New Jersey Health Care System
Pathology and Laboratory Medicine
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12/06/2017

STATEMENT OF WORK FOR AN AUTOMATED REAL TIME PCR PLATFORM

SCOPE

The VA New Jersey Health Care System (VANJHCS) Pathology and Laboratory Medicine Service is preparing to establish a Cost Per Test Rental (CPT/CPRR) base plus four one-year options BPA or IDIQ for an analyzer to perform **1. Hepatitis C (HCV) viral load quantization**, **2. HCV Genotyping analysis and, 3. Human Immunodeficiency virus (HIV) viral load quantization testing**. The platform shall utilize nucleic acid purification (NAT) utilizing Real Time PCR testing analysis/assays. The analyzer shall have minimal maintenance and allow for streamlined workload management with continuous access to reagents, samples and supplies.

MENU/ESTIMATED VOLUME

The following assays will be required to run a single, NAT based, walk away analyzer as specified below. Testing numbers may increase by 5% each year. See schedule of items for required Reagents and consumables.

GENERAL REQUIREMENTS

1. The analyzer shall be an automated NAT Analyzer, utilizing real time PCR technology.
2. The analyzer shall be a wheel equipped, floor standing analyzer, with specimen tracking software.
3. Analyzer shall accept the standard sample tubes.
4. The vendor shall provide an analyzer with the most current version of software and hardware, and will upgrade the software as it becomes available.
5. The vendor shall provide the facility with Food and Drug Administration (FDA) approved analyzer/equipment, reagents, controls, calibration materials, disposables, and any consumable parts necessary for analyzer operation. Also provide electronic operating manuals, technical/service manuals, troubleshooting guide, Safety Data Sheets (SDS), preventive maintenance guide, and record logs.
6. The vendor shall provide/install any routine and special items required to operate/maintain the equipment/analyzer in optimal condition such as but not limited to: printer, drainage systems, UPS, and surge suppressors. The cost of these items shall be incorporated in the price proposal.
7. The instrument shall be able to interface directionally with VISTA.
8. The vendor shall provide complete training program that is coordinated with and timely to the equipment installation.

EQUIPMENT FUNCTIONALITY/SALIENT CHARACTERISTICS (GENERAL)

1. The analyzer shall have a robotic sample handler that includes the following:
    a. Automatic reloading of a unique pipet tip for each sample assayed.
    b. Load up capacity to facilitate walk-a-way capabilities.
2. Ability to add additional assays and newly developed assays at a later date.
3. System shall be able to analyze serum and/or plasma.
4. Have Bar-code capabilities for reagents, controls, calibrators, patient samples and inventory management to include data archiving and active reagent volume monitoring and warning. Shall utilize and read samples with barcode types with or without bar-code languages, with Check digits/sums. The platform shall read the common bar codes.
5. Waste disposal of liquids output shall have onboard liquid waste container.
6. The analyzer shall have a quality control program for all assays, which includes at a minimum:
    a. Interactive, On-board quality control (QC) package.
    b. Ability to run new and old lot numbers of QC concurrently for parallel testing. Ability to evaluate and print QC results while the instrument is analyzing patient samples.
    c. The ability to review and print daily and monthly results. Computer print-out capability for calibrators, controls, patient results, and assay repeats.
7. The analyzer shall have positive specimen and reagent identification to reduce possible sources or error/delay and to improve laboratory efficiency.
8. The analyzer shall be able to store and retransmit results in case of interface downtime.
9. Interfacing requirements to be provided by the vendor:
    a. Bidirectional interface capability (broadcast download and host query).
    b. Any additional hardware and software needed to interface the analyzer and technical assistance with interfacing the analyzer and will remain onsite until the interface is complete.
10. The platform will allow for Open Mode Flexibility – Flexible protocols available for various sample types and volumes, including RNA, DNA and Total Nucleic Acid protocols.
11. Assays that have had FDA cleared testing methodologies assigned to them by the FDA shall utilize the FDA cleared technology for the assay.
12. The extractor shall allow access to the patient samples within ½ hour after the extraction process begins.

INSTALLATION AND VALIDATION

1. Vendor shall move instruments, free of additional charge, to final testing location upon completion of validation process.
2. Vendor shall provide the facility with all cross-over supplies and reagents needed at installation and during training of staff.
3. The vendor shall provide at installation/set-up and when bringing new tests on-line, a technical support specialist who shall assist in the performance/validation studies including: installation/set-up, correlation studies (evaluation/comparison data sufficient to satisfy CAP standards), staff training, in-services to laboratory personnel and clinicians, and assist with any methodology problems and questions. This service shall be available during regular office hours on a 5 days/week basis.
4. Throughout the life of the agreement, the vendor shall provide assistance to the user in setting up and maintaining/trouble shooting user-defined assays as additional tests are brought in-house.

