1. STATEMENT OF WORK

1.1. The contractor shall provide non-personal services to include, but not limited to, all personnel, equipment, transportation, tools, materials, supervision, training, and other items and services necessary to provide hemostasis automation systems and reagents. The contract pricing must be an all-inclusive price within the Cost Per Reagent purchase. The contractor selected is responsible for equipment and services at the main facility at Womack Army Medical Center (WAMC), Fort Liberty, NC. The contractor shall perform to the standards of this Statement of Work (SOW)

Validation Period	01 May 2025 through 31 July 2025
First Ordering Period	01 August 2025 through 30 September 2025
Second Ordering Period	01 October 2025 through 30 September 2026
Third Ordering Period	01 October 2026 through 30 September 2027
Fourth Ordering Period	01 October 2027 through 30 September 2028
Fifth Ordering Period	01 October 2028 through 30 September 2029
Sixth Ordering Period	01 October 2029 through 30 April 2030

1.2.For the purposes of this SOW, the automation system includes at a minimum:
- Two identical analyzers (one as backup)
- Peripherals (e.g., Uninterruptable Power Sources (UPS), instrument computers, Computer Processing Units (CPUs), printers, barcode scanners, terminals, monitors, etc.

2. TESTING SYSTEM

2.1. The testing system must be manufactured, sold, and supported by one Contractor. The testing system shall be serviced and supported by the awarded Contractor. This includes all on-site and off-site training, Information Technology (IT) management, IT implementation services, phone support, on-site and off-site services, as well as any future Food and Drug Administration (FDA) approved testing that can be performed on contractor supplied testing system. The testing system must be capable of interfacing with the military hospital computer system, i.e., MHS Genesis. The Contractor must have necessary driver(s) compatible for interfacing the analyzer with the MHS Genesis through vendor-provided middleware or existing middle platform currently in use at facility. The interface between MHS Genesis and the analyzer must be bi-directional.

2.2. The testing system must include a data management system for control of the operation of the analyzers, management of the quality control (QC) program, management of the on-instrument useful life of the reagents/reagent packs, and management of patient results; and a printer to produce hard copy of patient reports and other reports generated via the data management system.

2.3. All equipment displays and supporting literature must be in the English language. Lease of this equipment shall include delivery, installation, all calibrators/standards, reagents/reagent packs, linearity material, and QC materials necessary to perform the specified assays, initial Method Validations per Clinical Laboratory Improvement Act (CLIA)/College of American Pathology (CAP) guidelines.

2.4. The analyzers shall be fully automated with continuous operations to run 100 tests per hour, access for samples, a true walk-away system, and barcode reading for all reagents and samples.

2.5. All analyzers and associated parts and accessories will be new. Neither used, refurbished, or like-new equipment will be provided in support of this contract at any time.

2.6 The testing system shall have the capability to have one control center for central management of both analyzers.

2.7 The contractor is responsible for maintaining printers, peripherals, CPU, and other accessories throughout the duration of the contract period.

2.8 The contractor shall provide any external interferences that may affect testing system that can cause inaccurate results for patient testing.

2.9. The testing system must come equipped with UPS capable of providing all necessary electrical power to each analyzer system, to operate the data management and testing system for at least 15 minutes. The contractor should support the maintenance and replacement batteries to the UPS as needed.

2.10. Contractor shall provide updates and upgrades of testing system upon availability at no charge. The Contractor and Contracting Officer's Representative (COR) shall agree upon a date of installation of updates and upgrades.

3. INFORMATION MANAGEMENT

3.1 Contractor Information Systems (IS)/Network that are involved in the operation of systems in support of WAMC shall operate in accordance with controlling laws, regulations, Defense Health Agency (DHA) Cyber Logistics (CyberLOG) Cybersecurity/Risk Management Framework (RMF), and local policy. DHA CyberLOG requirements are detailed in Appendix 2, titled Defense Health Agency (DHA) Cyber Logistics (CyberLOG) Cybersecurity/Risk Management Framework (RMF) Requirements, 5 January 2022.

