

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval For

Other than Full and Open Competition

1. Contracting Activity: The U.S. Department of Veterans Affairs, VISN 18 Network Contracting Office, located at 3601 S. 6th Ave, Tucson, AZ 85723, proposes to enter into a firm-fixed purchase order on the basis of justification for other than full and open competition for the Southern Arizona VA Health Care System (SAVAHCS). The Purchase request number is 678-12-2-053-0399.

2. Nature and/or Description of the Action Being Requested: This is a new procurement and the contract contemplated will be sole source firm-fixed price purchase order to Cytoc Corp/Hologic, 250 Campus Drive, Marlborough, MA 01752-3064.

3. Description of Supplies/Services Required to Meet the Agency's Needs: This requirement is to provide SAVAHCS with pap smear test kits used in Cytology as part of Liquid-based Cytology Technology using the ThinPrep 2000 Instrument which is used primarily to detect premalignant and malignant lesions of the uterine cervix and other abnormalities of the female reproductive tract and to perform Reflex Human Papillomavirus Virus (HPV) testing. The ThinPrep collection test to be purchased includes: 500 filters, 500 glass slides, 500 plastic spatula and brush or broom-like device protocol with 500 vials containing a PreserveCyt solution, packaged specifically for use with the collection and preservation of gynecological specimens and materials necessary for the operation of the ThinPrep 2000 instrument. The test kits are used for direct patient care by the Cytology Section of the Anatomic Pathology Service, Diagnostic Service Line at SAVAHCS.


Five cases of the test kits are needed to support scheduled appointments within the medical facility. Five cases should be a year's worth of supplies for this station.

4. Statutory Authority Permitting Other than Full and Open Competition: 41 USC §253(c)(2), 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 per 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): The Cytyc Corp/Hologic pap test kits are the only kits that are compatible with the ThinPrep 2000 Instrument that is used within the SAVAHCS facility. The ThinPrep 2000 Processor is an automated slide preparation unit used with the ThinPrep Pap test for cervical cancer testing. The ThinPrep 2000 can also be used for non-gynecological specimens such as for the diagnosis of cancers of the lung, bladder, and gastrointestinal tract, and in the preparation of fine needle aspiration of the thyroid and breast. Further, specimen collection is a critical component of obtaining adequate and representative samples for analysis. The Cytyc/Hologic pap kits are specifically designed to optimize specimen collection and work in conjunction with the capabilities of the ThinPrep 2000. Kits manufactured by other companies are not compatible with the ThinPrep 2000 and therefore are not a viable option for conducting the necessary cell screening.
6. Description of efforts made to ensure that offers are solicited from as many potential sources as deemed practicable: A search of the internet as well as GSA eLibrary. The GSA eLibrary contains services for lab testing in the field of Cytology; however, lab testing services are not needed for this acquisition. Only the supplies to be used in gathering specimens and transporting them for lab testing are needed under this acquisition. Pap kit supplies were found on GSA Advantage; however, none were found to be compatible with the ThinPrep 2000. Similarly, through multiple searches, using internet search tools, on the Internet no pap kits (other than the Cytyc/Hologic pap kits) were found to be compatible with the ThinPrep 2000. A solicitation was posted on FedBid (Buy # 424928) and Federal Business Opportunities, and several vendors responded that Cytyc/ Hologic told them that they are the only provider of these items and that this product is not available through any other distributor.
7. Determination by the Contracting Officer that the anticipated cost to the Government will be Fair and Reasonable: The anticipated dollar value for this annual contract action is \$28,500.00. The price per case is \$ 5625.00 which compares favorably to the published catalog price of \$5,625.00. There is adequate acquisition history up to 23 Jul 2012 that demonstrates the price paid for this item was \$5,625.00. A quote will be received and the actual price will be compared to the previous acquisitions to determine price reasonableness in accordance with FAR 13.106-3(a)(2)(ii).
8. Description of the market research conducted and the results, or a statement of the reasons market research was not conducted: FAR Part 10 directs that market research be conducted on each acquisition appropriate to the circumstances. A search of the internet as well as GSA eLibrary was conducted. The GSA eLibrary contains services for lab testing in the field of Cytology; however, lab testing services are not needed for this acquisition. Only the supplies to be used in gathering specimens and transporting them for lab testing are needed under this acquisition. Pap kit supplies were found on GSA Advantage; however, none were found to be compatible with the ThinPrep 2000. Similarly, through multiple searches, using internet search tools, on the Internet no pap kits (other than the Cytyc/Hologic pap kits) were found to be compatible with the ThinPrep 2000. Previous acquisitions were examined for acquisition information and other possible sources to no avail.


9. Any other facts supporting the use of Other than Full and Open Competition: Market research, as described in paragraphs 6 and 8 above, yielded no results for other pap kit manufacturers whose products are compatible with the ThinPrep 2000. Posting on FedBid and FBO also revealed similar results. Previous acquisitions for this item have been of a sole source nature justified in accordance with VA policy and procedures.
10. Listing of sources that expressed, in writing, an interest in the acquisition: No advertising was performed due to the findings of the market research activity.
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 laboratory staff will continue to evaluate new technology as well as the development of kits by other manufacturers that are compatible with the Cyctyc/Hologic ThinPrep 2000.
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.


Susan T. Page, Chief Medical Technologist
Diagnostic Care Line
Southern Arizona VA Health Care System

09/26/2012
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.


Daniel C. Thiel
Contracting Officer
VISN 18 NCO, Tucson, AZ

Date

26 SEP 2012

- b. VISN/PCA OA (Required \$3K and above): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

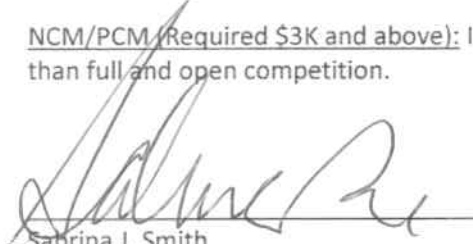

VISN18 QA/COMPLIANCE PROCUREMENT ANALYST

Paulette Pereira
Procurement Analyst
VISN 18 NCO

Date



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


Sabrina J. Smith
Network Contract Manager
VISN 18 NCO


Date