

Date: 26 Mar 2014

Procurement Action: 2268 Package

Description of Supply or Service: Reagents, Stains +
Antibodies for Cancer Diagnosis

Submitted by

Division and Team: Supply DIV II
Michael Lewis

Contracting Officer: Paul Gilhol

Action Required: Review & Signature

Comments:

Done - JGalt
3/27/14 11:03
Scanned & emailed

Please return to me after you have signed.

Thank you!

Felecia McIntosh

Department of Veterans Affairs		SMALL BUSINESS PROGRAM AND CONTRACT BUNDLING REVIEW		OSDBU CONTROL NUMBER	
CONTRACTING ACTIVITY AND PROGRAM OFFICE DATA					
1A. CONTRACTING ACTIVITY NCO 16 Division II Supply Station 502 ALEXANDRIA VAHCS			1B. ADDRESS (Include Street, City, State and Zip Code) 2495 Shreveport Highway Bldg 5 Rm 212 PINEVILLE LA 71630-9004		
1C. TELEPHONE NUMBER (Including Area Code) 318-466-4206			1D. CONTRACTING POINT OF CONTACT NAME AND EMAIL ADDRESS PAUL FILHIOL paul.filhiol@va.gov		
2A. NAME AND ADDRESS OF PROGRAM OFFICE GULF COAST VA HEALTH CARE SYSTEM Laboratory Building 3 Rm 3B101 400 Veterans Avenue BILOXI MS 39531			2B. PROGRAM MANAGER NAME AND EMAIL ADDRESS MARTHENA W GETHERS Marthena.Gethers@va.gov		
			3. REVIEW TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> MODIFICATION		
PROCUREMENT DATA					
4. DESCRIPTION OF SUPPLIES OR SERVICES REAGENTS, STAINS, AND ANTIBODIES FOR CANCER DIAGNOSIS TO BE USED WITH LABORATORY ANALYZER BRAND NAME VENTANA		5. EST. DOLLAR VALUE A. BASE YEAR B. TOTAL \$46,024.64 \$46,028.64		6A. NAICS AND SIZE STD. 325413 /500 Employees	6B. PSC 6550
7. SOLICITATION NUMBER VA256-14-Q-0668	8. PERFORMANCE PERIOD N/A	9. EST RELEASE DATE 03-27-2014	10. EST AWARD DATE 03-27-2014		
11. PROPOSED METHOD OF PROCUREMENT (Check all that apply)		<input checked="" type="checkbox"/> SOLE SOURCE <input type="checkbox"/> SET-ASIDE <input type="checkbox"/> PARTIAL SET-ASIDE <input type="checkbox"/> SDVOB <input type="checkbox"/> HUBZONE <input checked="" type="checkbox"/> UNRESTRICTED-INSUFFICIENT SMALL BUSINESS (Attach justification) <input type="checkbox"/> VOSB <input type="checkbox"/> 8(a) <input type="checkbox"/> FEDERAL SUPPLY SCHEDULE (FSS) NAME/# <input type="checkbox"/> WOSB <input type="checkbox"/> SMALL BUSINESS <input type="checkbox"/> MULTIPLE AWARD CONTRACT, TYPE/# <input type="checkbox"/> EDWOSB <input type="checkbox"/> OTHER (Affiliate, Ability One, etc.)			
12. MARKET RESEARCH/PUBLICATION EFFORTS <input type="checkbox"/> POSTED FCO <input type="checkbox"/> SOURCES SOUGHT <input type="checkbox"/> DSBS <input type="checkbox"/> RFI <input type="checkbox"/> FBO <input type="checkbox"/> VIP <input type="checkbox"/> GSA EBUI <input type="checkbox"/> SAM <input checked="" type="checkbox"/> FPDS		13. MARKET RESEARCH RESPONSES (Actual Number) — SDVOB — VOSB — WOSB/EDWOSB — SDB/8a — HUBZONE — SMALL BUSINESS — LARGE BUSINESS — 1 OTHER			
14. IPT REQUIRED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	15. PCR ASSIGNED? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	16. BUNDLING CHECKLIST REQUIRED? (Attach VA Form 2268a) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		17. SUBCONTRACTING PLAN REQUIRED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	
PROCUREMENT HISTORY					
18. WAS ITEM PREVIOUSLY AWARDED? <input checked="" type="checkbox"/> YES (Complete 19-23) <input type="checkbox"/> NO (Skip to item 24)	19A. CONTRACTOR NAME AND ADDRESS VENTANA MEDICAL SYSTEMS, INC. 1910 E INNOVATION PARK DRIVE TUCSON AZ 85737-1962		19B. BUSINESS TYPE <input type="checkbox"/> SDVOB <input checked="" type="checkbox"/> SMALL BUSINESS <input type="checkbox"/> OTHER <input type="checkbox"/> VOSB <input type="checkbox"/> WOSB <input type="checkbox"/> HUBZONE <input type="checkbox"/> SDB/8a <input type="checkbox"/> EDWOSB <input type="checkbox"/> LARGE BUSINESS		
20. DOLLAR VALUE \$46,028.64	21. PERIOD OF PERFORMANCE 07-01-2001 - 10-18-2013	22. NAICS/SIZE STD. 325413 /500 EMPLOYEES		23. PROCUREMENT METHOD FSS GS-24F-0043M	
24. COMMENTS The Biloxi VAMC Laboratory had been obtaining proprietary Antibody, Stain, and Reagent Packs from Ventana via GSA FSS GS-24F-0043M awarded to Ventana, which was then a SB. Ventana was acquired by Roche Holdings, AG, and lost their SB status. The GSA Contract was cancelled in Oct 2103. There has not been time to establish a new procurement strategy. Laboratory is currently out of supply and only able to operate on borrowed stock from local facilities.					
COORDINATION/CONCURRENCES					
25. CONTRACTING OFFICER (Print), SIGNATURE PAUL FILHIOL			DATE SIGNED 03-24-2014		
26. HEAD OF CONTRACTING ACTIVITY (HCA) OR DELEGATE (Print), SIGNATURE AARON VILLALPANDO			DATE SIGNED 3/27/2014		
27. SMALL BUSINESS LIAISON (Print), SIGNATURE MICHAEL E. LEWIS michael.lewis@va.gov			DATE SIGNED 25 Mar 14		
28. VA OSDBU REPRESENTATIVE (Print), SIGNATURE (Attach narrative documenting reasons for non-concurrence and recommendations)			<input type="checkbox"/> CONCUR <input type="checkbox"/> NON-CONCUR		DATE SIGNED
29. SUBCONTRACTING GOALS (%) — SDVOB — VOSB — HUBZONE — SDB — WOSB — SB					
30. NAME AND EMAIL ADDRESS OF SBA PCR (If assigned): Valerie Coleman valerie.j.coleman@nasa.gov			31. OTHER APPROVING AUTHORITY (as required):		DATE SIGNED

