

VA Texas Valley Coastal Bend Healthcare System
Pathology and Laboratory Medicine Service

STATEMENT OF WORK

A. GENERAL INFORMATION

1. Title of Project: Cost per reportable Fecal Immunochemical analyzer lease for the Harlingen Laboratory.
2. Scope of Work: The contractor shall provide a cost-per-reportable-result (CPRR) agreement for the VA Texas Valley Coastal Bend Healthcare System (VATVCBHCS) Pathology and Laboratory Medicine Service. Contractor agrees to furnish all personnel, labor, transportation, equipment, materials, and supplies necessary to provide means for VCB laboratories and testing staff to run laboratory cost per reportable and to provide guidance in Clinical Pathology Procedures as specified herein for eligible VA beneficiaries of the VATVCBHCS, 2601 Veterans Drive, Harlingen, TX 78550. The contractor shall provide initial one-day training on-site at no charge. Instrument service and maintenance shall be provided during business hours Monday thru Friday.
3. Background: The VA Texas Valley Coastal Bend Healthcare System Pathology and Laboratory Medicine Service has a requirement to provide Fecal Immunochemical testing services to the medical staff and veteran patients. The purpose of the resulting contract will be to provide cost per reportable result testing for the VA Texas Valley Coastal Bend Healthcare System.
4. Performance Period: Base + 4 Option Years
 - i. Base Year: 10/01/2019 to 09/30/2020
 - ii. Option Year 1: 10/01/2020 to 09/30/2021
 - iii. Option Year 2: 10/01/2021 to 09/30/2022
 - iv. Option Year 3: 10/01/2022 to 09/30/2023
 - v. Option Year 4: 10/01/2023 to 09/30/2024

Facilities of Performance

1. Harlingen Health Care Center, Pathology and Laboratory Department, 3rd Floor, 3G-101, 2601 Veterans Drive, Harlingen, TX 78550.
 - a. Estimated Number of Yearly Tests: 2,871

Equipment Required: One complete compact Fecal Immunochemical Testing analyzer for the Harlingen Laboratory.

5. Type of Contract: Firm Fixed Price

B. CONTRACT AWARD MEETING

1. The contractor shall not commence performance on the tasks in this SOW until the contracting officer has conducted a kick-off meeting or has advised the contractor that a kick-off meeting is waived.

C. GENERAL REQUIREMENTS

1. For every task, the contractor shall identify in writing all necessary subtasks (if any), associated costs by task, along with associated sub-milestone dates. The contractor's subtask structure shall be reflected in the technical proposal and detailed work plan.
2. All written deliverables shall be phrased in layperson language. Statistical and other technical terminology shall not be used without providing a glossary of terms.
3. The contractor shall have proven experience or previous VA contract with expertise in performing preventative maintenance (PM) biannually at a time mutually agreeable between the contractor and the Contracting Officer's Representative (COR). PM's will be performed in accordance with the manufacturer's instructions and specifications to include, as a minimum, the following:
 - i. Visual Inspections
 - ii. Calibration Checks
 - iii. Cleaning and Lubrication
 - iv. Performance Checks
4. The Contracting Officer's Representative (COR) is identified as the Administrative Officer for the Pathology and Laboratory Medicine Service. All work coordination shall be made through the COR. The contractor shall be provided a copy of the letter of delegation authorizing the COR at the commencement of the term of this agreement. No other person shall be authorized to act in such capacity unless appointed in writing by the Contracting Officer. The Contracting Officer is the only person authorized to approve changes or modify any of the requirements under this contract. The contractor shall communicate with the Contracting Officer on all matters pertaining to contract administration. Only the Contracting Officer is authorized to make commitments or issue changes which will affect price, quantity, or quality of performance of this contract. In the event the contractor effects any such changes at the direction of any person other than the Contracting Officer, the change shall be considered to have been made without authority and no adjustment will be made in the contract price to cover any increase in costs incurred as a result thereof.
5. The contractor shall not perform any inherently governmental functions. This includes, but is not limited to, determination of agency policy, determination of Federal program priorities for budget requests, direction and control of government employees, selection or non-selection of individuals for Federal Government employment including the interviewing of individuals for

employment, approval of position descriptions, and performance standards for Federal employees, approving any contractual documents, approval of Federal licensing actions and inspections, and/or determination of budget policy, guidance, and strategy.