3.2 The data management system shall offer software management features with rules capable of preparing data for auto validation prior to host transmission. The software shall have following capabilities:

- To write and validate user defined auto-verification/auto-result validation rules that can hold transmission of results for review by the user
- To write and validate user defined order /request rules
- To support patient delta checks as part of the auto-verification process

- To support rules that recognize linearity limits, repeat for critical value tests, review for specimen integrity and delta checks on previous patient results etc.
- To support specimen Integrity based rules to cancel/edit tests based on the test performed and the interfering substance. Cancelled test must be able to transmit to the host along with the appropriate comment.

3.3 All Contractor systems that wish to communicate with Department of Defense (DoD) systems and deployed vendor systems will need to initiate Business to Business (B2B) gateway approval through DHA, if not already approved. For all Web applications, Contractors will connect to a Defense Information Systems Agency (DISA)-established Web Demilitarize Zone (DMZ).

3.4 The Contractor shall establish appropriate administrative, technical, and physical safeguards to protect all Government data and compliance with Health Insurance Portability and Accountability Act (HIPAA) of 1996, to ensure the confidentiality, integrity, and availability of data. As a minimum, this shall include provisions for personnel security, electronic security and physical security.

3.5 The Contractor will provide a Thin Client-type data management system that allows for remote operational control of the analyzer system, dynamic/real-time review and management of the QC program, review of on-instrument useful life of the reagents/reagent packs, and management of patient results.

3.6 All software and software licenses, interfaces, and hardware (e.g., servers, printers, monitors, UPS, CPUs, barcode scanners, etc.) shall be included with cost of hardware required.

3.7 The software will provide proactive monitoring of key instrument parameters to allow for predictive diagnostics.

3.8 The results management application will manage patient data, sample and QC results by offering archiving, status, calculation of results and long-term results storage.

3.9 The Data Management system will have a comprehensive, fully integrated QC software module that stores and evaluates QC results. Results can be viewed in a variety of formats including Levy-Jennings charts and statistical summaries. The application will validate QC results by checking them against user-selected rules and automatically alert the operator when a rule violation has occurred.

3.10 The QC software will have a large capacity to store graphics and results, cumulative patient reports and QC files with statistics - all available to user. The QC software will provide the capability to write user defined Westgard QC Rules. In addition, it will integrate with the result manager for auto-verification of results, allow viewing and maintaining of QC data across multiple levels and lots for connected analyzers, provide a mechanism to maintain an action log of comments from QC review, provide real-time access to QC charts, graphs (Levy-Jennings) and provide the ability to add comments, and eliminate data point(s) from statistics. The QC

software must include the ability to apply Westgard QC result decision rules in real-time, with the ability of the user to individually select the rules to be applied.

3.11 The equipment proposed by the Contractor **MUST** be ATO approved at time of proposal submission and remain approved throughout the duration of the contract.

4. ANALYZERS

4.1 The Contractor shall provide a fully automated, continuous sample loading analyzer system capable of performing all of the required assays listed in Appendix 1. The system shall provide redundancy to ensure continuous operations, training, supplies, reagents, unscheduled maintenance, and preventive maintenance for the equipment.

4.2 The analyzer systems and all reagents shall be FDA approved. All analyzers and associated parts and accessories will be new. Neither used, refurbished, nor like-new equipment will be provided in support of this contract at any time.

4.3 The analyzer system must be capable of interfacing with the military hospital computer system, i.e., the MHS Genesis. The interface between the MHS Genesis and the analyzer must be bi-directional.

4.4 The analyzer must have the on-board ability to maintain all reagents at the proper storage temperatures for the assays listed in Appendix 1. The instrument shall have on-board reagent monitoring which shall include on board open reagent expiration, available volume, and number of tests remaining. The instrument shall have the ability to monitor multiple reagent bottles and Quality Control (QC) material simultaneously. The instrument shall have non-interrupted loading of reagents and consumables. The analyzer must be capable of maintaining calibration curves for all of the assays listed in Appendix 1 simultaneously.

