

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

2237 Transaction # or Vista Equipment Transaction #: 519-15-3-100-0584

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in paragraph 3 below is sole source; therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is limited 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: Abbott Laboratories Inc.

Manufacturer/Contractor POC & phone number: Neal Johnson (847) 935-2135

Mfgr/Contractor Address: 100 Abbott Park Road, Abbott Park, IL 60064

Dealer/Rep address/phone number: Brad Thompson (325) 370-8993

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

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs

West Texas VA Health Care System

Pathology and Laboratory Medicine

300 Veterans Blvd

Big Spring, TX 79720

VISN:

SAO West NCO 18 El Paso

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

The West Texas VA Health Care System (WTVAHCS) Pathology & Laboratory Medicine Service (P&LMS) is currently on a cost-per-test deliver order for the Abbott Architect ci41000 that will expire on March 31, 2015. This Chemistry/ Immunoassay Analyzer runs a variety of patient tests necessary for patient diagnosis. This limited sources justification is for issuance of a delivery order against Federal Supply Schedule (FSS) Contract V797P-7335A to continue the Abbott Cost per Test requirements of the West Texas VA Pathology & Laboratory Medicine Service.

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

The following are estimated quantities of reagents/supplies that will be ordered on an "as-needed" basis:

Test Name	Estimated Annual Volume
Albumin	21000
Alk Phos	21000
ALT	21000
Ammonia	350
Amphetamines/Methamphetamines (Urine)	4500

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Amylase	300
Anti HCV	1200
AST	21000
Barbiturate (Urine)	4500
Benzodiazepine (Urine)	4500
Buprenorphine (Urine)	4500
BNP or Pro BNP	800
Calcium	22000
Cannabinoids (Urine)	4000
CEA	200
Chloride	24000
Cholesterol	20000
CK	4000
CK-MB	1900
CO2	24000
Cocaine (Urine)	4500
Creatinine	24000
CRP	500
CSF Protein	40
Digoxin	300
Direct Bilirubin	22000
Ethanol	1400
Ferritin	1000
Folate	1100
Free T4	700
Gentamicin	100
GGT	400
Glucose	24000
Glycohemoglobin	14000
HAV IgM	900
HBc IgM	900
HBsAb	250
HBsAg	900
HDL	22000
HIV Ag/Ab 1 & 2	1300
Iron	1000

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LDH	20000
LDL (direct)	20000
Lipase	300
Lithium	200
Magnesium	1100
Methadone (Urine)	4500
Microalbumin	14000
Opiates (Urine)	4500
Oxycodone(Urine)	4500
PCP (Urine)	4500
Phenobarbitol	100
Phenytoin	120
Phosphorus	550
Potassium	24000
Prealbumin	50
Quantitative Beta HCG	100
Rhematoid Factor	500
Sodium	24000
Testosterone	2400
THC (Urine)	4500
Theophylline	100
Total Bilirubin	20000
Total Protein	23000
Total PSA	11000
Total T4	5000
Transferrin	300
Triglyceride	20000
Troponin I	600
TSH	13000
Urea Nitrogen	24000
Uric Acid	1000
Urine Protein	100
Valproic Acid	300
Vancomycin	150
Vitamin B12	3100
Vitamin D 25-OH	9000

(b) ESTIMATED DOLLAR VALUE: \$258,046.95

(c) REQUIRED DELIVERY DATE: April 1, 2015 through September 30, 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.

The WTVAHCS Pathology & Laboratory Medicine Service requires the ability to purchase reagents from Abbott Laboratories Inc to perform clinical laboratory testing. Abbott Laboratories Inc is the only source for these reagents, consumables and instrumentation CPT and no other supplies will satisfy agency requirements without compromising patient care. P&LMS must purchase the Abbott Laboratories Inc reagents that have been FDA approved to generate accurate results. Use of any other manufacturer's reagents on the Abbott Laboratories Inc Architect ci41000 will void the service delivery order agreement and be in violation of the laboratory's accrediting agency requirements. Procedure manuals have been written (and are routinely utilized by laboratory staff) for each test processed by this instrument based upon use of Abbott Laboratories Inc products. The WTVAHCS needs to continue the CPT delivery order with Abbott Laboratories Inc for continuation of patient care without delays. It would take a minimum of three (3) months to install, validate, train and implement a new Chemistry/Immunoassay Analyzer. This would delay patient care as well as change the current reference ranges for analytes that were just established and have been used by physicians for three (3) years.

