DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA250-17-AP-14409

1. **Contracting Activity:** The Department of Veterans Affairs (VA), VISN 10, Louis Stokes Cleveland Veterans Affairs Medical Center (CLE VAMC), Pathology and Laboratory Medicine Service (PLMS), has a request for Cepheid reagents, test kits, and materials for their GeneXpert equipment.

   Transaction: 541-18-1-775-0001

2. **Nature and/or Description of the Action Being Processed:** Network Contract Office (NCO) 10 intends to award a new, firm fixed price, Indefinite Delivery, Indefinite Quantity, base plus four (4) option years contract to Cepheid. The request is for reagents, test kits, and materials for the PLMS GeneXpert equipment. Cepheid reagents, test kits, and materials are needed for various molecular tests on CLE VAMC patients including MRSA, CDIFF, STD Screen and Flu testing. 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.

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

   (a) Description of Supplies:

   Cepheid reagents, test kits, and materials are needed for various molecular tests on CLE VAMC patients including MRSA, CDIFF, STD Screen and Flu testing.

Description	Total Quantity
CDIFF/EPI KIT GX.IVD	16 Boxes of 120 Count
GENEXPERT CT/NG KIT	22 boxes of 120 Count
XPERT FII & FV CONNBINED KIT	25 boxes of 10 Count
XPERT MRSA KIT	67 boxes of 120 Count
GENEXPERT FLU KIT	46 boxes of 10 Count

(b) ESTIMATED DOLLAR VALUE: $436,646.30 for the base year and $2,412,746.42 with four (4) option years.

(c) REQUIRED DELIVERY DATE: December 22, 2017-December 21, 2018

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

( ) (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;

FAR 13.5 Simplified Procedures for Certain Commercial Items:

The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by 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): Cepheid is uniquely qualified to provide the reagents, test kits, and materials based on the following: Cepheid is the only source that can provide the specific reagents, test kits, and materials for the GeneXpert equipment currently in use by the PLMS at the CLE VAMC to perform C. difficile, N. gonorrhoeae, and C. trachomatis testing. The reagents are specific to the equipment used and alternate vendors cannot provide acceptable reagent systems. The reagents are only available through Cepheid. The vendor was selected based on the availability of the reagents that meet the specific parameters of the equipment (chemical and antibody make-up, configuration, size, shape, etc.). This ensures that the highest standard of accuracy and validation is maintained, as required by the Collage of American Pathologists (CAP) and The Joint Commission (TJC). This presents a compelling need to continue this procurement with Cepheid.

- The reagents, test kits, and materials are proprietary to Cepheid;
- Cepheid has no VA distributors for the reagents, test kits, and materials;
- The GeneXpert is only compatible with Cepheid cartridges, in which currently the service uses;

- The sample process is fully automated and integrated with an automated real-time PCR system;
- The equipment, reagents, test kits, and materials, contributes to ease of use, productivity, reproducibility and reduced turn-around time;
- The simplicity and ease of use of this system for true employability and sustainability;
- Batching is not required to achieve either operational efficiency or cost savings;
- Allows true 24/7 results;
- Random access capability;
- Closed system;
- Does not require separately processed controls with each run; and
- Utilizes primarily freeze dried reagent technology vs. liquid reagents; and LIS capability.

Accordingly, Cepheid is the only firm capable of providing the supplies described in Section three (3) above without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A Sources Sought was posted on FBO from October 4, 2017 through October 18, 2017 with two responses. The responses were from two (2) Service Disabled Veteran Owned Small Businesses (SDVOSB); Orion Services, Inc., and Veterans Healthcare Supply Solutions (VHSS). Both Contractors do not have authorized distributor letters, and are not authorized by Cepheid to distribute to the VA. Cepheid does not have distributors for VA, at this time.

   An Intent to Sole Source, 36C25018Q0060, was posted on FBO from October 20, 2017 through November 2, 2017 with no responses.

7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The offeror will be evaluated In accordance with (IAW) FAR 13.106-2, the quotation will be evaluated for the following factors: Price and Past Performance. A determination of price fairness and reasonableness will be determined IAW FAR Part 13.106-3(2)(ii) and FAR Part 13.106-3(2)(iii), a comparison of proposed price with prices found reasonable on previous purchases and current price lists.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was conducted by the Contracting Officer and the PLMS to identify available sources to meet the requirements as follows:

   FSS, GSA, FBO, Vetbiz and the internet were reviewed with no results. Based on the results of market research, the Government determined that there is only one contractor, Cepheid, that can provide the reagents, test kits, and materials necessary for patient care. There are no SDVOSB's at this time to distribute the supplies needed, at this time.

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:** A Sources Sought was issued on FedBizOpps on October 4, 2017 through October 18, 2017, requesting that parties express their interest in writing.

    Orion Services, Inc.
    65 Aspen Lake Dr. East
    Newnan, GA 30263
    Phone: 510-766-6671
    Email: david.diaz@orionservicesinc.com

    Veterans Healthcare Supply Solutions
    13949 Alvarez Road, Suite 300
    Jacksonville, FL 32218
    Phone: 904-638-5519
    Email: gpierc@vhss1.com

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**: Due to the technical risks, compatibility requirements of the existing equipment, and proprietary rights of Cepheid, there are no ways to eliminate the restriction of this requirement. If a future requirement for the same solution is identified, a full and open competition after exclusion of sources, shall be promoted amongst Cepheid resellers if there are subsequent acquisitions.

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.

KRISTINE A. DIXON 295934 Digitally signed by KRISTINE A. DIXON 295934 Date: 2017.11.22 08:10:54 -05'00'

Kristine A. Dixon — Date
Pathology and Laboratory Medicine Service (PLMS)V
VISN 10 Louis Stokes Cleveland VA Medical Center

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.

Gina P. Crank 209604 Digitally signed by Gina P. Crank 209604 Date: 2017.11.21 16:33:37 -05'00'

11/21/2017

Gina P. Crank — Date
Contracting Officer
Network Contracting Office (NCO) 10

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.

TERRY L. SPITZMILLER 394683 Digitally signed by TERRY L. SPITZMILLER 394683 Date: 2017.12.05 11:04:45 -05'00'

Terry L. Spitzmiller — Date
Director of Contracting
Network Contracting Office (NCO) 10

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.

Randy L. Hays 534204 Digitally signed by Randy L. Hays 534204 Date: 2017.12.18 13:16:53 -08'00'

Randy L. Hays — Date
Acting Director, SAO Central
SAO Central Head of Contracting Activity