Special Notice

SUBJECT* Intent to Sole Source Notice-5 Year IDIQ for Chemistry, Immunochemistry, and Hematology Testing with Remisol Advanced Software Auto Verification Wilkes-Barre VA Medical Center

GENERAL INFORMATION

CONTRACTING OFFICE'S ZIP CODE*	18711
SOLICITATION NUMBER*	36C24426Q0756
RESPONSE DATE/TIME/ZONE	07-08-2026 10:00 EASTERN TIME, NEW YORK, USA
ARCHIVE	15 DAYS AFTER THE RESPONSE DATE
RECOVERY ACT FUNDS	N
PRODUCT SERVICE CODE*	6630
NAICS CODE*	334516
CONTRACTING OFFICE ADDRESS	Department of Veterans Affairs Network Contracting Office 4 Services 5 1111 East End Boulevard Wilkes-Barre, PA 18711
POINT OF CONTACT*	Contract Specialist Christa Stine christa.stine@va.gov

ADDITIONAL INFORMATION

AGENCY'S URL	
URL DESCRIPTION	
AGENCY CONTACT'S EMAIL ADDRESS	christa.stine@va.gov
EMAIL DESCRIPTION	

Special Notice

DESCRIPTION

INTENT TO SOLE SOURCE

The Department of Veterans Affairs, Network Contracting Office 4 (NCO4) intends to sole source a contract for the instrumentation, reagents supplies and services to perform Clinical Laboratory Chemistry, Immunochemistry, Chemiluminescent and Hematology Testing on an automation line with auto-verification. All work is to be completed in accordance with the Statement of Work. This sole source contract will be solicited and negotiated with Beckman Coulter, LLC under the authority of FAR 13.106-1 – Single Source Justification.

See attached Draft Statement of Work (SOW).

The North American Industry Classification System (NAICS) code for this procurement is 334516. The Small Business Administration (SBA) size standard is 1,000 employees.

Interested vendors that can meet this requirement, shall identify their interest and capability, and respond to this notice by 07/08/206 NLT 10:00 AM EST. Interested vendors must send a capability statement, no more than one page in length; to include Company Name, ueiSAM Number, Socioeconomic Category, brief description of your business entities capability to handle this project at the Wilkes-Barre VA Medical Center.

This Special Notice of Intent to Sole Source is for planning purposes only. No solicitation will be made available. This is NOT a request for quotations. All information shall be provided at no cost or obligation to the Government. Responses must be sent via email to the Contracting Specialist at christa.stine@va.gov.

Responses received will be evaluated; however, a determination by the Government not to compete the proposed procurement based upon the responses to this notice is solely at the discretion of the Government. If no responses are received, Contracting will proceed with the sole source negotiation with Beckman Coulter, Inc.

STATEMENT OF WORK

Clinical Laboratory Chemistry, Immunochemistry, Chemiluminescent and Hematology Instrumentation with Automation Line and Auto-verification

DESCRIPTION/SPECIFICATIONS/STATEMENT OF WORK

SCOPE OF PROCUREMENT:

1. The instrumentation shall have the capability of performing or reporting the clinical parameters as defined in the statement of work. The instrument shall have random access capability (if discrete testing is required) and be able to able to simultaneously perform the complete profile as described below to meet the performance characteristics for accuracy and precision as defined by the 1988 Clinical Laboratory Improvement Act (CLIA) and the Clinical and Laboratory Standards Institute (CLSI). This request is for the instrumentation, reagents supplies and services to perform Clinical Laboratory Chemistry, Immunochemistry, Chemiluminescent and Hematology Testing on an automation line with auto-verification.

2. **ORDERING METHOD**: The participating facility may order products via Electronic Data Interchange (EDI), telephone, Electronic mail or other written communication, identifying the products by number, quantity, purchase price, address for delivery, and any special instructions.

    2.1.1. Equipment must maintain, or preferably reduce the number of workstations or overall labor required to accomplish the required testing by each laboratory.

    2.1.1. Equipment should be acquired for Wilkes-Barre VAMC. Equipment must meet the volume and turnaround time requirements of Wilkes-Barre VAMC Lab. Typically routine hematology samples should be completed in under 20 minutes, routine chemistry in no more than 70 minutes and routine immunochemistry samples in 90 minutes. STATs are typically 60 minutes from receipt in lab to verification in lab computer.

    2.1.2. The Contractor is required to provide a continuously stocked inventory of reagents, standards, controls, supplies, disposables and any other materials required to properly perform tests on the equipment such that equipment operations are not interrupted. These items shall be of the highest quality, sensitivity, specificity and tested to assure precision and accuracy. Sigma performance may be included to support test quality. Expiration date must be clearly marked on reagent, standards and control containers. Unexpected changes in methodology/technology shall be at the expense of the Contractor.

Alert/Notification of any delays in shipment as well as any or all technical advisory/recalls/alerts, prior to or simultaneously with field alerts should be forwarded to the designated individuals determined at contract award. The Contractor shall provide a copy of all relevant permits/licenses and certifications inclusive of any sanctions current or pending throughout the United States of America.

2.1.3. Special handling for emergency orders of supplies: 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 for routine supply delivery, the Contractor is required to deliver the supplies within 24 hours of receipt of a verbal order for emergency delivery. If either circumstance has occurred, the Contractor shall deliver to the Government site in the most expeditious manner possible without additional cost to the Government, the necessary consumables in sufficient quantity as required to allow operation of the Contractor's equipment for one week (under normal Government test load volume). If additional requests for emergency supply delivery are required by the Government, they shall be honored by the Contractor until the arrival at the laboratory of the monthly standing order/routine supplies delivery.

