Statement of Work
Minneapolis Pathology and Laboratory Medicine Service Line
Protein Electrophoresis Analyzer

1. Basic Requirement:

The Contractor Shall provide the Minneapolis VA Healthcare System, 1 Veterans Drive, Minneapolis, Minnesota, 55417, hereinafter referred to as the MVAHCS, a five (5) year "cost per test" or "reagent rental" agreement; a base year, with four (4) twelve (12) month option renewal periods; with the base year beginning on April 1, 2019 for electrophoresis testing of serum, urine, and hemoglobin, characterization of abnormal monoclonal proteins, and identification and confirmation of abnormal hemoglobin patterns are part of the services provided.

MVAHCS is requesting an all-inclusive system which can analyze whole blood, serum and urine samples by Capillary Ion Electrophoresis and agarose Gel method. The Cost per test or reagent rental is to include reagents, controls, calibrators, service, technical support, training of users and for patient standardization purposes for serum, urine and hemoglobin electrophoresis and immunotyping/immunofixation and hemoglobin patter confirmation and quantitation.

The testing system must be able to perform the required testing as described below and meet the performance characteristics as defined by the 1988 Clinical Laboratory Improvement Act (CLIA) and the Clinical and Laboratory Standards Institute (CLSI). Instrument and testing methods must be FDA approved.

2. TEST MENU:

- Protein Capillary Electrophoresis (serum and urine)
- Identification of abnormal monoclonal proteins via Immunotyping (serum and urine)
- Hemoglobin Capillary Electrophoresis (whole blood)
- Agarose Gel processing and staining 9urine and rare serum monoclonal protein characterization and hemoglobin confirmation)

Projected test volume for these test are estimated quantities and volumes may vary.

Test Method	Test Volume
Serum CE	7236
Serum Immunotyping	515
Serum Immunofixation	60
Urine CE	625
Urine Immunotyping	125
Urine BJ	100

Hemoglobin CE	138
Acid hemoglobin	138

5. TECHNICAL FEATURES:

The contractor shall affirm that the testing system performance specifications for proposed instrumentation meet CLIA, CLSI and FDA regulations. Additionally, the contractor's products must meet the characteristics specified below:

a. Must utilize Capillary Ion Electrophoresis Technology to analyze serum and urine for protein electrophoresis and whole blood for hemoglobin electrophoresis

b. Must utilize Immunotyping/ Capillary Ion Electrophoresis Technology to characterize abnormal proteins by

c. Must utilize Capillary Ion Electrophoresis Technology to analyze whole blood for hemoglobin with no pre-analytical sample preparation requires.

d. Agarose Gel processor/stainer with built-in scanner to perform supplemental testing.

e. Provide a large database of Hemoglobin electrophoresis migration patterns to assist in classification of hemoglobins.

f. Provide positive sample identification from primary tube to final results utilizing barcoded racks and tubes and high resolution built-in barcode reader.

g. Direct sampling from primary tubes with mechanisms in place to avoid cross contamination

h. Electronic networking for immediate access to results by the pathologists.

i. Instrument must be equipped with Cap Piercing Technology for whole blood testing.

j. Instrument must have the capability to mix whole blood samples with multiple sample inversions.

6. OPERATIONAL FEATURES:

The contracted instrument shall possess the capability of performing analysis using capillary ion electrophoresis technology. Compatible instrumentation for agarose gel electrophoresis testing must also be provided for any supplemental testing required to fully confirm results. Other required features include:

a. The system must be user friendly and easy to operate with minimal training

b. Minimal maintenance that is easily performed.

c. Electronic reagent tracking of lot number and expiration date utilizing barcodes.

d. Safety features sufficient to avoid unnecessary exposure to biohazardous and chemical material.

e. The exposure to and the volume of biohazardous and chemical material generated by the equipment must be minimal and require a minimal amount of handling.

f. Uses small sample volumes

g. Comprehensive quality control program with Levy-Jennings charts

h. Comparative patient result recall useful in editing the current patient result

i. Automatic identification of fractions which simplifies operator editing.

j. Automation and semi-automation for workflow and operator safety

k. Throughput for the Capillary Ion electrophoresis instrument should be at least 38 serum protein samples per hour with STAT testing capability and continuous sample loading.

i. Compatible electrical power with the MVAHCS 110V outlets in the laboratory

j. UPS or surge protector provided if the system requires it.

