LIMITED SOURCES JUSTIFICATION
ORDER >$3,000
FAR PART 8.405-6

2237 Transaction # or Vista Equipment Transaction #: 528-14-2-4307-0156

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

Restricted to the following source: Provide *original manufacturer's* name for material or contractor's name for service. (If a sole source manufacturer distributes via dealers, *ALSO* provide dealer information.)

Manufacturer/Contractor: Roche Diagnostics Corporation
Manufacturer/Contractor POC & phone number: Angie Cope – 317-521-3086
Mfgr/Contractor Address: 9115 Hauge Road, Indianapolis, IN 46250-0457
Dealer/Rep address/phone number: Corrina Wilcox – 315-506-9236

☒ The requested material or service represents the minimum requirements of the Government.

(1) AGENCY AND CONTRACTING ACTIVITY: Department of Veterans Affairs
NCO 2
3495 Bailey Ave.
Buffalo, NY 14215

VISN: 2

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:
Award of a Firm Fixed Price BPA consisting of base year plus four (4) option years to Roche Diagnostics for HPV Testing.

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:
COBAS x 480 Instrument
COBAS z 480 Analyzer
Service & Preventative Maintenance for COBAS equipment
Reagents and Consumables for HPV Testing (See Attached Sheet)

(b) ESTIMATED DOLLAR VALUE: $53,619 Annually

(c) REQUIRED DELIVERY DATE: ASAP

(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE.

☒ Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.

Updated guidelines from the American Cancer Society (ACS), the American Society for Clinical Pathology (ASCP), and the American Society for Colposcopy and Cervical Pathology (ASCCP) now include HPV testing as part of the cervical cancer screening process. Of particular interest are two genotypes: HPV 16 and HPV 18. The required testing should be accomplished by molecular methodology as it is the most sensitive testing methodology presently available. Testing must also specifically identify HPV 16 and HPV 18 as well as the other 12 common HPV genotypes associated with elevated cervical cancer risk. All testing must be accomplished in a single test run with an ideal turn-around time of less than 6 hours. Due to limited staffing in laboratory service, any testing arrangement must be automated to the fullest extent possible, thereby minimizing hands-on time of laboratory staff. The Roche COBAS system is the only system presently available on FSS contract capable of presenting such a testing solution.

☒ The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.

The Buffalo VAMC owns and utilizes a Hologic ThinPrep Imaging System for the processing of PAP tests. The Roche COBAS system is compatible with the collection kits and sample preservation media that are used during sample collection for pap testing. Due to this compatibility, only a single sample would be required for both pap and HPV testing. In addition to minimizing the inconvenience of obtaining multiple samples from patients, this compatibility will eliminate many duplicative costs associated with having two sampling kits and preserving solutions as well as maintaining and properly disposing of two samples.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

This BPA is in agreement with the VA NAC in Federal Supply Classification of Group 66. VA NAC contracts awarded in FSC Group 66 are mandatory use and must be utilized if the necessary items are available (VAAR 808.002 – Priorities for use of Government supply sources). Furthermore, performing this testing in-house is expected to achieve a cost savings compared to the present practice of sending patient specimens to a reference laboratory to perform the testing. The Buffalo VA is currently charged approximately $45.00 per test by LabCorp for this testing compared to an estimated cost of $35.00 per test in this acquisition. Assuming historical testing volumes remain relatively constant, the Government anticipates realizing a savings of approximately $15,000 annually by performing the test in-house.

(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:

General internet research was performed initially in an attempt to identify as many manufacturers of molecular HPV testing equipment as possible. This research identified Qiagen, Roche, Gen-Probe, and Hologic, and Abbott as manufacturers presently offering testing solutions. Becton Dickinson and Cepheid were found to offer testing solutions that have been approved in Europe but are not presently available in the United States. The Abbott and Roche solutions were then researched in greater detail as both companies are known to have a FSS contract under GSA's Schedule 66-III, Cost-Per-Test. After examining these companies' FSS contracts, Roche's COBAS analyzer was found to be available on contract V797P-7037a. Abbott's m2000 analyzer was also found to be available under FSS contract V797P-7323a. The reagents and consumables necessary for HPV testing, however, were not found to be available on this contract. A sources-sought RFI was then posted to GSA eBuy in an effort to identify any other contracted sources for this testing solution that may have been overlooked. This RFI was posted from 3/24/2014 through 4/1/2014 and targeted all vendors listed in schedule 66-III. Roche provided the only affirmative response to this RFI.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

None.