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

1. **Contracting Activity:** Department of Veterans Affairs, VISN 16, VA Medical Center- Biloxi, MS VA Medical Center, 400 Veterans Blvd, Biloxi, MS 39531. The Purchase Request Number is 520-14-2-077-0152.
2. **Nature and/or Description of the Action Being Processed:** Justification of Other Than Full and Open Competition for a Firm Fixed-Price, Open Market Purchase Order solicited Sole Source to an Other Than Small Business, under \$150K IAW FAR 13.106-1(b). This will be a new PO and not a modification to a previous order.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:**
 - a. **The antibodies** required for the Ventana instrumentation are intended to standardize the processing of tissue specimens for diagnostic evaluation by pathologists. The antibodies required are equipment specific and no other supplies can be substituted..
 - b. **The reagents and supplies** for the Ventana instrumentation are intended to standardize the processing of tissue specimens for diagnostic evaluation by pathologists. These reagents are optimized and validated for use on the NexES Special Stains Instrument and are configured specifically for this instrumentation.

The 2237 Purchase Request is attached which describes the 86 line items required for this procurement.

Estimated Value: \$46,000.00

Transaction Number: 520-14-1-077-0046

Estimated Delivery Date: 3-31-2014

Required Delivery Date: The laboratory ran out of supplies on 3-21-2014

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

(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):**
 - a. **Only One Responsible Source {FAR 6.302-1} – The antibodies** required are equipment specific and no other supplies can be substituted. This is a sole source justification for the requirement to ensure continuation of service of the pathology and laboratory at Biloxi VAMC. This service recognizes that the interruption in services would severely hinder patient care and treatment. A delay in receiving the required reagents could cause further illness and potentially cause a Veteran's death if the laboratory is not able to analyze the specimens in a timely manner.

The pre-dilute, ready to use IVD antibodies for the Ventana instrumentation are intended to standardize the processing of tissue specimens for diagnostic evaluation by pathologists. The following antibodies used in this histological process are required, based on vendor availability or clone availability, to be purchased through Ventana Medical Systems. The CINtec p16 antibody is an IHC assay used for the qualitative detection of the p16 protein in cervical biopsies. This product is intended for in vitro diagnostic use (IVD) and should be evaluated by a qualified pathologist. This antibody is only offered through Ventana. No other vendor offers this product.

