

LIMITED SOURCES JUSTIFICATION

ORDER >SAT

FAR PART 8.405-6

Acquisition Plan Action ID: VISN20 VA Medical Centers

- 1. Contracting Activity:** Department of Veterans Affairs, VISN 20, All Medical Center's
2237: 463-19-1-044-0005, 648-19-1-093-0026, 653-19-1-028-0015, 663-19-1-019-0010, 668-19-1-139-0001, 687-19-1-020-0010, 692-19-1-021-0007
- 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](#)).

Order against: FSS Contract Number: V797P-7347A (2nd Bridge Order)

Name of Proposed Contractor: Roche Diagnostics Corporation

Street Address: 9115 Hague Road

City, State, Zip: Indianapolis, IN 46250

Phone: 317-521-3086

3. Description of Supplies or Services:

The estimated value of the proposed action is \$5,887,382.12 to include a 6-month base period plus an additional 6-month option using FAR 52.217-8 "Option to Extend Services" for a Cost Per Reportable Result (CPRR) Federal Supply Schedule (FSS) Order. The FSS Order includes costs covering (a) equipment use, (b) all reagents, standards, Roche manufactured controls, supplies, consumable/disposable items, parts, accessories and any other item required for the proper operation of the contractor's equipment and necessary for the generation of a patient reportable result as defined in Roche Authorized Federal Supply Schedule Price List see page 1 of attachment A.

The Automated Chemistry Immunochemistry Analyzers (Chemistry Analyzers – Cobas 6000's) for testing at Department of Veterans Affairs medical centers in Veterans Integrated Service Network 20 (VISN20) are used by laboratory staff employees for immunochemistry testing. This testing is a considered essential as it allows the medical staff to test patients' bodily fluids, assisting providers in diagnosis and in monitoring patients' health. Roche Diagnostic Corporation is currently the incumbent contractor and has instruments already available within the medical centers' laboratories for this use.

The original VISN Blanket Purchase Agreement (VA260-15-A-0034) expired on March 31st, 2017. The follow-on contract (V797P-7347A 36C26018A0005), which was competitively solicited, was protested and decision to resolicit the requirement was made. The final BPA calls expired on March 29th, 2018 leaving VISN20 without an ordering vehicle to purchase and pay for resulting tests. NCO20 issued seven limited source award orders to Roche on March 30, 2018 under an urgent and compelling circumstances (36C26018F0752, 36C26018F0754, 36C26018F0753, 36C26018F0756, 36C26018F2078, 36C26018F2060 & 36C26018F2069). These individual FSS orders expire on September 30, 2018.

(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;

Currently there are seven firms that possess a VA FSS schedules under the same SIN for high maintenance/high complex analyzers. Accurate laboratory chemistry testing is vital to the healthcare, even minor errors in standard laboratory testing of patient's samples could result in misdiagnose and medical malpractice consequently creating serious injury to Veterans and public trust. Therefore, all laboratory equipment must pass internal validation testing procedures as describes in the 96-page manual as attachment B. The usual time to conduct this internal validation testing takes approximately four to six months. Only the incumbent contractor, Roche Diagnostics, has systems that have been through this internal validation testing process.

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: (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:

Validation testing is required when a new instrument is installed in the lab. Testing is conducted congruently with the existing instruments before any permanent change is made to ensure reliability and safety. This testing can take up to six months to be completed. The Roche Cobas Chemistry Analyzer Instruments are currently on site at each VISN20 VA Medical Center laboratories as the incumbent contractor making them the only logical choice to continue services during this gap of competitive contract coverage. Discontinuing use of lab chemistry testing would severely affect patient care and safety, impacting the healthcare of thousands of Veterans’ across the Northwestern United States. Roche Diagnostics Corporation currently has a Federal Supply Schedule contract (V797P-7347A expiration date of October 31, 2018) as the incumbent contractor. Additionally, in accordance with FAR 8.404(d) the prices delineated under schedule contract have already been determined fair and reasonable. Roche Diagnostics Corporation has been determined to be a responsible contractor through reports available on the System for Award Management.

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

NCO20 has conducted market research and as a result issued a competitive Request for Quotes (RFQ) on June 8, 2017 to replace BPA VA260-15-A-0034 which expired on March 31, 2017. Service was continual through the procurement process utilizing BPA Call’s. An award was made to the RFQ on February 27, 2018 but was protested on March 9, 2018. NCO20 issued a Stop-Work on all work associated with Federal Supply Schedule (FSS) BPA 36C26018A0005 on March 16, 2018. No additional market research has been conducted since as market research was definitive enough to indicate that only, other than small business, FSS contract holders, were capable of providing the items required.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

NCO20 has a tentative award date of a new competitive action on around December 2018. A current timeline of events requires time for the procurement to be awarded, new instruments to be built (2-month process), to be shipped and installed (1 month) and the 4 to 6 months of validation testing before the incumbent's instruments are removed and returned. The duration for this justification incorporates this time frame.

(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 decision to seek corrective action, by agency, in response to the protest has resulted in a decision to make the following competitive solicitation less restrictive. The Contracting Officer's decision to award a 2nd bridge contract is essential to maintain critical testing while the agency improves its acquisition strategy to encourage a more competitive process among competing interested parties for this future acquisition.

(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.

Kathleen V.

Aldridge 345935

Digitally signed by Kathleen V.
Aldridge 345935
Date: 2018.09.26 10:03:30
-07'00'

SIGNATURE

Kathleen V. Aldridge, MS, MT(ASCP) Laboratory Manger

NAME

TITLE

Pathology and Laboratory Medicine

SERVICE LINE/SECTION

VA Puget Sound Health Care 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.

Jonathan D. Jewel 198381
Digitally signed by Jonathan D. Jewel 198381
Date: 2018.09.26 12:15:06 -07'00'

Jonathan D. Jewel
NCO 20, Supply II Branch Chief

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.

Stephen D. Allen 1565216
Digitally signed by Stephen D. Allen 1565216
Date: 2018.09.26 12:38:36 -07'00'

S. Dale Allen
Director of Contracting
Network Contracting Officer 20 (NCO20)

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.

Jordan, Curtis M. (SAO)
Digitally signed by Jordan, Curtis M. (SAO)
Date: 2018.09.27 15:35:02 -06'00'

Curtis M. Jordan
Acting Executive Director, SAO West
Head of Contracting Activity (HCA)