

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan Action ID: VA247-17-AP-6119

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: Roche Diagnostics

Manufacturer/Contractor POC & phone number: Chet Bounds 470.728.8592

Mfgr/Contractor Address: 9115 Hauge Road Indianapolis, IN 48250

Dealer/Rep address/phone number: Chet Bounds 470.728.8592

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

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs
Charlie Norwood VA Medical Center
Augusta, Georgia 30901

VISN: 07

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

This is a Firm Fixed Price task order written against contract number VA797P-5279B. A cost per test (CPT) contract that will provide a fully automated and integrated robotic testing platform. The automation platform will consist of a sample input station, centrifuges, cap-removal station, sample analyzers, and sample storage. Samples will move from station to station via robotic movement and conveyor belts. The integrated sample analyzer will perform a full range of routine and non-routine tests on whole blood, plasma, urine, and other body fluids. The test menu consists of over 80 different tests. The automation platform will always maintain positive ID control of all samples. The automation platform will include computers from which CNVAMC employees will monitor all aspects of the testing process. The laboratory results generated will be transmitted to the VA Laboratory Information System (LIS) via bi-directional interface. Results generated will be available to all health care providers for use in the development of individualized patient treatment plans.

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

All consumables required for operation of the automated testing platform, to include; reagents, controls, calibrators, calibration verification check samples, tubes, pipette tips, caps, labels, and ISE cartridges are provided at no charge as part of the cost per test contract. The Roche Cobas 8000 system uses only Roche prepackaged reagents and solutions that are specific for this instrument. Diagnostic and definitive treatment is needed by the health care team for patient care in all clinics including CBOC's, the ED, and the OR. Data Innovations Middleware and College of American Pathologists drivers are required for routine operations. The automated system must support HL7 protocol, and have a Quality Control

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integrated package that is real time integration of QC information with Bio-Rad. Thin Client License are required to access the instrument manager to manage test mapping, patient and QC data.

BASE YEAR	1 October 2017 – 30 September 2018	\$1,284,244.38
OPTION YEAR 1	1 October 2018 – 30 September 2019	\$1,279,120.38
OPTION YEAR 2	1 October 2019 – 30 September 2020	\$1,279,120.38
OPTION YEAR 3	1 October 2020 – 30 September 2021	\$1,279,120.38
OPTION YEAR 4	1 October 2021 – 30 September 2022	\$1,279,120.38
TOTAL		\$6,400,725.90

(b) **ESTIMATED DOLLAR VALUE:** \$1,284,244.38/base year if contract. (With option years estimated total for base + options are \$6,400,725.90)

(c) **REQUIRED DELIVERY DATE:** October 1, 2017

(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.

Roche Diagnostics is the only vendor to offer a fully automated and integrated testing platform that includes: a complete cardiac panel (that included Troponin T), complete hepatitis testing, and routine testing for anti-rejection drugs.

(Vendor memo attached)

☒ A patent, copyright or proprietary data limits competition.

Roche Diagnostics is the only vendor to offer the Troponin T test. This test is used in the management and diagnosis of patients who have experienced a heart attack. Roche is the only manufacturer and supplier of Troponin T for cardiac testing and the only vendor that has FDA approved High Sensitive Troponin T assay. This test has been available at the CNVAMC since 2003 and is well established as a diagnostic and treatment tool for CNVAMC providers.

☒ These are "direct replacements" parts/components for existing equipment.
The laboratory is currently using the Roche Cobas 6000 system to perform routine and STAT chemistry testing. Replacement equipment will expand our current test menu, increase the sample throughput, and decrease overall downtime given that the current system maintenance intensive due to a combination of equipment age and demands placed on it by the laboratory. The laboratory is currently undergoing extensive renovations. Moving the existing equipment is not desirable from both a financial point (approximately \$52,000 to move the current instruments) and a technical point (if the current instruments are moved, they would have to be re-validated prior to being placed back into service). Additionally, any delay new instrumentation may delay laboratory renovation. Any delay in the renovation initiate financial penalties for CNVAMC to the renovation contractor.

