LIMITED SOURCES JUSTIFICATION
ORDER >$150,000
FAR PART 8.405-6

2237 Transaction # or Vista Equipment Transaction #: 583-15-4-054-0100

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: Siemens Healthcare Diagnostics
Manufacturer/Contractor POC & phone number: 866-323-3468
Mfgr/Contractor Address: Norwood, MA 02062-4633
Dealer/Rep address/phone number: Robert Knapp 317-674-6069

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

(1) AGENCY AND CONTRACTING ACTIVITY: Department of Veterans Affairs
1481 West 10th Street
Indianapolis, IN 46202

VISN: 11

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:
Purchase of reagents and supplies for cost per reportable lab testing on Siemens Centaur from a single source.

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:
Reagents and supplies for cost per reportable lab testing on Siemens Centaur machines at the Indianapolis VA Medical Center. The period of Performance for this task order against FSS Contract Number V797D-30175 is Three (3) Months beginning July 1, 2015, and ending September 30,2015.

In order to continue the use of current lab equipment, the Siemens Centaur XP analyzers requires the supplies and reagents for the Cost per Reportable Result Agreement to be shipped regularly to insure the VA's ability to run crucial lab tests without interruption. The shipments need to be regular and timely considering forecasted use of the equipment and expiration dates of said supplies.

(b) ESTIMATED DOLLAR VALUE: $180,000

(c) REQUIRED DELIVERY DATE: 07/01/2015

(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. (CHECK ALL THAT APPLY AND COMPLETE)

☐ 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.
Siemens Centaur XP machines are currently being used and are within their useful life. The Chemistry section of the laboratory currently performs immunoassay testing on Siemens Advia Centaur XP analyzers. Chemistry immunoassay analyzers perform comprehensive assay groups that include fertility, thyroid function, oncology, cardiovascular, anemia, therapeutic drug monitoring, infectious disease, adrenal function and metabolic. The only reagents that can be used with these machines are the Siemens reagents specified by the manufacturer. The reagents, calibrators, and test kits are designed specifically for each type of analyzer to perform the required testing. No other reagents are designed to be compatible to operate with the Siemens systems than those designed by the manufacturer. These

are also the only approved reagents per FDA. The need for these and only these reagents constitutes a proprietary sole/limited source situation as to attempt to vary reagents for use with these machines would taint patient testing results and jeopardize patient care.

☐ 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:

This vendor being the only supplier of these reagents represents the best value to the government because it is the only possible way to utilize these machines for the care of the VA patients. Only these reagents and supplies will allow the current equipment to operate properly and provide accurate results.

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

Market research was not conducted due to the proprietary nature of the items and compatibility requirements .

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:
The facility has awarded a new contract for these services. A three month task order is needed to allow for the transition period needed to conduct reference testing which assures a new manufacturer's equipment will give the VA lab results that can be interpreted in conjunction with other lab systems.

(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 VA has awarded a competitive contract to a new vendor for these testing services. Abrupt replacement of the existing Siemens equipment is impossible due to 4-6 months of a transition period needed to conduct reference testing which assures the new manufactures equipment will give the VA lab results that can be interpreted in conjunction with other lab systems. This transition period and requirement must be taken into account when proposing future replacements of these machines.

(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.)*

Eric D Stovall — SIGNATURE
4-16-15 — DATE

Eric Stovall	Budget	Pathology & Lab 113
NAME	TITLE	SERVICE LINE/SECTION

STE-583
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.

Kevin P. Adkins 393019

Digitally signed by Kevin P. Adkins 393019
DN: dc=gov, dc=va, o=internal, ou=people, 0.9.2342.19200300.100.1.1=kevin.adkins@va.gov, cn=Kevin P. Adkins 393019
Date: 2015.04.16 14:30:20 -05'00'

CONTRACTING OFFICER'S SIGNATURE

04/16/2015
DATE

Kevin P. Adkins, Contracting Officer
NAME AND TITLE

Network 11 Contract Office
FACILITY

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

Toni D. Waggoner-Boykin 393105

Digitally signed by Toni D. Waggoner-Boykin 393105
DN: dc=gov, dc=va, o=internal, ou=people, 0.9.2342.19200300.100.1.1=toni.waggoner-boykin@va.gov, cn=Toni D. Waggoner-Boykin 393105
Date: 2015.04.16 16:57:07 -04'00'

SIGNATURE

04/16/2015
DATE

Toni Waggoner-Boykin, Supervisory Contracting Officer
NAME

NCO 11 PCO Director of Contracting