

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

**FAR PART 8.405-6
HPV and CT/NG Test Reagents and Consumables**

Acquisition Plan Action ID: VA259-17-AP-10968, VA-17-899904

- 1. Contracting Activity:** Department of Veterans Affairs, VISN 19, 635-Oklahoma City Medical Center, Pathology and Laboratory Medicine Service (113), Molecular Pathology Department, purchase request 635-18-1-223-0144.
- 2. Description of Action:** This acquisition is conducted under the authority of the Multiple-Award Schedule Program (41 U.S.C. 251 and 40 U.S.C. 501). The OKC VA HCS is requesting purchase of HPV and CT/NG test reagents and consumables for the performance of molecular infectious disease testing, as required per patient treatment protocols, in support of VHA Directive 1330 Health Care Services for Women Veterans, on the Roche cobas 4800 system currently in place and operational in this laboratory.

Order against: ☒ FSS Contract Number: V797D-70105

Name of Proposed Contractor: Roche Molecular Diagnostics

Street Address: 9115 Hague Road

City, State, Zip: Indianapolis, IN 46250-0457

Phone: 615-969-5011

3. Description of Supplies or Services:

The estimated value of the proposed action is \$ 238,518.00.

The requirement is for the acquisition of HPV and CT/NG test reagents and consumables for the performance of molecular infectious disease testing to include but not limited to cobas Liquid Cytology Kits, cobas Sample Preparation Kits, cobas Wash Buffer Kits, cobas Amplification/Detection Kits, and cobas Control Kits.

(4) IDENTIFY THE AUTHORITY AND SUPPORTING RATIONALE (see 8.405-6(a)(1)(i)(A), (B), and (C) or 8.405-6(b)), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE. (CHECK ALL THAT APPLY AND COMPLETE)

☒ An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.

☐ Only one source is capable of providing the supplies or services required at the level of quality required because the supplies or services are unique or highly specialized; *The Roche cobas 4800 System is currently installed in OKC VA HCS clinical laboratory for performance of highly specialized molecular infectious disease testing required by patient treatment protocols and in support of VHA Directive 1330 Health Care Services for Women Veterans. Roche Diagnostics is the sole manufacturer/distributor of Roche cobas assays and consumables which are the sole, proprietary test kits and supplies compatible with this equipment.*

☐ In the interest of economy and efficiency, the new work is a logical follow-on to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original order must not have been previously issued under sole source or limited source procedures.

☒ Items peculiar to one manufacturer:

☒ A patent, copyright or proprietary data limits competition. The proprietary data is: *Roche Diagnostics is the sole manufacturer/distributor of Roche cobas assays and consumables which are the sole, proprietary test kits and supplies compatible with equipment installed.* (If FAR 8.405-6(a)(2)iii before posting. Do not include specific proprietary data. Only mention the type of equipment, procedure, etc. to show that proprietary supplies or services are being procured.)

☐ These are "direct replacements" parts/components for existing equipment.

☐ 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.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.404(d) TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

The Oklahoma VAMC has the Roche cobas 4800 system in place within the laboratory. The method validation studies and correlations required by accreditation have already been completed, policies are written, staff is trained and competency has been assessed for medical technologists using equipment, test files are already set up in the lab package for reporting of patient results into the electronic medical record. HPV and CT/NG test reagents and consumables are the only products compatible with the available equipment to perform molecular infectious disease testing, as required per patient treatment protocols.

Due to the requirements that human papillomavirus (HPV) testing be a standard test for patients, the increased testing have depleted supplies, and requiring immediate replenishing. Patient care is at risk with the current low amount of supplies on hand. HPV causes cancer. When HPV is detected early, it is 99% curable. Delay in diagnosis can lead to delay in treatment that will impact the patient's quality of life.

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

Roche Diagnostics is the sole manufacturer/distributor of reagents and consumables required.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION: As of March 5, 2018, OKC VAMC is out of the HPV and CT/NG Test Reagents and had to "borrow" supplies from the University of Oklahoma Medical Center. On 3/6/2018, the Contracting Officer gave a notice to proceed to Roche to accept orders from the OKC VAMC not to exceed \$40,000.

(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: The Oklahoma VAMC has the Roche cobas 4800 system already in place within the laboratory. Roche Diagnostics is the sole manufacturer/distributor of reagents and consumables required. As long as the VA have the Roche equipment, they are required to keep using the proprietary supplies. When the equipment is no longer viable, the Government will compete for this requirement under a cost per test or cost per reportable strategy.

(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.



Michelle Vincent
Supervisory Medical Technologist

3-6-18

DATE

OKC VA Healthcare System

FACILITY

(10) APPROVALS IN ACCORDANCE WITH THE VHAPM Part 806.3 OFOC SOP:

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



Bai Perney, Contracting Officer
NCO 19 Branch Chief Services 2

3/7/2018

DATE

b. One Level Above the Contracting Officer (Required over \$150K but not exceeding \$700K):
I certify the justification meets requirements for other than full and open competition.

Albert Williams
NCO 19 Division Chief

12 Mar 2018

DATE