

13-1141-NC07 - Cepheid GeneXpert
 Infinity (E)
 KAW

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval
 For
 Other Than Full and Open Competition

- Contracting Activity:** Department of Veterans Affairs, SAO EAST, Network Contracting Office 7 plans to contract by means other than full and open competition for 2237 #: 534-14-1-025-0003
- Nature and/or Description of the Action Being Processed:** This is a request for a new firm fixed price contract by means other than full and open competition for a Reagent Rental Agreement for the automated Cepheid GeneXpert Infinity 48 to perform automated molecular testing for MRSA, C. difficile, and Chlamydia and Gonorrhea (CT/NG), inclusive of the reagents, and all consumables, maintenance, and training on a fixed monthly order amount for sixty (60) months.
- Description of Supplies/Services Required to Meet the Agency's Needs:** Since 2008, The Ralph H. Johnson VA Medical Center has used the Cepheid GeneXpert Infinity 48 to perform automated molecular testing for MRSA and C.difficile. Cepheid is the only vendor capable of providing the proprietary reagents necessary to perform testing utilizing the Cepheid Infinity 48 instrumentation.

For the one (1) year Base and each of the four (4) Option years, there will be the following:

Part Number	Reagent Product Description	Tests /Kit	Price /Test	Price /Kit	Quantity	\$/mo
GXM RSA-120	Xpert MRSA, IVD (120)	120	\$33.29	\$3,994.80	360	\$11,984.40
GXC DIFFICILE-10	Xpert C. difficile (10)	10	\$289.99	\$289.99	30	\$ 869.97
GXC CT/NG-10	Xpert CT/NGS	10	\$233.99	\$233.99	250	\$ 5,847.50
900-0370	Cepheid Collection Device	50	Included in the reagent cost per test	-	400	-
CT/NGSWAB-50 or CT/NGURINE-50	CT/NGS Collection Device	50	Included in the reagent cost per test	-	250	-
Monthly Purchase Commitment:						\$18,731.80

- Statutory Authority Permitting Other than Full and Open Competition:**
 41 USC §253(g), as implemented by FAR 6.302.

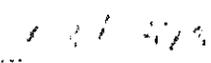
- (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- (2) Unusual and Compelling Urgency per FAR 6.302-2;
- (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- (4) International 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):** Since 2008, Cepheid has provided the Ralph H. Johnson VA Medical Center Laboratory Services with the capabilities to perform highly specialized real time PCR (MRSA and C.difficile) utilizing samples from various clinical sites. The availability of this highly specialized, proprietary instrumentation provides the laboratory with a faster specimen processing time to determine whether a patient should be isolated or if contact precautions should be taken to decrease the potential for hospital-acquired infections in the immunocompromised patient population. Cepheid also offers in-house testing for Chlamydia and Gonorrhea (CT/NG) which is currently being sent out for referral testing. The highly specialized Cepheid GeneXpert Infinity 48 that is less labor intensive, allows random access testing, and will increase turnaround time efficiency while employing a closed system. The Cepheid GeneXpert Infinity 48 allows for the growth of molecular testing in the laboratory with the future potential for expansion to add more tests due to the design of this highly specialized instrumentation. A competition for new services would result in a substantial duplication of cost to the government that is not expected to be recovered by competition in addition to unacceptable delays in providing patient care to our Nation's Veterans.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A Request for Information was posted to FedBizOps on 9/16/13 and remained open until 9/23/13 without any response from interested vendors. No responses were received because no other companies have the proprietary reagents necessary to support this requirement. Cepheid is the sole manufacturer and sole distributor of GeneXpert instruments. Cepheid does not have any authorized resellers of GeneXpert instruments. Based on current system performance and the fact that no other company responded to the RFI, VetBiz and Dynamic Small Business Searches, Cepheid is found to be the only source capable of performing these highly specialized services. In addition, Cepheid provided an official letter on 9/05/13 stating that Cepheid is the sole manufacturer and sole distributor of GeneXpert instruments.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated cost to the government is \$1,123,896.00, including options. Under section 3(a) above ("MRSA, IVD (10) with 10 tests/kit, \$33.29 price/test, \$332.90 price/kit, and 360 Tests/month for a total of \$11,984.40/month") part number GXM RSA-100N-10 is found on mandatory source VA NAC FSS # V797P-5967X price lists with a price of \$36.67 per test. We have a quote for the same part number: GXM RSA-100N-10 with a price of \$33.29 per test.
- The XPERT MRSA, IVD has also been purchased on past VA FSS Order # VA247-13-J-0072 for \$44.58 price/test. Our current \$33.29 price/test quote is significantly lower.
- In addition, past VA FSS Order # VA247-13-J-0072 purchased XPERT C.difficile for \$32.39 price/test. We are proposing to purchase XPERT C.difficile at \$29.99 price/test. This is also lower than previous VA purchases.
- The contract specialist also relied on the IGCE prepared by laboratory expert and Supervisory Medical Technologist, Joseph Pickett to determine that the costs associated with this procurement are fair and reasonable.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** As described in Section VI above, market research, in accordance with FAR Part 10, was conducted by an RFI issued 9/16/13, advising industry of the pending acquisition and soliciting inquiries from interested parties. VIP and Dynamic Small Business searches were conducted with NAICs Code 325413 and it was determined that none of the vendors were capable of performing these services since they are not authorized re-sellers of the Cepheid proprietary reagents required for this procurement.