4.5 The analyzer systems will provide users with rapid, reliable test results that are critical for patient care. These analyzer systems must be capable of performing in low, medium, and high-volume work periods to produce results that are accurate and precise throughout the manufacturer's stated linearity/analytic measurement range.

4.6 The analyzer shall have the ability to import reagent and quality control with ranges, expiration dates, lot numbers, ect. from the ease of scanning barcode information.

4.7 Analyzer initial startup from the shutdown state shall not exceed 10 minutes.

4.8 The analyzer system shall have the ability to store individual QC and allow easy export and archive of QC data to peer group program.

4.9 The system shall be able to run controls automatically at specific time (every eight hours) without operator intervention.

4.10 The system shall be able to manage calibration for multiple lots of reagents and shall be able to store multiple calibration curves.

4.11 The system shall have barcode reading capabilities for sample identification, reagents, and controls.

4.12 The analyzer shall have cap piercing capabilities with the use of multiple tube sizes such as pediatrics.

4.13 The system shall have the ability to detect tube volumes for under filled or over filled tubes or clotted sample with an alert to user.

4.14 The analyzer shall have ability to detect interference from hemolysis, icterus, and lipemia with an alert to user. It shall be able to give results if sample is hemolyzed, lipemic, and icteric with warning/alert that the threshold is exceeded.

4.15 The analyzer shall have user friendly procedures for operators to perform daily, weekly, or monthly maintenance with minimal time. Analyzer shall also be able to generate an on-board maintenance record and tracker.

4.16 The analyzer shall have the capability to automatically run, repeat, reflex and/or dilute specimens without operator interventions, by the use of user defined decision rules and without the need for additional hardware or middleware.

4.17 Each analyzer system must come equipped with an un-interruptible power supply capable of providing all necessary electrical power to each analyzer system, to include the data management system for at least 15 minutes.

4.18 Any item/part/supply excluded by the contractor but required for operation of the system at any time, must be delineated in their technical proposal. The cost of any excluded items must be disclosed in the cost proposal.

5. REAGENTS

5.1. The Contractor shall provide all of the tests listed in exhibits, to include reagents and calibrators. These products must be manufactured by the Contractor and not by a third party. The testing system and all assays must be FDA approved. All reagents provided will be identical to those used in the FDA approval application. For reagents with hazardous constituents, Contractor must provide a mechanism for the Laboratory to meet local discharge requirements. Unexpected changes in methodology/technology shall be at the expense of the Contractor. Alerts and notifications of all technical advisory/recalls/alerts, prior to or simultaneously with field alerts should be forwarded to the Contracting Officer Representative (COR), Hematology Supervisor and/or Quality Assurance Coordinator. All equipment displays and supporting literature must be in the English language. Lease of this equipment shall include delivery, installation, all calibrators/standards, reagents/reagent packs, linearity material, and QC materials necessary to perform the specified assays, initial Method Validations per Clinical Laboratory Improvement Act (CLIA) / Clinical and Laboratory Standards Institute (CLSI) guidelines and analyzer removal at the termination of the contract.

5.2. The Contractor will also estimate the volume of user-replaceable maintenance items that will be required to support the analyzer, and any analyzer specific tools/supplies necessary to perform operator-level periodic maintenance tasks at the level of volume specified in Appendix 1. The contractor shall provide the operator level maintenance tool/spare parts kits and replenish all expended items. Replenishment will be made as needed or on a periodic basis not to exceed the normal preventive maintenance cycle.

5.3. Delivery of the reagents will be on an as needed basis or delivery schedule based on workload and usage. Individual orders will be placed by the COR or other designated authorized government personnel. Name and point of contact of authorized personnel will be provided to the Contractor.

5.4. The workload listed in the exhibits is an estimate based on projected annual volume. Orders of required items will be called or emailed to the Contractor. Deliveries shall arrive within five working days after the order is placed. No deliveries shall be accepted on weekends or federal holidays. Emergency orders placed before 2:00 PM Eastern Standard Time (EST) will be delivered within 24 hours after the order is placed.

