

STATEMENT OF WORK (SOW)

A. GENERAL GUIDANCE

1. Title of Project: HbA1C Analyzer Equipment Lease with Reagents

2. Scope of Work: Vendor will provide an equipment lease agreement for the North Texas Veterans Health Care System, Pathology & Laboratory Medicine Service.

- This agreement shall cover all instruments, reagents, supplies and services for the term that are included in the cost-per-reportable testing agreement. The VA intends to award a single firm-fixed price contract with a base plus four option years.
- This agreement includes reagents, controls, calibrators, columns, M-F 8-5pm service, consumable and maintenance parts, including sample probes, filters, four(4) analyzers, four(4) reporting packages four(4) PCs, and four(4) printers.
- Vendor will perform preventative maintenance (PM) after 20,000 sample injections per instrument and validation of instrument performance after each PM.
- Two(2) instruments, reporting packages(2), PCs(2), and printers(2) will be placed in Dallas.
- One instrument, reporting packages(1), PCs(1), and printers(1) will be placed in Bonham.
- One instrument, reporting packages(1), PCs(1), and printers(1) will be placed in Fort Worth.
- Vendor will assist with instrument placement in each of the Dallas, Bonham, and Fort Worth facilities including but not limited to, instrument set-up, validation interface connectivity, training, etc.
- The scheduled and as needed reagents and supplies will be shipped to the appropriate locations.
- There is no minimum volume charges.
- Each patient sample reported is counted in LMIP program set up in VistA. At the end of each month, each VA site will submit the testing volumes to the Vendor, using LMIP report. Vendor will bill each month using the submitted volumes for each site against those volumes.
- Vendor will calculate the estimated quantity of reagents and supplies required to ship quarterly, to perform 11,000 tests per month.
- Below is a list of reagents, controls, calibrators, etc. to be shipped quarterly and as needed to Dallas, Bonham, and Fort Worth location based on combined testing average volume of 11,000 per month for all 3 facilities, Dallas(6500 tests), Bonham(1300 tests), and Fort Worth(3200 tests).

019680	Column	Each
019506F	Prefilter	5/pkg
019563	<i>Thermal Paper</i>	10 rolls/pkg
19552	Elution Buffer 1	800ml/Btl
19553	Elution Buffer 2	800ml/Btl
19554	Elution Buffer 3	800ml/Btl
18431	Hemolysis & Wash Solution	2 L/Btl
018767	Hgb A1C Calibrator Set	5/bx
992133	Controls	Box
0018723	Suction Filter S	Each

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019500	Sampling Needle	Each
018581	Sample Cup	Bag

3. Background:

4. Performance Period:

Base Period – 12 Months from effective date of award.

Option Periods – Four (4) additional Option Periods of 12 Months each.

5. Type of Contract: This is a Cost Per Reportable Reagent Rental Agreement for laboratory reagents, supplies, services, and the lease of necessary equipment.

B. CONTRACT AWARD MEETING

No “kick-off” meeting is required.

C. GENERAL REQUIREMENTS

Vendor will provide a cost-per-reportable-result (CPRR) agreement for the North Texas Veterans Health Care System, Pathology & Laboratory Medicine Service.

D. SPECIFIC MANDATORY TASKS AND ASSOCIATED DELIVERABLES

N/A

E. EVALUATED OPTIONAL FEATURES

Even though the contractor, at the Government’s option, provides the requirements specified in this section; they are nonetheless treated with the same level of control as the mandatory specifications. The CO shall only exercise these options when requested by the COR, and when the necessary funding is available.

F. SCHEDULE FOR DELIVERABLES

G. CHANGES TO THE STATEMENT OF WORK

Changes to the statement of work are unlikely, but can be made with acceptance by both sides.

H. REPORTING REQUIREMENTS

N/A

I. TRAVEL

No travel required.

J. GOVERNMENT RESPONSIBILITIES

N/A

K. CONTRACTOR EXPERIENCE REQUIREMENTS

Qualifications of Key Personnel (Standard mandatory language for all task orders)

N/A

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Time and Materials Task Orders

N/A

Firm-Fixed-Price Task Orders

N/A

L. CONFIDENTIALITY AND NONDISCLOSURE

Standard mandatory language for all task orders.

M. CONTRACTOR PERSONNEL SECURITY REQUIREMENTS

New contractor personnel security requirements, which facilitate the security programs for computer systems and automated information systems implemented by the Office of Security and Law Enforcement and Veterans Health Administration.

All records(administrative and program specific) created during the period of the contract belong to VA North Texas Health Care System (VANTHCS) and must be returned to VANTHCS at the end of the contract.

N. SECURITY CLAUSE :

1. During onsite service, the Vendor shall be chaperoned by VA Personnel.
2. Non-volatile memory devices, working or non-working, shall NOT be removed from the VA facility until the ISO has certified that the data has been destroyed. For magnetic devices and media, the data destruction will be by degaussing. Other forms of cleansing will be used for non-magnetic media.
3. The vendor will not have remote access to this equipment.
4. No other information except what is in this contract will be shared with the contractor in any follow up communication.
5. None of the information in this contract includes Protected Health Information (PHI) or Individually Identifiable Information (III).
6. NO VA DATA OF ANY TYPE SHALL BE TRANSFERRED FROM THE VA.
7. ALL DATA AND ELECTRONIC MEDIA WILL NOT LEAVE THE VA.

NARA RM Language Clause to be included in contracts, as necessary:

1. Citations to pertinent laws, codes and regulations such as 44 U.S.C Chapter 21 , 29, 31 and 33; Freedom of Information Act (5 U.S.C. 552); Privacy Act (5 U.S.C. 552a); 36 CFR Part 1222 and Part 1228.
2. Contractor shall treat all deliverables under the contract as the property of the U.S. Government for which the Government Agency shall have unlimited rights to use, dispose of, or disclose such data contained therein as it determines to be in the public interest.
3. Contractor shall not create or maintain any records that are not specifically tied to or authorized by the contract using Government 'IT' equipment and/or Government records.
4. Contractor shall not retain, use, sell, or disseminate copies of any deliverable that contains information covered by the Privacy Act of 1974 or that which is generally protected by the

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Freedom of Information Act.

5. Contractor shall not create or maintain any records containing any Government Agency records that are not specifically tied to or authorized by the contract or identified in the RCS 10-1.

6. The Government Agency owns the rights to all data/records produced as part of this contract.

7. The Government Agency owns the rights to all electronic information (electronic data, electronic information systems, electronic databases, etc.) and all supporting documentation created as part of this contract. Contractor must deliver sufficient technical documentation with all data deliverables to permit the agency to use the data.

8. Contractor agrees to comply with Federal and Agency records management policies, including those policies associated with the safeguarding of records covered by the Privacy Act of 1974. These policies include the preservation of all records created or received regardless of format [paper, electronic, etc.] or mode of transmission [e-mail, fax, etc.] or state of completion [draft, final, etc.].

9. No disposition of documents will be allowed without the prior written consent of the Contracting Officer. The Agency and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. Records may not be removed from the legal custody of the Agency or destroyed without regard to the provisions of the agency records schedules.

10. Contractor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (sub-contractor) in support of this contract requiring the disclosure of information, documentary material and/or records generated under or relating to this contract. The Contractor (and any sub-contractor) is required to abide by Government and Agency guidance for protecting sensitive and proprietary information.

References:

VHA Directive 6300

VA Handbook 6300.1

North Texas VA Medical Center Policy

VA Directive 6500

36 CFR Part 1222.32 (b)