

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

**1. Contracting Activity:** Department of Veterans Affairs, Central Arkansas Veterans Healthcare System, 2200 Fort Roots Drive, North Little Rock, AR 72114.

Pathology & Laboratory Medicine Service (P&LMS/113)

Transaction # 598-15-1-105-0067

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

The VAMC is requesting purchase of MRSA Molecular Microbiological test cartridges and consumables from Cepheid. 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 this equipment.

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

The VAMC is requesting purchase of MRSA Molecular Microbiological reagent cartridges and consumables from Cepheid. The test cartridges and consumables are equipment specific to the Cepheid equipment. No other test cartridges and consumables are compatible with the existing government owned equipment from Cepheid. The FSS contract expires on 10/31/14 and Cepheid is working with the NAC to procure a new contract for these items.

**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):**

GeneXpert Molecular Microbiological reagent test cartridges necessary to provide rapid turnaround time for bacteriological agents to aid in the management and prevention of Healthcare-Associated Infections (HAIs) on Government owned Cepheid equipment. The

reagent cartridges are single-use cartridges that contain the necessary reagents to perform the desired test. Using advanced microfluidics, all aspects of the testing process are handled within the sealed, disposable reagent cartridge chambers, from sample preparation and DNA extraction, amplification and detection. These are the only cartridges that can be used on the existing Government owned equipment. Cepheid does not use distributors for these items to Government accounts. Reagent cartridges and consumables are equipment specific. This sole source for the requirement is to ensure continuation of service for reagent cartridges and consumables to support P&LMS laboratory. The VAMC recognizes that the interruption in services would severely hinder patient care and treatment. An award to a new contractor would create a work stoppage within P&LMS while equipment has to be installed and personnel would have to be trained for utilization of said equipment.

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

Due to the nature of this requirement, no other reagent cartridges and consumables are compatible with the equipment.

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

Pricing will be analyzed against the independent government estimate and because this is a commercially available product it is anticipated the price will be fair and reasonable.

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

Due to the nature of this requirement and the reagent cartridges and consumables are equipment specific; there are no other reagent cartridges and consumables that will work on this equipment.

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

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

Cepheid

**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:**

The Agency will continue to utilize all the tools available in the marketplace to foster any future competition for this type of procurement. These reagent cartridges and consumables will be used with equipment specific.

**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.

X 

APPROVING OFFICIAL

**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.

  
CONTRACTING OFFICER  
NETWORK CONTRACTING OFFICE 16

**b. P&C:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

  
CHIEF, PURCHASING AND CONTRACTING  
NETWORK CONTRACTING OFFICE 16