3. DEFINITIONS:

3.1.1. **Cost per Patient Reportable Result (CPRR)-** *a Cost-Per-Test Clinical Laboratory Analyzers* - Contractors are required to provide a price for a reportable patient result. The per patient reportable result price shall include costs covering: (1) installation of new equipment and equipment use for the entire contract period, (2) all reagents, standards or calibrators, quality controls, supplies, consumable/disposable items to include but not limited to printer paper, Printer maintenance kits, printer cartridges, parts, accessories (including replacement of printers as they fail) and any other item required for the proper operation of the Contractor's equipment including water supply systems and maintenance of these systems and anything necessary for the generation of a patient reportable result. This per patient reportable result price shall also encompass all costs associated with dilution; repeat and confirmatory testing required producing a single patient reportable result. It shall also include the material to perform as well as all other costs associated with quality control, calibration and correlation study testing that is prescribed by the Clinical and Laboratory Standards Institute (CLSI). (3) all necessary maintenance to keep the equipment in good operating condition (This

element includes both preventive maintenance and emergency repairs) and (4) training for Government personnel both off-site and on-site. Contractors shall provide delivery, installation and removal of equipment at no additional charge.

3.1.2. **Cost per Test (CPT) -** *, Part III, Cost-Per-Test Clinical Laboratory Analyzers* – Contractors are required to provide a price for each test that can be performed on its equipment. The per test price shall include costs covering (1) equipment use for the life of the contract, (2) all reagents, standards/ calibrators, quality controls, supplies, consumable/disposable items, paper, parts, accessories (including replacement of printers as they fail) and any other item required for the proper operation of the Contractor's equipment including water supply systems and maintenance of these systems and anything necessary for the generation and reporting of a test result, (3) all necessary maintenance to keep the equipment in good operating condition (This element includes both preventive maintenance and emergency repairs) and (4) training for Government personnel both off-site and on-site. Contractors are required to provide delivery, installation and removal of equipment at no additional charge.

3.2. **TEST MENU**: Refer to Attachment A Test List for desired test menu and estimated annual volumes.

4. **GENERAL REQUIREMENTS:**

4.1. **<u>Automation Line/Middleware</u>**

4.1.1. Automation line must support all instruments provided by the vendor.

4.1.2. Must be able to connect instrumentation to an automated line. The automated line must be able to accept all size tubes, all types of caps, with minimal bar-code readers. It must contain an automated refrigerated stockyard that holds at least 10000 samples.

4.1.3. Automation line must have large input module for volume and have automated specimen retrieval capabilities.

4.1.4. Must have middleware to control all instrumentation, track all specimens on the system, and be programmable for automatic reflex testing and automatic rerun.

4.1.5. Automatic calculations performed by instrument or middleware

4.1.6. Specimen archival through mapping of specimens to racks; for easy retrieval once moved off-line.

4.1.7. Must support the current auto verification software in use at the WBVAMC which requires maintaining and adding rules for both the Remisol Advance software and Data Innovations Instrument Manager wrapper rules for the current instruments and

new instruments added to the automation line. There must be Data Innovations support included to assist in writing new rules for newly added instrumentation and for troubleshooting any issues that may occur that could break current rules.

4.2. **Chemistry and Immunochemistry**

4.2.1. Primary analyzer(s) – Base equipment offered that shall fully support the scope of operations (minimal requirements). Multiple analyzers are required to meet the productivity specifications defined herein. Therefore, additional analyzer(s) shall, likewise, be considered primary instrumentation and shall meet all of the technical specifications of this solicitation. (2 primary analyzers for Chemistry and 2 primary analyzers for Immunochemistry).

4.2.2. **Operational Features-** The instrumentation offered shall have the following:

4.2.2.1. The capability of performing analysis on 100% of the tests listed in Attachment A Test List.

4.2.2.2. Sufficient capacity and throughput to meet the volume/ service demands as defined in Attachment A Test List.

4.2.2.3. Safety features to avoid unnecessary exposure to biohazardous and chemical material. The exposure to and the volume of biohazardous and chemical material generated by the equipment must be minimal and require a minimum amount of handling. Contractor must provide a mechanism for the Clinical Laboratory to meet local discharge requirements (i.e. mercury and formaldehyde SDS sheets must be provided in advance for review).

4.2.2.4. A bi-directional, bar-coded computer interface compatible with the current VA laboratory information system. The fully operational interface (both hardware and software) shall be immediately available for implementation to the VA computerized hospital information system.

4.2.2.4.1. The accuracy of the barcode reading must have less than a 1% failure rate.

4.2.2.4.2. Equipment must be able to support multiple barcode formats (Code 39, Code 128) that may be enabled concurrently.

4.2.2.4.3. Equipment must accept, at a minimum, characters in specimen identifier that is all alpha.

4.2.2.5. Ability to prioritize STAT testing without compromising existing programmed testing.

4.2.2.6. Menu flexibility to accommodate batch testing.

4.2.2.7. Minimal daily, monthly, and periodic maintenance.

4.2.2.8. Ability to store and retransmit records (24 hours of maximal instrument throughput) in case of interface outage.

4.2.2.9. On board reagent stability sufficient to accommodate both high and low volume use. Contractor to provide expiration dates of at least six (6) months for reagents when available.

4.2.2.10. Ready to use reagents to ensure less test downtime.

4.2.2.11. Ability to accept serum/plasma, CSF, urine, body fluids, supernatants and whole blood

4.2.2.12. No requirements for sample pre-treatment for most assays.

4.2.2.13. 6 point calibrators for immune assays preferred.

4.2.2.14. Capability to detect out of range quality control and ensure ceasing of patient testing until resolution if the quality control is out of range.

