

**DEPARTMENT OF VETERANS AFFAIRS**  
**Justification and Approval**  
**For**  
**Other Than Full and Open Competition**

**1. Contracting Activity:** Department of Veterans Affairs, Network 16 Contracting Activity, Michael E. DeBakey VA Medical Center #580, VA Medical Center 2002 Holcombe Boulevard Houston, TX 77030  
# 580-18-2-026-0142

**2. Nature and/or Description of the Action Being Processed:** Cepheid GeneXpert System (Infinity) Xpert MRSA (120 tests/kit), Xpert MTB/RIF (10 tests/kit), Xpert C. difficile/Epi (10 tests/kit), XprsFLU/RSV-10 (10 tests/kit), Xpert Carba-R (10 tests/kit) and Xpert CT/NG (10 tests/kit).

These items are sole proprietary Kits and manufactured and sold only by Cepheid.

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

- 80 – REAGENT, MICRO ANALYZER, DETECTION, MRSA, XPERT, KIT, (120 TESTS/KIT)
- 180 – REAGENT, MICRO ANALYZER, DETECTION, C DIFFICILE/EPI, XPERT, (10 TESTS/KIT)
- 20 – KIT, INFECTIOUS DISEASE TESTING, AMPLIFICATION, MTB/RIF, XPERT, (10 TESTS/KIT)
- 5 – KIT, INFECTIOUS DISEASE TESTING, CT/GC, CARTRIDGE, 3 CONTROLS, (10 TESTS/KIT)
- 10 – CXCARBAR-10, (10 TESTS/KIT)
- 150 – KIT, INFECTIOUS DISEASE TESTING, FLU/RSV XPERT Xpress FLU/RSV, (10 TESTS/KIT))

**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):** Market research, as detailed in paragraph 8 below, shows that the required reagents are only available from Cepheid and that there are no equivalent items available on the market that would enable competition. As a result, it has been determined that this action must be solicited on a sole source basis in order to meet VA's need.

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

Please see paragraph #8 below which details the market research conducted in an attempt to find other sources that could potentially enable competition of this requirement.

**7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** This is a commercial acquisition so price risk is low, and prior to award price analysis will be conducted to ensure fair and reasonable pricing.

**8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** The VIP database was queried using the applicable NAICS code which revealed 76 SDVOSB/VOSBs and a SAM query revealed 173 SDVOSBs. On March 7, 2018 an RFI/Sources Sought notice was posted to FBO. The overall intent of the posting was to advise industry of the pending acquisition and to obtain information to support the formal procurement strategy by determining the availability of sources who could provide the exact brand name reagent or equivalent items that would enable competition. No responses were received. Based upon this market research it has been determined that to meet VA's need a sole source award will be made to 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:**

[REDACTED]

**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:**

Prior to awarding future acquisitions for the same or similar products, additional market research will be conducted to determine if market conditions have changed which would enable the competition of the 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.

2/15/2018

Date \_\_\_\_\_

### 13. 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.

Diyonne Williams  
Contracting Officer  
Network Contracting Office 16

Date \_\_\_\_\_

**b. VHAPM Part 806.3 OFOC SOP Approving Authority (One Level Above CO):** I certify the justification meets requirements for other than full and open competition.

[illegible]