

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: 36C252-19-AP-3104

1. **Contracting Activity:** Department of Veterans Affairs, VISN 12, Great Lakes Acquisition Center (GLAC), 537-20-1-944-0001, 550-20-1-949-0001, 556-20-1-2947-0001, 578-20-1-944-0001, 585-20-1-944-0001, 607-20-1-944-0001, 676-20-1-944-0001, 695-20-1-944-0001.
2. **Nature and/or description of the action being processed:** This is a sole source justification for a new, firm-fixed price contract in accordance with FAR 13.5 Simplified Procedures 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 Pathology and Laboratory Medicine Service Product Line of the Great Lakes Health Care System (Veterans Integrated Service Network (VISN) 12) is requesting acquisition of reagent test kits, consumable supplies, and instrument service from Cepheid, Inc. ("Cepheid") to perform clinical testing and identify colonization/infection by the Methicillin-Resistant *Staphylococcus Aureus* (MRSA) bacteria.

	Edward Hines, Jr. VA Hospital	Clement J. Zablocki VAMC	Jesse Brown VAMC	Captain James A. Lovell Federal Health Care Center	William S. Middleton Memorial Veterans Hospital	Tomah VAMC	Oscar G. Johnson VAMC	VA Illiana Health Care System
Estimated annual volume of Methicillin-Resistant <i>Staphylococcus Aureus</i> (MRSA) tests/year	9,900	8,500	8,400	4,700	6,800	1,440	1,000	1,500
GXM RSA-NXG-10 KIT, 10-TEST, MRSA required annually	0	0	0	467	684	0	0	150
GXM RSA-NXG-120 KIT, 120-TEST, MRSA required annually	86	72	70	0	0	12	9/10 (base/option)	0
Xpert Check required annually	7	4	4	10	2	2	1	4

Total estimated value and Period of Performance:

<u>Period of Performance</u>	<u>Price</u>
10/1/2019 – 9/30/2020 (Base)	
10/1/2020 – 9/30/2021 (Option Year 1)	
Total	\$2,672,128.00

4. **Statutory authority permitting Other than Full and Open Competition:** The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by 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):** In 2007, VISN 12 laboratories procured Cepheid GeneXpert Instrument Systems due to a national directive (VHA 1131(2)) that mandated all VA medical centers perform testing to detect MRSA using polymerase chain reaction (PCR) technology.

The Xpert MRSA NxG Assay is a Food and Drug Administration (FDA) 510(k)-cleared test approved for use on the Cepheid GeneXpert Instrument Systems. The test utilizes automated PCR technology for the amplification of MRSA-specific DNA directly from nasal swabs in patients at risk for nasal colonization and aids in the prevention and control of MRSA infections in healthcare settings. One of the terms of the FDA approval for the GeneXpert Instrument System is the need to calibrate all modules in the instrument annually or every 2,000 tests. This is accomplished using the Cepheid Xpert Check. Only Cepheid test kits are FDA-approved for use on the Government-owned GeneXpert Instrument System due to the proprietary nature of the instrumentation. Cepheid does not have any distributors authorized to sell MRSA test kits to VA Medical Centers. Therefore, Cepheid is the sole distributor and the only source capable of providing the requested products to VISN 12.

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 estimates a cost of approximately \$1,000,000.00 for the procurement of new MRSA diagnostic testing equipment which is currently cost-prohibitive for VISN 12. Further, this estimate does not 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 with the existing inventory of GeneXpert equipment and procure the compatible Cepheid reagents required for patient care.

Similarly, it is also not in the best interest to lease equipment – regardless if it includes reagents – as the VISN already owns MRSA diagnostic testing equipment. The Contracting Officer (CO) conducted a search on FPDS for "MRSA equipment lease" which returned few results. In particular, however, the North Texas Veterans Healthcare System leased equipment and reagents for MRSA and other tests on contract number VA257-17-D-0122. Several results were concluded from this market research:

1. If including new equipment, the facility is required by regulatory and accreditation agencies to validate new equipment to prove it functions properly and provides accurate results. This process requires significant personnel time and extra reagent cost for each site.
2. If equipment leasing is included in the contract, costs are significantly increased for smaller sites in VISN 12 that are currently spending less than \$50,000.00 annually. The Edward Hines, Jr. VA Hospital located in Hines, IL is projected to spend approximately \$310,000.00 in the base year of the contract. This is significantly less than the [REDACTED] that VA in North Texas is spending annually, despite similar test volumes.

3. All GeneXpert instruments in VISN 12 are functioning properly and are not experiencing downtime.

VISN 12 has reviewed its situation (equipment life cycle, budget constraints, etc.) and has determined continuing with the Cepheid equipment and reagents is in the best interest of the Government as purchasing other reagents would also necessitate the purchase of that manufacturer's platform and equipment system, creating and implementing new SOPs, and training the required staff on its operation.

The equipment currently in use, and with which these reagents must be compatible, was purchased in 2007. VISN 12 is aware the equipment is becoming dated but has determined it to be in their best interest to continue its use. The facility estimates the usable life of the equipment will last another five years but will only include one Option Year on this contract due to continual survey of Industry advances in technology and price.

To ensure continuity of care, VISN 12 also has the need for GeneXpert Instrumentation service and emergency repair. Cepheid does not certify or endorse third parties to perform these functions. Due to the complexity of the equipment, the lack of third-party certification for services, and the need for replacement parts, Cepheid is the only firm capable of providing the supplies and services described in Section 3 above without the Veteran's Health Administration experiencing unacceptable delays in fulfilling its requirements.