5.5. All reagents/reagent packs will be provided as follows:

- Be provided by the manufacturer of the equipment.
- Be marked with the required storage temperature.
- Be maintained at the proper storage temperature during transportation from the Contractor's storage facility to the Government acceptance site and be delivered on time at the appropriate storage temperature.

5.6. The contractor shall assure that all supplies provided/ordered for use on their equipment will be of the quality necessary to produce a quality product. The reagent quality must be acceptable to satisfy proficiency testing standards of CAP and the Joint Commission (JC). The Proficiency Test Program standards are used as Minimum Acceptable Standards (MAS) for assay performance. Reagent performance shall meet the MAS listed in the Appendix 2.

In the event that the supplies are found to be defective and unsuitable for use with the Contractor's equipment or the contractor has failed to comply with the requirements, the Contractor shall replace the supplies within 24 hours once the issue has been brought to the contractor's attention, at no cost to the Government. The Contractor shall reimburse the government for any costs/supplies related to tests performed by another contractor or sent to a referral laboratory when reagents were not available due to product issues or instrumentation failure.

5.7. Safety Data Sheets (SDS). For all products the contractor must provide a mechanism for the laboratory to meet local discharge requirement. The Contractor shall provide one set of paper copy and two electronic copies on Compact Disk (CD) of SDS of all reagents and consumables to be used on the system.

5.8 The contractor shall pay for the delivery charges for shipping and handling of the reagents. Any additional costs such as Industrial funding fees, special shipping and handling fees, or any other fee or charges must be included in CPR.

5.9 Any item/part/supply/reagent excluded by the contractor but required for operation of the system at any time, must be delineated in their technical proposal. The cost of any excluded items must be disclosed in the cost proposal.

6. INSTALLATION AND INITIAL SET UP

6.1. Prior to reporting to the laboratory, the contractor or contractor's representatives shall report to and obtain a visitor badge from the HTMB of the facility. The badge must be returned to the department prior to departing the facility.

6.2. The Contractor shall be responsible for installation, which consists of in-house delivery, positioning, and mounting of all equipment listed on the contract and connections of all equipment and interconnecting wiring and cabling if applicable in coordination with the facility biomedical engineer. Upon receipt of notice from the COR, an agreed date will be established to proceed with installation. It shall be the Contractor's responsibility to inform the COR of any problems which may be anticipated in connection with installation or those that will affect optimum performance once installation is completed. The Contractor will provide a qualified Technical Service Representative, who possesses a thorough knowledge of method validation and is familiar with the use of statistical evaluation software as determined by the Laboratory Director (e.g., EP Evaluator®), to provide technical assistance for the method validation studies. The Contractor will provide a dedicated team of project management professionals who are experienced in delivering on time installations. The Contractor shall not employ persons for work on this contract if such employee is identified to the Contractor by the COR as a potential threat to the health, safety, security, general well-being or operational mission of the installations and their population.

6.3 The Contractor will provide an Information Technology Project Manager (IT PM) for implementation of the instrument interface and middleware. The IT PM will have demonstrated working knowledge of Information Security Requirements specific to DHA installations as detailed in Section 5 of this SOW. The IT PM will have a demonstrated working knowledge and competency in the uses of and configuration options for instrument middleware. The IT PM will work with Department of Defense (DoD) subject matter experts (SMEs) to configure and test the instrument interface with MHS Genesis. The IT PM will be actively engaged in all aspects of this SOW. The IT PM will also actively collaborate with Laboratory SMEs to configure the system's middleware to optimally meet medical treatment facility (MTF) requirements.

6.4 The contractor shall specify any facility requirement such as capped drains, water supply, electrical voltage, and special power supply, required prior to equipment installation.

6.5. During the initial implementation, a technical representative must be available on site throughout the entire implementation period, ensuring the installation and validations be completed within 90 days of equipment arrival. The same technical representative (or contractor designated replacement) should be available throughout the entire implementation; there must be documentation of information "hand off" between the different Technical Representatives.

6.6. Upon completion of installation, on-site training, method validation studies, and analytical measurement range/linearity verification must be performed by Contractor personnel within the validation period to ensure that equipment is fully operational as negotiated.