6. Services provided under the terms of this contract are required to follow the College of American Pathologists accreditation policies and all applicable Federal, State, and Government laws.
7. Procedures performed on the equipment will be monitored and validated against billing using the VISTA laboratory package, VISTA Imaging, PCE (Patient Care Encounter), and PTF (Patient Treatment File). These systems will be used to verify statistics reflecting Current Procedural Terminology (CPT) codes that will be used to validate services provided under the terms of the contract.
8. Records Manager – There will be Federal records created, maintained, used or disposed with this contract regardless of format (paper, electronic, etc.) or mode of transmission (e-mail, fax, etc.).
9. The Contracting Officer Representative will track and record difficulties such as poor turnaround time. Any noted difficulties or deficiencies will be reported to the contracting officer for appropriate action and remedy.
 - i. Texas Valley Coastal Bend Healthcare Center
Julio Benavides
Administrative Officer for PALMS
2601 Veterans Drive
Harlingen, TX 78550
Phone (956) 291-9241
10. The COR shall provide the following information upon request.
 - i. Indication of average monthly volume of specified tests listed in this contract.
 - ii. Coefficient of variation of quality control samples of specified tests the laboratory performs.
 - iii. Provide address of processing sites under contract, including subcontracted testing location sites.
11. The contractor shall provide items such as reagents and quality control material and ship on a specified date unless materials are requested from the chosen vendor for early release. Additional material will be requested via telephone or written request on an as-needed basis. Service and operation of the above equipment will be supervised and monitored at all times by the laboratory supervisor or other laboratory personnel. Vendor management will ensure that employees properly comply with the performance work standards outlined in the statement of work.
12. The testing system will have high standards of operation and functionality to meet the needs of VATVCBHCS, regardless of workload.
13. The instrument must be compatible with Data Innovations.

14. The instrument must have bidirectional capability and interface to VISTA through Data Innovations.
15. The instrument must include all necessary reagents, consumables, papers, printers, calibrators, and controls to perform analysis.
16. For the delivery of repair parts or materials, the contractor shall provide all parts and materials at no additional cost to the government.
17. After preventative maintenance (PM), the contractor shall submit a detailed work report for notice at no additional cost to the government.
18. Contractor shall immediately notify the service of any changes in reagents, kit composition, procedure modification, recall notification or any changes that will affect the performance of the test or procedure according to FDA regulation.

D. SPECIFIC MANDATORY TASKS AND ASSOCIATED DELIVERABLES

1. For repairs or services performed during normal business hours, the contractor's repairman must report to the Laboratory Supervisor or designee. After work is completed, the repairman must report to the laboratory supervisor or designee and provide a written report of service or repairs performed for each item of equipment and must include a listing of replacements parts. Once a service call is place to the contractor must have a service technician onsite within 24 hours of the call.
2. Contractor must respond to service calls within one hour of notification. All work performed must be accomplished in accordance with the manufacturer's instructions. The contract is a full service contract to include all necessary service calls five (5) days a week between the hours of 8am to 4:30 pm, Monday through Friday and 24 hours a day telephone technical assistance, excluding Federal Holidays. Federal Holidays are as follows: New Year's Day, Martin Luther King's Birthday, President's Day, Memorial Day, Independence Day, Labor Day, Columbus Day, Veteran's Day, Thanksgiving Day, Christmas Day, and any other day specifically designated as a national holiday by the President of the United States. The repair services will cover all parts, labor, and travel.
3. The contractor guarantees all equipment covered in this contract shall be in optimum working condition throughout the lease of the equipment.
4. The vendor will provide all upgrades to the equipment hardware and operating system software without additional charge. These enhancements to the vendor equipment shall be delivered to the government site and installed by the vendor within sixty days of their issuance or date of first commercial availability.
5. The contractor must perform the required work in accordance with Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and Veterans Health Administration Standards. The JCAHO website is: <http://www.jointcommission.org/>. The Contractor must comply with all annual updates as issued. Contractor agrees to maintain the minimum acceptable service, reporting systems and quality control as specified herein. Failure to comply with the specified terms and conditions and/or adverse reports from external monitoring agencies that indicate poor quality of care may be grounds for

termination of the contract. Contract shall provide immediate notification, within 24 hours, to the responsible VA Official of any adverse action by a regulatory agency.

6. The contractor will furnish a statement in writing to the Contracting Officer at close out of the contract to include summary of the contractor actions and statement that all requirements of the contract were fulfilled as agreed. A summary evaluation of contract performance based upon the compliance or noncompliance of contract to include a summary of contractor actions and statement that all requirements of the contract were fulfilled as agreed.

E. EVALUATED OPTIONAL TASKS AND ASSOCIATED DELIVERABLES

F. SCHEDULE FOR DELIVERABLES

1. Items are delivered and accepted by warehouse personnel at the clinics, who will then deliver the materials to the laboratory.

G. CHANGES TO STATEMENT OF WORK

1. Any changes to this Statement of Work shall be authorized and approved only through written correspondence from the Contracting Officer. A copy of each change will be kept in a project folder along with all other products of the project. Costs incurred by the contractor through the actions of parties other than the Contracting Officer shall be borne by the contractor.

