

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan Action ID: VA263-17-AP-10606

- 1. Contracting Activity:** Department of Veterans Affairs, VISN 23, NCO 23 Contracting Activity, Fargo VA Medical Center
- 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: V797D-60637

Name of Proposed Contractor: Ortho Clinical Diagnostics

Street Address: 1001 Route 202 US Highway

City, State, Zip: Raritan, NJ 08869

Phone: 800-322-6374

3. Description of Supplies or Services:

The estimated value of the proposed action is NTE \$400,000.00 (per site). Vendor shall provide Chemistry/Immunochemistry Analyzer cost per reportable result (CPRR)/cost per test (CPT) testing under FSS Schedule V797D-60637. The Vendor is required to provide each participating facility with an FDA approved chemistry/immunochemistry testing system to include the following capabilities: Equipment must meet the test menu requirements of the using facility defined under VA263-BP-0144. Contractor must supply all instrumentation, reagents, controls, calibrators and replacement parts to perform testing at VISN 23 laboratories in Fargo, Ft. Meade, Hot Springs, Omaha, Lincoln, Grand Island, Sioux Falls, and St. Cloud

(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;

☐ 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.

VISN 23 is requesting a six month continuation of current equipment to allow contract award and equipment crossover per Regulatory Agency requirement. VISN 23 laboratories in Ft. Meade, Hot Springs, Fargo, Grand Island, Lincoln, Omaha, Sioux Falls, and St. Cloud have Ortho Clinical Diagnostics Instrumentation systems placed almost five years ago and have been using these analyzers along with their products/reagents to perform Chemistry/Immunochemistry testing for our VISN 23 veterans. Additionally, the process to change laboratory equipment is highly regulated by Joint Commission, College of American Pathologist, Food and Drug Administration, and CLIA. The process is extremely specific and failure to follow regulations will result in licensure revocation. For equipment of this magnitude, the crossover/transition period is typically 3-6 months. The prior BPA, VA263-BP-0144, expired September 30, 2016. Failure to perform chemistry testing/immunochemistry testing will result in significant patient delays that may impact mortality. These analyzers perform STAT testing, such as cardiac testing, that when delayed, impact patient treatment.

(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 order represents the best value to the Government as award will be made from a GSA-FSS contract V797D-60637 which includes fair and reasonable prices that have previously been negotiated. Further price discounts will be requested.

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

GSA, FBO, SBDS, VETBIZ, SAM, FCO, FPDS were all searched. VETBIZ was searched using NAICS and keyword searches. No SDVOSB or VOSB vendors were identified that could complete this procurement. Based upon this information it is recommended that a sole source procurement be set up so that FSS-BPA VA263-BP-0144 with Ortho Clinical Diagnostics can continue to provide services needed to Veterans and their families. The lab needs six more months of service to allow time for a new FSS-BPA to be completed. The scope and complexity of the requirements along with the technical qualification of the schedule holders needed for the CPRR procurement calls for a sole source. A sole source to Ortho Clinical Diagnostics to continue the services and tests on FSS-BPA VA263-BP-0144 is needed for another six months. The equipment from Ortho Clinical Diagnostics is already set up at the existing sites. By sole sourcing to them there will be no break in service thus will keep the labs up and running. A new solicitation, VA263-16-Q-0137, has already been posted to GSA eBuy so this six month sole source will not be needed after the award is made of the competed one.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

This sole source acquisition is to continue the Lab CPRR supplies and service provided by Ortho Clinical Diagnostics under FSS-BPA VA263-BP-0144, which expires on 9/30/2016. This proposed BPA will bridge the existing contract to new competitively awarded contracts being solicited under RFQ VA263-16-Q-0137. The solicitation for the follow on contract was released in late August. The proposed bridge extension consist of a six month period of performance and will prevent an adverse impact on the mission of the agency, which would occur with the interruption of the work presently performed. The statement of work under the bridge BPA remains the same as under BPA VA263-BP-0144.

(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:

A follow on contract has been solicited under VA263-16-Q-0137 so the barrier has been overcome. This sole source is just needed to bridge the gap so there is no break in service until the follow on solicitation is awarded.

(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. *(This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)*

SIGNATURE

Jill Johnson

NAME

VISN 23

DATE

Health System Specialist

TITLE

PLMS

SERVICE LINE/SECTION

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.

CONTRACTING OFFICER/DESIGNEE'S SIGNATURE

DATE

Lance Haman Contracting Officer
NAME AND TITLE

NCO 23
FACILITY

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.

SIGNATURE

DATE

Scott Petrin
NAME
NCO 23 Division Chief