

## Corbin, Susan

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**From:** Fowler, Maureen  
**Sent:** Thursday, October 24, 2013 9:45 AM  
**To:** Corbin, Susan  
**Subject:** For Ms. Howard's Signature (Biomerieux Limited Source Justification)  
**Attachments:** Biomerieux.pdf  
  
**Importance:** High

**LIMITED SOURCES JUSTIFICATION**

**ORDER >\$3,000**

**FAR PART 8.405-6**

**2237 Transaction # or Vista Equipment Transaction #: 509-14-1-549-0006**

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

**Restricted to the following source:** Provide original manufacturer's name for material or contractor's name for service. (If a sole source manufacturer distributes via dealers, ALSO provide dealer information.)

Manufacturer/Contractor: Biomerieux, Inc. – (NAC FSS V797P-7128A)

Manufacturer/Contractor POC & phone number: Adam Robinson (Cell#919-257-0493)

Mfrgr/Contractor Address: 100 Rodolphe Street, Durham, NC 27712(Distributor)

Dealer/Rep address/phone number: None – see manufacturer POC

☒ The requested material or service represents the minimum requirements of the Government.

**(1) AGENCY AND CONTRACTING ACTIVITY:**

Department of Veterans Affairs

Network Contracting Office -07

501 Greene Street,

Suite 2

Augusta, Georgia 30901

**VISN:**

07

**(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:**

Annual task/delivery order for disposables used on the BacT/ALERT at a firm, fixed –price against the NAC FSS V797P-7128a for use with the BacT/ALERT system from Biomeurieux, Inc. This is a reoccurring need for procurement, at a minimum volume, for disposable blood culture bottles needed to perform septicemia testing on patient samples of blood and body fluids. Continuation of a task/delivery order against the NAC cost per test contract will enable the Charlie Norwood VA Medical Center (CNVAMC) to schedule shipping of product and to reduce the cost of administrative time by issuing the contract for a base with two option periods.

**(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:**

Blood culture bottles are needed to provide critical diagnostic service for VA beneficiaries. Both disposable aerobic and anaerobic bottles are necessary for continuous monitoring of blood, sterile body fluids, and platelets from patients in the emergency room, all clinics, ancillary Community Based Outpatient Clinics and inpatients.

**(b) ESTIMATED DOLLAR VALUE:** \$31,040.00 (Base + 3 opts \$93,120)

**(c) REQUIRED DELIVERY DATE:** 12/14/2013

**(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE. (CHECK ALL THAT APPLY AND COMPLETE)**

☐ Specific characteristics of the material or service that limits the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.

Biomerieux, Inc., is the manufacturer and holds the registered trademark for the BacT/ALERT System. There are no authorized distributors for Biomerieux BacT/ALERT system and supply requirements are stated in the terms and conditions of the Cost-Per-Test NAC FSS V797P-7128A contract. October 24, 2011, obligation order 509-C25149 was issued for the following: BacT/ALET 3D Signature with observa, one (1) BacT/ALERT 3D Benchtop Cart, one (1) BacT/ALERT 3D Control Module/Starter kit, and one BacT/ALERT 3D Left Incubator Module with a minimum amount (2100) of disposables ordered on a quarterly basis. Disposables' pricing: BacT/ALERT SA at \$3.52/unit; BacT/ALERT SN at \$3.52/unit; BacT/ALERT PF at \$3.84/unit; BacT/ALERT FA at \$3.84 per unit; BacT/ALERT FN at \$3.84 per unit. No other company's blood culture bottles can be used on this equipment.

☒ A patent, copyright or proprietary data limits competition. The proprietary data is:  
(If FAR 8.405-6(a)(2)iii before posting. Do not include specific proprietary data. Only mention the type of equipment, procedure, etc. to show that proprietary supplies or services are being procured.)

