

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan Action ID: VA261-16-AP-7003

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: Quest Diagnostics Incorporated

Manufacturer/Contractor POC & phone number: Darlene Tjon (707)696-1448

Mfgr/Contractor Address: Three Giralda Farms Madison, NJ 07940

Dealer/Rep address/phone number: N/A

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

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs

Network Contracting Office (NCO) 21

3375 Koapaka Street Suite F250

Honolulu, HI 96819

VISN:

21

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

The limited source justification is for reference laboratory testing services for the VA Pacific Islands Healthcare System (VAPIHCS). The Network Contracting Office (NCO) 21 plans to award a firm-fixed price Basic Purchase Agreement (BPA) call against FSS contract V797P-7105a. The FSS contract expires on September 30, 2016. The Contracting Officer (CO) reached out to the FSS contract administrator and Quest Diagnostics regarding a follow-on contract. Both confirmed on August 10, 2016 that a new FSS contract for services will be awarded and effective on October 1, 2016. The BPA, VA260-16-A-0009, was awarded by the Western States Network Consortium (WSNC) on January 6, 2016 for a period of five years and a ceiling of \$50 million. To date, no calls have been placed against this BPA. The BPA has language stating that "if a new FSS contract is awarded to the current BPA holder before the BPA expires, the parties by mutual agreement may modify this BPA to reflect the new FSS contract number for the remaining term of the BPA." This order that falls under the BPA, VA260-16-A-0009, shall have the new FSS contract number incorporated via modification. The BPA call will be for a period of one year from October 1, 2016 – September 30, 2017 and one option year. The current BPA call order, VA260-13-A-0003 VA261-16-J-0042, expires on September 30, 2016 with no additional option periods other than FAR 52.217-8. However, the BPA ceiling on the current call has been exceeded. Therefore, no additional options or calls may be placed against BPA VA260-13-A-0003.

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

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The reference laboratory shall provide laboratory services to include pre-analytic processing as defined in its laboratory manual; analysis, reporting of analytic results, and interpretation. The reference laboratory is responsible for providing requisition forms, special instructions, and current list of tests with reference ranges, turnaround times, specimen requirement, specimen transport supplies, and courier service. The contractor is also responsible for providing an interconnection for exchanging data between Veterans Health Information Systems and Technology Architecture (VistA) Laboratory Electronic Data Interchange (LEDI) System owned by the VA and the Reference Laboratory's Electronic Data Interchange (EDI) System for the purpose of delivering laboratory orders to the reference laboratory and to deliver the reference laboratory test results to the VAPIHCS. This interchange connection shall be protected through the use of VA approved encryption algorithms and products as required. Connections at each end shall be located within a controlled access facility. All access shall be controlled by authentication methods to validated approved users.

The reference laboratory must be certified and accredited by CLIA, the College of American Pathologists (CAP) and/or The Joint Commission, and licensed by other federal and state regulatory agencies as mandated.

The contractor shall be responsible for courier pick up of samples from the VAPIHCS Monday through Friday, excluding Federal Holidays. The Contractor is responsible for the transport of samples in such a manner as to insure the integrity of the specimen. All transport of specimens shall be in compliance with the Department of Transportation (DOT) and International Air Transport Association (IATA) regulations and guidelines.

The contractor is responsible for uploading test results within 48-72 hours after pickup for most routine tests. Specialty test result turn-around-times may be longer depending on the test methodology and it will be expected to meet the Contractor's published turn-around-times. All test results must be electronically uploaded into the VistA system. Hard copy or imaged test results are not allowable except for use as an interim resulting vehicle when the interface connectivity is disrupted.

(b) ESTIMATED DOLLAR VALUE: REDACTED

(c) REQUIRED DELIVERY DATE: October 1, 2016

(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.

This service requires that the laboratory test results be uploaded electronically into VAPIHCS VistA onto custom interfaced forms. Each laboratory test requires a custom-built form that has been developed from scratch by the VAPIHCS laboratory and vetted and data field connectivity validated by a VA bio-medical engineer, before the test is considered to be interfaced in the VistA system. The electronic interface is required to insure the accurate capture, documentation, and timely receipt of the test results transmitted back to the VAPIHCS medical record. These laboratory forms are vendor-specific

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based on a vendor's test methodology and vendor's interfacing/IT system/software. Therefore, a new contractor cannot simply use the forms from the incumbent contractor. In addition, each station's VistA is location specific meaning a contractor currently performing in Palo Alto with forms built into Palo Alto's VistA will not have these forms in Hawaii's VistA. To get the forms into the Hawaii VistA would require building the forms, testing, interfacing, etc. Locally developed test forms in VistA are not shared across sites/stations.