☐ A patent, copyright or proprietary data limits competition. The proprietary data is:

☐ 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 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:

By placing an order against an FSS Schedule contract (V797P-7335A) using the procedures in FAR 8.405-3, the ordering activity has concluded that the agreement represents the best value (as defined in FAR 2.101, Definitions) and results in the lowest overall cost alternative to meet the Government's need. Under the FSS Schedules Program, the VA has determined that prices under FSS Schedule contracts are fair and reasonable.

Continued use of the Abbott Chemistry/Immunoassay Analyzer CPT currently in place will eliminate the need for capital outlay to send out testing, representing a savings to the Government of approximately \$2,363,260. In addition, continuity of equipment also represents a continuity of service to the facility.

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

A review of Federal Supply Schedule (FSS) national contracts and prime vendors showed that this Chemistry and Immunochemistry testing requirement are available from a VA NAC delivery order source under SIN 66 III Clinical Analyzers, Laboratory, Cost-Per-Test Category – 605-1A High Maintenance/Complexity Analyzers.

Review of Internet resources: GSA e-Library - <http://www.gsaelibrary.gsa.gov/>

The Chemistry Immunology Analyzer CPT is available under FSS Schedule SIN 66 III Clinical Analyzers, Laboratory, Cost-Per Test (Clinical Chemistry Analyzers) – Category 605-1A High Maintenance/Complexity Analyzers. Note out of the eight (8) vendors under this SIN there is only one (1) small business the rest are other than small businesses.

P&LMS must purchase the Abbott Laboratories Inc. reagents that have been FDA approved to generate accurate results. Use of any other manufacturer's reagents on the Abbott Laboratories Inc. Architect ci41000 will void the service contract agreement and be in violation of the laboratory's accrediting agency requirements. Procedure manuals have been written (and are routinely utilized by laboratory staff) for each test processed by this instrument based upon the use of Abbott Laboratories Inc. products. The WTVAHCS needs to continue the CPT contract with Abbott Laboratories Inc. for continuation of patient care without delays. It would take a minimum of three (3) months to install, validate, train and implement a new Chemistry Immunoassay Analyzer. This would delay patient care as well as change the current reference ranges for analytes that were just established and have been used by physicians for three (3) years.

They are the only vendor that can provide the Chemistry Immunoassay Analyzer CPT on schedule due to the fact there equipment has already been validated, staff is already trained and procedures have been implemented.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

Abbott Laboratories Inc. has successfully provided these products to other VA medical centers. They are the only vendor that can provide the Chemistry/Immunoassay Analyzer CPT on schedule due to the fact their equipment has already been validated, staff is already trained and procedures have been implemented.

(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 five (5) year Blanket Purchase Agreement (BPA) for Chemistry/Immunoassay Analyzer CPT will be established and effective on October 1, 2015. This procurement will be solicited competitively and all FSS Schedule contract holders will have fair opportunity to compete. The acquisition plan for the long term BPA has been approved by SAO West. The long term BPA requires CRT approval thus this delivery order will ensure that the testing remains uninterrupted for patient care while the long term BPA is awarded.

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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.)*


SIGNATURE

2/12/15
DATE

Lisa Patton
NAME

Laboratory Supervisor
TITLE

Pathology & Laboratory Medicine Service
SERVICE LINE/SECTION


West Texas VA Health Care System
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.


CONTRACTING OFFICER'S SIGNATURE

2/27/2015
DATE

 Carlos Leon, Contracting Officer
NAME AND TITLE

SAO West, NCO 18, El Paso
FACILITY

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


SIGNATURE

3/13/2015
DATE

Sabrina J Smith
NAME
NCO 18 Director of Contracting