

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. Contracting Activity:

U.S. Department of Veterans Affairs
Veteran's Health Administration
Network Contract Office (NCO) 15
3450 4th St Trafficway
Leavenworth KS 66048

Funding documents: 589-15-4-4731-0572, 589-15-4-5686-0384, 589-16-1-1614-0002
PSC code is J066 – MAINT/REPAIR/REBUILD OF EQUIPMENT- INSTRUMENTS AND LABORATORY EQUIPMENT. The NAICS code for this procurement is 811219 - OTHER ELECTRONIC AND PRECISION EQUIPMENT REPAIR AND MAINTENANCE, which presently has a size standard of \$20.5 million

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

- a. This acquisition is for the establishment of a sole source, firm-fixed-price modification to contract VA255-15-C-0005 for furnishing OEM full service maintenance and repair of recently installed bioMerieux brand VITEK MS automated mass spectrometry microbial identification systems and ancillary equipment on-site at the Marion IL, Columbia MO, Wichita KS, Kansas City MO and Topeka KS VA Medical Centers. Proposed contractor:
 bioMerieux Inc.
 100 Rodolphe St.
 Durham NC 27712-9402
- b. It is the intent of the government to modify existing contract VA255-15-C-0005 with bioMerieux Inc. by adding five additional facility's systems to the contract that is presently providing identical services to the St Louis MO VA Medical Center. The existing contract is in its base year, commencing November 7, 2014 and will expire November 6, 2015 with four (4) one (1) year options periods. The contract was awarded in accordance with FAR 13.106 – 3(b) which limited competition to a single source. The original contract price was \$25,443.88 for the base year and \$135,085.12 for base plus four option years. The systems to be added to the contract will be prorated from the time of their warranty expiration to the base year expiration date. The modified contract will be a base year price of \$40,585.71 and a base plus four option years price of \$734,539.30.
- c. Because the new systems are similar or identical to the system presently on contract (all being bioMerieux VITEK MS or VITEK MS PLUS), will require the same services as those specified in the contract, and it has already been documented in the original contract award that these services are only available from a single source, it is in the best interest of the Government to add the maintenance of the new equipment to the existing contract.

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- d. FAR13.5 Test Program: This procurement is for commercial services in accordance with FAR 13.5 Test Program 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:** The services required are for the furnishing of full service maintenance and repair of installed bioMerieux brand VITEK MS automated mass spectrometry microbial identification systems and ancillary equipment on-site at the St. Louis MO, Marion IL, Columbia MO, Wichita KS, Topeka KS and Kansas City MO VA Medical Centers. Coverage will include all parts, installation, calibration, labor, and travel, tools, test equipment and other incidentals necessary to maintain or restore the listed equipment to operating specifications according to manufacturer's recommendations throughout the term of the contract.
4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 USC §253(c)(1), as implemented by FAR 6.302-1.
- (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;
- FAR13.5 Test Program:** The authority for applying the Commercial Test Program of FAR 13.5 is (Section 4202 of the Clinger-Cohen Act of 1996) and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).
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 is uniquely qualified to provide these services to VISN 15 VA Medical Centers based upon the following:
- a. A bioMerieux VITEK MS is a Matrix Assisted Laser Desorption Ionization - Time of Flight Mass Spectrometry analyzer that has the capability of interfacing with the bioMerieux VITEK 2 system and BACT ALERT system currently in use in VISN 15 laboratories for antimicrobial susceptibility testing. The VITEK MS identifies the organisms and communicates the results to the VITEK 2. Susceptibility is performed based on the identification provided by the VITEK MS. Results are sent back to the laboratory information system using a proprietary bioMerieux middleware known as MYLA and VLINK. This information is used for capture of reports on blood culture positivity rates, epidemiology statistics, audit trails, review of potential contaminated cultures, workflow monitoring and guidance, information consolidation and reporting. No other vendor's middleware is compatible with or can be used to provide communication between the analyzers.

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- b. bioMerieux claims that all bioMerieux Field Service Engineers are certified and qualified with extensive factory training and experience in working on the entire range of bioMerieux products including the VITEK® MS instruments. If any other party is providing service on the bioMerieux instruments, bioMerieux does not certify or guarantee any defects or workmanship under any warranty.
 - c. No other source was found that could: (1). Provide unlimited on-site service/corrective maintenance and repair; unlimited telephone technical support; and all required labor, travel and parts required for the system to perform in accordance with manufacturer recommendations and Joint Commission requirements. (2). Provide Original Equipment Manufacturer (OEM) factory trained and authorized /certified technicians to accomplish the required service. (3). Have access to and furnish new FDA approved Original Equipment Manufacturer (OEM) or OEM approved parts and supplies. (4). Have access to and furnish updates to the hardware, software upgrades and field change orders. (5). Provide response via telephone within two (2) hours and on-site within twenty-four (24) hours of notification. The contractor shall be capable of providing coverage 7:00 am to 7:00 pm CT, 7 days/week and all holidays.
6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:
- a. A Sources Sought notice VA255-15-N-0027 was published in on the FedBizOps WEB site from 10/9/2014>10/16/2014 asking for sources to provide the required maintenance as required by FAR Subpart 5.2.

The announcement stated in part:

The Department of Veterans Affairs, Network Contracting Office (NCO) 15, Leavenworth KS 66048 is currently conducting a market survey to identify possible sources capable of providing "Full Service Preventive Maintenance (PM) and Repair of a government owned bioMérieux brand spectrometer system" on-site at the VA Medical Center in St. Louis MO.

NAME/DESCRIPTION OF EQUIPMENT:

EQUIPMENT – Automated mass spectrometry microbial system

MANUFACTURER – bioMérieux S.A.