The VAPIHCS requires lab test results to be transmitted on interfaced forms so that individual care providers have the ability to extract custom templated data reports to search historic lab results for single or multiple tests on a patient to track and trend patient medical condition over time. This function is critical to monitor disease progression over time. Without an interfaced lab package and test results electronically transmitted, the VAPIHCS would have no way to search historic laboratory data by test type or test result. The VAPHICS would also not be able to trend or run reports for each patient without manually re-entering test results into another system and then querying. The risk of clerical error in manual data re-entry is high and could be potentially detrimental to patient care.

In order to obtain access to the VA's network, establish a direct connection between a third party site and the Government, and access through the VA's firewall, the vendor must undergo a lengthy IT security process that involves collaboration with the National Security Operations Center (NSOC). The vendor must establish an Interconnection Security Agreement and Memorandum of Understanding (ISA MOU) with the Department of Veterans Affairs. Establishing an ISA MOU takes approximately 6 months to one year.

Multiple national laboratory companies already have national VA ISA MOUs. Once an ISA MOU is established, a vendor must then work with local IT personnel to establish an interchange to the local VistA system. In addition, the vendor must work with the local laboratory and bio-medical engineer to build the lab package (lab forms for each test). Each test form must undergo a production phase (where forms are created), then a test or validation phase (where forms are tested to determine transmission accuracy), and then a go-live phase. Each test form would take at least 3 hours to develop. There are 140 tests the VAPIHCS requires. The laboratory would require two FTEs for 6 months working on building new forms for a new vendor. A typical test/validation phase can take up to 4-6 months to complete depending on the complexity of the test form components and the number of test forms being validated concurrently.

The current BPA call order expires on September 30, 2016. The Government does not have the time or resources to compete the requirement. The VAPIHCS orders more than 17,000 lab tests per year and cannot afford even one day of lapsed service. The Chief of Lab Services at the VAPIHCS reports that if this service stopped even for one day, all clinical operations within the VAPIHCS would stop and the continuum of patient care critically disrupted. The Chief also stated that the lab does not have the resources or bodies at this time to fulfill the back-end work of building the lab package and forms for a new vendor. The VAPHICS laboratory is currently staffed only at 60% of its requirement. The local IT department also stated that it does not have the staffing levels or any on-site VistA interfacing specialist that can efficiently work with a new vendor for VistA access. Due to the time and resource constraints of the Government, only the incumbent vendor can perform this work on 10/1/16 without any lapse in service.

This BPA call order is limited in duration to the time in which the sole source environment will persist. The contracting officer and the end-user called Region 1 IT to determine a specific point-of-contact that

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could be assigned to work on interfacing a new vendor to the Hawaii Vista. The end-user also explored alternative options for creation of the lab package such as contracting for its services or including this requirement in the long-term contract prior to the period of performance for lab testing services (having the awardee build the forms in Vista). Given these alternatives to open up competition, this limited source BPA call order will be limited to a base year and one option year. The end-user is actively working to eliminate any competition barriers by planning for the long-term contract. The long-term contract will need to be awarded 6 months to 1 year in advance to allow for the proper mobilization if a new vendor is awarded the contract.

☐ 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 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:

The fixed prices for services under FSS contract V797P-7105A have already been determined to be fair and reasonable by the FSS contracting officer. Therefore, ordering activities are not required to make a separate determination of fair and reasonable pricing (FAR 8.404(d)). The WSNC BPA, VA260-16-A-0009, offers significant price reductions from the FSS catalog pricing ranging from 1.81%-56.78%. The applicable discount varies based on the Special Identification Number (SIN) associated to each test. The VAPIHCS estimates that certain tests will require a large annual volume. Further price discounts from the BPA pricing will be requested for these tests.

A call against the WSNC BPA to Quest Diagnostics represents the best value to the Government. Quest Diagnostics is able to perform with no transition or mobilization down-time. They currently have an interface set up with the Hawaii VistA, and the lab package with all test forms have been completed and tested. No additional transition time or effort would be required. In addition, as noted above, Quest Diagnostics has a VA FSS contract with discounted pricing and a WSNC BPA with even greater discounts from the FSS pricing. The VAPIHCS will ask for additional price discounts prior to award. The Government is obtaining significantly discounted rates.

