

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: 36C244-19-AP-3620

1. **Contracting Activity:** Department of Veterans Affairs, VISN 4, Cpl. Michael J. Crescenz Medical Center, 3900 Woodland Avenue Philadelphia, PA 19104. PR 642-20-1-025-0003
2. **Nature and/or Description of the Action Being Processed:**
This request is a new sole source requirement for the purchase of Cepheid MRSA testing kits to use with existing equipment and the provision of service on existing equipment. A firm fixed-price contract is anticipated and should include base year plus one option year.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:**
Laboratory analysis for detection of MRSA is performed using molecular PCR technology. The facility's existing system to perform these analyses is the GeneXpert Infinity48s, 48 Testing Site. This requirement is essential to providing patient care as all patients admitted to the medical center must have MRSA testing performed for infection control. Kits including Trichomonas, Flu/RSV, Carba R, and C. diff will need to be performed on the instrumentation and Cepheid is the only company where these kits can be purchased as well. The estimated cost is \$320,762.71 per year and the total estimated cost for the base year plus one option year is \$641,525.42 including reagents, equipment rental, and service.
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):**
Crescenz VA Medical Center requires characteristics proprietary to Cepheid's Rapid PCR testing system. Cepheid's testing provides a result within two hours where traditional microbiology testing for MRSA takes 48 hours to get a result. The Cepheid system is necessary to accomplish the VA initiative to provide rapid results for new admissions. Additionally, the Cepheid instrumentation allows for a wide range of testing including Trichomonas, Flu/RSV, Carba R. and C. diff which the facility will perform. No other vendors supply this wide range of testing kits for one piece of equipment. The equipment will also enable the completion of higher numbers of tests in less time because of enhanced automation.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**

The CO posted a Special Notice Intent to sole sources to FBO from 07/12/2019 to 07/22/2019 to allow industry to challenge the proposed limited competition. The ISS notice yielded no responses.

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

The CS will evaluate the vendor's offer against the IGCE, prior awards, and prior commercial invoices.

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

The technical team at Crescenz VA conducted research regarding the technical characteristics of the required items. The contracting specialist verified that the required items are exclusively produced and distributed by Cepheid.

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:

The posted Intent to Sole Source notice yielded no response.

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 currently the only vendor capable of meeting the Government's requirement.

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.

Sahil Patel
Core Laboratory Supervisor
CMC VAMC

7/3/2019

13. Approvals in accordance with the [VHAPM Part 806.3 OFOC SOP](#): This part if filled out by Contracting Staff as part of the Justification

- 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.

Ronald J. Kline
Contracting Officer
NCO4

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.

Darlene Seminko
Branch Chief
NCO4

Date

- c. **VHA SAO 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.

Name
VHA Head of Contracting Activity (HCA)

Date