Statement of Work
Reagent Rental Agreement for Test Systems with Laboratory Reagents and Supplies for C. Diff, CT/NG, and Influenza A/B Testing

1.0 Purpose

Request Rental agreement for two (2) Fully integrated and automated on-demand molecular diagnostic systems, 2 Testing Site Systems with 6 Color Modules, Two (2) Desktop Computers, Diagnostic Software, Two (2) Black & White Printers, Two (2) UPS, all accessories, reagents, and supplies for C.Diff, CT/NG, and Influenza testing.

2.0 Scope

Vendor will provide two (2) new Fully integrated and automated on-demand molecular diagnostic systems, 2 Testing Site Systems with 6 Color Modules, Two (2) Desktop Computers, Diagnostic Software, Two (2) Black & White Printers, Two (2) UPS with designated options, on-site initial training for instrument and new assays, 24/7 telephone technical support, and business-hours service plan for all equipment. The test menu must include C. Diff, CT/NG, and Influenza A/B tests. Pathology & Laboratory Medicine Service (P&LMS) at the Dallas VA will order reagents and supplies from The Vendor as needed to perform testing on the analyzer.

3.0 Location

Two (2) Fully integrated and automated on-demand molecular diagnostic systems, 2 Testing Site Systems with accessories will be located and testing performed in (P&LMS) at Sam Rayburn Memorial Veterans Center, 1201 E. 9th St., Bonham, TX 75418; one Fully integrated and automated on-demand molecular diagnostic systems 2 Testing Site Systems with accessories will be located and testing performed in (P&LMS) at Ft. Worth VA Outpatient Center, 2201 SE Loop 820, Fort Worth, TX 76119. Test kits will be used at Dallas, Bonham, and Ft. Worth sites. All test kits and supplies will be delivered Pathology & Laboratory Medicine Service at the VANTHCS, 4500 S. Lancaster Rd, Dallas, TX 75216.

4.0 Performance

Maintenance includes the following:

4.1.1 Inventory and recording of systems components.
4.1.2 Monthly deliverables shall be ordered as needed by CSI personnel and received in full.
4.1.3 All system and software upgrades will be provided and installed by the vendor at no cost to the government.
4.1.4 Testing all components for proper test performance. Equipment shall reproduce results according to manufacturer's specifications.
4.2. Repairs and Support.
4.2.1 Technical Support: Support Personnel will be available by telephone 24/7.
4.2.2.1 On-site Repairs: With respect to any technical support issue with the test system, printer, ore UPS that the vendor determines to require replacement, the vendor will send the replacement module normally within 24 business hours after the complaint has been logged by Customer Support. This includes all components of the The Vendor Fully integrated and automated on-demand molecular diagnostic systems 2 Testing Site system. Replacement module is shipped overnight and at no cost to the government. VANTHCS will decontaminate and package the defective unit per vendor's instructions and return it to the vendor. Vendor will supply return postage at no cost to the government.
4.3. Vendor shall remove all parts, equipment or materials replaced, or upgraded by the vendor due to and not limited to repairs, replacements, recall, and upgrades without any cost to the government.

4.4 Training: The vendor will provide onsite training for the analyzer during initial installation and with any new assays.
4.4.1 Vendor will provide all training materials free of charge.
4.4.2 Validations: The vendor will provide initial installation and validation of the new system and any replacement systems.
4.5 Safety
4.5.1 Vendor shall immediately notify the service of any changes in reagent composition, procedure modification, recall notification or any changes that will affect the performance of the test or procedure according to FDA regulations.
4.6 Test Performance: All test, procedures, and equipment must perform at manufacturer specifications; deviations from the performance specifications shall be corrected by the vendor.
4.6.2. All test performance will be evaluated by and not limited for performance thru peer comparison, quality control and CAP peer evaluation.

5.0 Period of Performance

Reagent Rental Agreement for the Fully integrated and automated on-demand molecular diagnostic systems, 2 Testing Site Systems, reagents and supplies for C.Diff, CT/NG, and Influenza testing will be in effect 12 months from date of award with four additional 12 month option periods. Vendor shall provide option to upgrade to newer version of instrument, additional modules, or additional assays, if available, in option years.

Base Period: date of award – October 31, 2018
Option 1: November 1, 2018 – October 31, 2019
Option 2: November 1, 2019 – October 31, 2020
Option 3: November 1, 2020 – October 31, 2021
Option 4: November 1, 2021 – October 31, 2022

6.0 Deliverables/Supplies

Reagent Rental agreement for two (2) Fully integrated and automated on-demand molecular diagnostic systems, 2 Testing Site Systems with 6 Color Modules, Two (2) Desktop Computers, Diagnostic Software, Two (2) Black & White Printers, Two (2) UPS and reagents and supplies for C.Diff, CT/NG, and Influenza testing. Reagents and supplies will be purchased under the terms of the reagent rental purchase agreement.