6.7. Method Validation will be conducted in accordance with method validation protocols established by CLSI and/or required by CAP. Method Validation will include but not be limited to, correlation with current methods (comparison of methods study), validation of analytical measurement range (AMR), validation of precision (replication study) and establishment or verification of QC ranges. All reagents, QC materials, calibrators and linearity materials used in the Method Validation Study will be provided by the Contractor at no cost to the Government. These materials will not be used in the analysis of specimens for patient care.

6.8. Contractor shall perform all validation studies at no cost to the government, to include manpower, linearity material and reagents, calibrators, controls and be consistent with current CLSI Standards and related documents, CAP Standards and Federal Regulations, for the following:

- Correlation studies should include a minimum of 30 samples, spanning the reportable range, shall be run by the present and the new method. Contactor shall analyze numbers and provide statistical data to accept the new method. Statistics shall consist of at least mean, bias, slope, y-intercept, correlation coefficient, and meet current standards defined by CLSI.
- Linearity analysis shall be performed on new contracted instrument for each analyte to determine reportable range using statistical tool in accordance with CLSI.
- Precision study shall be performed utilizing normal an abnormal control material. This should consist of a within run precision study of 10 normal and 10 abnormal controls or patient samples.

- Carryover studies shall be performed, as applicable, as part of the initial evaluation of the instrument. Contractor shall provide interpretation of raw data and validate no carryover exists within the testing system.
- Sensitivity: Sensitivity may be validated concurrently with the linearity verifications.
- Specificity studies: Adverse effects for increased bilirubin, hemolysis, lipemia, or other interrupting substances including blood and urine container are evaluated for interfering substances for each method performed.
- Reference Range: Determine a reference range for each test following CLSI guideline C-23A. Samples used for the reference range study must be representative of the patient population being tested. Reference range assessment must be performed for each lab. A verification of the manufacturer's suggested reference range may be performed as long as the suggested range is based on a comparable population of test subjects. The manufacturer must provide specific information defining how the suggested range was determined. A minimum of 30 reference individuals must be used to verify the manufacturer's range. Any apparent outliers should be discarded, and new specimens obtained to provide a statistically valid verification.
- If the suggested manufacturer's range is not appropriate for the patient population, a reference range must be established. Establishing a reference must follow CLSI-28A guidelines. This requires a minimum of 100 reference individuals be used to establish a reference range.
- Therapeutic range validation studies must be performed by contractor for applicable analytes.

6.9. The Contractor will provide statistical reports of method validation study and all result print outs, package inserts of materials used for method validation study in an organized fashion to the hematology supervisor before using the analyzer systems for patient testing. In addition to the hard copy, the Contractor will provide method validation study results and reports electronically. The Contractor will provide instrument settings and other configurations on a paper as well as electronically.

6.10 In the event that progress of the installation is interrupted through no fault of the contractor, the continuous installation referenced in the preceding paragraphs may be modified until such time as the cause of delay has been eliminated, and then shall be resumed within 24 hours after the contractor has been notified that work may again proceed.

7. MAINTENANCE AND SERVICES

7.1. Prior to performing maintenance and repair work, the contractor or contractor's representative shall report to and obtain a visitor badge from the HTMB of the facility. The badge must be returned to the department prior to departing the facility.

7.2. The Contractor shall provide a list of maintenance options. The Contractor shall provide a full preventative maintenance service for the lease period at no additional cost. Service shall include repair and replacement of defective parts, complete maintenance program (as required by

the manufacturer's maintenance manuals), and hotline telephone service, to assist operators in troubleshooting problems.

7.3. The performance of scheduled periodic preventive maintenance, safety checks, and calibrations that are not normally performed at the operator level will be performed by Contractor personnel in accordance with requirements as specified in the Contractor's instrument manual. A preventive maintenance service shall include, but is not limited to, safety, calibration, complete operational testing, lubrication, adjustments, and cleaning of equipment to which the operator does not have access. This also includes the installation of all non-operator parts required to ensure proper operation. Completion of installation of the analyzers will establish time zero for determination of time frames for performance of the above periodic services.

