



**Department of Veterans Affairs
SAO West, Network Contracting Office (NCO) 19
Rocky Mountain Acquisition Center
6162 South Willow Drive, Suite 300
Greenwood Village, CO 80111**

**Brand Name for Hologic's Inc.
Reagents, Consumables and Supplies**

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

Acquisition Plan Action ID: VA259-17-AP-8467

1. Contracting Activity: Department of Veterans Affairs (VA), NCO 19 Contracting Office in support of the Eastern Colorado Health Care System (ECHCS), Denver VA Medical Center (VAMC), 1050 Clermont Street, Denver, CO 80220: Future name and location Rocky Mountain Regional VA Medical Center (RMR VAMC), 13611 E. Colfax Avenue, Aurora, CO 80045. In support of the Denver VAMC Pathology and Laboratory Medicine Services (P&LMS). The Purchase Request for this action is Transaction Number (2237): 554-17-3-023-0759.

2. Nature and/or Description of the Action Being Processed: The Contractor Hologic, Inc Brand Name (BN) reagents, consumables and supplies are required for operation of VA-Owned Hologic's Thin Prep (TP) processors in the Denver VAMC Laboratory the gynecologic and non-gynecologic services. The reagents, consumables and supplies being requested are specifically for the successful operations of the manufactured Hologic's processors models TP2000 and TP5000.

2.1. This contemplated contract action is a follow-on contract supplies requirement, and the type of contractual strategy is to award a firm-fixed price Blank Purchase Agreement action with a base year (12 months) with four (4) inclusive option years (5 years total).

2.2. Restricted to the following source: In the existing Contract VA259-12-C-0316 dated September 30, 2012, the Denver VAMC previously purchased the Hologic's Thin-Prep processors to perform these tests and their results in-house. Presently this contract will expire September 29, 2017, and now the VA-Owned processors are still in operation (10-year life span). To maintain the successful operations of these laboratory instruments and test results—the brand name reagents consumables and supplies must be acquired and utilized.

2.3. FAR13 Simplified Procedures for Certain Commercial Items: This procurement is for Gynecological and Non-gynecological supplies which will be acquired in accordance with FAR 13 Simplified Procedures for Certain Commercial Items, 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.

3. Description of Supplies/Services Required to Meet the Agency's Needs: The Contractor Hologic shall provide Thin Prep Processor gynecologic and non-gynecologic cytology testing reagents, consumables and supplies with an estimated value base year value at \$47,074.00, and aggregated total value \$235,204.50 for five years (Base plus four years). Similar items that are not Hologic Thin Prep

specific brand will not be accepted, as they may not be compatible for usage in the VA-Owned Hologic's instruments. This especially applies when other than brand name items may damage the instruments and/or desired end state laboratory test results are not attained.

3.1. The estimated period of performance for this contemplate contract delivery is for 09-30-2017 through 09-29-2022. The actual delivery dates shall be coordinated with the Denver VAMC P&LMS Contract Manager and the Contractor within scope of all period of the total period of performance of this acquisition.

3.2. The required Thin Prep brand name reagents, consumables and/or supplies are as follows:

| Product Name/Description | Part # | Estimated Annual Volume |
|---------------------------------------|---------------|--------------------------------|
| Thin Prep Pap Test Kit | 70096-003 | 3 test kits |
| Preservcyt Solution Vials | 234005 | 25 boxes |
| Cytolyt Solution Prefilled (30 ml) | 236080 | 11 boxes |
| Cytolyt Solution Bottles (32 oz) | 236004 | 2 boxes |
| Preservcyt Solution (32 ox) | 234004 | 3 boxes |
| Non-gynecologic filters | 70205-001 | 12 trays |
| Thin prep microscope slides | 70372-001 | 10 boxes |
| Cytolyt Solution Collection Cups | 236050 | 1 box |
| ThinPrep Urocyte Filters | 70472-001 | 1 box |
| ThinPrep Urocyte Microscopic Slides | 70471-001 | 1 box |
| ThinPrep Urocyte Preservcyt Vials | 70991-001 | 1 box |
| ThinPrep Urocyte Urine Collection Kit | 70908-001 | 1 kit |
| ThinPrep pap test kit w/ brooms | 70096-001 | 1 box |
| Broom Collection Device | 70101-001 | 1 kit |
| Cytobrush/spatula Collection Device | 70124-001 | 1 kit |
| Base Liners | 70280-001 | 1 box |
| HPV Invader HR Molecular Assay | 95-438 | 5 kits |

4. Statutory Authority Permitting Other than Full and Open Competition:

- (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): The Hologic's Thin Prep processors are owned by ECHCS Denver VAMC, and substituting to another brand or like items would

cost over \$100,000.00 in upfront costs and additional costs in training, in which, this would not be cost effective and not in the best interest of the Government.