H. REPORTING REQUIREMENTS

I. TRAVEL

J. GOVERNMENT RESPONSIBILITIES

K. CONTRACTOR EXPERIENCE REQUIREMENTS

L. CONFIDENTIALITY AND NONDISCLOSURE

1. It is agreed that: The preliminary and final deliverables, and all associated working papers, application source code, and other material deemed relevant by the VA which has been generated by the contractor in the performance of this task order are the exclusive property of the U.S. Government and shall be submitted to the CO at the conclusion of the task order. Press releases, marketing material or any other printed or electronic documentation related to this project shall not be publicized without the written approval of the Contracting Officer.

M. CONTRACTOR PERSONNEL SECURITY REQUIREMENTS

1. All contractor employees who require access to the Department of Veterans Affairs' computer systems shall be the subject of a background investigation and must receive a favorable adjudication from the VA Office of Security and Law Enforcement prior to contract performance. In addition, other Contractor personnel may require background investigations- depending upon a risk assessment to be accomplished by the VA Using Service in coordination with the VA's Information Security Officer. This requirement is applicable to all subcontractor personnel requiring the same access. The contractor shall be responsible for ensuring that all necessary documentation is submitted for his/her employees and the employees of his/her employees and the employees of his/her subcontractors. Contractor employees will not require access to the VA Texas

Valley Coastal Bend Health Care System computer systems or patient information to carry out the tasks outlined in the Statement of Work.

2. Privacy Officer – The contractor will not have access to Patient Health Information (PHI) nor will they have the capability of accessing patient information during the services provided to the VA.
3. Information Systems Officer, Information Protection: The contractor will not have access to VA desktop computers nor will they have access to online resources belonging to the government while conducting services.
4. Position Sensitivity – The position sensitivity has been designated as Low Risk.
 - i. Background Investigation – The level of background investigation commensurate with the required level of access is National Agency Check with Written Inquiries.
 - ii. Contractor Responsibilities
 1. The contractor shall bear expenses of obtaining background investigations.
 2. The contractor shall prescreen all personnel requiring access to the computer systems to ensure they maintain a U.S. citizenship and are able to read, write, speak, and understand the English language.
 3. The contractor shall submit or ensure that their employees submit the required information to the Contracting Officer and the Contracting Officer's Representative (COR). The contractor shall submit the required forms to the VA Security and Investigations Center within 5 days of receipt of the e-mail they receive with instructions to do so. The contractor shall not allow contractor personnel who require a background investigation to start performing until the contractor has received written confirmation from the Contracting Officer that the SIC has initiated a background investigation.
 4. The contractor, when notified of an unfavorable determination by the Government, shall withdraw the employee from consideration from working under the contract.
 5. The contractor shall ensure that all personnel requiring computer access will complete the VA's Cyber Security Training and Privacy Training prior to obtaining computer access and annually thereafter.
 6. Failure to comply with the contractor personnel security requirements may result in termination of the contract for default.
 - iii. Personal Identify Verification of Contractor Personnel
 1. If required, Contracting Officer Representatives will be responsible for coordination with the VA Police Department to obtain identification badges for contract personnel working under contract for which he/she has responsibility. Contractors will wear/display issued identification badges in a visible manner while on

VATVCBHCS property. These procedures implement Homeland Security Presidential Directive – 12 (HSPD-12), Office of Management and Budget (OMB) guidance M-05-24, and Federal Information Processing Standards Publication (FIPS PUB) Number 201, for contracts requiring contractor to have physical access to a federally-controlled facility or access to a Federal Information System.

iv. Contractor Automation Security Requirements

1. Unless written authorization is issued by the Contracting Officer, contractor employees will not use any form of removable storage media when providing services under the terms of this contract. Removable storage media includes, but is not limited to, USB thumb Drives, MP3 Players, and external hard drives. Should the contractor determine that the use of removable storage devices is required they must submit a written request with full justification to the Contracting Officer. For contractor employees who have access to and store VA information, the Contracting Officer must receive written permission from a VA supervisor and VA Information Security Officer (ISO) before authorizing Contractor employees to use such devices, and if used to store sensitive information and Technology (OI&T) official. Unless and until this written authorization is received, Contractor personnel are not authorized to use any form of removable storage media when providing services under the terms of this contract.

v. Security Controls Compliance Testing

1. On a periodic basis, the VA, including the Office of Inspector General, reserves the right to evaluate any of all the security controls and privacy practices implemented by the contractor under the clauses contained within the contract. With 10 working-days' notice, at the of the government, the contractor must fully cooperate and assist in a government-sponsored security controls assessment at each location wherein VA information is processed or stored, or information systems are developed, operated, maintained, or used on behalf of VA, including those initiated by the Office of Inspector General. The government may conduct a security control assessment on shorter notice (to include unannounced assessments) as determined by VA in the event of a security incident or at any other time.