

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval (J&A)  
For  
Other Than Full and Open Competition (>\$150K)**

2237 numbers:  
REDACTED

**1. Contracting Activity:**

**Department of Veterans Affairs  
Network Contracting Activity (2-90NCA) VISN 2**

Albany VA Medical Center 113 Holland Avenue Albany, NY 12208	Syracuse VA Medical Center 800 Irving Avenue Syracuse, NY 13210	Buffalo VA Medical Center 3495 Bailey Avenue Buffalo, NY 14215
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Facility Points of Contact:  
Albany VA Medical Center: COR  
Buffalo VA Medical Center: COR  
Syracuse VA Medical Center: COR

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

Award of a firm fixed price indefinite delivery indefinite quantity contract for the procurement of Genexpert test kits for the Albany, Syracuse and Buffalo VA Medical Centers. Period of performance will be 1/1/2016 – 12/31/2020. These tests kits will be used to detect Influenza A&B in nasopharyngeal samples, C. difficile toxin in stool samples and BCR-ABL in blood samples. Albany, Syracuse and Buffalo currently own Cepheid GenXpert instruments and they are already in house.

**3. Description of Supplies/Services Required to Meet the Agency's Needs:**

**Individual sites will have their own Purchase Orders:**

**Buffalo purchase order will include the following:**

ITEM	QUANTITY
Genexpert C.Difficile/EPI, 120 tests/kit	6 KITS
Genexpert TB/RIF, 10 tests/kit	20 KITS
Genexpert Flu Test Kit, 10 tests/kit	54 KITS
Genexpert CT/NG, 10 test/kit	90 KITS

Chapter VI: Other Than Full and Open Competition (OFOC) SOP  
Attachment 3: Request for Sole Source Justification Format >\$150K

Urine collection kits, 50/kit	10 KITS
Swab collection kits – 50/kit	20 KITS

**Estimated total per year =**

**Albany purchase order will include the following:**

Clostridium Difficile / Epidemic 027 Strain, 10 tests/kit	15 KITS
xpert MRSA/SA BC Assay, 10 tests/kit	15 KITS
Xpert MRSA/SA SSTI Assay	10 EACH
Genexpert Flu Test Kit, 10 tests/kit	20 KITS
Genexpert Flu/Respiratory Syncytial Virus, 10 test/kit	70 KITS
Genexpert CT/NG, 10 test/kit	50 KITS
Urine collection kits, 50/PK	10 PK
Vaginal collection swabs, 50/PK	6 PK

**Estimated total per year =**

**Syracuse purchase order will include the following:**

Genexpert C.Difficile/EPI, 120 tests/kit	7 KITS
Single Use Disposable Swab For Use With C. Diff Kit, 120 Swabs/Pkg	7 PKG
Genexpert Flu Test Kit, 10 tests/kit	57 KITS
Genexpert CT/NG Kit, 10 Tests/Kit	106 KITS
Urine collection kits, 50/kit	15 KITS
Swab collection kits – 50/kit	10 KITS

**Estimated total per year =**

**VISN 2 total =**

**VISN 2 base plus 4 option year total =**

**4. Statutory Authority Permitting Other than Full and Open Competition:**

*41 USC §3304(a)(1), as implemented by FAR 6.302-1. The specific paragraph must be cited. Most likely, only the -1 or -2 authorities will be cited. Please be aware that failure to adequately plan for future requirements does not constitute appropriate use of the unusual and compelling urgency statutory authority.*

- (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;

**5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**

Cepheid is the only responsible source for the proprietary test kits required to perform highly specialized molecular testing on the state-of-the-art Cepheid GeneXpert instrument which is owned by the Albany, Buffalo and Syracuse VAMCs. The molecular testing performed using this instrumentation/test kits provides for timely, sensitive and specific test results that can be used for the real time management of patients infected with MRSA/SA, Influenza virus or toxin producing C. difficile, or presenting with hematological disorders such as CML.