6.1 The vendor shall provide one on-site customer training slot to meet the objectives identified in paragraph 4. In addition, the vendor shall provide handouts and training materials in sufficient quantity for each participant when applicable. The vendor shall provide lesson plan, course materials and media (DVD's, CD's, videos, etc. if required), and editable procedures at no additional cost.
6.2 The vendor shall deliver all equipment necessary for test performance at no additional cost.
6.2.1 The vendor shall deliver all and not limited to operational, maintenance, troubleshooting, repairs, equipment specifications and test manuals.
6.3 The vendor shall install the equipment and perform test verification according to manufacturer specification and CAP requirements. Vendor shall provide annual linearity/verification.
6.4 The vendor shall provide equipment: reagents and supplies for C.Diff, CT/NG, and Influenza testing.
6.4.1 In the event that requested supplies are on back-order, vendor is to proactively provide information as to the estimated time of availability and to provide updates when applicable.
6.5 The vendor shall deliver all invoices for review per the established contract at the end of each billing cycle.

6.5.1 All items not contracted shall be specifically detailed on the invoice including description, quantity acquired, and government cost.

6.6 Remedies:

6.6.1 Any changes in reagents or equipment modifications shall be immediately disclosed by the vendor electronically as well as by postal mail with supporting documentation of the change and, detailed guidance against implementation within twenty four hours of its application.

6.6.2 Additional charges incurred by the government to provide the continuity of contracted tests to patients and not limited to out sourcing, transportation and or any other additional cost shall be covered by the vendor at no additional charge to the government.

7.0 Salient Characteristics

7.1 Instrument must consist of the following to meet the needs of the customer:

- The Vendor is must supply all equipment, test kits, and supplementals via the reagent rental agreement. The Vendor must provide a system is that FDA-approved for molecular testing for C.Diff, CT/NG, and Influenza testing.
- Unit can be interfaced via Data Innovations (DI).
- Does not use the following software: Windows XP Embedded Service Pack 3, Windows Server 2003 or Windows XP

8.0 Vendor Security Contract Requirements

8.1 The Vendor will not have the capability for remote access for service related issues, with no access to PHI, and the vendor must follow the terms of the agreement outlined in the VA National site-to-site agreement.

8.2 There will be supervised access when the vendor is physically present for technical support, service calls, and scheduled preventative maintenance. Vendor will not be granted access afterhours unless previously agreed upon by P&LMS Supervisor or designee.

8.3 The instrument hard drive will remain on site for external repairs or termination of the lease.

NO VA DATA OF ANY TYPE SHALL BE TRANSFERRED FROM THE VA.

9. Records Management

9.1 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.

10. Quality Assurance Surveillance Plan (QASP) and its performance are as follows:

Task	ID	Indicator	Standard	Acceptable Quality Level	Method of Surveillance	Incentive
Safety	4.5.1	Recall Notification	Timely recall notification of reagent and supplies.	100%	Monthly monitoring	Exercise of Option Period and past performance.
	4.5.1	Changes in reagent and equipment modifications.	Timely distribution / notification of	100%	Direct Observation	Exercise of Option Period and past performance.

Quality Assurance	4.2.2.1	Emergency Repairs	Within 24 hours <2 Repairs by quarter by equipment.	95%	Monthly monitoring	Exercise of Option Period and past performance.
	4.2.1	Trouble-shooting via phone.	Within 24 hours	95%	Monthly Monitoring	Exercise of Option Period and past performance.
	4.5.2	Successful reporting of results	Repeat runs are minimal	95%	Direct Observation, Quality control reports run as needed.	Exercise of Option Period and past performance.
	4.5.3	Successful Peer group comparison	CAP survey performance	95%	Direct Observation CAP survey report	Exercise of Option Period and past performance.
Documentation	6.5	Invoice Accountability	Monthly invoices	100%	Invoices received through OLCS via Austin, Texas	Exercise of Option Period and past performance.
	6.5.1	Invoice Verification	Monthly invoices	100%	Invoices contain all necessary information for proper processing.	Exercise of Option Period and past performance
	6.2.1	Equipment specifications and user manuals	Provided prior to delivery of equipment.	100%	Up to date information supplied by vendor as changed.	Exercise of Option Period and past performance
Customer Satisfaction	11.2	Substantiated complaints from lab users	≤ 1 complaint per quarter	100%	Reports of contacts or other documentation.	Exercise of Option Period and past performance
	6.1	Training of laboratory personnel	Provided upon activation of new system.	100%	Reports of contacts or other documentation.	Exercise of Option Period and past performance

NARA RM Language Clause

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. Vendor 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. Vendor 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. Vendor 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 Freedom of Information Act.
5. Vendor 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. Vendor must deliver sufficient technical documentation with all data deliverables to permit the agency to use the data.
8. Vendor 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 vendors 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. Vendor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (sub-vendor) in support of this contract requiring the disclosure of information, documentary material and/or records generated under or relating to this contract. The Vendor (and any sub-vendor) is required to abide by Government and Agency guidance for protecting sensitive and proprietary information.