ELISA OD units below an established threshold). The assay will be considered fully transferred only once the FDA has reviewed and concurred with tech transfer acceptability through review of documentation submitted to a DMF or through other negotiated means.

Conversely, the reporter VN assay relies on a luminescence readout. This assay will be transferred in a qualified state and the receiving lab will be required to validate the assay. Assay validation will be considered complete only once the FDA has reviewed and concurred with validation report acceptability through review of documentation submitted to a DMF or through other negotiated means.

Details of the protocol for both the assays will be provided by the ADL in the course of jointly preparing the technology transfer protocol package.

- Base Period: Technology Transfer of validated and qualified OWS neutralization assays, subsequent method equivalency demonstration and validation, and sample testing of 1000 clinical trial samples inclusive of a an equivalency convalescent serum panel
- Options 1-20: Sample testing of 1000 clinical trial specimens
- Options 21-30 : Sample testing of 2000 clinical trial specimens
- Options 31-35: Sample testing of 5000 clinical trial specimens

The proposal's basic framework should include the following specific tasks:
Base Period (CLIN 0001-CLIN 005): Technology Transfer of one validated and one qualified OWS VN assay. After contract award, the offeror will host an audit and should provide a project plan (in coordination with ADL) that describes the approach to 1) technology transfer the validated WT virus assay and demonstrate method equivalence with a panel of test serum samples provided by the USG and 2) technology transfer the qualified reporter virus assay and subsequently validate the assay. Offerors are encouraged to describe their testing workflow in detail to include the use of robotic systems in order to increase sample throughput. Assay validation and overall readiness to test Phase 3 samples from the clinical trials includes FDA concurrence with the assay documentation submitted to the DMF

CLIN0001: Technology transfer the validated WT VN assay.

o Technology transfer package (documentation from ADL) will include the following:

(i) An assay specific SOP for WT VN assay
(ii) A validation protocol designed to evaluate precision, dilutional linearity, limit of detection, limit of quantification,

selectivity (matrix effects), and specificity as appropriate. The validation protocol shall include a statistical analysis plan.
(iii) Serum equivalence panel (see 5. Critical reagents)
(iv) A validation report

- The offeror shall provide:

i. A proof-of-concept data report on assay performance conducted prior to assay validation or equivalence execution, capturing, at a minimum, a demonstration of precision with two samples tested over three days.
ii. Technology transfer assay protocol to demonstrate method equivalence (in coordination with the ADL)
iii. Submission of the technology transfer protocol to the FDA DMFs
iv. Execute the technology transfer assay protocol
v. A draft and final technology transfer report
vi. Copies of FDA's concurrence with WT VN assay equivalence testing indicating readiness to initiate Phase 3 clinical trial sample testing

CLIN0002: Technology transfer the qualified reporter VN assay and subsequent validation

- Technology transfer package (documentation from ADL) will include the following:

(i) An assay specific SOP for live reporter VN assay
(ii) A qualification protocol designed to evaluate precision, dilutional linearity, limit of detection, limit of quantification, selectivity (matrix effects), and specificity as appropriate. The qualification protocol shall include a statistical analysis plan.
(iii) Serum equivalence panel (see 5. Critical reagents)
(iv) A qualification report.

- The offeror shall provide:

(i) A draft and final validation protocol
(ii) A Validation Report
(iii) Submission of the validation report to the FDA DMF
(iv) Copies of FDA's concurrence with validation report indicating readiness to initiate Phase 3 clinical trial sample testing

CLIN0003: Testing of 1000 clinical trial specimens using the validated assays. (500 samples for WT and 500 samples for live virus reporter) The offeror shall provide:

- The proposed sample testing turnaround time when operating at full capacity for extended periods
- The offeror should provide a sample management plan that describes in substantial detail the procedures for serum sample accessioning, handling, safety and integrity (including power failures and other risks), with auditable tracking systems throughout the chain of custody.
- The offeror should provide a data management plan describing the information technology infrastructure to receive the serum samples data and demonstrate data integrity, accuracy and security thought the life cycle of the sample and completion of the project.

CLIN0004: Drug Master File (DMF) WT Neutralization VN Assay

CLIN0005: Drug Master File (DMF) Reporter VN Assay

CLIN0006: Technology transfer the validated WT VN assay.

CLIN0007: Technology transfer the validated WT VN assay.

CLIN0008:: Technology transfer the validated WT VN assay.