6. **Description of efforts made to ensure that offers are solicited from as many potential sources as deemed practicable:** An Intent to Sole Source notification (36C25219Q0791) was posted to the Governmentwide Point of Entry (GPE), FBO.gov, for a period between 7/26/2019 and 7/31/2019. Zero responses were received.
7. **Determination by the CO that the anticipated cost to the government will be fair and reasonable:** FAR 8.404(d) states GSA has already determined the prices of supplies to be fair and reasonable and ordering activities are not required to make a separate determination of fair and reasonable pricing. Although Cepheid's National Acquisition Center (NAC) Federal Supply Schedule (FSS) contract (V797P-5967X) recently expired (09/2017), Cepheid is offering these reagents now at the same price that they offered them under that contract. A previous purchase made by NCO 12 (VA69D-17-F-3236 awarded in 2017), which was determined at the time of award to be fair and reasonable IAW FAR 8.404(d), confirms the current pricing matches the previous NAC pricing. Because the NAC CO determined the prices of these supplies to be fair and reasonable when the schedule contract was established; and because Cepheid is continuing to offer these reagents at those same fair and reasonable prices; and because a comparison of these current prices with those under previous contract VA69D-17-F-3236, which were determined to be fair and reasonable, confirm the pricing remains unchanged; the CO has determined that the anticipated cost to the Government will be fair and reasonable IAW FAR 13.106-3(a)(2)(ii).
8. **Description of the market research conducted and the results, or a statement of the reasons market research was not conducted:** In accordance with the Veterans First Program (Rule of Two), a search on Vendor Information Pages (VIP) for keyword, "MRSA" and NAICS 325413 (In-Vitro Diagnostic Substance Manufacturing) produced zero results for Veteran-Owned Small Businesses (VOSBs) or Service-Disabled Veteran-Owned Small Businesses (SDVOSBs). This requirement was

previously provided on an FSS contract with the NAC, contract number V797P-5967X. A previous GLAC procurement (VA69D-17-F-3236) was completed, using the NAC FSS contract, without providing for full and open competition IAW FAR 8.405-6 (Limited Sources). However, the manufacturer declined to renew the contract with the NAC after expiration for unspecified reasons but is currently offering the same Government-discounted rate of approximately [REDACTED] that was provided on the NAC FSS contract. A search was conducted on the NAC MedSurg catalog and GSA Advantage! catalog for keywords "MRSA" and "reagent." Zero results were returned on the GSA Advantage! catalog. Several results were returned on the NAC MedSurg catalog, but none for MRSA reagents together.

As described in Section 6 above, market research, in accordance with FAR Part 10, was conducted by synopsis of the proposed acquisition, advising industry of the pending acquisition and soliciting inquiries from interested parties.

9. **Any other facts supporting the use of Other than Full and Open Competition:** None.
10. **Listing of sources that expressed, in writing, an interest in the acquisition:** Cepheid, Inc.
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:** Cepheid is the only known manufacturer of the requested reagents for its GeneXpert analyzer. The requiring and contracting activities will conduct market research prior to new purchase requirements to determine if there have been any changes in the marketplace, including considering the possibility of leasing. A single source effort is required for the planned duration to maximize efficiency of the acquisition process and maintain favorable pricing (best value) for the Government.
- VISN 12 is only doing a Base Year with one Option Year to afford the VISN enough time to conduct a thorough review of its current equipment and inventory to determine if it is within the Government's best interest to procure a completely new system if a new system is identified and able to meet the strict regulatory and accreditation requirements or continue with the current system. This review shall consider all associated costs, training requirements, supply/logistics concerns, storage capacity of new items, and any tertiary effects not known at this time and compare this against what is currently owned.
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.

Courtney A
Feldmann 393653
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Feldmann 393653
Date: 2019.09.10 12:43:29
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Courtney A. Feldmann
Business Manager, VISN 12 PLMS
Edward Hines, Jr. VA Hospital

9/10/2019

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.

James R. Hedman
1081322

Digitally signed by James R. Hedman 1081322
Date: 2019.09.10 09:05:42 -05'00'

9/10/2019

Jim R. Hedman
Contracting Officer
Network Contracting Office 12
Great Lakes Acquisition Center

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.

Daniel R.
Rasmussen 457897

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Date: 2019.09.10 12:53:36 -05'00'

9/10/2019

Dan R. Rasmussen
Supervisory Contracting Officer
Network Contracting Office 12
Great Lakes Acquisition Center

Date

- c. **Division Manager 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 approve for other than full and open competition.

Ivy, Scott A

Digitally signed by Ivy, Scott A.
Date: 2019.09.10 14:27:50 -05'00'

9/10/2019

Scott A. Ivy
Division Manager, Equipment, Medical Sharing, Services and Supply
Network Contracting Office 12
Great Lakes Acquisition Center

Date

- d. **Director of Contracting 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 approve for other than full and open competition.

Paul M. Lauro
1463508

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Lauro 1463508
Date: 2019.09.10 20:58:57
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Paul M. Lauro
Director of Contracting
Network Contracting Office 12
Great Lakes Acquisition Center

10 Sep 2019

Date

- e. **VHA RPO 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 \$68 million) or approve (\$700K to \$68 million) for other than full and open competition.

TERRY L.
SPITZMILLER
394683

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L. SPITZMILLER 394683
Date: 2019.09.13 07:20:46
-05'00'

Terry L. Spitzmiller
Executive Director
Regional Procurement Office Central (VHA)

09/13/2019

Date