The mandatory sources available on GSA and the NAC VA Federal Supply Schedules were reviewed in addition to examining the acquisition history and experience with the marketplace under previous acquisitions for the same or similar items. While MRSA, IVD (10) with 10 tests/kit is found under Mandatory Source VA NAC FSS # V797P 5967X, the other mix of reagents required are not. Thus we are requested to procure these Cepheid proprietary items Open Market. On 9/05/13, Cepheid provided an official letter stating that Cepheid is the sole manufacturer and sole distributor of GeneXpert instruments.

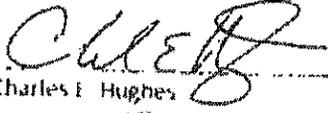
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The Cepheid Infinity 48 has been on site in the Ralph H. Johnson VAMC since 2008 where it has been performing automated molecular testing for MRSA, C. difficile and Chlamydia/Gonorrhea, inclusive of the proprietary, specialized Cepheid reagents and all consumables, maintenance, and training provided by authorized Cepheid specialists. On 9/05/13, Cepheid provided an official letter stating that Cepheid is the sole manufacturer and sole distributor of GeneXpert instruments.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None. There were zero responses from interested vendors, because no other companies have the proprietary reagents necessary to support this requirement. On 9/05/13, Cepheid provided an official letter stating that Cepheid is the sole manufacturer and sole distributor of GeneXpert instruments.
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:** Approval is sought for a one year base with four, twelve month option periods, sole source contract with Cepheid in order to utilize highly specialize equipment and services already in place, and to avoid substantial duplication of costs associated with any competitive action. This acquisition strategy will ensure that our Veteran's patient care is not interrupted with unacceptable delays or disruption in services.
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.


Joseph Pickett
Supervisory Medical Technologist
Ralph H. Johnson VA Medical Center

 Date

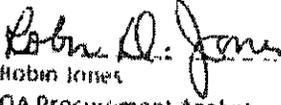
13. Approvals in accordance with FAR 6.304

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


Charles E. Hughes
Contracting Officer
NCO 7

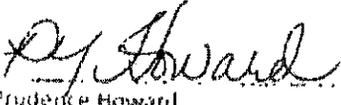
9-24-2013
Date

VISN/PCA QA: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief


Robin Jones
QA Procurement Analyst
NCO 7

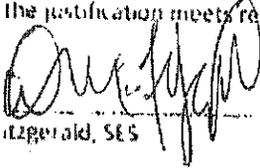
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Date

- b NCM/PCM: I certify the justification meets requirements for other than full and open competition


Prudence Howard
Network Contract Manager
NCO 7

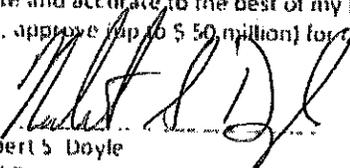
9/25/13
Date

- c SAO: I certify the justification meets requirements for other than full and open competition


David M. Fitzgerald, SES
Director
Service Area Office, East

9-26-13
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 (over \$50 million), approve (up to \$ 50 million) for other than full and open competition


Norbert S. Doyle
Chief Procurement and Logistics Officer
VHA Head of Contracting Activity (HCA)

9/27/13
Date