

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan Action ID: VA69D-17-AP-8816

This acquisition is conducted under the authority of FAR 8.405-2 Ordering Procedures for Supplies, and Services Requiring a Statement of Work. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required is precluded for the reasons indicated below and IAW FAR 8.405-6(a)(1)(i)(B).

Restricted to the following source: Immucor, Inc.

Manufacturer/Contractor: Immucor, Inc.

Manufacturer/Contractor POC & phone number: Amy Barnhart 800-829-2553 x4770

Mfgr/Contractor Address: 3130 Gateway Drive Norcross, GA 30071

NAC FSS Contract/Expiration Date: V797D-70110 - 03/15/2017 – 03/14/2022

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

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs

Great Lakes Acquisition Center

115 South 84th Street Ste. 101

Milwaukee, WI 53214

VISN: 12

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

In 2011 the Great Lakes Acquisition Center used competitive procurement procedures to create a FSS Blanket Purchase Agreement (BPA) for a recurring need for products that are used for blood typing patient samples and donor units, antibody screens, antibody identification, phenotyping and cross-matching blood units for the blood and blood product transfusion needs of VISN 12 patients. The base period of performance also included the purchase of the equipment that would be required to process these tests on site. Each of the seven facilities purchased their own piece of equipment in an effort to standardize the procedures across NCO 12.

All seven facilities in NCO 12 continue to have a need to process these tests for their patients. Because of this, another VISN-Wide action is being considered. Since each facility already has the equipment used to process these tests, this action is being set up using sole source procedures IAW FAR 8.405-6(a)(1)(i)(B) as the reagents and test kits must be fully compatible with the existing equipment and only the provider of the equipment (Immucor, Inc.) can provide the reagents and test kits as it is all proprietary and another company's reagents and test kits would not function properly.

- (3) (a) **A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:**
The products required are used for blood typing patient samples and donor units, antibody screens, antibody identification, phenotyping and cross-matching blood units for the blood and blood product transfusion needs of VISN 12 patients.

(b) **ESTIMATED DOLLAR VALUE:** [REDACTED]

- (c) **REQUIRED DELIVERY DATE:** Established delivery schedule over the course of one year and four one year options.

(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.

The products needed are used for blood typing patient samples and donor units, antibody screens, antibody identification, phenotyping and cross-matching blood units for the blood and blood product transfusion needs of the VISN 12 patients. Each of the facilities has already purchased and is currently using Immucor equipment (Echo and Neo) to process these tests on site. The Immucor Echo and Neo automated equipment is programmed to move micro-well strips, liquid reagent fluids, and blood samples to different processing areas to perform immunohematology testing. The instrument was designed and FDA approved for use with the Immucor reagents only. No other reagents or test kits are authorized or can be used with the Immucor equipment; therefore, Immucor is the only responsible source available that can meet the need of the Government as the products needed must be compatible in all aspects with the existing equipment.

☐ 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:

In 2011 the GLAC used competitive procedures IAW FAR 8.404 Use of Federal Supply Schedules to set up a BPA for reagents, test kits, and the necessary equipment to process the tests onsite. Each of the seven facilities in VISN 12 purchased equipment used to process these reagents and tests. If another manufacturer's reagents and test kits are purchased, new equipment from the same manufacturer must also be purchased due to standardization and compatibility reasons. The estimated cost of purchasing new equipment VISN-wide is in excess of approximately \$880,000 which is cost prohibitive and not in the best interest of the Government.

The required reagents are included in Immucor's VA NAC FSS contract V797D-70110. IAW FAR 8.404(d) the prices of supplies and fixed-price services, and rates for services offered at hourly rates, have been determined to be fair and reasonable for the purpose of establishing the schedule contract.

Furthermore, a search of the applicable SIN Category 555-1 Blood Bank in the VA NAC database for keywords "antibody screen" and "Indicator", showed comparable pricing offered by other vendors. It is based on this comparison that the contract price offered by Immucor is fair and reasonable. IAW FAR 8.405-4 the Contracting Officer will request additional discounts.