7.4. If any deficiencies are found due to negligence of the service representative, the Contractor shall correct the deficiency to a fully operational status in accordance with manufacturer specifications at no additional cost to the Government. During the contract period, should the repair record of any laboratory equipment reflect a downtime of more than 72 continuous hours in one calendar month, a determination will be made by the COR to replace the initial laboratory equipment with new equipment.

7.5 Repair:

- The Contractor shall provide direct customer hotline telephone service and support, 24 hours/7 days a week, and on-call emergency repair service support, to assist operators in correcting equipment problems. The Contractor shall respond to telephonic requests for unscheduled repair within same working day.

- Upon the failure of any analyzer the Contractor's qualified service technician shall be on-site to provide unlimited emergency service (service requiring immediate repair; an unscheduled maintenance/service requirement) within 24 hours. The equipment shall be repaired and operational within a minimum of 48 hours after initial response by the Contractor.

- Emergency Services and unscheduled services outside contractor's regular working hours, on weekends, and on Federal Holidays will be identified in contractor's proposal. The Contractor's qualified service technician shall be on-site to provide unlimited emergency service (service requiring immediate repair in the event of single instrument failure) within 24 hours. The equipment shall be repaired and operational within a minimum of 48 hours after initial response by the Contractor. Estimated emergency visits per year are six.

- Should both instruments at the WAMC become inoperable, the Contractor's technical specialist must be on-site within four hours of initial notification of emergency repair. The repair of at least one analyzer must be completed within 24 hours of initial notification. If at least one

analyzer cannot be repaired within 24 hours of the initial notification, and if deemed necessary by COR, the contractor will arrange for the pickup and delivery of all critical specimens to a CAP accredited clinical laboratory of the Government's choice for testing. During the period when both analyzers are inoperable, each patient report must include the testing laboratory's reference range for the test being performed. The Contractor will pay all costs associated with the provision of this service, including those for delivery of hard copy patient results by express courier, for as long as both analyzers remain inoperable, at no additional cost to the Government.

- If the equipment cannot be repaired, a replacement instrument will be provided within 72 hours.

- All work shall be performed in a professional manner by an authorized service representative. If any deficiencies are found due to negligence of the service representative, the Contractor shall be required to correct the deficiency to a fully operational status in accordance with manufacturer specifications at no additional cost to the Government. During the contract period, should the repair record of any laboratory equipment reflect a downtime of 10% or more working days in one calendar month, a determination will be made by COR to replace the initial laboratory equipment with new equipment.

- Within one working day after completion of service, the contractor shall furnish the copy of a service report for all services performed to the hematology supervisor.

7.6 The report shall be in English, and a copy should be given to the Laboratory representative for the location where the work is performed. The report shall contain, at a minimum, the following information:

- Nomenclature and serial number.
- Date.
- Description of services performed (i.e., preventive maintenance service, or unscheduled repair service).
- Location and services performed.
- Duration of performance (hours).
- List of parts replaced or other actions taken to restore operability of the instrument.
- Name of Technician.

8. TRAINING

The Contractor shall provide initial on-site operator training up to 20 government technicians. In addition, the Contractor shall provide training for three primary operators at the Contractor's training site. The Contractor will also provide one training slot per contract year, at the Contractor's training site. The off-site training cost shall include all costs, i.e., transportation (air and ground), room and board. The contractor shall identify this cost in exhibits.

9. SPECIAL TASKS

9.1. The Contractor will provide one paper and one electronic copy of the Operator and Maintenance manuals and a statement of the warranty terms in the English language. The level of detail required of appropriate instrument maintenance manuals extends only to routine maintenance procedures performed by the user. All instrumentation specified as non-Government owned equipment are serviced and maintained by the Contractor.

9.2. The Contractor will provide one paper and one electronic copy of Standard Operating Procedures (SOPs) for each, and every methodology included under the Proposal. The SOPs will include all relevant technical information regarding the methodology and shall be provided in Microsoft Word, capable of being customized/modified by the end user.