4.2.2.15. Ability to accept various types of sample containers.

4.2.2.16. Specimen indices (hemolysis, icteric, and lipemia) are required to be determined for each specimen at no additional charge.

4.2.2.17. On board dilution capability (desired).

4.2.2.18. Must have accurate metering capability for monitoring reagent usage or accept CMCVAMC's monthly LMIP statistics generated from VistA computer system.

4.2.2.19. Instruments should have the ability to perform infectious disease testing.

4.2.3. **Technical Features-** The instrumentation must be approved by the Food and Drug Administration (FDA) and shall have the following:

4.2.3.1. On-board QC data management system with a storage capacity for QC files and includes Levy-Jennings graphs. Analyzer must have the ability to capture, store and electronically transfer QC data.

4.2.3.2. Ability to monitor instrument performance, preferably using a secure, direct data connection to a technical support center so instrument performance can be managed in real time.

4.2.3.3. On board reagent inventory system.

4.2.3.4. Minimal carryover, no carryover preferred.

4.2.3.5. Minimal reagent preparation, preferably no reconstitution required.

4.2.3.6. Antigen excess checks (immunochemistry).

4.2.3.7. Ability to run replicate testing with one sample.

4.2.3.8. Testing for adulteration of urine samples for DAU.

4.2.3.9. Ability to change reagents while instrument is in operation.

4.2.3.10. Onboard calibration and lot (calibrator and reagent) tracking.

4.2.3.11. Long calibration stability.

4.2.3.12. Minimal specimen volume.

4.2.3.13. Adequacy of sample detection.

4.2.3.14. Equipment performance evaluations will be based on at least the following:

2.4.4.15.1 Quality and accuracy of testing,

2.4.4.15.2 Amount of downtime of each analyzer,

2.4.4.15.3 Competence of service personnel, and

2.4.4.15.4 Number of times the service engineer has to return to fix the same instrument issue

Other performance categories can be added or removed as needed.

4.2.4. **Hardware Features-** The instrumentation shall have the following:

4.2.4.1. A total equipment footprint that when installed in the laboratory shall not impact the functionality/operations of that laboratory.

4.2.4.2. Total equipment footprint cannot require major construction projects.

4.2.4.3. An on-board monitor/screen that is easily readable.

4.2.4.4. A printer that has the capability of printing a patient report with patient demographic information that includes minimally the patient's name and accession or unique identifier number (UID).

4.2.4.5. An uninterruptible power supply with line conditioner for each instrument provided.

4.2.4.6. An auto sampling system that includes cap piercing closed tube aspiration, auto-loader, and auto-mixing.

4.2.4.7. Primary tube sampling.

4.2.4.8. Clot detection.

4.2.4.9. Manual sampling mode that reads barcode label; ideally both closed and open manual sampling modes is desirable.

4.2.4.10. Connection to technical support to monitor instrument/QC performance.

4.2.4.11. A quality control user group comparison program.

4.2.4.12. The Contractor shall be able to provide any incremental support equipment, e.g. water system, ultracentrifuge, for their systems.

Method Performance/Validation Requirements

1. Method performance/comparison shall be at the expense of the Contractor, shall include linearity material and reagents, and be consistent with current CLSI guidelines and related documents, College of American Pathologists (CAP) standards and Federal regulations.

2. Correlation studies for each analyte: A minimum of 30 samples spanning the reportable range shall be run by the present and the proposed method. In systems where multiple sampling modes exist, mode to mode correlation studies must also be performed. Contractor should analyze results and provide statistical data to support acceptance of the new method for above studies. Statistics shall consist of at least mean, bias, slope, y-intercept, correlation coefficient, ROC analysis, and meet current standards defined by CLSI.

3. Analytical Measurement Range (AMR) Validation shall be performed on proposed instrument(s) for each analyte to validate the reportable range. The material must have values, which are near the low, mid, and high values of the AMR and be of appropriate matrix for the clinical specimens assayed by that method. A minimum 5-point linearity analysis that adheres to the Beer-Lambert Law and spans the entire range shall be performed as a minimum.

4. Precision study using normal and abnormal control material. This shall consist of a within run precision study of 10 normal and 10 abnormal controls and a day-to-day precision study of normal controls and abnormal controls for 10 days (maybe run twice a day) for a total of 20 values per level of control.

5. Sensitivity. Sensitivity may be validated concurrently with correlation studies. Mathematical calculations to determine efficiency, sensitivity, false positive rate and false negative rate are applied.

6. Specificity Studies. A review of product literature and assay inserts to determine any adverse effects for increased bilirubin, hemolysis, lipemia, or other interfering substances.

7. Carryover Studies. Successful carryover studies shall be completed by the contractor on all analyzers during installation. These studies shall be performed using either contractor developed program(s) or program(s) developed by a third party (CAP/CLSI). The programs shall be provided to the Michael J Crescenz VA Laboratory at no charge.

4.2.5. **Reference Range-** A reference range must be determined for each test following

CLSI/regulatory guidelines. 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. One of the following protocols shall be used:

4.2.5.1. 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 should provide specific information defining how the suggested range was determined. A minimum of 50 reference individuals shall be used to verify the manufacturer's range. Any apparent outliers should be discarded and new specimens obtained to provide a statistically valid verification.

4.2.5.2. If the suggested manufacturer's range is not appropriate for the patient population, a reference range shall be established. Establishing a reference must follow CLSI guidelines. This requires a minimum of 120 reference individuals to be used to establish a reference range. The reference interval should be determined using the nonparametric method.

4.2.5.3. If a laboratory is currently using the proposed instrument/reagent system, the "in-use" reference range can be transferred to the "new" system if a method comparison study between the two systems proves to be acceptable. If comparison studies are not acceptable, one of the two above items must be performed.