k. Continuous sample loading

l. Tube capacity for Proteins: 104 samples, for hemoglobins: 88 samples

7. <u>HARDWARE/SOFTWARE FEATURES:</u>

a. The instrument when installed in the Minneapolis VA laboratory shall not negatively impact on the functionality/operations of the laboratory and shall not require signification and/or costly infrastructure changes to the government.

b. The instrumentation must be able to fit into the current footprint space as available in the laboratory. The dimensions shall not exceed (L) 37 x (W) 25 x (H) 17 in.

c. The instrument's computer operating system must be Windows 10 or higher. In addition, the instrumentation shall have:
   - Bi-directional host and host query capabilities utilizing Data Innovations
   - Must be capable of data storage. In the event that the Laboratory Information System (LIS) is down, the system must be capable of retransmitting the results to the LIS upon restoration of the LIS function.
   - Instrument software capable of transitioning to paperless records.
   - Capability of storing scans, curves, and results on hard drive.
   - Vendor will ensure that the instrument is utilizing the latest software revision.

d. Monitor, PC, UPS, and printer included with CE instrument.

e. Hydrasys 2 includes scanner

f. Networking package included

8. SUPPORT FUNCTIONS:

Training and Technical Support:
The contractor shall provide training of end users at the time of equipment installation.

a. This includes training on the operation of the system, maintenance, data manipulations, basic trouble-shooting and repair.
b. The training shall match the scope of facility's services and be minimally equivalent to that offered in the commercial marketplace.
c. Key Operator training, for at least 2 key operators shall be provided as part of the purchase price of the analyzer.
d. As appropriate, training will be provided either at the work site or at a contractor's training site.
e. If training is conducted off-site, the contractor shall provide all costs for trainee (e.g. airfare, room and board, training materials, shuttles, etc.).

Technical support for the analyzer will be provided by the contractor during and after instrument setup from 8 am to 5 pm (CST) Monday through Friday.

a. The contractor shall provide standard warranty response on instrumentation, as required.
b. The contractor shall provide applicable manuals and schedules upon delivery and installation of the equipment.
c. The contractor shall perform annual preventative maintenance inspections during the contract period arranged with the COR or laboratory staff in accordance with the published preventive maintenance manuals for the equipment listed on the schedule. The contract shall utilize the original equipment manufacturers established preventative maintenances procedures and checklists. A field service report shall be supplied to the COR or laboratory staff at the completion of each preventative maintenance inspection. Preventative maintenance inspection shall include but is not limited to the following:
    i. Cleaning the equipment.
    ii. Completing original equipment manufacturer field service updates for operational and reliability engineering changes.
    iii. Performing remedial maintenance of non-emergent nature.
    iv. Testing and replacing faulty or worn parts.
    v. Inspecting/replacing electrical wiring and cables for wear and fraying.
    vi. Inspecting all mechanical components including but not limited to; cables and mounting hardware, chains, belts, bearing and tracks, motors for mechanical integrity.
    vii. Requiring the equipment to operating condition defined in the original equipment manufacturer specifications.
    viii. Providing documentation of services provided/performed.
e. If the repair record of any individual piece of the contractor's equipment reflects a downtime of 5% or greater of the normal working days in one calendar month from the time of dispatch, the designated representative may make a determination to have the contractor replace the malfunctioning equipment with new equipment at no charge to the customer. The contractor is ultimately responsible for ensuring its equipment is furnished in good condition in accordance with manufacturer's instructions. The customer is ultimately responsible for ensuring the manufacturer's recommended daily, weekly, monthly, and periodic maintenance is performed appropriately.
f. Each instrument provided by the contractor shall maintain an uptime of 95% during each month of the term of the agreement.
g. Each notification for an emergency repair service call will be treated as a separate and new service call.
h. Scheduled preventative maintenance call, per manufacturers' recommendations.

Manufacturer's recommendation is _____ PM's per year. (Contractor to complete)

Contractor's Service Phone Number is: _____

Validation:
The contractor shall assist in performing validation studies and method comparisons with the current analyzer as part of the setup requirements. In addition, the contractor will perform all of the statistical analysis and report data in an organized, clearly comprehensible format. Contractor shall provide assistance with references ranges to include handling data with appropriate software to establish or validate reference intervals. The contractor shall have provided all equipment, reagents, calibrators, controls, consumable/disposable items, parts, and accessories required to establish operation and perform all validation studies and method comparisons with the current analyzer as part of the startup requirements.