9.3 In addition to performing linearity studies initially during the validation period, the contractor shall perform, assist, and/or be available for the linearity studies on all of the analytes performed on all of the analyzers provided by the contractor for every lot change that is required for linearity studies. The contractor shall provide the technical representative to perform, assist and/or be available for the study and the linearity materials needed for the study at no additional cost to the Government. The representative will analyze the linearity study data and provide the statistical reports to the technical supervisor for review. The contractor shall perform the linearity studies in accordance with the term listed above for every lot change requiring linearity studies for the duration of the entire contract period, including option year/s and extension period/s.

9.4. New Test Method/s or Generation change of current test reagent/s: The contractor shall perform all validation studies including installation/set-up, linearity, precision, accuracy, and correlation studies when new test(s) that are not listed in the exhibits are added to the current test menu or new generation of reagent/s are placed in use at no additional cost to the Government. The contractor must provide reagents and materials needed for the validation studies. The validation studies must be completed, and statistical reports must be presented for evaluation before placing new test/reagents in use.

9.5. Upgraded Software/ Equipment: The Contractor shall provide all upgrades to the equipment hardware and operating system software without additional cost to the Government. These enhancements to the Contractor's equipment shall be delivered to the Government site and installed by the contractor within 60 days of their issuance or date of first commercial availability.

9.6. Upgrades or Replacement: Request for instrumentation upgrades or replacement, due to workload increase, menu changes, technological upgrades, excessive instrumentation failures/malfunctions, breakdowns, etc., or service calls will be evaluated as needed with communication to the contractor for modification of the contract. A high incidence of problems with any equipment/analyzer supplied may indicate probable non-compliance with the terms of this contract and will entitle the Government to its replacement with another analyzer(s) that can produce the required criteria of this contract satisfactorily to the user at no additional cost to the Government. Removal of instrument by the contractor shall be performed within 60 days after request at no additional cost to the Government.

10. ADDITIONAL REQUIREMENTS

10.1 The system shall have STAT priority passage over routine samples and a turnaround time not to exceed 10 minutes for all testing listed in Appendix 1.

10.2 The contractor shall have the ability to sequester same lot numbers for reagents and controls for a minimum of one year from initial date of delivery for PT and Activated Partial Thromboplastin Time (APTT) testing.

10.3 All reagents shall have at least a 3 day on board stability to minimize waste in liquid form or lyophilized. All other controls and calibrators shall have at least 24 hour stability onboard instrument.

10.4. The international Sensitivity Index (ISI) for PT reagent shall not exceed 1.3.

10.5 The contractor shall have the ability to perform onsite lot conversions and provide data for lot changes such as Geometric mean, validate reference ranges, and PTT/Heparin therapeutic ranges using the EP evaluated or similar software reports.

10.6 The contractor shall provide access to real time peer group data for Quality control and reagents lots for reference for troubleshooting, lot changes, and IQAP reports.

10.7 All Quality control material for all tests listed in Appendix 1 are preferred to be used for multiple analytes to minimize the need for multiple quality control materials.

10.8 PTT therapeutic range for heparin shall meet the DHA requirement range to be maintained between 60-94 seconds for all lot numbers.

11. EQUIPMENT REMOVAL

At the end of the contract term, the contractor shall remove all equipment within 60 days after notification of the expiration of the terms of this contract but not until the completion of new contractor's equipment installation inclusive of completed cross over studies. This includes the analyzer and all accessories provided by the contractor to be removed at the end of contract such as printers, peripherals, UPS, and computers. Contractor shall not remove hard drive from premises. All drives with patients' information remains the property of the Government.

Appendix 1 – Test Menu and Workload

	WAMC Lab Test Menu	Estimated Annual Usage
1	Prothrombin Tme (PT)	7900
2	Activated Partial Thromboplastin time (aPTT)	6700
3	Fibrinogen	800

4	D-Dimer	1300
5	Thrombin	40
6	Heparin, Unfractionated	1000
7	Heparin, LMW	500