

**LIMITED SOURCE JUSTIFICATION**

**ORDER >SAT**

**FAR PART 8.405-6**

**Acquisition Plan Action ID:** 36C257-19-AP-2120

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

**Contracting Activity:** Network Contracting Office 17 (NCO-17)  
7201 W. Interstate 40, Ste. 100  
Amarillo, TX 79106-2616

**Purchase Request #:** 671-20-1-121-0009

**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 VA National Acquisition Center (NAC) Federal Supply Schedule (FSS) for the acquisition of reagents and consumable items. The action will be awarded as a new contract action. The proposed period of performance for the action will be for one year and two one-year option periods. The estimated base period of performance is 10/1/2019 through 9/30/2020.

Order against:  FSS Contract Number: V797D-70105

Name of Proposed Contractor: Roche Diagnostic Corporation

Street Address: 9115 Hague Rd.

City, State, Zip: Indianapolis, IN 46250-0456

Phone: 800-722-7552

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

Item Description	Item Number	Est. Annual QTY
Sample Input Tubes with Barcode Clips	03137040001	20
K-Tips, Racks, 12 X 36	03287343001	15
SPUs, 12 X 24	03755525001	20
K-Tubes, Rack, 12 X 96	03137082001	7
HCV Test, V2.0	05480442190	104

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

HIV-1 Test, V2.0	05212308190	44
HPV Amplification/Detection Kit	05235880190	12
HPV 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	5
Reagent Reservoir, 200 mL, 12 X 100	05232759001	5
Microwell Plate and Sealing Film, 24 X 50	05232724001	15
CT/NG Amplification/Detection Kit, V2.0	07102569190	10
CT/NG Controls Kit	05235928190	10
PCR Urine Kit	05170486190	6
System Control Diluent Kit	05235847190	10
HBV Test Kit	05027012190	26
PCR Female Swab Kit	05170516190	18
System Wash Reagent, 5.1L	03587797190	80

Estimated annual quantities. The resultant contract will be considered a standing order. Items in the delivery order will be ordered on an as-needed basis throughout each period of performance.

The estimated value of the proposed action, to include 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;

The South Texas Veterans Health Care System, Pathology and Laboratory Medicine Service, owns and operates a Roche Diagnostics Corporation COBAS 4800 system. The requested reagents and consumable supplies are the only supplies compatible with Roche COBAS systems. Roche is the only VA NAC vendor that offers hepatitis B (HBV) reagents on an FSS.

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) 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 requested reagents and consumable supplies are manufactured (packaging) to meet all aspects of function, fit and form for Roche COBAS systems. Roche is the sole manufacturer and distributor for all assays performed on COBAS systems in the United States.

**(5) DETERMINATION BY THE ORDERING 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 Diagnostics Corporation for the requested supplies is a best value consistent with FAR 8.404(d). The Contracting Officer will compare the proposed prices with the vendor pricelist and may compare the prices of past delivery orders to verify the proposed prices are a best value.

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

A search of all Special Item Number (SIN) 66 III (Clinical Analyzers, Laboratory, Cost-Per-Test), category 605-6A/B (Clinical Immunochemistry Analyzers), VA NAC vendor pricelists revealed that Roche Diagnostic Corporation is the only vendor that offers the HBV reagent on an FSS pricelist.

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

N/A

**(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 government ownership of a Roche COBAS 4800 system restricts the purchase of reagents and consumable supplies to only those compatible with the COBAS systems. The Pathology and Laboratory Medicine Service will conduct market research prior to future procurements to consider any advances 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// 8/6/2019  
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// 8/5/2019  
REDACTED Date:  
Contracting Officer

**b. One Level Above the Contracting Officer:**

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

//SIGNED// 8/6/2019

REDACTED Date:

Chief, Division I

Network Contracting Office 17

**c. Two Levels Above the Contracting Officer:**

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

//SIGNED// 8/22/2019

REDACTED Date:

Director of Contracting

Network Contracting Office 17

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

**d. 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.

//SIGNED// 8/29/2019

REDACTED Date:

Executive Director, Regional Procurement Office (RPO) – West  
Head of Contracting Activity (HCA)