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☒ 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.
Current equipment will be replaced in its entirety. The new equipment must interface, bi-directionally, with VistA.

☐ 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:

Overall cost is comparable to other vendors who may offer similar capabilities. The training necessary for laboratory would be minimal due to retaining the Roche Diagnostics COBAS system. Also, the bi-directional interface between the COBAS and VistA would require little to no adjustment/rewriting due to the already existing interface between the current COBAS and VistA. This order will be placed in accordance with FAR 8.404. General Services Administration has already negotiated fair and reasonable pricing. Prior to issuance of the Order, technical acceptability and total overall price reasonableness will be considered.

(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 performed to determine, primarily, the test menus of other vendors. The market research did not proceed beyond test menu inquire since no other vendor offers the troponin T test. A formal source sought was not conducted, however, market research was conducted through VIP; four (4) vendors were revealed using NAICS codes 325413 (Invitro Diagnostic Substance). Emails were sent to each vendor requesting capability of providing supplies and services, two negative responses were received. A search of the Small Business Dynamic website revealed zero (0) vendors; a search of the GSA website revealed 3 large businesses.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

Service can VPN into Cobas Link and Instrument Manager to trouble shoot problems and help with service calls preventing downtime.

(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:

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(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.)*

8/3/2017

X C.T. Bruker, M.D.

C.T. Bruker

Signed by: CHARLES T. BRUKER 1408174

SIGNATURE

DATE

Charles Bruker, M.D.

Chief Pathology & Laboratory Medicine

NAME

TITLE: SERVICE LINE/SECTION

CNVAMC Augusta

FACILITY

(10) APPROVALS IN ACCORDANCE WITH THE VHAPM, Volume 6, Chapter VI: OFOC SOP: *This part if filled out by Contracting Staff as part of the Justification*

a. CONTRACTING OFFICER'S CERTIFICATION (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Brigitte R. Huffin

1362863

Digitally signed by Brigitte R. Huffin 1362863
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=brigitte.huffin@va.gov,
cn=Brigitte R. Huffin 1362863
Date: 2017.08.09 15:16:44 -04'00'

8/9/2017

CONTRACTING OFFICER/DESIGNEE'S SIGNATURE

DATE

Brigitte Huffin

Contracting Officer

Network Contracting Office

NAME AND TITLE

FACILITY

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

Bonita L Floyd-ross

187732

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0.9.2342.19200300.100.1.1=bonita.floyd-ross@va.gov,
cn=Bonita L Floyd-ross 187732
Date: 2017.08.11 11:57:29 -04'00'

08/11/2017

SIGNATURE

DATE

Prudence Y. Howard

NCO 7 Director of Contracting

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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

Joseph P. Maletta
VHA Head of Contracting Activity (HCA)

JOSEPH MALETTA
1347841

Digitally signed by JOSEPH MALETTA
1347841
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0.9.2342.19200300.100.1.1=joseph.maletta
@va.gov, cn=JOSEPH MALETTA 1347841
Date: 2017.08.15 12:27:54 -04'00'



Charlie Norwood VA Medical Center
1 Freedom Way
Augusta, GA 30904
Mr. Joshua Edwards

August 2, 2017

Roche Diagnostics as sole source provider of cobas 8000

Mr. Edwards,

At Roche, we are focused on improving the lives of patients. **Cobas** systems are designed with your needs in mind to support the work you do and the Veterans you serve.

- Roche is the sole distributor of the **cobas** 8000 analyzer series, a fully automated integrated testing chemistry/immunoassay testing platform. Roche is the sole manufacturer of reagents and sole provider for the analyzer series.
- Roche is the only manufacturer and supplier of Troponin T for cardiac testing, and the only vendor that has FDA approved High Sensitive Troponin T assay. Roche offers a complete cardiac panel including ProBNP.

Roche is committed to helping you provide excellent healthcare to the Veteran patients you serve. Thank you for the opportunity. *Doing now what patients need next.*

Sincerely,

Juliette Bradley
Regional Account Specialist
678-294-2207
Juliette.bradley@roche.com