

DEPARTMENT OF VETERANS AFFAIRS
VISN 6
Justification and Approval
For
Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 6, Centralized Acquisition Service (CAS) intends to execute a Justification for Other Than Full and Open Competition in support of the Durham, NC VAMC transaction number 558-14-3-678-0038.
2. **Nature and/or Description of the Action Being Processed:** This is a request for other than full and open competition for the procurement of laboratory molecular diagnostic analyzer kits to detect Tuberculosis(TB) and Rifampin (RIF) resistant TB. Requested product must work with the GeneXpert® equipment previously purchased from CEPHEID used in the Pathology Laboratory at the Durham VAMC. This is a new Firm Fixed Price Contract at a cost of \$61,572.00 with an estimated delivery date of 2 days after order is placed.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** GXMTB/RIF-US10 Kit, MTB, IVD, US. 120 Kits are needed at \$513.10 per kit. Total value of procurement is \$61,572.00 with an estimated 2 day delivery after order is placed. Addition of new reagent to enable existing GeneXpert lab equipment to rapidly detect tuberculosis in lab samples. Enhanced capability will reduce time from 24-72 hours (current status) to 1-2 hours, providing rapid diagnosis and rule-out capability to patients. This also protects VA staff from occupational exposure and precludes unnecessary use of isolation rooms and personal protective equipment. Cepheid is the sole-source supplier for Xpert® reagents to government purchases.
4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 USC §253(c)(1), as implemented by FAR 6.302-1.
 - (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):** Approval and funding were given by VHACO for this specific procurement. *This is the only product that works with the Cepheid® GeneXpert® Model XVI PCR molecular diagnostic analyzer used in the Lab at the Durham VAMC. This is a highly specialized piece of equipment and only the requested product will work with the existing equipment. The only Responsible Source is Cepheid. Cepheid is the original and sole manufacturer of GeneXpert® reagents, including the Xpert MTB-RIF reagent. Cepheid is also the sole distributor for government entities, excluding unincorporated US territories. As per letter from Cepheid attorney, Mary Ann Nguyen, dated 4/2/14.*

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** No other vendors were solicited since GXMTB/RIF-US-10 KITs, MTB, IVD, US are only compatible with the Cepheid GeneXpert® equipment used in the lab at the Durham, VAMC.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** A search of the Internet, GSA Advantage, and NAC website produced negative results. Cepheid's quote included a GSA discount. *The price to the government is \$513.10 per kit which is a 26.70% less than the \$700.00 per kit the public would pay. Therefore the price quoted to the government is fair and reasonable.*
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** *Cepheid is the sole manufacturer and sole distributor for the government for Xpert® reagents.*
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** It would not be cost effective to replace the existing GeneXpert® equipment currently used at the Durham VAMC.
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:** *No actions are planned to eliminate the single source for GXMTB/RIF-US-10 Kits used with the GeneXpert® equipment manufactured and distributed by Cepheid.*
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.
(This signature is the requestor's supervisor, fund control point official, chief of service, someone with responsibility and accountability)

Michael J. Boucher
210152

Digitally signed by Michael J. Boucher 210152
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07/28/2014

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