5.1. The Manufacturer and Distributor Hologic only allows its own brand (Hologic Thin Prep) of reagents, consumables and supplies to be utilized to operate the Hologic's Thin Prep TP2000 and the TP5000 processors proper operational functionality.

5.2. These brand name reagents, consumables and/or supplies cannot be substituted by like items as it may cause errors and results in damage to the equipment. Hologic Inc, is the only authorized distributor of Hologic Thin Prep supplies; moreover, the Contractor Hologic advised the Denver VAMC and Contracting Officer not to use off-brand reagent and supplies can damage the Thin Prep processor to include the accuracy of the test results.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable: There were a Request for Information (RFI)/Sources Sought Notice sent out on GSA e-buy and a Sources Sought Synopsis sent out on FBO.gov to rule out the VA's Rule of Two SDVOSB / VOSB Set-aside process—to see if there were any qualified SDVOSB/VOSB's in the market place that offer these brand name supply items.

6.1. There were no responses received from SDVOSB/VOSBs within the GSA e-buy of showing interest in this contemplate procurement. One SVOSB responded to the Sources Sought on FBO.gov—M&D Medical claiming to be the one and only small business affiliated distributor of these supplies, but the Hologic representative conveyed and concluded unreservedly that Hologic is the only authorized manufacturer and distributor of the supplies required to operate the Thin Prep processors.

6.2. The NCO19 Small Business Liaison conducted a FED Mine check to confirm the Contracting Officer's market place findings and rationale—that there was no small business socioeconomic concerns available to meet these brand name Hologic Thin Prep supply requirement. Therefore, the Hologic Inc is the only responsible source capable of meeting this Denver VAMC P&LMS procurement need.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable: This proposed procurement will be a FAR 13 buy, and the anticipated cost will be considered fair and reasonable prior to award with a price reasonableness determination. The basis for the determination will be based on combination of 1) comparison of proposed pricing of previous pricing found reasonable; 2) current advertising (catalogs, pricing list); 3) comparison of IGCE; and 4) Contracting Officer's personal knowledge of the items being purchased.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted: The Rule of Two Set-aside determination process was conducted by researching the GSA E-Buy, VIP, SBA, and FBO.gov—to include a FED Mine report from the NCO19 SBL. These market research processes revealed no other responsible sources that could meet this brand name Hologic Thin Prep gynecological and non-gynecological reagent, consumables and supplies for the VA-Owned TP2000 and TP5000 processors. The only responsible source is Hologic Inc Thin prep products, and under these circumstances—only these brand name products will satisfy the Denver VAMC P&LMS needs. Therefore, market research results have validated and confirmed a high level of confidence that no other qualified sources exist that could successfully meet this supply requirement.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition: The previous purchased Hologic Thin Prep instrument processors must be maintained to provide the most optimal

operations practicable, and any substitute products and /or supplies will risk the required reliability and the accuracy of the laboratory equipment and test results. Hologic is the only authorized manufacturer and distributor of the Thin Prep supplies required to effectively operate the VA-Owned Thin Prep 2000 and the 5000 processors.

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

10.1. M&D Medical -SDVOSB (Open Market): Conveyed that they are the only SDVOSB affiliated Hologic Inc. that can provide and distribute the Thin Prep supplies (not factual).

10.2. Hologic, Inc (Incumbent) – Large (Open Market): The only authorized manufacturer and distributor of the supplies required to operate the Thin Prep processors (see attachments).

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: In the future, the NCO 19 will monitor when other like items are satisfactory products and supplies become available to assess to see if full and open competition is appropriate. If no satisfactory substitutes are found to be compatible to successfully operate with these specific Thin Prep processors the sole source (brand name supplies) efforts will remain in effect. This sole source brand name supplies will be required for the planned processors life expectancy (10 years) and/or the time remaining within the totality of this procurement action.

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.

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| _____ Name Kevin Ibershoff Title: P&LMS Contracts Manager Facility: Denver VAMC | 09-06-2017 _____ Date |
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13. Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.

13.1 Contracting Officer or Designee's Certification (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

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| _____ Name: Edward E. Marshburn Title: Contracting Officer NCO19 | 09-06-2017 _____ Date |
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13.2. Director of Contracting /Designee (Required over\$150K but not exceeding \$700K): I certify the justification meets requirements for other than full and open competition.

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| _____ Name: Bai Perney Title: Branch Chief, Services II NCO 19 | 9/7/2017 _____ Date |
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(End of the JOTFOC)