

## DEPARTMENT OF VETERANS AFFAIRS

### Justification and Approval (J&A) For Other Than Full and Open Competition (>SAT)

Acquisition Plan Action ID: VA252-18-AP-5561

1. **Contracting Activity:** Department of Veterans Affairs, Veterans Integrated Service Network (VISN) 12, Great Lakes Acquisition Center (GLAC) on behalf of the Edward Hines Jr. VA Hospital and multiple facilities within VISN 12 for multiple purchase requests.

2. **Nature and/or Description of the Action Being Processed:**

**FAR13.5 Simplified Procedures for Certain Commercial Items:** This is a sole source justification to establish a new firm fixed-price indefinite delivery indefinite quantity (IDIQ) contract with Biomerieux, Inc. for automated Blood Culture testing on a cost per test basis.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** VISN 12 Pathology & Lab Medicine Service (PLMS) requires a Federal Drug Administration (FDA) approved automated platform for blood culture testing on a cost per test basis. This includes the implementation of instruments and equipment, reagents, service and maintenance, and ancillary supplies. Blood culture testing allows for the identification and diagnosis and treatment of microbes in blood samples. VISN 12 locations currently have implemented the Biomerieux system within all lab facilities and conducts blood culture testing on a daily basis. Testing volumes vary but an estimated testing volume annually across the VISN is approximately 53000 bottles, including pediatric bottles. The period of performance will be three one-year ordering periods to start 9 May 2018 through 8 May 2021, for the remaining period of performance as was originally awarded in the base and four, one-year options periods with the FSS competitive requirement awarded 9 May 2016. The approximate value per year is \$187,968.45. The approximate value for the three-year ordering period is \$563,905.35.

4. **Statutory Authority Permitting Other than Full and Open Competition:**

**FAR13.5 Simplified Procedures for Certain Commercial Items:** The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2)-only one source.

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** In all VISN 12 PLMS locations, the Biomerieux blood culture system was implemented after award to the contractor on 9 May 2016. The contractor implemented instruments across the VISN and the VISN underwent validations and development of standard operating procedures (SOP) as is required for College of American Pathologist (CAP) and Clinical Laboratory Improvement Amendments (CLIA) established by the Centers for Medicare & Medicaid (CMS). In order to prevent disruption of lab testing within VISN 12 on a this specialized testing system the incumbent must continue to provide Blood Culture equipment and supplies. Additionally, the requirement was competed and awarded two years ago and re-competing the requirement would result in significant duplication of costs and resources to

the Government whereby it is not anticipated the VA would achieve a benefit whether by price paid or superior system offering.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** This requirement was solicited amongst NAC FSS schedule holders in this category in 2016 and the proposed contractor was selected as the successful contractor based on criteria set forth in the solicitation. For the purposes of this requirement, recompeting the action has not been sought as it is not anticipated that recompeting the action would provide an overall benefit to the VA with consideration of the resources required to reprocur and implement a new platform.
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The contractor will continue to offer pricing in accordance with pricing that was established on the NAC FSS contract. Price analysis was conducted by the NAC and determined to be fair and reasonable.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** In accordance with Vets First Contracting Program, 38 U.S.C. 8127 & 8128 Implementation Policy and Procedures, a search was conducted on the Vendor Information Pages (VIP) using NAICS 334516 yielded multiple contractors. A search of NAICS and keyword blood yielded three results. A search of NAICS and keyword blood culture yielded three contractors. Upon review of the contractors none were found to offer an automated blood culture testing system on a cost per test basis. A search on Dynamic Small Business Search (DSBS) yielded multiple results under the applicable NAICS, however no small business entities have been identified with an automated blood culture testing system on a cost per test basis. A known NAC FSS contractor was identified, however, this contractor was involved when the requirement was competed in 2016 and did not meet the technical specifications required by the service line. Another open market contractor has a blood culture system, however, it could not be determined if the contractor offers a system on a cost per test basis. Due to the requirement to continue Automated Blood Culture testing and a system implemented within the labs is already established, functioning, and implemented across VISN 12 labs, a sole source justification will be generated for continued use of the Biomerieux system.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The original action was competed and established in accordance with the NAC FSS as the base agreement for the established agreement between VISN 12 and Biomerieux, providing additional protections to the Government. This action is a continuation of the originally established agreement and services will continue as was originally agreed upon which decreases risk to Government. In the event a new open market requirement had to be pursued it would be incumbent on the Contracting Officer to ensure all considerations built into the NAC FSS schedule 66III contracts are included in the solicitation and evaluation which would be time consuming with little to no benefit to the Government for duplication of effort. A significant consideration in continuing the agreement with the incumbent contractor is the implementation time for VISN 12 laboratory locations to include validations and the development of SOPs based on the equipment that is placed within the labs in accordance with CAP and CLIA requirements.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Not applicable.
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:** For

subsequent requirements for Blood Culture competition will be pursued where applicable as was accomplished for selection of the incumbent contractor.

- 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.

\_\_\_\_\_  
Donna Wray  
Business Manager  
VISN 12 PLMS

\_\_\_\_\_  
Date

**13. Approvals in accordance with the [VHAPM Part 806.3 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.

\_\_\_\_\_  
Jessica Rasmussen  
Title  
Facility

\_\_\_\_\_  
Date

- b. **One Level Above the Contracting Officer (Required over SAT but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

\_\_\_\_\_  
David Picchi  
Supply Team Branch Chief  
NCO 12

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Date