

LIMITED SOURCES JUSTIFICATION

ORDER >SAT

FAR PART 8.405-6

Acquisition Plan Action ID: 36C256-18-AP-2591

- 1. Contracting Activity:** Department of Veterans Affairs, NCO 16, Division II, Supply Team C, Overton Brooks VA Medical Center, Shreveport, LA. 2237# 667-19-1-059-0011.
- 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](#)). Action will result in a new Deliver Order with a Base year and Four Option Years, beginning in October 2018.

Order against: ☒ FSS Contract Number: V797D-60637
Name of Proposed Contractor: ORTHO CLINICAL DIAGNOSTICS

Street Address: 1001 US HIGHWAY 202

City, State, Zip: RARITAN, NJ 08869

Phone: 585-453-6141

3. Description of Supplies or Services:

The estimated value of the proposed action is \$ 252,012.90

| Time Period | Cost |
|--------------------|---------------------|
| Base Period | \$ 50,042.58 |
| Option Year 1 | \$ 50,042.58 |
| Option Year 2 | \$ 50,042.58 |
| Option Year 3 | \$ 50,042.58 |
| Option Year 4 | \$ 50,042.58 |
| Total Order | \$ 252,12.90 |

The analyzer, reagents and supplies for this order are to be used in the testing of patients and donor units for the purpose of transfusion of blood and blood products. Reagents are critical to

direct patient care and must meet FDA, AABB, Joint Commission, CAP and CLIA regulations for patient care and safety. The analyzer is the updated version of the Provue currently in use to perform blood bank assays. This is a lease (CPRR/reagent rental) for the analyzer. Cartridges, reagents, controls, and supplies will be purchased over a base year plus 4 option years for a total of \$250,212.90. The VISION is on FSS — V797D-60637

(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; Standardization: Current in-use supplies and technician training are compatible with this system. Use of another system would induce an uneconomical investment in supplies. Medical Technologists and Lab Technicians would be required to conduct training and re-write SOPs. This, along with the increased potential for errors would negatively impact our Veteran population.
- ☒ 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: ID-Micro Typing System™ Gel technology reagent products.
- ☐ 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: Ortho Clinical Diagnostics is one of three FDA licensed distributors for an automated immunohematology analyzer. We are currently utilizing MTS reagents which

are specific for the current instrument P&LMS uses for automated testing. We have Ortho reagents, cards and supplies in our inventory. The other manufacturers use an eight well gel card. Ortho has a 6 well gel card. Ortho workstations will only work with 6 well cards which we currently use. Ortho is a sole source supplier of the 6 well gel cards. No other manufacturer has a product that will function for the type of instrument used for blood bank testing. Instrument is classified by the FDA as a medically regulated device. The Ortho analyzer is compatible with VBECs which will be interfaced in our network. All our manual methods use Ortho reagents and cartridges. Changing instruments would require us to revamp our entire blood bank processes, which is not cost effective or a viable option. All our SOPs would have to be rewritten and MTs/MLTs would have to be retrained.

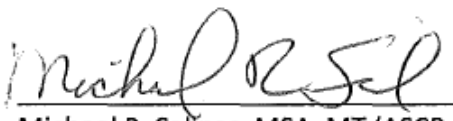
(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:


Market Research indicates that there are multiple manufactures of immunohematology reagents in that supply automated equipment and reagent supplies for transfusion medicine. The in-use inventories, SOPs, and current training would require an uneconomical investment of funds and technician and pathologist time if another brand of instrument were to be procured. Ortho has stated they are the only source providing the instrument to healthcare organizations.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION: The potential for increased errors caused by unfamiliar procedures and the impact of such errors on the Veterans we support should a different analyzer be procured must also be considered.

(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: N/A


(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.)*


Michael R. Salinas, MSA, MT (ASCP)
Laboratory Manager
TITLE


Date
Overton Brooks VAMC
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.

| | |
|--------------------------------------------------------------------------------------------|-----------------------------------------------------------|
|  _____ | 8/22/2018 _____ |
| CONTRACTING OFFICER/DESIGNEE'S SIGNATURE | DATE |
| Contracting Officer _____ NAME AND TITLE | NCO 16 Division II Supply Team C _____ FACILITY |

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.

SIGNATURE

DATE

NAME

NCO/PCO XX Duty Title