Additionally, new equipment and products would need to be validated before used which is a lengthy process used to ensure everything is correct and functioning. Furthermore, personnel using the equipment and reagents from all the facilities would need to be retrained on the new equipment and processes, and create new VISN-wide SOPs, which would be expensive and time consuming and would increase the risk of adverse patient care situations at the outset because the processes would be new and unfamiliar. The only responsible source available is Immucor, Inc. All VISN 12 facilities currently use Immucor analyzing equipment and simply need the reagents to continue providing patient care.

Based on the facts above, it has been determined that this order represents the best value to the Government.

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

The IGCE for this acquisition is [REDACTED]. The NAICS is 325413. The FSC is 6550. The Size Standard is 1,250 employees. The IGCE dictates that the NMR does apply. A Sources Sought notice was posted on 8/21/2017 requesting information from those capable meeting the need of the VA and which stated that responses are to be received by 10:00am CST on 8/24/2017. One response was received and is delineated below:

Ortho Clinical Diagnostics: Did not come up in an SBA dynamic search using their DUNS number so they are a Large Business. They are offering their own reagents and equipment. However, the VISN12 sites already own Immucor equipment and are simply in need of reagents.

Market research and discussions with the vendor and end user indicates only Immucor reagents are compatible with the Immucor equipment (ECHO/NEO) currently on site and in-use at the facility and therefore Immucor is the only responsible source that can meet the need of the VA. Immucor has stated via email they do not have any authorized distributors of these reagents, to include SDVOSB/VOSB, so it has been determined that the U.S.C. 8127 & 8128 Vets First Contracting Program Rule of Two cannot be met. Immucor has a VA NAC Contract which includes the necessary reagents and which expires on 3/14/2022.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

None.

(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:

VISN 12 intends to review the current equipment, system, and testing processes annually. This review will include an assessment of the equipment life cycle and status and when it is determined the equipment is beginning to fail, or when it is in the best interest of the Government to compete/procure new testing equipment for any other reason, the Contracting Office will conduct market research at that time and determine an acquisition strategy that is in the best interest of the Government and will result in the most competition practicable.

(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.)*

Donna M. Wray Digitally signed by Donna M. Wray 394473
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=donna.m.wray@va.gov,
cn=Donna M. Wray 394473
Date: 2017.09.21 13:01:31 -05'00'
394473 September 21, 2017
SIGNATURE DATE
Donna Wray Business Manager VISN 12 PLMS
NAME TITLE SERVICE LINE/SECTION
VA Hines 578
FACILITY

(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.

Daniel R. Rasmussen Digitally signed by Daniel R. Rasmussen 457897
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=daniel.rasmussen@va.gov,
cn=Daniel R. Rasmussen 457897
Date: 2017.09.21 13:06:59 -05'00'
457897
CONTRACTING OFFICER/DESIGNEE'S SIGNATURE DATE

Daniel Rasmussen
Contracting Officer
Great Lakes Acquisition Center NCO 12
FACILITY

b. **Director of Contracting/DESIGNEE:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Paul M. Lauro Digitally signed by Paul M. Lauro
1463508
DN: dc=gov, dc=va, o=internal,
ou=people,
0.9.2342.19200300.100.1.1=paul.lauro@va.gov,
cn=Paul M. Lauro 1463508
Date: 2017.09.21 13:27:52 -05'00'
1463508 21 Sep 2017
SIGNATURE DATE

Paul Lauro
NCO/PCO 12 Director of Contracting
Great Lakes Acquisition Center NCO12

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

c. **VHA SAO HCA REVIEW AND APPROVAL (over \$700,000 to \$13.5 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

Linda S. Greaves
404790

Digitally signed by Linda S. Greaves 404790
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cn=Linda S. Greaves 404790
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9/26/2017

DATE

Linda S. Greaves
Acting Director, SAO Central Region
VHA Head of Contracting Activity (HCA)