4.2.6. **Support Features-**

4.2.6.1. Commercial marketing. The equipment models being offered shall be in current production as of the date this offer is submitted. For purposes of this solicitation, "current production" shall mean that the clinical laboratory analyzer model is being offered as new equipment. Discontinued models that are only being made available as remanufactured equipment are not acceptable.

4.2.6.2. Start-Up Reagents. The Contractor shall provide all reagents, calibrators, controls, consumable/disposable items, parts, accessories and any other item included and any other items that is required to establish instruments for operation for performance of acceptance testing. The Contractor shall perform, to the satisfaction of the Government, all validation studies including: precision, method comparison with current analyzer, accuracy (recovery), linearity (reportable range), calibration verification, verification of reference interval, and determination of sensitivity and specificity at no cost to the Government. The Contractor shall perform all of the statistical analysis as

stated in the Method Performance/Validation section above and report data in an organized, clearly comprehensible format.

4.2.6.3. Training. The Contractor shall provide an instrument training program that is coordinated with and timely to the equipment installation, sufficient to the size and scope of Wilkes-Barre VAMC laboratory services. This shall include training on the operation of the system, data manipulation, and basic trouble shooting and repair. Thereafter, the Contractor shall provide training for 2 operators the first year of the contract and 1 operator per year at the discretion of the Government for each model of instrumentation placed. Utilization of the training slots shall be mutually agreed upon between the VA and the Contractor. A training program that involves off-site travel shall include the cost of airfare, room and board for each participant.

4.2.6.4. The Contractor shall provide all necessary procedures manuals, troubleshooting manuals, operator manuals (also available on computer disc format). Procedures should be in Clinical and Laboratory Standards Institute (CLSI) format.

4.2.6.5. Equipment Preventative Maintenance/Repair Service. The Contractor shall be able to provide emergency equipment repair and preventative maintenance on all primary and back-up instrumentation and any incremental support equipment, e.g. water system, offered according to the following terms:

<u>Service Requirements</u>

1. A technical assistance center shall be available by telephone 24 hours per day, 7 days per week with a maximum callback response time of 30 minutes.
2. Equipment repair service shall be provided during business hours Monday through Friday on site service as needed. However, if both analyzers are down, then service will be provided 24 hours/ 7 days per week. All arrangements shall be coordinated between the Contractor and VA laboratory personnel.
3. Equipment repair response time at the site shall be no more than 2 hours for service personnel.
4. Preventative maintenance will be performed as frequently as published in manufacturer's operators manual and within 2 weeks

of the scheduled due date. Scheduled maintenance times should be flexible to minimize interruptions during peak workload times.

5. Contractor shall provide service for monthly instrument maintenance.
6. A malfunction incident report shall be furnished to the Laboratory upon completion of each repair call. The report should include, as a minimum, the following:
    a. date and time notified
    b. date and time of arrival
    c. serial number, type and model number of equipment
    d. time spent for repair, and
    e. proof of repair that includes documentation of a sample run of quality control verifying acceptable performance.
    f. Each notification for an emergency repair service call shall be treated as a separate and new service call.
    g. Assist the user in setting up and maintaining/troubleshooting user-defined assays.
    h. If the equipment provided by the contractor is requiring repair and is down in excess of 24 hours and the second analyzer goes down, the Contractor is to bear the cost of testing at an alternative location until the equipment is returned to a fully functional level.

4.2.6.6. 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 Government. These shall 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, correction of hardware defect, upgrade offered to commercial customers at no additional charge, upgrade to replace model of equipment no longer Contractor supported, etc. This does not refer to replacing the original piece of equipment provided under the contract; however, it does refer to significant changes in the hardware operational capability.

4.2.6.7. Ancillary support equipment - The Contractor shall provide, install and maintain through the life of the Contract , as indicated, any and all ancillary

support equipment to fully operate the analyzer as defined in these specifications, e.g. cabinetry to support/house the analyzer (if necessary), water systems (including consumable polishers, filters, etc.), and universal interface equipment, etc. In addition, the Contractor shall include all ancillary components that are customarily sold or provided with the model of equipment proposed, e.g. starter kits, tables/stands, etc.

4.2.6.8. The Contractor will notify, within 24 hours, all participating facilities of any recalled reagents or equipment components. This must be accomplished by telephone, email, and/or certified mail. The contractor will provide sufficient replacement items to resolve the problem so no break in service is realized by the Wilkes-Barre VAMC laboratory.

4.2.6.9. In the case of a company merger and/or acquisition, the contractor will immediately notify the Contracting Officer for this Contract and provide a contingency plan of services to assure that no break in services is realized by the Wilkes-Barre VAMC Laboratory.

4.2.6.10. The Contractor shall provide a directory with the names and telephone numbers of all contact persons to be used by the participating facilities to inquire about billing issues, reagent shipments, service concerns, etc.

4.2.6.11. The contractor is encouraged to quote a spectrum of value added incentives. Such incentives may include customer and professional service programs (i.e. PACE approved continuing education programs for clinical laboratory staff) and new innovations to assist the Wilkes-Barre VAMC with the usage of the contractor's products/services in the most efficient manner.

<u>Interface Requirements</u>

1. The Contractor shall be responsible for providing all hardware required for the connection, implementation, and operation of the interface to the universal interface and any incremental fee that is required each time an instrument is added to an existing universal interface system (see Attachment A).
2. The Contractor shall provide any and all necessary software support for ensuring that successful interfacing has been established. Specific requirements for the communication of the data streams will be unique to the instrument system involved and dictated by the manufacturer itself. Information necessary to make the type and amount of interfacing equipment is supplied in Attachment A.
3. If the Wilkes-Barre VAMC Laboratory already has a universal interface box, the Contractor is responsible for everything leading up to the box including

any incremental fee required to add additional equipment (e.g. licenses, ports/cards, cables, software, etc.) to the universal interfacing system.

