

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 4, Erie VA Medical Center

The Pathology & Laboratory Medicine department requires the purchase of VRE Testing kits and submits this justification for other than full and open competition. Transaction number: 562-13-1-023-0001.

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

Purchase of VRE testing kits as a one-time order for patient testing from the following vendor:

*Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089-1189
888-838-3222*

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

Item: GXVANA-10, Xpert vanA

Quantity: (182)

Historical price: \$366.70 ea.

Item: GXCDIFF/EPI-10

Quantity: (6)

IGCE average price: \$316 ea.

Total estimated value of acquisition = \$68,636

Delivery date: Standing order to be determined once vendor award occurs.

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

- (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):**

Laboratory analysis for detection of Vancomycin-Resistant Enterococcus (VRE) and Clostridium difficile (C. diff) is performed using molecular PCR technology. The existing system to perform these analyses is the Cepheid GeneXpert. The requested material is the actual testing reagent pack utilized by this system. There is no known substitute. This requirement is essential to providing patient care as all patients admitted to the medical center must have VRE testing performed for infection control. Also, for inconclusive C. diff antigen and toxin determinations, reflexing these cases to PCR testing will yield a highly accurate result.

These are the only test kits products that will interface with the existing laboratory testing system utilized by the Erie VA Medical Center.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** There are no other equal or substitute reagent packs that can be utilized in the system. When the equipment becomes obsolete, life cycle cost analysis (to include costs of product that must be utilized in the test process as well as availability and interoperability of equal/substitute products) will be taken into consideration.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** In accordance with FAR 13.106-3 (a)(2)(ii), price is determined fair and reasonable based on independent government cost estimate and with those prices found reasonable on previous purchases.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** There are no other equal or substitute reagent packs that can be utilized in the system. When the equipment becomes obsolete, life cycle cost analysis (to include costs of product that must be utilized in the test process as well as availability and interoperability of equal/substitute products) will be taken into consideration. Given these circumstances, no subsequent market research has been conducted.
7. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Vendor has a Federal Supply Schedule contract with the National Acquisition Center. Many testing supplies can be procured through this source. However, the required reagents in this case are not included on FSS contract. Therefore this requirement must be processed as an open market procurement.
8. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** See Section 6 above.
9. **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:** See Section 6 above. Life expectancy of the equipment utilized is 8 additional years from now. Therefore the process described in Section 6 will be followed leading up to that timeframe for reprocurement.
10. **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.

Bernadette McNall

Bernadette Hall
Supervisor, Pathology & Laboratory Medicine
Erie VA Medical Center

7/12/12

Date

11. 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.

Jennifer Balsiger

Name Jennifer Balsiger
Title Contracting Officer
Facility Erie VAMC

July 25, 2012

Date

- b. **One Level above Contracting Officer:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Jaimy Raul
Name Jaimy Raul
Title Supv. Contr. Spec.
Facility Erie VAMC/NCO4

7-30-2012

Date

- c. **Network Quality Assurance/Compliance Review:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

N/A


Name
Title
Facility

Date

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

Jaimy Raul

7-30-2012

 Network Contract Manager
VISN 4

Date 7-30-2012

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

N/A

David Fitzgerald
Director
Service Area Office, East

Date

- f. **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.

N/A

Norbert Doyle
Head of Contracting Activity (HCA)
Veterans Health Administration

Date

- g. **VHA Senior Procurement Executive Approval (over \$50 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 other than full and open competition.

N/A

Jan R. Frye
Deputy Assistant Secretary
Office of Acquisition and Logistics
Senior Procurement Executive (SPE)
Department of Veterans Affairs

Date