

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)

Acquisition Plan Action ID: VA261-16-AP-4282

- Contracting Activity:** Department of Veterans Affairs, VISN 21, VA Palo Alto Health Care System (VAPAHCS), 2237 No. 640-17-1-034-0002.
- Nature and/or Description of the Action Being Processed:** This is a new action to purchase infection test kits for the VA Palo Health Care System (VAPAHCS). The VAPAHCS is requesting a sole source requirements contract with Cepheid, Inc. for a base year and four option years due to the upcoming expiration (09/30/2016) of their current contract for this requirement. The current order was placed off of the contractor's VA FSS, Schedule 65 VIII NAC Contract (V797P-5967X). After reviewing this requirement, it was determined that the majority of the requested infection test kits are considered open market items. Therefore, this requirement will be procured as an open market order. The period of performance will be from 10/01/2016 to 09/30/2021.

FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for infection test kits in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.

- Description of Supplies/Services Required to Meet the Agency's Needs:** The VAPAHCS is requesting a contract for the infection test kits manufactured by Cepheid listed within the table below:

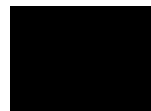
Description	Catalog Number	Manufactuer	Est Qty	Unit	Price	Extended Amount
Xpert MRSA, IVD (120)	GXM RSA-120	Cepheid	90	KT	\$	\$
Xpert C. Diff/Epi (10)	GXC DIFF/EPI-10	Cepheid	120	KT	\$	\$
Xpert Flu/RSV (10)	GXFLU/RSV -10	Cepheid	120	KT	\$	\$
Xpert Ct/NG, IVD (10)	GXCT/NG-10	Cepheid	150	KT	\$	\$
CT/NG and TV Swab Collection Kit	SWAB/A-50	Cepheid	50	KT	\$	\$
CT/NG and TV Urine Collection Kit	URINE/A-50	Cepheid	50	KT	\$	\$
Xpert MRSA/SA BC (10)	GXM RSA/SA-BC-10	Cepheid	150	KT	\$	\$
Xpert MTB/RIF (10)	GXMTB/RIF-US-10	Cepheid	200	KT	\$	\$
Xpert Carba-R, IVD (10)	GXC ARBAR-10	Cepheid	60	KT	\$	\$
Est Total						\$

NOTE: Xpert MRSA, IVD (120) is available under Cepheid's VA FSS, Schedule 65 VIII NAC Contract (V797P-5967X). All the other requested infection test kits are considered open market items.

These kits will be used in the Microbiology Lab at the VAPAHCS to diagnose VA patients for various infections. These clinical tests from Cepheid are required to run on a current Cepheid VA owned piece of equipment. The quantities listed within the table above are estimated. The requested infection test kits will be ordered on an "AS NEEDED" basis throughout the period of performance.

Estimated Dollar Value for the Period of Performance: [REDACTED]

Base year (10/01/2016 – 09/30/2017):
Option Year 1 (10/01/2017 – 09/30/2018):
Option Year 2 (10/01/2018 – 09/30/2019):



Option Year 3 (10/01/2019 – 09/30/2020):
Option Year 4 (10/01/2020 – 09/30/2021):
Estimated Total if all years are exercised



4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 USC §3304(a)(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.

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):** Previously, the VAPAHCS awarded a delivery order (VA261-16-F-2159) to Cepheid, Inc. on June 29, 2016 for a Polymerase Chain Reaction (PCR) Testing Instrument in response to a competitive solicitation (VA261-16-Q-0621) off of their GSA contract (GS-07F-0597T). The requested infection test kits for this requirement are also manufactured by Cepheid and are only compatible with the Cepheid PCR Testing Instrument due to the proprietary nature. No other manufacturer's infection test kits can be run on the Cepheid VA owned PCR Testing Instrument. Additionally, Cepheid does not have authorized distributors contracted to sell the requested infection test kits to VA Medical Centers. Therefore, Cepheid is the sole distributor and the only source capable of providing the requested infection test kits to the VAPAHCS.

Based on the aforementioned, Cepheid, Inc. has been identified as having a unique and innovative concept to solely provide the supplies due to the proprietary nature and compatibility requirement with existing VA owned Cepheid equipment IAW FAR 6.302-1.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** An RFQ (Sources Sought) (RFQ1090281) was issued via GSA eBuy and a Presolicitation Notice (VA261-16-N-0855) was issued via FBO on 07/19/2016 and closed on 07/29/2016. The notice included the requested infection test kits from Cepheid and indicated that the VA Palo Alto Health Care System (VAPAHCS) intends to negotiate a sole source contract with Cepheid, Inc. for a five (5) year contract for infection test kits. However, any firm that believed it could provide the required Cepheid infection test kits or a potential equal product, were encouraged to submit written notification to the Contract Specialist with for consideration before the close of the Sources Sought Notice. Cepheid emailed the contract specialist indicating that they could provide the requested infection test kits. No other sources expressed interest or provided a response to the sources sought notice.

Additionally, the contract specialist contacted Cepheid to confirm that they did not have any authorized distributors for the requested infection test kits. Furthermore, a search on VetBiz was conducted using the search term "infectiontestkits" in NAICS 3254133. The search produced no results.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** By signing this document the Contracting Officer is determining that the anticipated cost to the Government will be fair and reasonable. This requirement is for a

commercial item and is therefore exempt from requiring certified cost or pricing data. However, data other than certified cost or pricing data will be requested to ensure VA is receiving a fair and reasonable price for all open market items consistent with Cepheid's best commercial customer. The Xpert MRSA, IVD (120) infection test kit is available under Cepheid's VA FSS, Schedule 65 VIII NAC Contract (V797P-5967X). The contractor will be providing this kit as an open market item due to the estimated dollar value of the additional open market tests. The Contracting officer will ensure VA is receiving pricing for this kit consistent with the pricing listed on the contractor's GSA contract. The fixed prices for supplies and services listed under Cepheid's VA FSS NAC contract (V797P-5967X) have already been determined to be fair and reasonable by GSA. Therefore, ordering activities are not required to make a separate determination of fair and reasonable pricing. However, the VA will seek additional discounts when negotiating the sole source action for this kit.

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. Additionally, a search on VetBiz.gov was conducted for SDVOSB/VOSB sources that resulted in no sources being identified.

Since the Government owns an existing Cepheid PCR Testing Instrument, it has been determined and confirmed that only Cepheid manufactured infection test kits are compatible due to the proprietary nature. Therefore, no other infection test kits manufactured by another source would be compatible with existing VA owned Cepheid equipment. Furthermore, Cepheid has confirmed that it does not have any authorized distributors contracted to sell the requested infection test kits to the VA.

Based on the market research conducted, Cepheid is the only source capable of providing the requested infection test kits that are compatible with existing VA owned Cepheid equipment.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition: Specifications, engineering descriptions, statements of work, statements of objectives, or purchase descriptions suitable for full and open competition are not being used because VA has determined that only Cepheid can provide the infection test kits which VA requires.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: Cepheid has expressed interest in the acquisition. No additional sources expressed interest in the acquisition.

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 follow-on competitive acquisition is planned at this time. However, VA will continue to monitor the commercial marketplace to determine if other sources are capable of providing infection test kits that can be run on Cepheid VA Owned equipment. Additionally, the VA will solicit a competitive acquisition when the existing VA owned Cepheid is required to be replaced.

