

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE S	PAGE OF PAGES 1 5
2. AMENDMENT/MODIFICATION NO. 0001	3. EFFECTIVE DATE 13-May-2015	4. REQUISITION/PURCHASE REQ. NO.		5. PROJECT NO.(If applicable)
6. ISSUED BY W6QK ACC-APG NATICK 1564 FREEDMAN DRIVE FORT DETRICK MD 21702	CODE W911QY	7. ADMINISTERED BY (If other than item 6) See Item 6		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		X	9A. AMENDMENT OF SOLICITATION NO. W911QY-15-R-0018	
		X	9B. DATED (SEE ITEM 11) 16-Apr-2015	
			10A. MOD. OF CONTRACT/ORDER NO.	
			10B. DATED (SEE ITEM 13)	
CODE	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input checked="" type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input checked="" type="checkbox"/> is not extended. Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning <u>1</u> copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.				
12. ACCOUNTING AND APPROPRIATION DATA (If required)				
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.				
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).				
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:				
D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input type="checkbox"/> is required to sign this document and return _____ copies to the issuing office.				
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Respond to Offeror's questions.				
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)		
		TEL:	EMAIL:	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA		16C. DATE SIGNED
_____ (Signature of person authorized to sign)		BY _____ (Signature of Contracting Officer)		13-May-2015

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

Solicitation W911QY-15-R-0018 Request for Proposal (RFP) and Product Demonstration Model (PDM) Questions and Responses

a. Request for Proposals (RFPs) Questions and Responses

1. Question: Page 29, Section L 52.216-19 ORDER LIMITATIONS. (OCT 1995), the order limitation is mentioned as any order for combination of items not in excess of \$7,000,000. Does it mean the total cost for the contract will not exceed \$7,000,000?

Response: No. It does not mean the total cost for the contract will not exceed \$7,000,000.

2. Question: Would the Government consider the potential cost savings for LFIs without Hook effect, e.g., false negative results in the presence of high concentrations of an antigen?

Response: No. There is not a requirement to address the Hook effect and therefore it is not being evaluated under this solicitation.

3. Question: Are Offerors required to have an active security facility clearance to bid on solicitation?

Response: No. Offeror's must demonstrate that Offeror has ability to obtain. Reference Facility Security Requirements in Section L under Technical requirements and DD254.

b. Product Demonstration Model (PDM) Questions and Responses

1. Question: Are more housings available for participant internal PDM testing?

Response: Yes. Although the CRP feels that the amount of housings (620) provided would have been sufficient, an additional 200 housing will be provided to better align with each participants internal testing procedures. This has been revised in solicitation in Section L, Section L, Attachment 2: Product Demonstration Model Plan - 3.0 TECHNICAL REQUIREMENTS - 3.1 GOVERNMENT FURNISHED MATERIAL (GFM) - Table 1.

2. Question: Participants received one antibody per target. Are we supposed to use it for both capture and detector for each target?

Response: Yes. The antibody received is to be used for both the capture and detector for each target. Refer to Section L, Attachment 2: Product Demonstration Model Plan - 3.0 TECHNICAL REQUIREMENTS - 3.1 GOVERNMENT FURNISHED MATERIAL (GFM) - Table 1.

3. Question: What are the concentrations of both Antibodies?

Response: Antibody 1 has a concentration of 2.0 mg/ml and Antibody 2 has a concentration of 4.8 mg/ml. This has been revised in solicitation Section L, Attachment 2: Product Demonstration Model Plan - 3.0 TECHNICAL REQUIREMENTS - 3.1 GOVERNMENT FURNISHED MATERIAL (GFM) - Table 1.

4. Question: Polyclonal antibody (1 mg for each antigen) is provided for PDM. Is this amount enough to make the required number of strips?

Response: Yes. However, a reassessment of antibody requirements was conducted to better align with a multitude of participants testing processes and thus an additional 2 mg of antibody for each antigen will be provided (Total 3.0 mg for each antigen). This has been revised in solicitation Section L, Attachment 2: Product Demonstration Model Plan - 3.0 TECHNICAL REQUIREMENTS - 3.1 GOVERNMENT FURNISHED MATERIAL (GFM) - Table 1.

5. Question: It is mentioned that antibodies are not affinity purified. Does it mean antigen affinity purification? Or the antibodies are not purified by Protein A or Protein G purification?

Response: These antibodies did not go through any purification processes.

6. Question: Has the polyclonal antibody to each antigen shown required sensitivity of detection with the antigen supplied in previous government testing using reference LFI strips?

Response: Yes. The Government has shown required sensitivity of detection with the polyclonal antibody. Sensitivity requirements are described in Section L PDM Plan and Section M evaluation criteria.

7. Question: Has the polyclonal antibody to each antigen shown required specificity of detection with the cross reactant panel of substances in previous government testing using reference LFI strips?

Response: Yes. The Government has shown required specificity of detection with the polyclonal antibody. Specificity requirements are described in Section L PDM Plan and Section M evaluation criteria.

8. Question: Can any other alternate combination of antibodies be used in the PDM phase?

Response: No. The PDM requires the use of CRP provided materials which have been aligned equally amongst all participants.