4. If Wilkes-Barre VAMC laboratory does not have a universal interface and one is needed to optimally interface the instrument, then the Contractor is responsible for the acquisition of the universal interface box and everything else needed to connect with VA computerized hospital information system.
5. 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 computerized hospital information system.

4.2.6.12. Commercial offerings - The Contractor shall provide any additional support material that is routinely provided to equivalent commercial customers and assists in regulatory compliance, e.g. Computer disc containing their procedure manual in CLSI format and/or an on-line procedure manual in the instrument software.

4.2.6.13. Characterization of waste – The Contractor shall provide documentation that it has characterized the hazardous nature of all wastes produced by all equipment, devices, reagents, and discharges in accordance with the requirements of the Code of Federal Regulations Title 40 “Protection of the Environment” Part 261 et seq. and applicable state and local requirements. Documentation shall include a description of the characteristics of the hazardous waste produced as a byproduct of the instrument operations, Safety Data Sheets (SDS) meeting the requirements of the Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA), the analytical process used to determine the hazardous nature and characteristics of the waste, and the analytical test results. Testing of hazardous waste is to be done in accordance with testing protocol specified for each individual waste as described in the Code of Federal Regulations Title 40 to make a determination if the waste is a hazardous waste or otherwise regulated.

4.2.6.13.1. The determination and description shall address the following:

4.2.6.13.1.1. Waste toxicity (Reference 40 CFR §261.11 and 40 CFR §261.24)

4.2.6.13.1.2. Waste ignitability (Reference 40 CFR §261.21)

4.2.6.13.1.3. Waste corrosivity (Reference 40 CFR §261.22)

4.2.6.13.1.4. Waste reactivity (Reference 40 CFR §261.23)

4.2.6.13.1.5. Hazardous waste from non-specific sources (F-listed) (Reference 40 CFR §261.31)

4.2.6.13.1.6. Discarded commercial products (acutely toxic or P-listed and toxic or U-listed) (Reference 40 CFR §261.33)

4.2.6.13.1.7. Solid Waste (Reference 40 CFR §261.2)

4.2.6.13.1.8. Exclusions (Reference 40 CFR §261.4)

4.2.6.13.2. The contractor will provide written instructions and training material to ensure VHA laboratory staff are trained as needed to properly operate devices with special emphasis to managing and disposing of hazardous waste in accordance with EPA and state requirements. Additionally, the training provided by the contractor must fulfill Resource Conservation and Recovery Act (RCRA) requirements for training as applicable to devices.

4.2.6.13.3. Contractor shall provide a description of all wastes the process or equipment may discharge so that the facility can determine whether the discharge meets Local Publicly Owned Treatment Works (POTW), State and Federal discharge requirements. At a minimum the characteristics of ignitability, corrosivity, reactivity and toxicity as defined in 40 CFR §261 must be determined and documented. Any mercury containing reagents must be identified in any concentrations. All test results shall be provided. All listed chemicals (F, U, K and P) found in 40 CFR §261 shall be provided in product information and their concentrations documented. For those materials with a positive hazardous waste determination, a mechanism for the laboratory to meet local discharge requirements (i.e. mercury, thimerosol and formaldehyde) must be developed and SDS sheets must be provided in advance for review. At a minimum, documentation shall include, but not be limited to the concentration/measures of the elements and parameters listed below and must be included with vendor response:

4.2.6.13.3.1. Barium (Total)

4.2.6.13.3.2. Cadmium (Total)

4.2.6.13.3.3. Chromium (Total)

4.2.6.13.3.4. Copper (Total)

4.2.6.13.3.5. Cyanide (Total)

4.2.6.13.3.6. Lead (Total)

4.2.6.13.3.7. Mercury (Total)

4.2.6.13.3.8. Nickel (Total)

4.2.6.13.3.9. Silver (Total)

4.2.6.13.3.10. Zinc (Total)

4.2.6.13.3.11. Arsenic (Total)

4.2.6.13.3.12. Selenium (Total)

4.2.6.13.3.13. Tin (Total)

4.2.6.13.3.14. pH

4.2.6.13.3.15. Flash point (to higher than 200□F)

4.2.6.13.3.16. BOD; biochemical oxygen demand

4.2.6.13.4. The documentation the contractor provides will be used to work with the VAMC and the public and/or private organization (e.g., POTW) to determine whether or not the waste from each device can legally be disposed of via the sewerage system

4.2.6.14. Implementation/transition timeframe - The implementation of the services/requirements described in this solicitation shall be completed no later than 90 days after the award of the contract. This timeline is based on a reasonable attempt of the Contractor to complete all of the necessary implementation requirements within the stated timeframe. Contractor shall not be penalized for implementation timelines that extend beyond the 90 day timeframe, if the extension is through no fault of the Contractor and is a result of delays due to the Government.

4.2.6.14.1. Upon award of a contract, the transition period for the awarded Contract to have all equipment and peripherals installed and operational shall be from date of award through 90 days. During this same period all initial training of VA personnel in the operation and maintenance of said award shall also be completed.

4.2.6.14.2. Contractor shall provide with its quotation and implementation plan for installation of new equipment. Contractor's submitted plan shall not exceed 60 days for the transition of all services under the awarded contract including installation and training of personnel, transition of all testing materials, reagents and supplies, etc., performance of all correlations and validations. Failure of the Contractor to conform to the transition period shall be considered as sufficient cause to terminate contract for cause under the Termination for Cause clause of the contract.

