

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: 36C256-18-AP-2422

1. Contracting Activity:

Department of Veterans Affairs, VISN 16, Central Arkansas Veterans Healthcare System Medical Center
2237 - 598-19-1-105-0036

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

CAVHS is requesting to purchase Cepheid GeneXpert Cepheid reagent cartridges and consumables for the performance of Molecular Microbiological testing on Government owned GeneXpert Systems. These reagents are required to perform testing for Clostridium difficile, Chlamydia trachomatis, Neisseria gonorrhoeae, MRSA, Factor II, Factor V and Flu testing. The test cartridges and consumables are equipment specific to the existing government owned equipment from Cepheid. No other test cartridges and consumables are compatible with the equipment.

This procurement request is for the Molecular Microbiological testing for the period FY19 October 1, 2018 - September 30, 2019.

This procurement action has been identified as a simplified acquisition for commercial items and will be conducted as a sole source acquisition according to FAR Part 13.501 with the emphasis on the special documentations and postings that are required.

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

CAVHS is requesting purchase of Cepheid GeneXpert Clostridium difficile, Chlamydia trachomatis, Neisseria gonorrhoeae, MRSA, Factor II, Factor V and Flu reagent cartridges and consumables for the performance of Molecular Microbiological testing on Government owned GeneXpert Systems.

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

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):

According to FAR 6.302-1 Only One Responsible Source can provide the Cepheid supplies because of the substantial duplication of cost to the Government that is not expected to be recovered through competition or unacceptable delays in fulfilling the agency's requirements.



[REDACTED] These are the only cartridges that can be used on existing Governments equipment. Cepheid does not use distributors for these items to Government accounts.

Past market research supports the sole source of this procurement action because of the non-compatibility of utilizing other reagents on the equipment or the expense of buying or leasing other equipment at the enormous cost to the Government.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

Past market research provided by other COs indicate that the Cepheid GeneXpert Clostridium difficile, Chlamydia trachomatis, Neisseria gonorrhoeae, MRSA, Factor II, Factor V and Flu reagent cartridges and consumables are not interchangeable with other machines nor would it be cost effective to purchase or lease other machines for the Cepheid GeneXpert Cepheid reagent cartridges and consumables because that procurement action could cause an enormous financial burden to the CAVHS and delay to patient care.

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

This procurement action has been a continuous need dating back from FY 17, FY 18 and currently FY 19. CAVHS has purchased the Cepheid equipment therefore the only cost to the Government is for the Cepheid GeneXpert Cepheid reagent cartridges and consumables and the comparison of past procurements shows that the current procurement action is fair and reasonable to the Government.

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

The VIP portal provided 84 potential SDVOSB and VOSB identified with NAICS code 334516 that could potentially provide the Cepheid GeneXpert Cepheid reagent cartridges and consumables, but prior research conducted by other COs for FY 17, & FY18 has shown that this unremitting requirement cannot be fulfilled with other reagent cartridges and consumables and that there will be enormous cost to the Government if new equipment is leased or purchased to replace the existing equipment.

This procurement action is being govern utilizing authority FAR 6.301 as only one responsible source being able to fulfill the requirement with minimum cost to the Government.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition.

This procurement action is being relied upon through the intense examination of the acquisition history and experience with the marketplace from previous acquisitions for the same items.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:


CEPHEID
904 CARRIBEAN DRIVE
SUNNYVALE, CA 94089-1189

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:

Future procurement actions should be researched to ensure that the market is still consistent with previous findings and perhaps examine the life cycle of the residing equipment to ensure that newer equipment could possibly provide better results, etc. with no major cost to the Government.

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

- 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.


Digitally signed by Monica
Blakely 292400
Date: 2018.09.30 09:48:26 -05'00'
Assistant Laboratory Manager
NCO 16

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.


Williams 335553
Date: 2018.09.26 16:25:13 -05'00'


NCO 16

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.



NCO 16


Date: 2018.09.28 14:18:32 -05'00'

