

**LIMITED SOURCE JUSTIFICATION**

**ORDER >SAT**

**FAR PART 8.405-6**

**Acquisition Plan Action ID:** VA257-18-AP-5366

**1. Agency:** Department of Veterans Affairs (VA)

**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 order against Roche Diagnostic Corporation's National Acquisition Center (NAC) Federal Supply Schedule (FSS) for the acquisition of reagents and consumable supplies. The delivery order will be considered a standing order; where, the items are requested throughout the period of performance, on an as-needed basis. The action will be awarded as a new contract action. The period of performance of the proposed action will be for one year. Est. POP: 10/1/2018 thru 9/30/2019.

Order against: ☒ FSS Contract Number: V797D-70105

Name of Proposed Contractor: Roche Diagnostics Corporation

Street Address: 9115 Hague Rd.

City, State, Zip: Indianapolis, IN, 46256-1025

Phone: 317-521-3086

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

Item Description	Item Number	Quantity
System Wash Reagent, 5.1L	03587797190	80
Sample Input Tubes with Barcode Clips	03137040001	19
K-Tips, Rack, 12 x 36	03287343001	13
SPUs, 12 x 24	03755525001	19
K-Tubes, Rack, 12 x 96	03137082001	5
HCV Test, V2.0	05480442190	104
HIV-1 Test, V2.0	05212308190	39
HPV Amplification/Detection Kit	05235880190	12

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

HVP Controls Kit	05235855190	12
Sample Preparation Kit	05235782190	12
Liquid Cytology Preparation Kit	05235812190	12
System Wash Buffer Kit	05235863190	12
CO-RE Tips, 1000 uL	04639642001	8
System Extraction Plate, 24 x 50	05232716001	3
Reagent Reservoir, 50 mL, 6 x 200	05232732001	2
Reagent Reservoir, 200 mL, 12 x 100	05232759001	2
Microwell Plate and Sealing Film, 24 x 50	05232724001	12
CT/NG Amplification/Detection Kit, V2.0	07102569190	10
CT/NG Controls Kit	05235928190	10
PCR Urine Kit	05170486190	6
PCR Female Swab Kit	05170516190	18
System Control Diluent Kit	05235847190	10
HBV Test Kit	05027012190	14

The estimated value of the proposed action 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.**

☐ 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 South Texas Veterans Health Care System, Pathology & Laboratory Medicine Service, owns and operates Roche Diagnostic Corporation's COBAS 4800 system. The requested reagents and consumable materials are manufactured for the intended use on Roche COBAS systems. Roche Diagnostic Corporation does not use third party vendors to distribute their products.

☐ 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) is applicable) 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.

The reagents and consumable supplies must be compatible with all aspects of fit and function on the government owned Roche COBAS 4800 system. The requested items are manufactured specifically for the analysis of patient specimens on Roche COBAS instruments.

**(5) DETERMINATION BY THE ORDERING ACTIVITY CONTRACTING OFFICER THAT THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.404(d):**

The Contracting Officer has determined that placing a delivery order with Roche Diagnostic Corporation to be a best value consistent with FAR 8.404(d). The Contracting Officer can compare the proposed prices with the vendor’s FSS pricelist prices to identify the costs are consistent. The Contracting Officer can also compare the proposed prices with prices found to be a best value on previous delivery orders placed with Roche Diagnostic Corporation.

**(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 vendors listed in SIN 66 III, Clinical Analyzers, Cost-Per-Test, Category 605-6B, Clinical Immunochemistry Analyzers, identified there are three (3) vendors within the category. The other vendors do not offer Roche Diagnostic Corporation supplies or services. Roche Diagnostics Corporation has allowed the VA to purchase the requested supplies from their NAC FSS for the operation of government owned Roche brand-named instruments.

A special notice, notice of intent to award a sole source procurement, was posted to the Federal Business Opportunities (FBO) website under RFI 36C25718U0003 on 8/31/2018. The notice provided a description of the requested items and stated that all responsible sources may submit a capability statement, proposal or quotation, which shall be used by the agency to determine if a comparable source is available and more advantageous to the government. The notice archived in FBO on 9/16/2016 with no responses from the notice.

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

The requested Roche Diagnostic Corporation molecular reagents are approved by the FDA and are the only reagents compatible with Roche Diagnostic Corporations COBAS instruments. The requested items are manufactured for the Roche COBAS 4800 system test menu for assays of infectious disease, microbiology, virology and women’s health.

**(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 Diagnostic Corporation is the only know firm capable of providing the requested supplies without the Veterans Health Administration experiencing duplication of cost that could not be expected to be recovered through competition and unacceptable delays in fulfilling its requirements. The STVHCS pathology and laboratory medicine service will conduct market research prior to new requests 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// 9/17/2018  
REDACTED Date:  
Laboratory Manager  
Pathology & Laboratory Medicine Service  
South 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.

//SIGNED// 9/18/2018  
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.

<u>//SIGNED//</u>	<u>9/27/2018</u>
REDACTED	Date:
Branch Chief, Services III	
Network Contracting Office 17	