4.2.6.14.3. At the end of 90 days from award of the contract, the awarded Contractor shall have full and sole responsibility for services under the awarded contract.

4.2.7. **Standard and Quality of Performance-** This paragraph establishes a standard of quality performance that shall be met before any equipment listed on the delivery order [or contract] is accepted by the Government. This also includes replacement, substitute machines and machines that are added or field modified after a system has demonstrated successful performance. The acceptance period shall begin on the installation date. It shall end when the equipment has met the standard of performance for a period of 30 consecutive calendar days by operating in conformance with the Contractor's technical specification or as quoted in any contract at an effectiveness level of 90% or more.

4.2.7.1. In the event that equipment does not meet the standard of performance during the initial 30 consecutive calendar days, the standard of performance tests shall continue on a day-by-day basis until the standard of performance is met for a total of 30 consecutive days.

4.2.7.2. If the equipment fails to meet the standard of performance after 90 calendar days from the installation date, the user may, at his/her option, request a replacement or terminate the order in accordance with the provisions of FAR 52.212-4 entitled "Termination for cause." (The Contractor shall receive revenue for tests reported during the 90-day acceptance period.)

4.2.7.3. Operational use time for performance testing for a system is defined as the accumulated time during which the machine is in actual use. System failure downtime is that period of time when any machine in the system is inoperable due to equipment failure. Downtime for each incident shall start from the time the Government makes a bona fide attempt to contact the Contractor's designated representative at the prearranged contact point until the system or machine(s) is returned to the Government in proper operating condition.

4.2.7.4. During the performance period for a system, a minimum of 100 hours of operational use time with productive or simulated work shall be required as a basis for computation of the effectiveness level. However, in computing the effectiveness level, the actual number of operational use hours shall be used when in excess of the minimum of 100 hours.

4.2.7.5. The Government will maintain daily records to satisfy the requirements of the Standard and Quality of Performance section and shall notify the

Contractor in writing of the date of the first day of the successful period of operation. Operations use time and downtime shall be measured in hours and whole minutes.

4.2.7.6. During the term of the contract, should the repair record of any individual piece of laboratory equipment reflect a downtime of 10% or greater of the normal working days in one calendar month, a determination shall be made by the COR to replace the malfunctioning equipment with new equipment. The responsibility for maintaining the equipment furnished in good condition in accordance with manufacturer's instructions, shall be solely that of the Contractor. Each instrument provided by the Contractor shall maintain an uptime of 90% in each month of the term of the agreement for equipment.

4.2.8. **Government's Responsibility-** The user will perform routine maintenance and cleaning as required in the manufacturer's operation and maintenance instructions. The user shall maintain appropriate records to satisfy the requirements of this paragraph.

4.2.9. **Ownership of Equipment-** Title to the equipment shall remain with the Contractor. All accessories (unused consumables, etc.) furnished by the Contractor shall accompany the equipment when returned to the Contractor. The Contractor, upon expiration of order(s), at termination and/or replacement of equipment, shall remove the equipment. The Contractor shall disconnect the analyzer (gas, water, air, etc.) and shall be responsible for all packing and shipping required to remove the analyzer.

4.2.10. The Contractor will identify if removable media is required to perform their duties. The Clinical Engineering Department will ensure the removable media is scanned with anti-virus software running current virus definitions prior to connection to any medical device/system. Any Contractor with patient sensitive information that is imported into the removable media device for any reason must purge all patient sensitive information prior to departure from the facility.

4.2.11. Prior to termination or completion of this contract, Contractor/subcontractor must not destroy information received from VA, or gathered/created by the Contractor in the course of performing this contract without prior written approval by the VA. Any data destruction done on behalf of VA by a Contractor/subcontractor must be done in accordance with National Archives and Records Administration (NARA) requirements as outlined in VA Directive 6300, *Records and Information Management* and its Handbook 6300.1 *Records Management Procedures*, applicable VA Records Control Schedules, and VA Handbook 6500.1, *Electronic*

Media Sanitization. Self-certification by the Contractor that the data destruction requirements above have been met must be sent to the VA Contracting Officer within 30 days of termination or completion of the contract.

4.2.12. All electronic storage media used on non-VA leased or non-VA owned IT equipment that is used to store, process, or access VA information must be handled in adherence with VA Handbook 6500.1, *Electronic Media Sanitization* upon: (i) completion or termination of the contract or (ii) disposal or return of the IT equipment by the Contractor/subcontractor or any person acting on behalf of the Contractor/subcontractor, whichever is earlier. Media (hard drives, optical disks, CDs, back-up tapes, etc.) used by the Contractors/subcontractors that contain VA information must be returned to the VA for sanitization or destruction, or the Contractor/subcontractor must self-certify that the media has been disposed of per 6500.1 requirements. This must be completed within 30 days of termination or completion of the contract or disposal or return of the IT equipment, whichever is earlier

4.2.13. Bio-Medical devices and other equipment or systems containing media (hard drives, optical disks, etc.) with VA sensitive information must not be returned to the Contractor at the end of lease, for trade-in, or other purposes. The options are:

4.2.13.1. Contractor must accept the system without the drive;

4.2.13.2. VA's initial medical device procurement includes a spare drive which must be installed in place of the original drive at time of turn-in; or

4.2.13.3. VA must reimburse the company for media at a reasonable open market replacement cost at time of purchase.

4.2.14. Due to the highly specialized and sometimes proprietary hardware and software associated with medical equipment/systems, if it is <u>not possible</u> for the VA to retain the hard drive, <u>then</u>;

4.2.14.1. The equipment Contractor must have an existing BAA if the device being traded in has protected health information stored on it and hard drive(s) from the system are being returned physically intact; and

4.2.14.2. Any fixed hard drive on the device must be non-destructively sanitized to the greatest extent possible without negatively impacting system operation. Selective clearing down to patient data folder level is recommended using VA approved and validated overwriting technologies/methods/tools. Applicable media sanitization specifications need to be pre-approved and described in the purchase order or contract.