CLIN0009: Technology transfer the validated WT VN assay.

CLIN0010: Technology transfer the validated WT VN assay.

Contract Options (Options 1-35) : Testing of clinical trial samples using one of the validated
CLIN 1001-1020 Option 1-20: Testing of 1,000 clinical trial samples using one of the validated assay
CLIN 1021-1030 Option 21-30: Testing of 2,000 clinical trial samples using one of the validated assay
CLIN 1031-1035 Option 31-35: Testing of 5,000 clinical trial samples using one of the validated assay

5. Critical reagents

The USG will provide certain reagents (e.g. SARS-CoV-2 virus seed) and a panel of 18 human serum samples to assay equivalence between different sites executing the same assay. This panel comprises 15 COVID-19 convalescent samples (equally distributed among samples with low, medium and high antibody titers) with certified titers and 3 negative controls.

6. Capacity

Minimum 1000 samples /week. The maximum capacity within the accepted proposal is expected to be 1,000 samples for the WT VN assay and 2000 for the reporter VN assay tested every seven days. Testing under options that are exercised will be IAW the accepted proposals stated capacities.

7. Period of Performance

The Base Period of Performance (POP): The proposed OWS VN assay capacity must be available for use in full no later than July 31 2021(after FDA concurrence with the tech transfer and equivalence report). The total proposed duration of this work is 12 months from award.

8. Personnel and Place of performance

The proposal should describe the key personnel and provide CVs to document training and experience for the project as well as the overall staffing plan for the proposed activities.

The facilities where the work will be conducted as well as supporting activities should be described in sufficient detail to support assessment of fitness for purpose.

9. Deliverables

The following deliverables would be provided by the offeror. The following proposed deliverable schedule is of critical importance to the USG.
General Deliverables

a) PERIODIC TELECONFERENCES (Biweekly or as negotiated)

1) Draft bulleted agenda provided 48 hours prior to teleconference.
2) Meeting minutes provided 3 business days after teleconference.

b) COMMUNICATION MANAGEMENT PLAN

1) Outlines communications goals and strategies for the task order. Template will be provided.

c) MONTHLY REPORTS

1) Reports shall describe progress of meeting contract milestones- overall project assessment, problems encountered

and recommended solutions. The USG will receive information on the Tech transfer results/report, testing status, number of samples processed, and number samples that are outstanding

2) Reports shall detail the planned progress and actual progress during the period covered, explaining occurrences of any differences and corrective steps/actions planned if behind schedule. Deviation reporting should occur in real time.
3) Reports shall detail estimated invoice submissions/acceptance dates, and a narrative of the percentage of work completed.
4) Reports shall include an updated Gantt.

d) DRAFT FINAL REPORT

1) A final report shall be provided for USG review and comment. The report shall summarize all work conducted during the period of performance and provide all results (include specific items required in the report).

e) FINAL REPORT

1) The final report shall address USG comments regarding the draft report.

Technical deliverables

	Deliverable Description	Due Date
	Host a facility Audit	2 weeks from award
	Procurement of critical reagents and equipment; Proof-of-concept data report, as described under CLIN001	6 weeks after contract award
	Assay technology transfer protocol for WT virus (in coordination with ADL and BARDA)	2 weeks from receipt of WT VN assay technology transfer package (documentation from ADL) as described under CLIN001
	Validation protocol for reporter virus assay(in coordination with ADL and BARDA)	2 weeks from receipt of reporter VN assay technology transfer package (documentation from ADL) as described under CLIN002
	Establishment of DMF(s)	2 weeks from contract award
	Submission of technology transfer protocol (WT assay) and validation protocol (Reporter assay) to DMF(s)	5 weeks from receipt of technology transfer package (documentation from ADL)
	Draft technology transfer Report for WT virus assay	6 weeks from DMF submission of the technology transfer protocol
	Final technology transfer Report for WT virus assay and submission to DMF	1 week from draft technology transfer report

		Copy of FDA concurrence on WT virus assay readiness for Phase 3 sample testing	Not applicable (dependent on FDA)
		Draft validation report for the reporter virus assay	8 weeks from DMF submission of the validation protocol
		Final validation report for the reporter virus assay and submission to DMF	1 week from draft validation report
		FDA concurrence on reporter virus assay readiness for Phase 3 sample testing	Not applicable (dependent on FDA)
		Testing batch of sera samples (1,000)	3 weeks from sample receipt
		Testing batch of 1,000 sera samples per option (Option 1-20)	3 weeks from sample receipt
		Testing batch of 2,000 sera samples per option (Option 21-30)	4 weeks from sample receipt
		Testing batch of 5,000 sera samples per option (Option 31-35)	6 weeks from sample receipt