MODELS – VITEK® MS, with Myla™ Laboratory Software Interface

The prospective contractor will be responsible for:

- (1). Providing preventative maintenance and performance verification on the following schedule:
 - (a). Once per year for the MYLA Interface Software.
 - (b). Twice per year for the VITEK MS Automated mass spectrometry microbial system.

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- (2). The preventative maintenance shall consist of cleaning of equipment, reviewing operating system software diagnostics to ensure that system is operating to the manufacturer's specifications, calibrating and lubricating the equipment, performing remedial maintenance of non-emergent nature, test and replacing faulty and worn parts and/or parts which are likely to become faulty fail or become worn, adjusting and calibrating as necessary, inspecting electrical wiring and cables for wear and fraying, inspecting all mechanical components including bearing and tracks, interlocks, clutches, motors, mechanical integrity, safety, and performance and performing electrical safety inspections,
 - (3). Providing unlimited on-site service/corrective maintenance and repair; unlimited telephone technical support; and all required labor, travel and parts required for the system to perform in accordance with manufacturer recommendations and Joint Commission requirements.
 - (4). Providing Original Equipment Manufacturer (OEM) factory trained and authorized /certified technicians to accomplish the required service.
 - (5). Having access to and furnishing new FDA approved Original Equipment Manufacturer (OEM) or OEM approved parts and supplies.
 - (6). Having access to and furnishing updates to the hardware, software upgrades and field change orders.
 - (7). Providing response via telephone within two (2) hours and on-site within twenty-four (24) hours of notification. The contractor shall be capable of providing coverage 7:00 am to 7:00 pm CT, 7 days/week and all holidays.
 - b. No responses were received and no potential contractors chose to identify themselves in the "Interested Vendors List".
 - c. No replacement or new requirements for the Datex-Ohmeda equipment is presently budgeted for or forecast.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated five year price (base and four option year extensions) for the services is \$734,539.30. The Contracting Officer will determine that the anticipated price(s) will be fair and reasonable by requiring the contractor to provide a written quote and additional information (other than cost or pricing data), which will include commercial price lists and prices for similar or the same services provided to other customers, to assist the Contracting Officer in determining if the contractor's proposed prices are fair and reasonable for the services being provided. The final price(s) will be negotiated. The Contracting Officer anticipates that the final prices(s) will 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.**
- a. Sources capable of providing bioMerieux OEM service and parts were sought. Reviewed GSA Advantage and schedules library, Small Business Administration Quick Market Search, VetBiz , reviewed existing FBO postings, published a Sources Sought on FBO, reviewed FBO notices declaring sole sources agreements with bioMerieux, utilized on-line search engine Google for existing contracts or agreements, reviewed GE Healthcare Bioscience site to review

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maintenance agreement terms and conditions, searched the WEB for pricing information and economic forecasts, searched System for Awards Management (SAM). No vendors capable of providing the required services with the propriety equipment diagnostic software, OEM parts and within the required repair response time were identified except bioMerieux Inc. No other vendors were identified, no responses were received and no potential contractors chose to identify themselves.

- b. As described In Section 5 above, market research, in accordance with FAR Part 10, was conducted by posting a Sources Sought in FBO soliciting inquiries from interested parties.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Failure to properly and timely maintain the installed bioMerieux brand VITEK MS automated mass spectrometry microbial identification systems will reduce the capability of the Department of Veterans Affairs to provide health care to the beneficiaries being served. The health of the veteran beneficiary is of paramount importance in this acquisition and any factors which may influence the quality of care to the beneficiary is a critical consideration. The VA Medical Centers must be able to provide critical healthcare to veteran beneficiaries in the safest possible manner.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** No responses have been received and no potential contractors have chosen to identify themselves.
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:**
Unless the manufacturer choses to license its software and authorize local service providers to maintain test and calibrate its equipment sometime in the future, the only alternative that may be available to us is to replace the existing bioMerieux brand equipment with a more generic brand that may have a wider installed base and which does not have proprietary software. However, considerations other than sole source must be considered when contemplating replacement, specifically the anticipated remaining life span of the presently installed equipment, need for sufficient budget to acquire replacement capital items, the need to provide the most reliable and best equipment for the price, and the availability of quality maintenance and repair services. Right now the six facilities who will be participating in this contract are satisfied with the quality and operation of the installed equipment, its maintenance and repair, and they do not have sufficient budget to replace the equipment.
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.



Name: Brenda Hinck
Title: VISN 15 Regional Laboratory Manager
Facility: VISN 15

8/12/2015
Date

13. **Approvals in accordance with FAR 6.304**

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

Larry A BUELL
346126

Digitally signed by Larry A BUELL 346126
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ou=people,
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gov, cn=Larry A BUELL 346126
Date: 2015.08.12 10:40:59 -05'00'

08-12-2015

Name: Larry A Buell
Title: Contracting Officer
Facility: General Services,
Network Contracting Office (NCO) 15

Date

- b. **Director of Contracting /Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

SCOTT R FISCUS
381888

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381888
Reason: I agree to specified portions of this document.
Date: 2015.09.11 10:30:29 -05'00'

Name: Scott Fiscus
NCO 15 Director of Contracting
Network Contracting Office (NCO) 15

Date

- c. **SAO (If over \$650K):** I certify the justification meets requirements for other than full and open competition.


Name: Rick Lemmon
Director, Service Area Office, Central

9-16-15
Date

- d. **VHA 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 recommend approval (if over \$12.5 million) or approve (\$650K to 12.5 million) for other than full and open competition.


Norbert S. Doyle
VHA Head of Contracting Activity (HCA)

9/16/15
Date