

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA244-17-AP-8535/460-18-1-164-0003

- Contracting Activity:** Department of Veterans Affairs, VISN 04, Wilmington VA Medical Center (WVAMC), Wilmington, DE, SAO East, Network Contracting Office 4 (NCO4), Clinical Support Services (Med 2).
- Nature and/or Description of the Action Being Processed:** The WVAMC's Pathology & laboratory Medicine Service (P&LM) is requesting award of fixed price, Indefinite Delivery, Indefinite Quantity (IDIQ) contract with a five year ordering period. Contract type was selected as the Government cannot adequately predict the exact number of supplies that will be needed in any given period of time. Award is to be made on a sole source basis to **Cepheid**, 904 Caribbean Drive, Sunnyvale, CA. This procurement is 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.
- Description of Supplies/Services Required to Meet the Agency's Needs:** Said contract will provide proprietary Cepheid reagents for testing of patient specimens for the presence of harmful organisms such as Methicillin-Resistant Staphylococcus Aureus (MRSA), Clostridium Difficile (C.Diff), Mycobacterium Tuberculosis (MTB), and Carbamazepine Resistant Enterococcus (CRE). Total estimated value is **\$421,849.31**. Applicable NAICS and PSC codes are 325413- In-Vitro Diagnostic Substance Manufacturing, and 6550-In-Vitro Diagnostic Substances, Reagents, Test Kits and Sets. Anticipated ordering period is 10/19/2017 through 10/18/2022. Specific reagents to be ordered along with estimated quantities, unit, and total prices are listed in the table below:

Description	QTY	UOM	Unit Price	Total
GENEXPERT GXCDIFF/EPI-120 C. DIFFICILE/EPI	15	KT	\$ 3,622.05	\$ 54,330.75
GXMRSA-NXG-120, 120 PER KIT	50	KT	\$ 3,892.39	\$ 194,619.50
MRSA SKIN AND SOFT TISSUE TESTING KITS, 10 PER KIT	220	KT	\$ 608.18	\$ 133,799.60
GXMTB/RIF-US-10 MTB, IVD, US	33	KT	\$ 567.63	\$ 18,731.79
CARBA-R,IVD,GX, 10 PER KIT	33	KT	\$ 445.99	\$ 14,717.67
STARTER KIT,GX CARBA-R,IVD	1	KT	\$ 3,750.00	\$ 3,750.00
START PAK FOR MRSA NXG ASSAY	1	KT	\$ 1,900.00	\$ 1,900.00

4. **Statutory Authority Permitting Other than Full and Open Competition:** Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1; *also*, the authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented for 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):** The required reagents support the continued use of current Cepheid testing instrumentation already installed in the WVAMC P&LM. In 2008, the medical center purchased the Cepheid GenExpert PCR (Polymerase Chain Reaction) Analyzer in support of Department of Veterans Affairs initiatives to reduce the spread of MRSA. PCR testing methods provide increased detection capabilities while dramatically reducing the time required to obtain a result. Traditional methods of MRSA detection typically took one to two days. The GenExpert performed testing in under two hours with a high degree of accuracy. The instrument has since been used to support a number a VA initiatives requiring rapid test results. Since the initial acquisition, the laboratory has added C.Diff and MTB. The VA has established new requirements for testing a new highly resistant organism. Carbamazepine Resistant Enterococcus (CRE). The ability to rapidly test for the presence of these organisms with a high degree of accuracy greatly contributes to the quality of patient care. *Cepheid is the sole manufacturer and distributor of the compatible testing reagents for the GenExpert PCR Analyzer.* Only the reagents listed above in item 3 can be used in conjunction with the GenExpert PCR Analyzer to test for MRSA, C.Diff., MTB, and CRE. No other manufacturer's reagents are compatible.

The anticipated useful life/life cycle of the GenExpert PCR Analyzer is 10 to 15 years. At this time, the WVAMC P&LM is aiming to utilize the analyzer for up to 15 years or about 2023. During the life cycle of this analyzer, it is necessary to have a contract for supply of Cepheid reagents. The contemplated contract is the most efficient means to secure an adequate and predictable source of supply for these reagents and thereby ensure that the referenced organism testing goes on without interruption. Until such time as when installation of a new analyzer is determined to be required, a sole source contract with Cepheid for the supply of their reagents is appropriate and necessary. Accordingly, Cepheid is the only firm capable of providing the reagents described in Section 3 above without the WVAMC P&LM experiencing unacceptable delays in fulfilling its organism testing requirements

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** As mentioned in item 5 above, **since the** GenExpert PCR Analyzer is still well within its useful life/life cycle, competition among potential competing offerors is not desired at this time. In the future, towards the end of the analyzer's useful life WVAMC P&LM in conjunction with NCO4 will conduct a competitive best value procurement for a new analyzer to test for the referenced organisms. At that time, competitive supply of required reagents will also be considered. Competitive offers will be solicited from as many potential sources as are available.
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** Prices under the contemplated contract are anticipated to be fair and reasonable based on the following rationale:
- Prices are expected to be equal to or less than prices paid under previous procurements of these same Cepheid reagents by NCO4 and VISN4.
  - Furthermore prices are anticipated to be equal to or less than Cepheid's current open market price list prices applicable to these reagents.

- This Contracting Officer further anticipates that the Government and VISN4 will pay the same prices as similarly situated healthcare networks in the commercial marketplace.

**8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons**

**Market Research Was Not Conducted:** WVAMC P&LM most recently ordered the required organism testing reagents under open market purchase order VA244-17-P-0076 in the amount of \$93,172.95. These reagents have been ordered yearly on a Federal Supply Schedule limited source or open market sole source basis since approximately 2008 when the previously referenced Cepheid equipment/analyzer was installed. The VA's Vendor Information Pages (VIP) was reviewed by the Contracting Officer on 10/16/2017 via search under NAICS code 325413 without keywords. This search returned 19 results. These 19 results were reviewed to see if any vendors marketed and sold the required Cepheid reagents; it was subsequently found that none did. To further confirm that only Cepheid reagents may be used in conjunction with the referenced analyzer; on 10/17/2017, this Contracting Officer spoke with medical technologists from laboratory technology industry leaders Beckman Coulter, Inc and Abbott Molecular. Both medical technologists confirmed that their companies do not manufacture and distribute compatible reagents and that to the best of their knowledge; only Cepheid manufactures and distributes the required compatible reagents.

**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:** Cepheid, 904 Caribbean Drive, Sunnyvale, CA.

**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:**

WVAMC P&LM will stay abreast of the latest FDA organism testing methodologies and products and conduct a competitive best value procurement at a time when it is deemed prudent to change their testing methodologies and instruments or otherwise consider use of organism testing reagents other than Cepheid for detecting MRSA, C.Diff., MTB, and CRE.

**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.

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David Skomorucha  
Supervisory Medical Technologist  
Wilmington VA Medical Center

10/17/2017

\_\_\_\_\_  
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.

10/17/2017

Matthew D. Parlett  
Contracting Officer  
NCO4, Clinical Support Services (Med 2)

Date

- b. **One Level Above the Contracting Officer (Required over \$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

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Nancy L. Porter  
Branch Chief  
NCO4, Clinical Support Services (Med 2)

10/17/2017  
\_\_\_\_\_  
Date