Ancillary Support Equipment:
The contractor shall provide all equipment, reagents, calibrators, controls, consumable/disposable items, parts, and accessories required to establish full operation of the instruments. In addition, ancillary components that are customarily provided with the model of equipment proposed, such as starter kits, will be provided. The contractor shall provide a PC computer disk of their procedures, formatted in accordance with current CLSI guideline's, and updates as they occur.

Interface:
MVAHCS uses Data Innovations as the universal interface. The vendor is responsible for providing everything required for the installation, implementation and operation of the interface right up to the universal interface box, including the software license that may be required each time an instrument is added to an existing universal interface system (e.g. ports, cards, cables, software, licenses, etc.). If there are any software upgrades in the instrument during its life, the contractor is responsible for seeing that the interface can accommodate any changes in the data stream going to the VA's computerized patient record system.

Prior to any contract award, the contractor will consult with the laboratory Facilities Engineering staff to ensure that existing laboratory space and existing laboratory utilities will accommodate the proposed equipment and is compatible with the hospital's 110V outlets in the laboratory. Contractor will furnish written documentation to the contracting office certifying equipment is compatible with site

Repair Service

The contactor will provide standard warranty response 8am-5pm, Monday through Friday. The contractor's telephone response time shall be within four hours of notification. Preventative maintenance coverage will be negotiated. During standard response hours, the contractor will make commercially reasonable efforts to provide on-site engineering support within 48 hours of determination that an on-site is necessary. Parts will be new standard parts manufactured by the contract for that specific piece of equipment. Each notification for an emergency repair service call will be treated as a separate and new service call.

Upgrades

The contractor shall provide upgrades to both the equipment hardware and software in order to maintain the integrity of the system and the state of the art technology at no additional charge to the customer. These must be provided as they become commercially available and at the same time as they are being provided to commercial customers. This requirement only applies to "system upgrades" that enhance the model of equipment being offered, i.e., new version of software, including database upgrades, correction of hardware defect, upgrade offered to commercial customers at no additional charge, upgrade to replace model of equipment no longer vendor supported, etc.

10. HARD DRIVE ERASE:

Prior to removing equipment from VA premises, the contractor will erase any patient information that may be stored on equipment hard drives, i.e. hard disk erase, using a two pass overwrite VA or DOD approved software. Contractor will provide written certification to the VA site Information Security Officer that equipment hard drives have been erased.

The contractor will remove equipment from VA premises within 60 days after expiration of BPA. Prior to removal, contractor will erase any patient information that may be stored on equipment hard drives, i.e. hard disk erase using a two pass overwrite VA or DOD approved software. Contractor will provide written certification to the VA site Information Security Officer that equipment hard drives have been erased. Equipment will not be repaired or refurbished at VA expense so that it may be returned to the contractor in the same condition as received. Contractor shall retain ownership and title to the equipment.

12. MSDS, HAZARDOUS MATERIALS and WASTE STREAM ANALYSIS:

The contractor shall provide the MVAHCS, with a listing of the vendor's products used with this analyzer(s) that are considered hazardous. The listing

should also include a determination as to what can be considered harmless to be disposed of by normal methods, such as disposing down the sink or disposing in the trash and what has to be specially handled for disposal and how it is handled.

The contractor is required to provide a list identifying any "hazardous materials" that may be provided as a part of this contract that are defined as hazardous under the latest version of Federal Standard No. 313. Material Safety Data Sheets (MSDS) shall be submitted for all products.

Contractor shall provide a complete chemical analysis of waste, to include mercury Na azides, carcinogens, reproductive toxins, acute toxins and all other waste that may be considered ignitable, corrosive, reactive or toxic. Contractor will also be required to provide additional subsequent waste analysis studies in the case of any new test or new test formation introductions. Documentation of all analysis will be provided to the VA Contracting Officer for review by the VISN-23 Green Environmental Management Systems (GEMS) Coordinator prior to contract award or introduction of new product after award.

13. RECALLED AND DEFECTIVE PRODUCTS:

The Contractor will immediately notify the Contracting Officer of any recalls of product or other important safety issues. As appropriate, the Contractor will replace and/or reimburse recalled/defective products at no cost to the government. The Contractor may be liable for costs of processing recalls, i.e. administrative and clinical services to replace recalled/defective products.