CONTRACT ADMINISTRATION

Government Contract Administration:

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

Contracting Officer:

(b) (6)
Email (b) (6)
(b) (6)

Procurement Specialist:

(b) (6)
(b) (6)
Email: (b) (6)
(b) (6)

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

Government Technical Points of Contact:

Contracting Officers Representative (COR):

(b) (6)
Health Scientist
(b) (6)
Email: (b) (6)
Office: (b) (6)
Cell: (b) (6)

Technical Point of Contact:

(b) (6)
Biologist, Influenza and Emerging Diseases Division
(b) (6)
Email: (b) (6)
Office: (b) (6)
Cell: (b) (6)

Quality Assurance Point of Contact:

(b) (6)
Title:Senior Regulatory Affairs Analyst
Email (b) (6)
(b) (6)
Phone: (b) (6)

Contractor's Contract Administration

Technical Point of Contact:

(b) (6)
Senior Scientist
Email: (b) (6)
Office: (b) (6)
Cell: (b) (6)

Administrative Point of Contact:

(b) (6)
Vice President (b) (6)
Email: (b) (6)
Office: (b) (6)
Cell: (b) (6)

Contractor's Past Performance Point of Contact (POC):

Annual contract past performance evaluations will be performed by the government. The offeror shall identify a Point of Contact (POC) to participate in these on-line evaluations. This individual is required to register in the Contractor Performance Assessment Reporting System (CPARS @ http://www.cpars.csd.disa.mil) and respond to the government evaluations in a timely manner. The contractor POC responsible for this action is:

(b) (6)
Vice President (b) (6)
Email (b) (6)
Office: (b) (6)
Cell (b) (6)

Notifications of Revisions and Changes:

Notification of revision or changes to names or email addresses will be provided by official correspondence from the PCO/ACO or office of the PCO/ACO in lieu of a contract modification. This does not apply to any such revisions or changes in the event this contract includes a key personnel clause.

DELIVERY OR PERFORMANCE

F.1. Technical Deliverables

TECHNICAL DELIVERABLES	OWNER	PLANNED START	PLANNED FINISH	NOTES
Award of Contract	(b) (4)	11/9/2020	11/09/2020	
Establishment of DMF with FDA		11/17/2020	11/23/2020	
Facility Audit		11/17/2020	12/18/2020	
Procurement of critical reagents and equipment. Begin installation.		11/17/2020	12/27/2020	
Complete installations (IQOQPQ etc.) & receive materials.		01/24/2021	06/01/2021	
Receipt of tech transfer package		11/9/2020	Outstanding	(b) (4)
Receive virus stock, cells, and other reagents for the tech transfer		11/17/2020	01/14/2021	(b) (4)
Expand provided cells to generate master cell bank		11/14/2021	12/11/2020	
Complete qualification of master cell bank		12/5/2020	03/03/2021	
Expand provided virus stock to complete master virus bank		1/15/2021	01/17/2021	
Complete qualification of virus master bank		6/21/2021	07/06/2021	(b) (4)
Hire additional staff as desired		11/17/2020	12/07/2020	

Complete onboarding process	[redacted]	11/8/2020	12/07/2020	
Complete assay specific training for additional staff	[redacted]	03/1/2021	06/01/2021	
Work with ADL to understand assay being transferred	[redacted]	11/17/2020	11/23/2020	
Receipt of final of Umbrella protocol	[redacted]	TBD	TBD	
Issue draft of tech transfer protocol	[redacted]	01/24/2021	03/15/2021	
CLIN001-Perform proof of concept. Materials provided by ADL/USG	[redacted]	03/08/2021	04/06/2021	
Issue Proof of Concept data report to ADL/USG	[redacted]	03/29/2021	04/06/2021	
Complete and Issue Tech Transfer Protocol for assay (Final)	[redacted]	11/24/2020	04/07/2021	(b) (4) [redacted]
Submission of tech transfer protocol for WT assay to DMF	[redacted]	12/1/2020	04/07/2021	(b) (4) [redacted]
Execute Tech Transfer Protocol	[redacted]	04/11/2021	06/09/2021	
Draft tech transfer report for WT virus	[redacted]	04/07/2021	06/09/2021	
Complete & Issue Final Tech Transfer Report	[redacted]	05/14/2021	06/24/2021	(b) (4) [redacted]
Final tech transfer report for WT virus submission to DMF	[redacted]	05/14/2021	06/24/2021	(b) (4) [redacted]

