

**LIMITED SOURCES JUSTIFICATION**

ORDER >\$150,000

FAR PART 8.405-6

**2237 ID: 437-18-3-029-0095**

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

**Restricted to the following source:** Provide original manufacturer's name for material or contractor's name for service. (If a sole source manufacturer distributes via dealers, ALSO provide dealer information.)

Manufacturer/Contractor: ORTHO-CLINICAL DIAGNOSTICS

Manufacturer/Contractor POC & phone number: Lisa Guarino, 585-453-5558

Mfgr/Contractor Address: 1001 RTE 202 US HWY, RARITAN NJ 08869

Dealer/Rep address/phone number: \_\_\_\_\_

☒ The requested material or service represents the minimum requirements of the Government.

**(1) AGENCY AND CONTRACTING ACTIVITY:**

Department of Veterans Affairs

Fargo VA

2101 North Elm Street

Fargo, ND 58102

**VISN:**

23

**(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:**

This action is for a firm fixed priced blanket purchase agreement (BPA) whereby the holder shall provide Chemistry/Immunochemistry Analyzer cost per reportable result (CPRR)/cost per test (CPT) testing under FSS Schedule V797D-30175.

**(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:**

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 V797D-30175.

Contractor must supply all instrumentation, reagents, controls, calibrators and replacement parts to perform testing at VISN 23 laboratories in Des Moines and Iowa City.

**(b) ESTIMATED DOLLAR VALUE:** \$347,937.11

**(c) REQUIRED DELIVERY DATE:** 4/1/2018 – 9/30/2018

**(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE.**

☐ Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.

☐ 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 Black Hills City 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. **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. 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 three-six months.

☐ 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.

☐ An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.

**(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:**

The BPA represents the best value to the Government as award will be made from a GSA-FSS contract V797D-30175 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 showed that there were no SDVOSB/VOSB that could meet this requirement. NAICS 325413 and keyword searches were used in this search. Based upon this information it is recommended that a sole source procurement be set up so that FSS contract 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 awarded and implemented. 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 V797D-30175 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 V797D-30175. This proposed BPA will bridge the existing contract to new competitively awarded contracts being solicited under RFQ VA263-16-Q-0137. The new FSS-BPA is expected to be awarded soon. The proposed bridge extension consists 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.

**(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.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Jill Johnson

\_\_\_\_\_  
Health Systems Specialist

\_\_\_\_\_  
Pathology/Laboratories

\_\_\_\_\_  
VISN 23

**(10) APPROVALS IN ACCORDANCE WITH THE [VHAPM, Volume 6, Chapter VI: 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.

\_\_\_\_\_  
Darryl W. Moon  
Contracting Officer  
NCO 23 Fargo

\_\_\_\_\_  
Date

**b. Director of Contracting/DESIGNEE:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief, and approve for other than full and open competition.

\_\_\_\_\_  
Scott J. Petrin  
NCO23 Division Chief

\_\_\_\_\_  
Date