4.2.14.3. A statement needs to be signed by the Director (System Owner) that

states that the drive cannot be removed and that (a) and (b) controls above are in place and completed. The Information Security Officer (ISO) needs to maintain the documentation.

HEMATOLOGY REQUIREMENTS

4.2.15. Test Menu and Parameter definitions-

4.2.15.1. CBC- Complete Blood Count

4.2.15.2. WBC- White Blood Cell Count

4.2.15.3. Diff- Automated Differential

4.2.15.4. RBC- Red Blood Cell Count

4.2.15.5. Platelet Count

4.2.15.6. MCH- Mean Corpuscular Hemoglobin

4.2.15.7. MCV- Mean Corpuscular Volume

4.2.15.8. MCHC-Mean Corpuscular Hemoglobin Concentration

4.2.15.9. RDW- Red Cell Distribution Width

4.2.15.10. MPV-Mean Platelet Volume

4.2.15.11. Monocyte Distribution Width (MDW) Sepsis

4.2.15.12. Cell count for body fluids

4.2.16. **Complete Blood Count (CBC) and White Blood Cell (WBC) Automated Differential (DIFF) Reticulocyte and Monocyte Distribution Width (MDW) and a Digital cell morphology system (such as the Scorpio)**

4.2.16.1. Must meet the current auto validation configuration with the Remisol Software and the digital cell morphology system interface to include all the existing indices associated with both the automated differential and manual differential configurations.

4.2.16.2. Accepts body fluid samples for analysis, body fluid analysis with diff preferred.

4.3. **TEST Volumes**: Refer to Attachment A Test List for historical volumes.

4.4. **GENERAL REQUIREMENTS:**

4.4.1. Primary analyzer(s) – Base equipment offered that shall fully support the scope of operations (minimal requirements). Multiple analyzers are required to meet the productivity specifications defined herein. Therefore, additional analyzer(s) shall, likewise, be considered primary instrumentation and shall meet all of the technical specifications of this solicitation. Two Hematology analyzers (mirror images) , and a reflex analyzer. One slide maker stainer , and middleware software (Remisol) with WRAPPER are required to meet the scope of operations

4.4.2. **Operational Features-** The instrumentation offered shall have the following:

4.4.2.1. The capability of performing analysis on 100% of the tests listed in Attachment A Test List.

4.4.2.2. Sufficient capacity and throughput to meet the volume/ service demands.

4.4.2.3. Safety features to avoid unnecessary exposure to biohazardous and chemical material. The exposure to and the volume of biohazardous and chemical material generated by the equipment must be minimal and require a minimum amount of handling. Contractor must provide a mechanism for the Clinical Laboratory to meet local discharge requirements (i.e. mercury and formaldehyde SDS sheets must be provided in advance for review).

4.4.2.4. A bi-directional, bar-coded computer interface compatible with the current VA laboratory information system. The fully operational interface (both hardware and software) shall be immediately available for implementation to the VA computerized hospital information system.

4.4.2.4.1. The accuracy of the barcode reading must have less than a 1% failure rate.

4.4.2.4.2. Equipment must be able to support multiple barcode formats (Code 39, Code 128) that may be enabled concurrently.

4.4.2.4.3. Equipment must accept, at a minimum, characters in specimen identifier that is alpha numeric.

4.4.2.5. Ability to prioritize STAT testing without compromising existing programmed testing.

4.4.2.6. Minimal daily, monthly, and periodic maintenance.

4.4.2.7. Ability to store and retransmit records (24 hours of maximal instrument throughput) in case of interface outage.

4.4.2.8. On board reagent stability sufficient to accommodate both high and low volume use. Contractor to provide expiration dates of at least three (3) months for reagents.

4.4.2.9. No requirements for sample pre-treatment.

4.4.2.10. Capability to detect out of range quality control and flag patient results if the quality control is out of range.

4.4.2.11. Ability to accept various types of sample containers.

4.4.2.12. Must have accurate metering capability for monitoring reagent usage or accept VAMC's monthly LMIP statistics generated from VistA computer system.

4.4.3. **Technical Features-** The instrumentation must be approved by the Food and Drug Administration (FDA) and shall have the following:

4.4.3.1. On-board QC data management system with a minimum storage capacity of three QC files and includes Levy-Jennings graphs. Analyzer must have the ability to capture, store and electronically transfer QC data.

4.4.3.2. Ability to monitor instrument performance, preferably using a secure, direct data connection to a technical support center so instrument performance can be managed in real time.

4.4.3.3. On board reagent inventory system.

4.4.3.4. Ability to calibrate in all sample modes.

4.4.3.5. Minimal carryover, no carryover preferred.

4.4.3.6. Minimal reagent preparation, preferably no reconstitution required.

4.4.3.7. Acceptability of various sample containers.

4.4.3.8. Ability to change reagents while instrument is in operation.

4.4.3.9. Onboard calibration and lot (calibrator and reagent) tracking.

4.4.3.10. Long calibration stability.

4.4.3.11. Minimal specimen volume.

4.4.3.12. Adequacy of sample detection.

4.4.3.13. Equipment performance evaluations will be based on at least the following:

2.4.4.13.1 Quality and accuracy of testing,

2.4.4.13.2 Amount of downtime of each analyzer,

2.4.4.13.3 Competence of service personnel, and

2.4.4.13.4 Number of times the service engineer has to return to fix the same instrument issue

Other performance categories can be added or removed as needed.