F.2. Supply Chain Resiliency Plan: The contractor shall develop and submit within 30 calendar days of contract award, a comprehensive Supply Chain Resiliency Program that provides identification and reporting of critical components associated with the secure supply of. cells, virus, and assay positive and negative controls. The USG will supply reagents associated with technology transfer but the organization is expected to subsequently produce and procure their own critical reagents.

a) A critical component is defined as any material that is essential to the assay t or the testing services associated with this contract. Included in the definition are cell banks and virus seed stocks NOT included in the definition are facility and capital equipment.

A clear example of a critical component is one where a sole supplier is utilized.

The contractor shall identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award.

a) Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.
b) The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries.

The contractor shall articulate in the plan, the methodology for inventory control, , scheduling processes and ordering mechanisms, as part of those agreed deliveries.

a) lead times shall be understood and communicated to the Contracting Officer or the Contracting Officer's Representative as necessary.
b) Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items should include the following information:

a) Critical Material
b) Vendor
c) Supplier, Manufacturing / Distribution Location
d) Supplier Lead Time
e) Shelf Life
f) Transportation / Shipping restrictions

The CO and COR reserve the right to request un-redacted copies of technical documents, during the period of performance, for distribution within the Government. Documents shall be provided within ten (10) days after CO issues the request. The Contractor may arrange for additional time if deemed necessary, and agreed to by the CO.

F.3. Product Development Source Material and Manufacturing Reports and Projections: The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States.
F.4. Contractor Locations: The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.

Contractor will submit Work Locations Report:

- Within 5 business days of contract award
- Within 30 business days after a substantive location or capabilities change
- Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO

F.5. Access and General Protection/Security Policy and Procedures: This standard language text is applicable to ALL employees working on critical information related to Operation Warp Speed (OWS), and to those with an area of performance within a Government controlled installation, facility or area. Employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The performer also shall provide all information required for background checks necessary to access critical information related to OWS, and to meet Government installation access requirements to be accomplished by installation Director of Emergency Services or Security Office. The workforce must comply with all personnel identity verification requirements as directed by the Government and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the security status of OWS change the Government may require changes in performer security matters or processes. In addition to the industry standards for employment background checks, The Contractor must be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States Government.

F.6. Operational Security (OPSEC): The performer shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90)-calendar-days of project award to be reviewed and approved by the responsible Government OPSEC officer. This plan will be submitted to the COR for coordination of approvals. This SOP/Plan will include identifying the critical information related to this contract, why it needs to be protected, where it is

located, who is responsible for it, and how to protect it.

F.7. Security Plan: The contractor shall develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan shall establish security practices and procedures that demonstrate how the contractor will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing, and shall be delivered to the Government within 30 calendar days of award. The contractor shall also ensure all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, comply with all Government security requirements and prime contractor security plans.

a) The Government will review in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within (10) calendar days after receipt of the comments.
b) The Security Plan shall include a timeline for compliance of all the required security measures outlined by the Government.
c) Upon completion of initiating all security measures, the Contractor shall supply to the Contracting Officer a letter certifying compliance to the elements outlined in the Final Security Plan.

At a minimum, the Final Security Plan shall address the following items:

Security Requirements:

1. Facility Security Plan Description: As part of the partner facility's overall security program, the contractor shall submit a written security plan with their proposal to the Government for review and approval by Government security subject matter experts. The performance of work under the contract will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:	
Security Administration	organization chart and responsibilities written security risk assessment for site threat levels with identification matrix (High, Medium, or Low) enhanced security procedures during elevated threats liaison procedures with law enforcement annual employee security education and training program
Personnel Security	policies and procedures candidate recruitment process background investigations process employment suitability policy employee access determination rules of behavior/ conduct termination procedures non-disclosure agreements
Physical Security Policies and Procedures	internal/external access control protective services identification/badging

	employee and visitor access controls parking areas and access control perimeter fencing/barriers product shipping, receiving and transport security procedures facility security lighting restricted areas signage intrusion detection systems alarm monitoring/response closed circuit television product storage security other control measures as identified
Information Security	identification and marking of sensitive information access control storage of information document control procedures retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	intrusion detection and prevention systems threat identification employee training (initial and annual) encryption systems identification of sensitive information/media password policy (max days 90) lock screen time out policy (minimum time 20 minutes) removable media policy laptop policy removal of IT assets for domestic/foreign travel access control and determination VPN procedures WiFi and Bluetooth disabled when not in use system document control system backup system disaster recovery incident response system audit procedures property accountability
2. Site Security Master Plan Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.	
3. Site Threat / Vulnerability / Risk Assessment Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.	
4. Physical Security Description:	
Closed Circuit Television (CCTV) Monitoring	a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored.

	CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. Video recordings must be maintained for a minimum of 30 days. CCTV surveillance system must be on emergency power backup. CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. Video recordings must be maintained for a minimum of 30 days. CCTV surveillance system must be on emergency power backup.
Facility Lighting	Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. Lighting must have emergency power backup. Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	Must have CCTV coverage and an electronic access control system. Must have procedures in place to control access and movement of drivers picking up or delivering shipments. Must identify drivers picking up Government products by government issued photo identification.
Access Control	Must have an electronic intrusion detection system with centralized monitoring. Responses to alarms must be immediate and documented in writing. Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.). The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of 12 months. Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company. Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. Should have written procedures to prevent employee piggybacking access to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. Must have a written manual key accountability and inventory process. Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Identification	Should issue company photo identification to all employees. Photo identification should be displayed above the waist anytime the employee is on company property. Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.
Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.

Protective Security Forces	Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces Operations	Must have in-service training program. Must have Use of Force Continuum. Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer). Must have Standing Post Orders. Must wear distinct uniform identifying them as securityofficers.
5. Security Operations Description:	
Information Sharing	Establish formal liaison with law enforcement. Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented. Implement procedures for receiving and disseminating threat information.
Training	Conduct new employee security awareness training. Conduct and maintain records of annual security awareness training.
Security Management	Designate a knowledgeable security professional to manage the security of the facility. Ensure subcontractor compliance with all Government security requirements.
6. Personnel Security Description:	
Records Checks	Verification of social security number, date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, sex offender registry, credit check based upon position within the company; motor vehicle records check as appropriate; and local/national criminal history search.
Hiring and Retention Standards	Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures. Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.
7. Information Security Description:	
Physical Document Control	Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings. Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents must be destroyed using approved destruction measures (i.e., shredders/approved third party vendors / pulverizing / incinerating).
8. Information Technology & Cybersecurity Description:	
Identity Management	Physical devices and systems within the organization are inventoried and accounted for annually. Organizational cybersecurity policy is established andcommunicated. Asset vulnerabilities are identified and documented.

	Cyber threat intelligence is received from information sharing forums and sources. Threats, vulnerabilities, likelihoods, and impacts are used to determine risk. Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes. Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals' security and privacy risks and other organizational risks)
Access Control	Limit information system access to authorized users. Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. Limit physical access to information systems, equipment, and server rooms with electronic access controls. Limit access to/ verify access to use of external information systems.
Training	Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months. Ensure the actions of individual information system users can be uniquely traced to those users. Update malicious code mechanisms when new releases are available. Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.
Configuration Management	Establish and enforce security configuration settings. Implement sub networks for publically accessible system components that are physically or logically separated from internal networks.
Contingency Planning	a) Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.
Incident Response	Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually.
Media and Information Protection	Protect information system media, both paper and digital. Limit access to information on information systems media to authorized users. Sanitize and destroy media no longer in use. Control the use of removable media through technology or policy.
Physical and Environmental Protection	Limit access to information systems, equipment, and the respective operating environments to authorized individuals. Intrusion detection and prevention system employed on IT networks. Protect the physical and support infrastructure for all information systems. Protect information systems against environmental hazards. Escort visitors and monitor visitor activity.
Network Protection	Employ intrusion prevention and detection technology with immediate analysis capabilities.

9. Transportation Security Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	Drivers must be vetted in accordance with Government Personnel Security Requirements. Drivers must be trained on specific security and emergency procedures. Drivers must be equipped with backup communications. Driver identity must be 100 percent confirmed before the pick-up of any Government product. Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency. Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.
Transport Routes	Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.
Product Security	Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed. Tamper resistant seals must be verified as "secure" after the product is placed in the transport vehicle. Government products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented. Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.

10. Security Reporting Requirements Description: The partner facility shall notify the Government Security Team within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.

11. Security Audits Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and subcontractor.

(End of Summary of Changes)