SERVICE AND MAINTENANCE

1. Instrument support service shall provide assistance with troubleshooting and repair of the analyzers. On-site service shall be available Monday through Friday during regular business hours (8am-5pm). The support service shall follow-up all down time calls within 1 hour.
2. In the event of a failure to perform the vendor agrees, with the service agreement in force, to facilitate instrument repair, if deemed necessary outside the Monday through Friday window stated in #1 above.
3. Uptime Guarantee: Contractor shall agree that all equipment provided under the agreement shall be operable and available for use 98% of the time. Operational time is considered 8-5, M-F. Downtime shall be computed from time contractor is notified of the incident.
4. The vendor shall provide a twenty-four hour/seven-day service hotline with technical support.
5. The vendor shall provide a preventative maintenance schedule to include timely scheduled vendor preventative maintenance visits as required.
6. Vendor shall provide standard and routine software and hardware upgrades to the equipment hardware and operating systems, without additional charge (e.g. upgrades that correct or improve either the mechanical operations or software of the system and would keep the instrument performing optimally). At the end of the lease contract the vendor shall provide the VA with the instrument hard drive that has VA sensitive information, before taking the instrument out of the premises.
7. Vendor shall define daily, weekly, monthly, and as needed maintenance and the time required to perform each maintenance task. Vendor shall indicate which tasks are user level and which are service level.

8. Vendor required service will be scheduled in such a manner as to minimize disruptions to day to day operations.

TRAINING:

The contractor shall provide an instrument training program that is coordinated with and timely to the equipment installation. This shall include training on the operation of the system, data manipulation, and basic trouble shooting and repair. Thereafter, the Contractor shall provide off-site training for two operators at the Contractor's training facility. A training program that involves off-site travel shall include the cost of airfare, room and board for each participant. Onsite training shall be provided by Contractor during the installation process for a technical representative.

SALIENT CHARACTERISTICS

HIV -1 Viral Load Quantization

1. The platform specimen input shall have multiple sample input volumes, which may include 1.0 mL, 0.6 mL, 0.5 mL and 0.2 mL.
2. The platform subtype analysis shall include Group M subtypes A-H, Group O and Group N in plasma.
3. The platform target region shall be targeted to the integrase region of the polymerase gene.
4. Thermocycling shall be a low temperature PCR reaction <40 degrees C.
5. The control system shall not exceed 3 controls per batch of 21 to 93 patient specimens.
6. The calibration system shall utilize not less than a 2-point external calibration to generate a calibration curve that can be stored from run to run.
7. The sensitivity of the platform shall be a minimum of 40 copies/mL for 1.0mL and 0.6mL input, 75 copies/mL for 0.5mL input and 150 copies/mL for 0.2mL input.
8. The standard deviation (SD) shall not exceed of ≤ 0.25 log copies/mL
9. There shall be an internal control added to lysis buffer during extraction and detected at all levels.
10. The platform shall discriminate the following subtypes of HIV-1 virus: Group M, Group O, and Group N, delivering reliable results for patient management. Abbott accomplishes this through the assay design incorporating a novel partially double stranded probe design, which tolerates the genetic diversity of HIV-1, leading to reliable HIV-1 results.
11.The platform linear range of 40, or less, copies/ml to 10 million copies/ml at the upper levels of the analytical measurement range (AMR).
1. Platform sensitivity shall be able to discriminate Group M, Group N, and Group O at a 100% level.
12. The real time PCR HIV-1 Assay shall be 100% specific.

13. Freshly drawn specimens (whole blood) shall be capable of being held at 15-30°C for up to 6 hours or at 2-8°C for up to 24 hours, prior to centrifugation, and testing

HCV Viral Load Quantization

1. The proposed platform for HCV Viral Load detection shall accurately quantify all HCV Viral Loads in both plasma and serum.
2. Cycling conditions – Thermocycling shall be a low temperature PCR reaction <40 degrees C.
3. The control system shall not exceed 3 controls per batch of 21 to 93 patient specimens.
4. The calibration system shall utilize not less than a 2-point external calibration to generate a calibration curve that can be stored from run to run.

HCV Genotype

1. The proposed platform for HCV genotype detection shall accurately quantify all HCV genotypes in both plasma and serum
2. Cycling conditions – Thermocycling shall be a low temperature PCR reaction <40 degrees C.
3. The control system shall not exceed 3 controls per batch of 21 to 93 patient specimens.
4. The calibration system shall utilize not less than a 2-point external calibration to generate a calibration curve that can be stored from run to run.
3. Platform sensitivity shall not be any higher than 12 IU/mL
4. Linear Range shall be no less than 12 IU/mL to 100 million IU/mL or greater.

SCHEDULE OF ITEMS

Reagents

1. Reagents, Controls and Calibrators needed for HIV Viral Load testing
2. Reagents, Controls and Calibrators needed for HCV Viral Load testing
3. Reagents, Controls and Calibrators needed for HCV Genotype testing

Consumables

1. Pipettes
2. Pipette tips
3. Tubes needed for amplification and extraction.