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

Per VA Procurement Policy Memorandum (PPM) 2016-05, which implements policy concerning the *Kingdomware Technologies v. U.S.*, 136 S.Ct 1969 (2016), court holding, a search in the VIP database was done using NAICS 621511, medical laboratories, for the State of Hawaii (non-strict). Two vendors were listed in VIP: Navarre Corporation and Vital Health Links. Additional market research was conducted to determine if these two vendors were qualified and capable of performing the requirement. A search in www.sam.gov was conducted to verify if the applicable NAICS, 621511, was also listed in www.sam.gov as a small business. The www.sam.gov profiles for both Navarre Corporation and Vital Health Links did not contain NAICS 621511 in the profile NAICS section or the representation of size status clause, FAR 52.219-1. The Contracting Officer emailed directly Navarre Corporation and Vital Health Links with a sources sought inquiry that included the scope of work and a listing of the laboratory tests required by the VAPIHCS. Neither vendor responded. A further search was conducted on their websites to determine if they were a Clinical Laboratory Improvement Amendments (CLIA) registered laboratory. The Centers for Medicare and Medicaid (CMS) regulates all laboratory testing performed on humans in the United States through the CLIA. Neither vendor is listed as a CLIA registered laboratory. There are no VIP registered SD/VOSB vendors that can perform this service on the open market. The Rule of 2 established by 38 U.S.C. §§8127, 8128 is therefore not satisfied as there are not two SDVOSB or VOSB vendors that can provide this service.

A Sources Sought was posted on GSA E-Buy on July 29, 2016 with a close date of August 3, 2016 under FSS Schedule 62 II, Medical Laboratory Testing and Analysis Services. There were no SD/VOSB vendors under this FSS schedule. The CO received two responses from Quest Diagnostics Incorporated and Laboratory Corporation of America, both large businesses. In addition to schedule contracts, both Quest Diagnostics and Laboratory Corporation of America have WSNC BPAs. The VAPIHCS is an authorized ordering facility listed on the WSNC BPAs. The use of existing contract vehicles such as the WSNC BPAs are also considered a preferred (non-mandatory) source under VAAR 808.004-70 Deviation. Quest Diagnostics is the incumbent vendor. Of the 140 types of tests required by the VAPIHCS, Quest has 139 tests on their FSS schedule and Lab Corp. has 135 tests on their FSS schedule. Quest is the incumbent vendor and already has a lab package and interfacing set up with the VAPIHCS VistA. Lab Corp. has a national ISA MOU for interfacing but does not have a local interface established or a lab package for the Hawaii VistA. Therefore, given the time constraints of this requirement and that continuity of services is required when the current contract ends, this requirement cannot be competed. However, please see #8 below for steps already being taken so that competition may be obtained in the future.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

The VAPIHCS submits over 17,000 reference laboratory tests per year. The VAPIHCS is a small clinical lab that does not have the ability or resources to perform a majority of its specialty tests in house and must therefore source out these tests to contracted laboratories. A lapse of even one-day of service under contract would result in a complete shutdown of VAPIHCS clinic operations. The VAPIHCS cannot operate without this service.

(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 end-user consulted with the Office of Information Technology (OIT) and other VA laboratories to understand the processes and lead time required to initiate an interface with a third party vendor to the VAPIHCS Vista system. While resources (staffing) at the VAPIHCS are low, the OIT Region 1 is able to assist with interfacing a third party company with the local Vista system. Almost all, if not all, of the vendors on the FSS schedule 621 II have national VA ISA MOUs so that access to the local VA systems and firewall port is obtainable within a relatively short period of time (1 month). If a vendor that does not already have a national VA ISA MOU were awarded the contract, the process to obtain a VA ISA MOU would take one year.

The middleware portion of the interface requirement requires building of the lab package. The lab package consists of pre-populated forms (one for each test). The construction of these forms requires coordination with a bio-medical engineer and the laboratory for validation and testing to insure accurate and complete transmission of electronic results. The end-user is now looking into either hiring a third-party contractor to assist with the building of these forms when a long-term order/contract is put in place or requiring that the awardee of the long-term requirement also provide the service of providing the lab package and all required validation and testing of each form. While typically this function can be done in-house, the VAPIHCS does not have laboratory resources (approximately 2 FTE for 6 months) to build forms, test, and validate for hundreds of individual tests.

In planning ahead for the long-term contract/order, the above two barriers which create the sole source environment may be overcome. As such, this limited source justification is only for a base period and one option year. Within two years and with proper planning, the VAPIHCS believes this requirement will no longer be a limited source requirement.

(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.)*

REDACTED

(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*

REDACTED