**6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**

GSA, NAC, FBO, FPDS and Internet research was conducted in order to find alternative sources for these products. The searches did not produce any results, (see Section 8, below).

**7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:**

Prices were determined Fair and Reasonable by analyzing current market prices and comparing them with the prices by other facilities. The tools used to determine fair and reasonable pricing were invoices showing prices paid by other facilities and prices quoted by the vendor.

PROPRIETARY INFORMATION ON MARKET RESEARCH AND EXPENDITURES REDACTED FROM THIS SECTION.

PROPRIETARY INFORMATION REDACTED

**8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**

The overall North American Industry Classification System (NAICS) code was determined to be 325413 (In-Vitro Diagnostic Substance Manufacturing); with the small business size standard of 500 employees.

A search on Vetbiz using the NAICS code 325413 – In-Vitro Diagnostic Substance Manufacturing indicated that there are four SDVOSB’s that are registered with that NAICS code on Vetbiz.

A search on SBA Dynamic Search Tool using the NAICS code 325413 – In-Vitro Diagnostic Substance Manufacturing indicated that there are three hundred sixty five small business vendors that are registered with that NAICS code.

A sources sought notice was posted on FBO (4/7/2015 – 4/14/2015). The sources sought notice was posted to seek alternative vendor’s solutions to the government’s need for brand name or equal reagent test kits to be used in Cepheid Genexpert instrument systems. One response was received, which was from the requested vendor, Cepheid (large business). The vendor confirmed that the requested items are open market. No other vendor’s responded to the sources sought notice. The vendor also confirmed that only Cepheid test kits can be used on these instrument systems and these test kits cannot be used on any other brand of instrumentation.

Discussions with the vendor indicated that they are the only source of this product. The vendor confirmed they only market this system in the United States through direct sales. The vendor further confirmed that only their products can be utilized in their analyzers.

Market research on FBO has also shown that other VA Medical Centers, including VISN 2 Medical Centers, the Cleveland VA Medical Center, and the West Palm Beach VA Medical Center as well as the Walter Reed National Military Medical Center, have sole sourced the requested products from Cepheid, Inc. in the past.

Finally, a review on FPDS showed that 258 awards were made to Cepheid in Fiscal Year 2015. A sample of 10 was surveyed and all acquisitions were determined to be procured as Sole Source or if full and open competition was used, only one quote was received in response to their solicitation.

The extensive market research conducted concluded that only one source was available to provide the Cepheid reagent test kits.

**9. Any Other Facts Supporting the Use of Other than Full and Open Competition:**

N/A

**10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**

N/A

**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:**

Although current market research indicates that there are no known reagents available in the marketplace that are able to be used with Cepheid analyzers at this time, all efforts will be made to find alternative solutions for future requirements. The government will continue to conduct market research to ascertain if there are changes in the marketplace that would enable future competition.

**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.

\_\_\_\_\_  
– NAMES REDACTED  
Clinical Laboratory Manager  
Buffalo VA Medical Center  
VISN 2

\_\_\_\_\_  
Date

**13. Approvals in accordance with the [VHAPM, Volume 6, Chapter VI: OFOC SOP](#). This part if filled out by Contracting Staff as part of the Justification**

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

\_\_\_\_\_  
Mary Betker  
Contracting Officer  
VISN 2 NCA

\_\_\_\_\_  
Date

Chapter VI: Other Than Full and Open Competition (OFOC) SOP  
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- b. **Director of Contracting /Designee (Required \$150K and above)**: I certify the justification meets requirements for other than full and open competition.

\_\_\_\_\_  
\_ NAMES REDACTED  
Director of Contracting  
VISN 2

\_\_\_\_\_  
Date

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

\_\_\_\_\_  
\_ NAMES REDACTED  
Director, SAO East (Acting)  
SAO East Region Head of Contracting Activity (HCA)

\_\_\_\_\_  
Date