9. Question: Section L, Attachment 2: Product Demonstration Model Plan 3.1 GOVERNMENT FURNISHED MATERIAL (GFM), Table 1 states that we will receive a panel of 28 cross reactants. Is this correct?

Response: No. There are 27 cross reactants in the panel as shipped. This has been revised in solicitation Section L, Attachment 2: Product Demonstration Model Plan - 3.0 TECHNICAL REQUIREMENTS - 3.1 GOVERNMENT FURNISHED MATERIAL (GFM) - Table 1 and Section 4.3 Specificity.

10. Question: Section L, Attachment 4 –LFI Strip Drawing are difficult to read. Is there a better copy?

Response: Yes. An enhanced copy is now provided as a separate link on the solicitation main page at <http://www3.natick.army.mil/W911QY-15-R-0018.aspx>

11. Question: Item #13 on PDM box 3 of 3 was not readable. What is it?

Response: Item #13 on PDM box 3 of 3 is Escherichia coli (per Packing List).

12. Question: For purposes of coding the test strips is it acceptable to use white adhesive backed paper label stock imprinted with Code Description?

Response: Yes. Labeling specifications for individual PDMs are laid out in Section L, Attachment 8 – PDM Labeling and Packaging Instructions

13. Question: If an Offeror does not have a CAMAG scanner, can it use any other alternative testing methods to prepare this PDM?

Response: Yes. It is up to the Offeror to determine how to best align their internal PDM testing with the PDM Plan. The Government has chosen to utilize a CAMAG TLC-3 scanner to test PDM signal intensity as stated in the PDM Plan. All PDMs will be tested with this capability.

14. Question: How much material of Scanner Reference Standard will be provided to the performers?

Response: A single reference standard strip that has several test line intensities that can be used to normalize each participant's scanner values to the CAMAGTM TLC-3 scanner values will be provided.

15. Question: Regarding the reference standard strip provided, listed are the test line intensities as: 38.1/ "35.7"/ 266.4/ 461.3/ 651.5/ 805.0. Could the Government clarify if 35.7 is a typo?

Response: No. The bottom two intensities are reference standard strip intensities near the threshold level.

16. Question: Is it permissible to use a composite conjugate pad (2 layers) provided its length and width meet specifications for this PDM?

Response: Yes. The Government has no specific layer of quantities requirement within a single conjugate pad as long as it meets the physical specifications laid out in Section L, Attachment 4 LFI Strip Drawing.

17. Question: There was no information about the inactivation of any of the items. Will this be provided?

Response: Yes. Inactivated documentation (Death and Inactivated Certificates) will be provided.

18. Question: The buffer composition and any additives are required before we use the antibodies to build the LFI. Will these be provided?

Response: Yes. Listed in Section L, Attachment 2: Product Demonstration Model Plan 3.2 PDM TEST PLAN, Sample buffer is sterile Phosphate Buffered Saline + 0.1% Triton X-100 and 0.4% Kathon (pH = 7.4)

19. Question: Section L Attachment 5, shows the dilutions. Are these the dilutions that will be used for testing?

Response: Yes.

20. Question: Participants received Ricin A chain without a death certificate. Should participants assume that it is an active toxin (not toxoid), which will need to be tested in BL2?

Response: No. It is an inactivated toxin.

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO BIDDERS

The following have been modified:

Attachment 2: Product Demonstration Model Plan

3.1 GOVERNMENT FURNISHED MATERIAL (GFM)

Eligible Respondents will be provided GFM specified in **Table 1**.

Table 1: Government Furnished Material

Item	Description
Antigens (Ag)	<ul style="list-style-type: none"> Antigen 1 – 1.0 ml (4.19e8 cfu/ml) Antigen 2 – 1.0 ml (3.09e10 cfu/ml)
Specificity panel	<ul style="list-style-type: none"> Panel of 27 relevant environmental and biological entities
Antibody set for Antigen 1* (Ab are not affinity purified)	<ul style="list-style-type: none"> Polyclonal Antibody 1 – 3.0 mg (2.0 mg/ml)
Antibody set for Antigen 2* (Ab are not affinity purified)	<ul style="list-style-type: none"> Polyclonal Antibody 2 - 3.0 mg (4.8 mg/ml)
Carrier (top and bottom)	<ul style="list-style-type: none"> 820 tops 820 bottoms
Specifications and Procedures	<ul style="list-style-type: none"> LFI physical specifications (drawing) PDM assembly instructions Packaging and shipping procedures
Scanner Reference Standard**	<ul style="list-style-type: none"> Scanner units (intensity) ladder

*Labeling or conjugating of antibodies is the responsibility of the Respondent

**Reference standard will have several test line intensities that can be used to normalize Respondents scanner to the CAMAG™ TLC-3 scanner values.

4.3 SPECIFICITY

Specificity will be assessed against a panel of **twenty-seven (27)** relevant environmental (vehicular, battlefield, non-biological contaminants) and biological entities (near neighbor organisms, suspicious powders, biological contaminants) at concentrations appropriate for CRP requirements. PDMs for both Antigens will be chosen at random and tested against each panel member. Any replicate that develops a signal intensity equivalent to or greater than 30 CAMAG™ TLC-3 scanner units in the test window will render the PDM cross reactive for that environmental/biological entity.

(End of Summary of Changes)