

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: 36C249-19-AP-2313

1. **Contracting Activity:** Department of Veterans Affairs, VISN 09, NCO-9, and Lexington VA Medical Center. PR: 596-20-1-030-0024
2. **Nature and/or Description of the Action Being Processed:**
This is a new requirement under a firm-fixed price contract that the station will invoice against for the procurement of reagent supplies for testing on their Cepheid GeneXpert IAW FAR13.5 Simplified Procedures for Certain Commercial Items.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The reagent supplies expect to include MRSA(Methicillin Resistant Staph aureus), *C. difficile*, *hlamydia/Neisseria gc*, Influenza A & B/RSV and proprietary collection swabs/containers needed for those tests.

Estimated dollar value: \$300,000.00 per year. No options are considered. Length of contract is for one year, from 10/1/2019 – 9/30/2020.

4. **Statutory Authority Permitting Other than Full and Open Competition:** *41 USC §3304(a)(1), as implemented by FAR 6.302-1*, Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements

FAR13.5 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):** Only One Responsible Source (FAR 6.302-1): The Lexington VAMC owns an analyzer used for detection of MRSA in patient nares swab samples. The instrument is a Cepheid GeneXpert, and only Cepheid MRSA cartridges can be used on the instrument. The cartridges are distributed only by Cepheid, Inc. Other tests performed on the instrument include *C. difficile*, *Chlamydia/Neisseria gc*, and Influenza A & B/RSV. The collection containers/swabs for those tests are also specific to the Cepheid GeneXpert.

The test cartridges are placed directly into the Cepheid GeneXpert analyzer, where they are processed and read by the instrument. There are no other testing supplies available to meet this need. The sample collection devices must be compatible with the system, and Cepheid is the sole-source provider for these devices.

The MRSA test cartridges are an important part of the MRSA Surveillance program in Lexington, KY.

VHAPM Part 806.3 Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Sole Source Justification Format >SAT

Failure to order these supplies will result in unacceptable delays in testing patients for the presence of MRSA (methicillin Resistant Staph aureus). This test is used in the rapid identification of patients who carry MRSA, and is necessary to allow infected patients to be isolated quickly, before other patients are exposed to the MRSA. The other tests performed on the system are important to patient diagnosis and Infectious Disease surveillance.

Accordingly, Cepheid, Inc. is the only firm capable of providing the supplies and services described in Section 3 above without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition and unacceptable delays in fulfilling its requirements.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A Notice of Intent to Sole Source was posted on FBO.gov with no response from other vendors.
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated cost will be considered fair and reasonable as past buy history has shown since 2010 prices have not changed with the exception of the flu reagents. Certified cost or pricing data, technical evaluations, and audits will not be required as the procurement is for commercial items and is below the \$750,000.00 threshold.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** As described in Section 6 above, market research, in accordance with FAR Part 10, was conducted by synopsis of the proposed acquisition, advising industry of the pending acquisition and soliciting inquiries from interested parties."
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:** None.
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:** Until the station decides to procure a replacement for the currently used equipment there is nothing that will overcome the barriers to competition for the supplies requested.
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.

Vicki Richardson
Laboratory Manager
Lexington (KY) 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.

Contracting Officer
Branch Chief, Supply West
NCO-9

- 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.

Robert Kellner
Division Chief
NCO-9