

## DEPARTMENT OF VETERANS AFFAIRS

### Justification and Approval (J&A) For Other Than Full and Open Competition (>\$150K)

Acquisition Plan Action ID: VA263-17-AP-1438

1. **Contracting Activity:** Department of Veterans Affairs, NCO 23, Fargo VA HCS.
2. **Nature and/or Description of the Action Being Processed:** The VA is contemplating a sole source IDIQ contract for Vitek reagent cards. The IDIQ will be a firm fixed priced contract with total potential value of \$1,130,560.00 the annual orders are estimated to be approximately \$226,112.07. The contract will allow facilities to issue orders for reagents as needed.

***FAR13.5 Simplified Procedures for Certain Commercial Items:** This procurement is in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.*

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** VISN 23 has a requirement for Vitek identification and susceptibility cards to perform clinical testing for each of the clinical laboratories located at the following VA facilities:
  - Black Hills Health Care System, Hot Springs, SD
  - Black Hills Health Care System, Fort Meade, SD
  - Central Iowa Health Care System, Des Moines, IA
  - VA Medical Center, Iowa City, IA
  - VA Medical Center, Minneapolis, MN
  - Nebraska-Western Iowa Health Care System, Omaha, NE
  - VA Medical Center, St. Cloud, MN
  - Royal C. Johnson VA Medical Center, Sioux Falls, SD
  - VA Medical Center, Fargo, ND.

This testing is performed on the Vitek Compact and Vitek MS instrumentation. Test cards are proprietary to the equipment. The award date requested is May 1, 2017 with annual option years. The contract scheduled to end on April 30, 2022. Delivery dates will vary by sites and will be on demand. See attached Proposed Price-Cost-Delivery Schedule.

4. **Statutory Authority Permitting Other than Full and Open Competition:**
  - (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
  - ( ) (2) Unusual and Compelling Urgency per FAR 6.302-2;
  - ( ) (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
  - ( ) (4) International Agreement per FAR 6.302-4
  - ( ) (5) Authorized or Required by Statute FAR 6.302-5;
  - ( ) (6) National Security per FAR 6.302-6;
  - ( ) (7) Public Interest per FAR 6.302-7;

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** On May 14, 2012 VISN 23 and NCO 23 solicited using full and open competition for a commercial solution to standardize the testing cards across VISN 23. VA263-12-D-0211 was competitively awarded to Fisher Scientific to provide Vitek Identification and Susceptibility Test Cards. Due to the highly specialized nature of equipment, there are only two FDA approved vendors capable of supplying analyzers – Biomerieux and Becton Dickinson. Each vendors AST and ID susceptibility cards are proprietary to their own analyzers. They cannot be used interchangeably. Identification (ID) and Anti-microbial Susceptibility Testing (AST) are key steps to provide information necessary for targeted clinical responses and better patient-care outcomes. ID cards are used to safely test and identify a wide range of clinically relevant organisms and AST cards are used to identify the best treatment option. These cards are FDA approved and proprietary only for these specific analyzers. No other cards are approved for the analyzer.

Since these analyzers have been standardized across VISN 23 as the only method of performing these tests, using anything other than Biomerieux ID and AST cards would be against FDA, Joint Commission, College of American Pathologists, CLIA, and other regulatory agency regulations and would result in loss of licensure. Vitek ID and AST testing cards were previously available through Biomerieux or two distributors: Cardinal Health and Fisher. On April 7, 2016, VISN 23 was notified that Biomerieux would no longer honor orders through either Fisher or Cardinal after the expiration of our current contract on April 30, 2016 (see attached letter). Accordingly, Biomerieux is the only firm capable of providing the supplies and services described in Section III above without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition and unacceptable delays in fulfilling its requirements.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Biomerieux is the only firm capable of providing the supplies and services since no other cards/supplies will work in the VISN 23 Pathology and Laboratory equipment.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** VISN 23 will use past pricing data available to further ensure a price to be fair and reasonable. For example: most recent option year (4) pricing for this product from VA263-12-D-0211 was \$199,905.00. A sample comparison of the pricing from that contract with the proposed pricing for this new contract shows an actual decrease in items surveyed. Therefore, it is belief that these efforts sufficiently allow the prices offered to be fair and reasonable and in the best interests of the Government.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was not conducted –only Biomerieux products will work in these VISN 23-owned analyzers. In addition, NCO 23 contacted Biomerieux and they confirmed that they do not have any distributors and that they are the **only** vendor that supplies these items.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Five (5) VISN 23 facilities currently own a Biomerieux Vitek MS and four (4) own a Vitek Compact for microbial identification (ID) and antibiotic susceptibility testing (AST). All Vitek MS analyzers are less than 3 years old. Replacement cost of a Vitek MS is \$215,000 each. The replacement cost for a Vitek Compact is \$56,000 each. If new equipment is to be pursued, as opposed to the proposed sole source, the minimum additional total replacement costs of new equipment would be approximately \$1.3M; \$2.4M after you include the cost of the reagents.

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Biomerieux, 100 Rodolphe St, Durham, NC 27712.

**11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:**

Competition is the default acquisition strategy for NCO 23. When the existing analyzers reach their end of life, a competitive procurement will be conducted, ideally to include all consumables.

**12. Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

JILL M JOHNSON  
531094

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0.9.2342.19200300.100.1.1=jill.johnson2@va.  
gov, cn=JILL M JOHNSON 531094  
Date: 2017.02.24 14:18:10 -06'00'

2/24/2017

Jill Johnson  
Health System Specialist  
Facility

Date

**13. Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.**

- a. **Contracting Officer or Designee's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

DARRYL W  
MOON 324732

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Date: 2017.02.24 14:24:10 -06'00'

27 FEB 2017

Darryl W. Moon  
Contracting Officer  
NCO 23, Fargo VA HCS

Date

- b. **Director of Contracting:** I certify the justification meets requirements for other than full and open competition.

Daryl A. Berg  
429170

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cn=Daryl A. Berg 429170  
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03/01/20107

Daryl A. Berg  
NCO 23 Director of Contracting

Date

- c. **VHA SAO HCA Review and Approval:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

Linda S.  
Greaves 404790

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3/13/2017

Linda S. Greaves  
SAO Central Head of Contracting Activity (HCA)

Date

Attached:

~~Proposed Price-Cost-Delivery Schedule~~  
~~Sole Source Justification from BioMerieux~~

OFOC SOP Revision 05

Original Date: 03/22/11

Revision 05 Date: 05/02/2016