

Attachment 2: Request for Sole Source Memo Format

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. Contracting Activity: Department of Veterans Affairs, VISN 8, James A. Haley VA Medical Center. Pathology and Laboratory Medicine Service. 2237-673-14-1-023-0002.
2. Nature and/or Description of the Action Being Processed: This is a Firm Fixed Price Procurement. The cytology department of Pathology and Laboratory Medicine Service requires an automated cytology processor to generate slides that contain a single layer of cellular material free of debris and of the high degree of quality necessary to diagnose malignancies and disease.
3. Description of Supplies/Services Required to Meet the Agency's Needs: Cytology processor(s) and all consumable and reagents required to process 2500-3000 specimens. Consumables and reagents include, but are not limited to, filters, slides, vials, and preservative solutions. Training, on-site service, an operator's manual, and all shipping/freight charges are included in the cost of the contract. Total estimated costs is \$148,699.00
4. Statutory Authority Permitting Other than Full and Open Competition: The James A Haley Veterans' Hospital intends to solicit and negotiate with only one source for this contract under the authority of FAR Subpart 6.302-1. Only one responsible source and no other supplies or services will satisfy agency requirements.
 - () {1} Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
 - (X) (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): Market research yielded only two manufactures of automated cytology processors. The Hologic processor is superior for our needs based on the following criteria.

Processing: Hologic Thin Prep vials are ready to process through an automated system immediately after collection. The BD SurePath system requires 13 time-consuming preparatory steps including two centrifugations, decanting, and vortexing prior to loading onto the processor.

Automation: The Hologic Thin Prep system has the capability to run any sample one at a time using a vial, filter, and slide. The BD SurePath system is intended for large volumes. It processes 48 sample containers regardless of how many samples are present. Therefore, the reagents required to process 48 specimens are used even if only one specimen is processed through the system.

Capability: Gynecological specimens cannot be processed at the same time as non-gynecological specimens. This would result in both processing delays and additional wastage of reagents.

The SurePath system requires a second vial to be collected to perform HPV reflex testing. The HPV reflex testing can be performed on the same vial with the ThinPrep system.

Stability: The websites of four large national laboratories that offer HC2 testing of referred SurePath samples all indicated that SurePath samples are stable at room temperature for::: 1month compared to 90 days/3 months for the FDA-approved ThinPrep vial.

Safety: Human papillomavirus testing with the SurePath HC2 hrHPV test has not been approved by FDA. BD recently sent out a technical bulletin stating, "The BD SurePath sample medium has not been approved by FDA for use with the HC2 Test and use of the SurePath sample may under certain conditions provide false negative results. False negative results could lead to inappropriate patient management and potentially compromise patient safety." An article in *Drug, Healthcare and Patient Safety*, {2012:4}, states, "An avoidable increase in false negative hrHPV results in women with both precancer and early invasive cervical cancer will place patients at unnecessary risk."

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

Market research and a survey of VISN 8 and other VA/DOD facilities indicate that there are two manufacturers of cytology processors, Bectin Dickinson (BD) and Hologic. All VA, military, and Department of Defense installations use the Hologic Thin Prep in their cytology departments. There decisions were based on similar criteria that are listed in item #5.

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

The anticipated price to the Government is \$148,699 for one year period. The equipment rental cost and service is included in the reagent pricing. Previous contract VA248-P-1383/ VA248-13-J-2398 for \$61, 087.00 was for six month but did not include shipping charges that Hologic now charges. Also for comparison a recent PO (VA248-13-P-6303) was issued.

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

The following websites were used to determine if other vendors or small businesses could offer the Hologic instruments. www.marketresearch.com, www.usaspending.gov, <http://dsbs.sba.gov>, and www.thomasregister.com. Internet searches and expert opinions were also utilized in the market research. A cytotechnologist who has experience working with both systems provided input on the pros and cons of each. No small business or distributor was found that could supply an automated cytology processor. Market research indicated that the Hologic ThinPrep would meet our needs in a much greater capacity than the BD SurePath. Market research documentation is on file.

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

The Hologic Thin Prep processors have been used in our facility for several years. All staff, including nurses, physicians and employees located at the CBOCs are fully trained in the use of the Thin Prep system.

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

Bectin Dickinson (BD) responded to a request for information.

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 Government shall post a notice on Federal Business Opportunities that permits prospective vendors to submit their respective technical capabilities for consideration in future acquisitions for similar equipment, supplies, and service.

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.

Nancy Hartline
Nancy Hartline, MT(ASCP), SH, MBA
Chief Medical Technologist
James A. Haley VA Hospital

10-31-2013
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.

Ronald D. Music
Name Ron Music
Title C.O. Team Lead
Facility JAHVH

17 Dec 2013
Date

- PLS (upto SAT)
b. NCM/PCM (Required \$3K and above): I certify the justification meets requirements for other than full and open competition.

Karen P
Name
~~Network Contract Manager~~
~~VISN/PCAX~~ PLS Tampa
Commodities
Title
Facility

19 DEC 2013
Date