(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:

A cost-per-test solution is being utilized as ownership of the equipment in such arrangements remains with the contractor. At the conclusion of the BPA, the Government may return the equipment and seek a new testing solution. This better positions the Government to respond to changes in the marketplace and emergence of new technology compared to purchasing equipment outright. As part of their mission, Laboratory Service, in conjunction with Biomedical Engineering, routinely monitor the marketplace for the introduction of new technology that would be beneficial. Any subsequent procurements will take into account the up-to-date knowledge. If newer, more appropriate products become available, a competitive solicitation will be conducted.

(9) 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. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.

Barbara M. Bauers 256448

Digitally signed by Barbara M. Bauers 256448
DN: dc=gov, dc=va, o=internal, ou=people, 0.9.2342.19200300.100.1.1=barbara.bauers@va.gov, cn=Barbara M. Bauers 256448
Date: 2014.08.05 10:42:04 -04'00'

Barbara Bauers
Histology Supervisor
Buffalo VAMC

(10) APPROVALS IN ACCORDANCE WITH FAR 8.405-6(d):

a. CONTRACTING OFFICER'S CERTIFICATION (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Marc Z Amorese
316785

Digitally signed by Marc Z Amorese 316785
DN: dc=gov, dc=va, o=internal, ou=people, 0.9.2342.19200300.100.1.1=marc.amorese@va.gov, cn=Marc Z Amorese 316785
Date: 2014.08.05 13:52:13 -04'00'

Marc Amorese
Contracting Officer
NCO 02

c. **NCM/PCM/DESIGNEE**: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Irma Ferro
194366

Digitally signed by Irma Ferro 194366
DN: dc=gov, dc=va, o=internal, ou=people, 0.9.2342.19200300.100.1.1=irma.ferro@va.gov, cn=Irma Ferro 194366
Date: 2014.08.05 14:24:27 -04'00'

Irma Ferro
Supervisory Contract Specialist
NCO 02

Roche HPV Testing Reagents & Consumables

Item #	Description
HPV Specific Reagents	
05235898190	cobas® 4800 HPV Amplification/Detection Kit
05235880190	cobas® 4800 HPV Amplification/Detection Kit
05235855190	cobas® 4800 HPV Controls Kit
cobas® 4800 GPRs	
05235804190	cobas® 4800 System Sample Preparation Kit
05235782190	cobas® 4800 System Sample Preparation Kit
05235839190	cobas® 4800 System Liquid Cytology Preparation Kit
05235812190	cobas® 4800 System Liquid Cytology Preparation Kit
05235871190	cobas® 4800 System Wash Buffer Kit
05235863190	cobas® 4800 System Wash Buffer Kit
cobas® 4800 Consumables	
04639642001	CO-RE Tips, 1,000 µl
05232716001	cobas® 4800 System Extraction Plate
05232732001	Reagent Reservoir, 50 mL
05232759001	Reagent Reservoir, 200 mL
06395023001	Sarstedt Tubes
06395015001	Sarstedt Caps
cobas® z 480 Consumables	
05232724001	cobas® z 480 Microwell Plate and Sealing Film
cobas® 4800 Ancillary Items	
04639669001	Hamilton Star Plastic Chute
04647416001	cobas® IT Firewall
04691989001	Solid Waste Bag, large
04704002001	Hamilton Trolley S201
04639502001	Rack Sample Carriers
05329990001	Rack PlateTip Carrier
05330009001	Rack Reagent Carrier, 50 mL
05330017001	Rack Reagent Carrier, 200 mL
05340403001	Swan Neck Display Monitor Support
05440777001	Standalone Magnetic Plate
05530873001	Solid Waste Bag, small
05547466001	Waste Container