

**LIMITED SOURCE JUSTIFICATION**

**ORDER >SAT**

**FAR PART 8.405-6**

**Acquisition Plan Action ID:** VA257-18-AP-5685

**1. Agency:** Department of Veterans Affairs

**Contracting Activity:** Network Contracting Office 17 (NCO-17)  
7201 W. Interstate 40, Ste. 100  
Amarillo, TX 79106-2612

**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](#)). NCO-17 intends to place a sole source delivery/task order against Roche Diagnostic Corporation's VA National Acquisition Center (NAC) Federal Supply Schedule (FSS) for the acquisition of an immunochemistry Cost-Per-Test (CPT) program. The action will be awarded as a new contract action. The period of performance of the proposed action will be for one year and four one-year option periods. Est. Base POP: 10/1/2018 through 9/30/219.

Order against:  FSS Contract Number: V797D-70105

Name of Proposed Contractor: Roche Diagnostics Corporation

Street Address: 9115 Hague Rd.

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

Phone: 800-722-7222

**3. Description of Supplies or Services:**

Immunochemistry Cost-Per-Test (CPT) program. CPT program consists of equipment rental, reagents & consumable supplies, and equipment maintenance services. The CPT program will be administered at the Central Texas Veterans Health Care Service, Waco, Texas location – Doris Miller VA Medical Center. Analyzer rented is a Roche COBAS 4800 system. Reagents and consumable supplies are for the detection of Chlamydia (CT), Gonorrhea (NG), and Human Papilloma Virus (HPV). Costs for the program are for a committed annual number of reagents and consumable supplies. Costs for the equipment and equipment maintenance services are included in the cost of reagents.

VHAPM Part 808.405-6 Limiting Sources  
Attachment 2: Request for Limited Sources Justification Format >SAT

<u>Description</u>	<u>Item Number</u>	<u>Est. Annual Quantity</u>
CT/NG Amplification/Detection Kit	07102569190	25
CT/NG Controls Kit	05235928190	25
HPV Amplification/Detection Kit	05235880190	10
HPV Controls Kit	05235855190	10
PCR Urine Kit, COBAS	05170486190	25
PCR Female Swab Kit	05170516190	20
Sample Preparation Kit	05235782190	35
Control Diluent Kit	05235847190	25
Wash Buffer	05235863190	35
Liquid Cytology Preparation Kit	05235812190	10
CO-RE Tips, 1000 uL	04639642001	20
Extraction Plate	05232716001	8
Reagent Reservoir, 50 mL	05232732001	4
Reagent Reservoir, 200 mL	05232759001	4
Kit, COBAS PCR Media, Tube Cap	07958056190	5
Microwell Plate & Sealing Film	05232724001	8
Hamilton Star, Plastic Chute	04639669001	1

The estimated value of the proposed action (including all options) is \$REDACTED

**(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;

Polymerase Chain Reaction (PCR) testing is recommended by the CDC for the early detection of CT, NG and HPV diseases in non-symptomatic patients. The Roche 4800 system is the only analyzer offered in SIN 66 III (Clinical Analyzers, Laboratory, Cost-Per-Test), Category 605-6B (Clinical Immunochemistry Analyzers), that includes HPV testing parameters.

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 redacted (If FAR 8.405-6(a)(2)(iii) applies) before posting.
- 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) DETERMINATION BY THE CONTRACTING OFFICER THAT THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.404(d):**

The Contracting Officer has determined that placing a delivery/task order with Roche Diagnostics Corporation to be a best value. The Contracting Officer anticipates the proposed prices to be equal to or less than the prices published in Roche’s NAC FSS price list.

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

A review of the three (3) vendors in category 605-6B noted that all are large businesses. A search of the other two (2) vendors price lists noted that neither offers HPV reagents.

A special notice, notice of intent to award a sole source procurement, was posted on the Federal Business Opportunities (FBO) website for the requirement on 6/27/2018. The notice stated that all responsible sources may submit a capability statement, proposal or quotation, which shall be considered by the agency to determine if a comparable source is available and more advantageous to the government. The notice archived in FBO on 7/13/2018 with no responses to the notice.

**(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:**

The Roche COBAS 4800 system is the only PCR system that offers fully automated sample preparation with real-time PCR technology. The ability to run CT, NG and HPV tests on a single platform, from a single specimen, will save the laboratory time and money and will be less invasive for patients.

**(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:**

Roche Diagnostics Corporation is the only known firm capable of providing the requested supplies and services without the Veterans Health Administration experiencing duplication of

costs that could not be expected to be recovered through competition and unacceptable delays in fulfilling its requirements. The CTVHCS pathology and laboratory medicine service will conduct market research prior to the exercise of option renewals and new requirements to determine if there have been any changes in the marketplace.

**(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.

Signature:

//SIGNED// 7/27/2018  
REDACTED Date  
Chief Technologist, Pathology & Laboratory Medicine Service  
Central Texas Veterans Health Care System

**(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.

Signature:

//SIGNED// 8/3/2018  
REDACTED Date:  
Contracting Officer

**b. One Level Above the Contracting Officer (Required over the SAT but not exceeding \$700K):**

I certify the justification meets requirements for other than full and open competition.

Signature:

//SIGNED// 8/3/2018  
REDACTED Date  
Chief, Division I  
Network Contracting Office 17, SAO-W

**HIGHER LEVEL APPROVAL (Required for orders over \$700,000):**

**c. VHA SAO HCA REVIEW AND APPROVAL (over \$700,000 to \$68 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.

Signature:

//SIGNED// 9/11/2018  
REDACTED Date  
Acting Executive Director, SAO West  
Head of Contracting Activity (HCA)