A delay in receipt of the required supplies would result in an interruption of processing, and the inability to deliver patient results. The Ventana system and supplies, when used in conjunction, are an FDA approved solution for the clinical diagnosis of patient samples at VA Medical Center Biloxi.

b. **The staining kits and bulk reagents** required by the Ventana NexES Special Stains Platform are equipment specific and no other supplies can be substituted in the processing of histological specimens.

No other staining kits fit on this instrument. Reagents and supplies for the Ventana instrument are designed to standardize the preparation and staining of cells mounted on a microscope slide for examination by pathologist.

A delay in receipt of the required supplies would result in an interruption of processing, and the inability to deliver patient results. The Ventana system and supplies, when used in conjunction, are the only FDA approved solution to be used on the Ventana equipment at VA Medical Center Biloxi. No other contractor is able to provide an FDA approved solution for the Ventana NexES equipment.

Reagents and supplies are equipment specific. This is a sole source justification for the requirement to ensure continuation of service for staining kit reagents to support the pathology and laboratory at

Biloxi VAMC. This service recognizes that the interruption in services would severely hinder patient care and treatment. A delay in receiving the required reagents could cause further illness and potentially cause a Veteran's death if the laboratory is not able to analyze the specimens in a timely manner.

The instrument used in histology for the staining of special slides that are specimens obtained typically during a surgical procedure will only accept this particular stain. No other stain is compatible with this equipment.

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

The VA Prime Vendor does not manufacture these items nor can they provide these items.

Internet search for these particular products do not reveal acceptable alternatives. This vendor is the sole manufacturer and only sells direct.

As technology becomes available, research will be performed to consider other products that meet or exceed the current requirements. The notice required by FAR 5.201 will be published.

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

Anticipated cost will be considered fair and reasonable and provide the basis for this determination IAW FAR Part 13.106-3(a). The cost of these supplies is consistent with industry standards for other pathology antibodies and supplies to be acquired for other machines.

One or all Price analysis techniques will be used to verify that the overall price offered is fair and reasonable:

- a. Comparison of previously proposed prices and contract prices with current proposed prices for the same or similar service.
- b. Comparison of proposed prices with independent Government cost estimates.
Comparison of proposed prices with prices obtained for maintenance services on similar medical

equipment or prices obtained for other VA contracts for the same equipment.

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

Market research was completed to determine if there is other supplier available that could provide those specific supplies or if other manufacturer's product could be used on the equipment presently used in Biloxi VAMC pathology and laboratory. Ventana Medical Systems Inc., as the manufacturer of the equipment, holds all intellectual/proprietary rights for the equipment and supplies to be used on this equipment. They do not certify or authorize any third party distributor to sell its products. At this time, there were no other sources available for competition for this unique purchase request.

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

Medical device product and the supplies manufacturing is heavily regulated industry. The Food and Drug Administration (FDA) is the principal healthcare regulatory authority in the United States, having jurisdiction over medical devices, drugs, biologics, and combination products. The paramount objectives driving policy decisions by the FDA are safety and efficacy of healthcare products.

For that reason, the manufacturer of the equipment holds all intellectual/proprietary rights to the equipment, associated parts and accessories and its operating system and does not certify or authorize any third party service provider to maintain its products and in many instances to provide the specific antibodies or chemical components to be used on the equipment.

At the time we acquired the equipment from Ventana, they were a Small Business and had a GSA Contract (GS-24F-0043M). This contract was cancelled October 18, 2013 because Ventana was acquired by the Roche group of companies. This also caused them to no longer qualify as Small Business under the NAICS size standards. We still use the equipment, and Ventana still provides the stains, reagents, and antibodies, but since they are no longer under a GSA Schedule, we are unable to procure these items IAW FAR Part 8. Also, without status a Small Business, we must ask for the Small Business set-aside IAW FAR Part 19 to be dissolved so that we can continue to offer our Veteran population the cancer diagnostic services using our existing equipment.

The items which were under GSA Contract for Ventana will eventually be added to the FSS for Roche Diagnostics, however, this has not yet occurred.

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** See Section 6 above.

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:**

See Section 9 above.

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.




Edward P. Fuller, M. D.
Chief of Pathology & Laboratory Medicine Service
Gulf Coast Veterans Health Care System

3/24/2014

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.



