

**LIMITED SOURCES JUSTIFICATION**

**ORDER >\$150,000**

**FAR PART 8.405-6**

**Acquisition Plan Action ID: VA69D-17-AP-3432**

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is limited 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:**

Manufacturer/Contractor: Cepheid

Manufacturer/Contractor POC & phone number: 408-400-4475

Mfgr/Contractor Address: 904 Caribbean Drive Sunnyvale, CA 94089

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

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

Department of Veterans Affairs  
Great Lakes Acquisition Center  
115 South 84<sup>th</sup> Street  
Milwaukee, WI 53214

**VISN:** VISN12 All Facilities

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

The action being approved is a limited source justification IAW FAR Part 8 for Cepheid MRSA test and calibration kits to be used by seven facilities in VISN12 (Jesse Brown VAMC in Chicago, IL; James Lovell FHCC in Chicago, IL; Edward Hines VAMC in Hines, IL; Iron Mountain VAMC in Iron Mountain, MI; William Middleton VAMC in Madison, WI; Tomah VAMC in Tomah, WI; Clement Zablocki in Milwaukee, WI).

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

VISN12 requires reagent test kits and consumables in order to test and identify colonization and/or infection by the Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteria. Each of the listed facilities requires these reagents at different times and in different quantities but the times and quantities are known.

**(b) ESTIMATED DOLLAR VALUE:** \$2,930,671.75

**(c) REQUIRED DELIVERY DATE:** Deliveries are required periodically throughout one six-month Base Year (4/1/2017 – 9/30/2017) and potentially two subsequent Option Years (**OY1:** 10/1/2017 – 9/30/2018 and **OY2:** 10/1/2018 – 9/30/2019).

**(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.**

☐ Specific characteristics of the material or service that limit 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.

☐ 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.)

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

☒ **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.**

Polymerase chain reaction (PCR) instrumentation, GeneXpert, was purchased from Cepheid, Inc. in July 2007 for all of the VISN12 laboratories. It was acquired as a result of National Directive 2007-002 dated 1/12/2007 that mandated all VA medical centers to perform testing to detect Methicillin-resistant *Staphylococcus aureus* (MRSA) using the PCR methodology.

Cepheid has approval from the Food and Drug Administration to market their PCR equipment as a mechanism to test for MRSA. The procedure to screen for MRSA involves the use of a kit system that includes reagents and supplies to prepare the specimen and perform the analysis to produce a test result. One of the terms of the FDA approval is that the equipment be recertified annually or at less than 2000 cycles, whichever comes first. Failure to meet the recertification deadline would necessitate ceasing of the performance of the MRSA test on the equipment. The recertification must be performed by qualified Cepheid service personnel who have access to the appropriate parts for module replacement and the capability and training to perform the requirements of proper recertification. Only Cepheid can do this.

The reagent kit manufactured by Cepheid is proprietary to the Cepheid GeneXpert equipment platform and, as such, is the only reagent system that can be used to produce an accurate and reliable result. Cepheid has confirmed via email they do not have any authorized distributors capable of servicing the Department of Veterans Affairs, to include SDVOSB and VOSB distributors, and no other manufacturers are capable of providing compatible reagents for the GeneXpert equipment.

☐ The new work is a logical follow-on to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original order must not have been previously issued under sole source or limited source procedures.

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

**(4) 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:**

The required reagents are manufactured by Cepheid and are proprietary. They are the only reagents compatible with the Cepheid GeneXpert equipment platform currently owned by the facilities and, as such, are the only reagents that can be used to produce an accurate and reliable result. Cepheid has confirmed via email they do not have any authorized distributors capable of servicing the Department of Veterans Affairs, to include SDVOSB or VOSB distributors, and no other manufacturers are authorized and/or recognized by Cepheid as providing compatible reagents for their proprietary GeneXpert equipment.

If other reagents were used each facility would also need to purchase that manufacturer's platform equipment, validate the tests, adopt new SOPs, and train the necessary staff. The facility technical expert has said it would be an estimated cost of approximately \$1,000,000.00 for the procurement of new MRSA diagnostic testing equipment which is currently cost prohibitive for VISN 12. Furthermore, this estimate doesn't factor in the additional cost of test kits, consumables, validation downtime, and training associated with procuring new equipment. It is currently in the best interest of the Government to continue to use of its existing inventory of GeneXpert equipment and procure the compatible Cepheid reagents required for patient care.

Cepheid has a VA awarded NAC FSS contract (V797P-5967X) which includes the needed items and per FAR Part 8.404(d) supplies offered on the schedule are listed at fixed prices. The NAC CO has determined the prices of these supplies to be fair and reasonable when the schedule contract was established.

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

The NAICS code is 325413, the SBA size standard is 1,250 employees, and the FSC is 6640. The IGCE is \$2,930,671.75 and therefore the Non-Manufacturer Rule applies; however, there is no SBA class waiver based on the above NAICS, FSC, and description so no set-aside can be sought. Market research indicated Cepheid reagents are the only reagents available that can properly work with the Cepheid GeneXpert equipment currently owned and used by each of the facilities. Cepheid has confirmed via email they do not have any authorized distributors capable of servicing the Department of Veterans Affairs, to include SDVOSB distributors, and no other manufacturers are authorized and/or recognized by Cepheid as providing compatible reagents for their proprietary GeneXpert equipment. Cepheid is the sole provider of these reagents and is the only source reasonably available that can meet the need of the Government. Cepheid has a VA NAC FSS contract (V797P-5967X) which includes these reagents.

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

None.

**(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:**

VISN12 has reviewed their MRSA testing procedures, equipment life cycle, and budgetary constraints. They have determined it is in the best interest of the VISN to continue use of the current equipment, but plan to revisit phasing out existing equipment and to research alternative MRSA testing solutions prior to the ultimate completion date of this order (9/30/2019).

If VISN12 decides to pursue alternative solutions in the future the Contracting Office will complete all the necessary market research, to include a formal Sources Sought notice posted to FBO, with a focus on SDVOSBs, VOSBs, and Small Businesses.

**(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.)*

Donna M. Wray  
394473

Digitally signed by Donna M. Wray 394473  
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0.9.2342.1.9200300.100.1.1=donna.wray@va.gov,  
cn=Donna M. Wray 394473  
Date: 2017.03.09 14:07:45 -06'00'

March 9, 2017

SIGNATURE

Donna Wray

Business Manager

DATE

PLMS

NAME

VA Hines

TITLE

SERVICE LINE/SECTION

FACILITY

**(10) APPROVALS IN ACCORDANCE WITH THE VHAPM, Volume 6, Chapter VI: OFOC SOP:**

**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/DESIGNEE'S SIGNATURE

3/9/2017  
DATE

Daniel Rasmussen - Contract Officer  
NAME AND TITLE

NCO12 Great Lakes Acquisition Center  
FACILITY

b. **Director of Contracting/DESIGNEE:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



Paul Lauro

Director of Contracting, Network Contracting Office (NCO) 12

10 Mar 2017  
DATE

**HIGHER LEVEL APPROVAL (Required For orders over \$700,000):**

c. **VHA SAO HCA REVIEW AND APPROVAL (over \$700,000 to \$13.5 million):** 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 restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4

Linda S. Greaves  
404790

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gov, cn=Linda S. Greaves 404790  
Date: 2017.03.13 10:06:11 -05'00'

Linda S. Greaves

Acting, SAO Director, Central Region (10NA2)  
SAO Central Head of Contracting Activity (HCA)

13 March 2017  
DATE