Biomerieux is the manufacturer and holds the registered trademark for the BacT/ALERT System. There are no authorized distributors for Biomerieux BacT/ALERT System and supply requirements are as listed on the NAC FSS V797-7128A contract.

☒ These are "direct replacements" parts/components for existing equipment.

Installation of BacT/ALERT System occurred 12/14/2011. In accordance with the federal supply schedule, Biomerieux agreed to provide maintenance service at no charge for four years after the one year warranty period. Biomerieux continues to provide maintenance services and responds to urgent repair requests in a timely manner, if required.

☒ The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.

Only BacT/ALERT aerobic and anaerobic bottles may be used on the Biomerieux' s BacT/ALERT system located in the Microbiology Department at the CNVAMC. Terms in the cost-per-test federal supply contract is the purchaser is required to procure the medium, reagents and/or controls necessary to run programed tests on the system to obtain accurate test results. Biomerieux will install the equipment and maintain it for five years at no additional cost to the government. This saves the government the cost and administrative time of issuing a preventative maintenance contract to include the cost of the equipment. Continuation of these supplies is critical in providing uninterrupted patient care.

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☒ An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.

The CPT for aerobic and anaerobic blood cultures bottles for the BacT/ALERT System are critical to avoid interruption in veteran beneficiary care, meet VHA mandates for sepsis diagnosis, and to support hospital infection control program.

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**(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:**

Results of the market research determined that Biomerieux holds the registered trademark for the BacT/ALERT System and is the manufacturer of the supplies to be used with the analyzer. The CPT contract offers the laboratory management an opportunity to customize their equipment based on their need, spacing and cost containment measures (higher volume of tests offers a lower cost). Replacement of another manufacturer's blood culture analyzer would not be cost effective due to government budget constraints. Pricing of the disposable has been consistent since the installation of the equipment in 12/14/2011 only the volume of disposables may have changed slightly. Past procurements indicate that both types of bottles were priced at \$3.52/each. IAW FAR 8.4 it would be in the best interest of the Government to continue with the BacT/ALERT System and order placement of supplies from the suggested source.

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**(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:**

The market was reviewed for new technology of automated microbiology testing. There are other blood cultures analyzers on FSS such as Siemens Healthcare and Becton, Dickinson and Company that offer their own brand name manufactured microbiology blood culture analyzers and supplies. The microbiology staff is trained in the use and operation of the BacT/ALERT 3D automated system, and as required by the College of American Pathologists, JCAHO and VHA Handbook 1106.01, "Pathology and Laboratory Medicine Service Procedures," validation studies have already been completed. A replacement system would require new validation studies, retraining of staff, and consideration of footprint spacing and installation fees that could delay diagnostic results and the treatment of the beneficiaries. Additional cost could be incurred for reconstruction of the microbiology laboratory should new equipment not fit space layout.

**(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:**

Continuation of original cost per test agreement is critical in providing uninterrupted patient care utilizing the existing BacT/ALERT System.

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**(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:**

Market research will be conducted for each requirement, and new companies will be considered as they become available.

**(9) 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. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4. *(This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)*

Michael Moosariparambil

SIGNATURE

10/22/13

DATE

Michael S. Moosariparambil

NAME

Supervisor Microbiology Dept., Pathology and Lab Medicine Svc.

TITLE

SERVICE LINE/SECTION

FACILITY: Charlie Norwood VA Medical Center, Augusta, Georgia

**(10) APPROVALS IN ACCORDANCE WITH FAR 8.405-6(d):**

**a. CONTRACTING OFFICER'S CERTIFICATION (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

  
CONTRACTING OFFICER'S SIGNATURE

10/23/2013  
DATE

Shirley B. Adams  
Contracting Officer

Network Contracting Office 07  
Augusta, Georgia  
FACILITY

**c. NCM/PCM/DESIGNEE:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

*MUF*  
  
SIGNATURE

10/28/13  
DATE

Prudence Y. Howard  
VISN 7 NCM/PCM