PAUL FILHIOL
CONTRACTING OFFICER
NCO 16 Supply Team Div II

3/26/2014

Date

b. P&C: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

michael.lewis@va.gov
Digitally signed by michael.lewis@va.gov
DN: cn=michael.lewis@va.gov
Date: 2014.03.26 08:45:01 -05'00'

MICHAEL E. LEWIS
CHIEF, PURCHASING AND CONTRACTING
NCO 16 Supply Team Div II

26 Mar 14

Date

Market Research Report - Contracting

1. Purchase Request #: 520-14-2-077-0152
2. Title: Emergency Lab Order Ventana Analyzer Packs BIL
3. Product or Service Code (NAICS): 325413
4. Estimated Contract Value (including options): \$ 46,028.64
5. In accordance with Federal Acquisition Regulation (FAR) Part 10, market research has been conducted for this acquisition. The following techniques were used (**check all that apply and provide a narrative of the nature of the information obtained and the contact information identified for each reference checked below**):

- ☐ Historical acquisition information (review of recent market research results for similar or identical supplies/services).
- ☐ Personal knowledge/experience in procuring supplies/services of this type.
- ☐ Contact with the requester and/or other knowledgeable people in Government and industry regarding the commercial nature of this requirement and standard industry practices in this area of supply/service.
- ☐ Publication of a formal request for information through the Government-wide point of entry.
- ☐ Publication in appropriate technical journals.
- ☒ Review of Government and/or commercial databases for relevant information:
 - Sources Checked: ☐ GSA Advantage ☐ VetBiz Registry ☐ SBA Dynamic Small Business Search ☒ Other FPDS; eCMS
- ☐ Review of Internet resources.
- ☐ Use of source lists for identical or similar items obtained from Government, professional, and/or industry sources.
- ☐ Review of catalogs and other generally available product literature (online and/or in hard copy).
- ☐ Interchange meetings or presolicitation conferences with potential offerors.

Comments/Narrative (**response required**): FPDS search by vendor DUNS shows Items have been purchased by many VA Medical Centers directly from Ventana using GSA Contract GS-24F-0043M. Search of eCMS records reveals that this contract was terminated 10-18-2013. FY 14 orders are Open Market.

6. On the basis of the results of the above research, it is determined that this requirement:

☒ *Can* be met by commercial items, commercial items with customary or minor modifications, or nondevelopmental items.

OR

☐ *Cannot* be met by commercial items, commercial items with modifications, or nondevelopmental items. Further, a reevaluation has been made in accordance with FAR 10.002(b), and the Government requirement cannot be modified in a way that will allow a commercial item to meet the need. *Note*: Any presolicitation synopsis of this requirement must include Numbered Note 26.

Summarize the reasons for this determination: Item available commercially.

Market Research Report - Contracting

(Example: Market research may reveal that a combination of commercial/noncommercial items can meet the Government's needs.)

7. On the basis of the results of the above research, it is determined that this requirement:

☐ Can ☒ Cannot be set-aside for Service Disabled Veteran Owned Small Business or Veteran Owned Small Business because **(response required)**: Only Ventana Stain, Reagent, and Antibody packs can be used on Ventana equipment. Ventana is not SDOSB.

8. Based on the following, it has been determined by the CO that this requirement: ☐ Can

☒ Cannot be set-aside for Small Business because **(response required)**: Ventana lost their SB status in 2013, and their GSA Contract was cancelled.

(Example: A review of the SBA Dynamic Small Business search shows no small businesses available (explain); please include specific information related to results of 8(a) / WOSB / HUBZone / etc.:)

9. Pricing factors (e.g., pricing history, competitive conditions, overall level of demand, trends in supply and demand, pattern of demand, other impacting market forces, pricing strategies, sources of supplies) **(response required)**: Orders placed within VISN 16 over the past two years have been researched in eCMS. Current pricing is the same as the old GSA Contract Pricelist.

10. Standard industry terms and conditions (e.g., warranty, maintenance, discounts, liability, delivery, acceptance/rejection) under which commercial sales of the required supplies/services are made (respond as applicable): Standard commercial warranties, user agreements, discounts, etc. apply. Also the liability for accuracy of results/misdiagnosis if user agreements are violated (e.g., using another manufacturer's reagents, stains or antibodies on these analyzers.)

11. Laws or regulations unique to the required supplies/services (respond as applicable): commercial laws, regulations.

12. On the basis of the above information, the basic clauses and provisions prescribed in FAR Part 12:

☒ are sufficient for use in this acquisition and do not require any substantial tailoring to be consistent with industry's commercial practices.

OR

☐ require tailoring to be consistent with industry's commercial practices. All such tailoring will be included in the solicitation issued for the required supplies/services.

13. Based on the above market research, it is determined to be in the best interest of the Government to **(response required)** (Identify here a summary of the acquisition strategy being used): Obtain authority to dissolve SB set-aside and solicit sole source Ventana IAW FAR 13.106-1(b) to issue a Firm Fixed-Price Simplified Purchase Order.

Market Research Report - Contracting

Signed: _____ (Service / End User)

Date: _____

Signed:  _____ (Contracting Officer)

Date: 3-26-2014