

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)
For
Other Than Full and Open Competition (>= AT)

Acquisition Plan Action ID: 36C25618-AP-0128

1. **Contracting Activity:**

Department of Veterans Affairs
South Central VA Health Care Network (SCVAHCN)
Central Arkansas Veterans Healthcare System
Contracting Office (90C)
North Little Rock, AR
Network Contracting Activity: 16

2. **Nature and/or Description of the Action Being Processed:** The proposed action by SCVAHCN is for a follow-on, sole-source, short-term Blanket Purchase Agreement (BPA) award to BioMerieux, Inc. The award will be a VISN-wide Cost Per Test (CPT) BPA for the period of October 1, 2018 through September 30, 2019. BioMerieux currently meets and satisfies the needs of VISN 16 facilities and fulfills recurring requirements. A firm fixed price CPT BPA for instrumentation, repair, reagents and consumables for automated microbiological identification and susceptibility (ID & Suscept) analysis instrumentation and testing will be established. The basis for the sole source award is Federal Acquisition Regulation (FAR) FAR 6.302-1, only one responsible source and no other supplies or services will satisfy agency requirements. The award of a short-term BPA to BioMerieux for VISN 16 will continue to secure price reductions and volume discounts for Medical Centers for automated microbiological identification and susceptibility instrumentation and testing until such time as a new competitive long-term BPA using FAR 8 procedures is solicited and awarded. A group of laboratory subject matter experts has been convened and is currently developing the technical requirements package for a competitive VISN-wide standardized CPT BPA. The award of a short-term BPA will provide the continuity of contract coverage needed to ensure critical patient care testing needs are not interrupted. The award will also allow sufficient time for the procurement process, as well as the sufficient lead time for a new contractor (if applicable) to meet security and connectivity requirements. The award of a short-term BPA to BioMerieux for VISN 16 will allow labs to continue to perform critical patient care testing while continuing to secure price reductions and volume discounts for Medical Center laboratories.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** BioMerieux will continue to provide highly specialized instrumentation, equipment repair, reagents and consumables to each participating Medical Center laboratories. Award of a new short term BPA will ensure the vendor continues to provide instrumentation and testing reagents and supplies under a CPT agreement. It will also ensure the vendor continues to meet all licensing and accreditation requirements, permits, certifications required by the FDA and the Government. All provisions within the original BPA and Statement of Work will be incorporated into the new short term BPA, including use of specialized equipment (testing instrumentation, automation/robotics, UPSs, water purification systems),

preventative maintenance, emergency repair, training, technical expertise, reagents, controls, calibration materials, replacement parts, etc. The period of performance will be October 1, 2018 through September 30, 2019 with an estimate of \$251,270.50.

4. **Statutory Authority Permitting Other than Full and Open Competition:** BioMerieux will continue to provide instrumentation, repair, reagents and consumables to each V16 participating Medical Center laboratory. Award of a new short term BPA will ensure the vendor continues to provide instrumentation and testing as defined for CPT in the Federal Supply Schedule FSC Group 66 III Cost Per Test Program. It will also ensure the vendor continues to meet all licensing and accreditation requirements, permits, certifications required by the FDA and the Government. All provisions within the original BPA and Statement of Work will be incorporated into the short-term BPA, including use of equipment (testing instrumentation, automation, data management systems, interfacing of test results, (as applicable), UPSs, water purification systems, etc.), training, preventative maintenance, emergency repair, adapters, replacement parts, etc.

(b) **ESTIMATED DOLLAR VALUE:** \$ 251,270.50 (one year)

(c) **REQUIRED DELIVERY DATE:** October 1, 2018 through September 30, 2019

- (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):** BioMerieux has successfully provided Automated Microbiological Identification and Susceptibility analysis instrumentation, training, repair, reagents and consumables to all VISN 16 medical center laboratories. Instrumentation in use has already been extensively validated by the laboratory in accordance with accreditation requirements. Testing instrumentation is interfaced at several of the labs to the Vista laboratory package eliminating the need to manually input patient test results. Without the provision of equipment and supplies for microbiological identification and susceptibility analysis, labs would be unable to perform critical patient testing. Instrumentation also includes the provision of a data management system which pulls anit-biograms and individualized reports specific to Methicillin Resistant Staphylococcus Aureus (MRSA), Vancomycin Resistant Enterococcus (VRE), and Carbapenem Resistant Enterobacteriaceae (CRE) and other Multi Drug Resistant Organisms (MDRO) for regular reporting as required by VHA, the College of American Pathologists and Joint Commission. Equipment is validated and already in place, procedures are written, staff is trained, competencies are accessed, test files are built in Vista and discounted pricing is established, awarding of a short term BPA will prevent an interruption in the provision of patient care testing without unnecessary time and expense to the government.

BioMerieux identification and susceptibility instrumentation is already in use at each participating VISN 16 Medical Center. Biomerieux will continue to provide usage of equipment, training, service

and repair, reagents and consumables at current BPA CPT pricing. Cost avoidance for FY17 was over \$600,000 when compared to FSS pricing.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A competitive procurement will occur utilizing FAR 8 during this short-term agreement.
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** BioMerieux will continue to honor terms and conditions of the previous BPA to include use of equipment, service, repair, training, technical expertise and consumables. Current BPA is further discounted from previous FSS pricing, which has already been determined by the NAC 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:** Market Research was conducted for the new long-term BPA and revealed there is adequate competition among FSS contract holders. However, for this requirement, extensive market research was determined not feasible as a sole source BPA is being requested with the incumbent to use existing contractor-owned specialized instrumentation currently on-site at Medical Centers. The award of this bridge BPA to existing Contractor will prevent a disruption in the provision of laboratory testing need for patient care.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** A previously awarded VISN wide competitive BPA for Chemistry/Immunochemistry was protested which has impacted all VISN wide standardized laboratory contracting actions. The protest has delayed the completion of posting and evaluation of automated hematology instrumentation. Other VISN wide laboratory procurements are ahead of this requirement in the queue. A new Chemistry/Immunochemistry BPA has now been successfully awarded and VISN 16 is working down the backlog of VISN standardized RFQs, resulting from the protest.

Access to timely, accurate testing results is critical to the mission of the laboratory. Approval of this sole source action is necessary to ensure that patient care is not interrupted.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None
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:** As stated above, competition is planned among FSS contract holders for the new long-term BPA. This short-term BPA will allow for no lapse in service so that patient care will not be negatively affected.
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.

Kaleem M

Sayyed 432377

Digitally signed by Kaleem
M Sayyed 432377
Date: 2018.08.30 08:32:19
-05'00'

Kaleem Sayyed, MD, MPH
V16 CSPO Program Manager

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.

**Sheila D
Reed 383041**

Digitally signed by Sheila
D Reed 383041
Date: 2018.08.30 08:37:58
-05'00'

Sheila D. Reed
Contracting Officer
NCO 16

- 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.

CLAY K JONES 685130

Digitally signed by CLAY K JONES
685130
Date: 2018.09.01 09:04:29 -05'00'

Clay K. Jones
Chief Supply Team
NCO 16