4.4.4. **Hardware Features-** The instrumentation shall have the following:

4.4.4.1. A total equipment footprint that when installed in the laboratory shall not impact the functionality/operations of that laboratory.

4.4.4.2. An on-board monitor/screen that is easily readable.

4.4.4.3. A printer that has the capability of printing a patient report with patient demographic information that includes minimally the patient's name and accession or unique identifier number (UID).

4.4.4.4. An uninterruptible power supply with line conditioner for each instrument provided.

4.4.4.5. An auto sampling system that includes cap piercing closed tube aspiration, auto-loader, and auto-mixing.

4.4.4.6. Primary tube sampling.

4.4.4.7. Clot detection.

4.4.4.8. Manual sampling mode that reads barcode label; ideally both closed and open manual sampling modes is desirable.

4.4.4.9. Modem to technical support to monitor instrument/QC performance (Pro Service). A quality control user group comparison program.

4.4.4.10. The Contractor shall be able to provide any incremental support equipment, e.g. back up label printer and hand scanner.

4.4.4.11. Specific Equipment Requirements

4.4.4.12. Option for an Integrated Clinical Laboratory Hematology Analyzers and robotic system (Automated track and connectivity). A turnkey system with a single inlet and single outlet with connectivity to two hematology analyzers and one slide maker stainer will be provided to the Wilkes-Barre VAMC Laboratory.

The following are specifications for the automation system:

i. Provision of several data managers as needed, Single inlet and single outlet,
ii. Automated repeat and/or reflex testing based on established rules developed by the Laboratory,
iii. Ability to auto-verify results,
iv. Specimen archival through mapping of specimens to racks; for easy retrieval once moved off-line.
v. Both Hematology analyzers will be a mirror image of one another.

4.4.4.13. Method Performance/Validation Requirements

1. Method performance/comparison shall be at the expense of the Contractor, shall include linearity material and reagents, and be consistent with current CLSI guidelines and related documents, College of American Pathologists (CAP) standards and Federal regulations.
2. Correlation studies for each analyte: A minimum of 30 samples spanning the reportable range shall be run by the present and the proposed method. In systems where multiple sampling modes exist, mode to mode correlation studies must also be performed. Contractor should analyze results and provide statistical data to support acceptance of the new method for above studies. Statistics shall consist of at least mean, bias, slope, y-intercept, correlation coefficient, ROC analysis, and

meet current standards defined by CLSI.

3. Analytical Measurement Range (AMR) Validation shall be performed on proposed instrument(s) for each analyte to validate the reportable range. The material must have values, which are near the low, mid, and high values of the AMR and be of appropriate matrix for the clinical specimens assayed by that method. A minimum 5-point linearity analysis that adheres to the Beer-Lambert Law and spans the entire range shall be performed as a minimum.

4. Precision study using normal and abnormal control material. This shall consist of a within run precision study of 10 normal and 10 abnormal controls and a day-to-day precision study of normal controls and abnormal controls for 10 days (maybe run twice a day) for a total of 20 values per level of control.

5. Sensitivity. Sensitivity may be validated concurrently with correlation studies. Mathematical calculations to determine efficiency, sensitivity, false positive rate and false negative rate are applied.

6. Specificity Studies. A review of product literature and assay inserts to determine any adverse effects for increased bilirubin, hemolysis, lipemic, or other interfering substances.

7. Carryover Studies. Successful carryover studies shall be completed by the contractor on all analyzers during installation. These studies shall be performed using either contractor developed program(s) or program(s) developed by a third party (CAP/CLSI). The programs shall be provided to the Michael J Crescenz VA Laboratory at no charge.

8. **Reference Range-** A reference range must be determined for each test following CLSI guidelines. 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. One of the following protocols shall be used:

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 should provide specific information defining how the suggested range was determined. A minimum of 20 reference individuals shall 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 shall be established. Establishing a reference must

follow CLSI guidelines. This requires a minimum of 120 reference individuals to be used to establish a reference range. The reference interval should be determined using the nonparametric method.

9. If Wilkes-Barre VAMC laboratory is currently using the proposed instrument/reagent system, the "in-use" reference range can be transferred to the "new" system if a method comparison study between the two systems proves to be acceptable. If comparison studies are not acceptable, one of the two above items must be performed.

4.4.4.14 **Ordering/Billing:** Orders will be placed using purchase order via telephone, mail, fax, or online. Billing will be monthly in arrears for the level of tests by each facility. Monthly payments include equipment, service, and reagents necessary to perform tests provided to the contractor. Deliveries will be F.O.B. destination.

4.4.4.15 Contractor performance evaluations will be based on at least the following:

2.4.9.3.1 Timeliness and accuracy of invoicing,

2.4.9.3.2 Timeliness and accuracy of quarterly sales reports,

Other performance categories can be added or removed as needed.

4.4.4.16 **Support Features-**

1. Commercial marketing. The equipment models being offered shall be in current production as of the date this offer is submitted. For purposes of this solicitation, "current production" shall mean that the clinical laboratory analyzer model is being offered as new equipment. Discontinued models that are only being made available as remanufactured equipment are not acceptable.

2. Start-Up Reagents. The Contractor shall provide all reagents, calibrators, controls, consumable/disposable items, parts, accessories and any other item required to establish instruments for operation for performance of acceptance testing. The Contractor shall perform, to the satisfaction of the Government, all validation studies including: precision, method comparison with current analyzer, accuracy (recovery), linearity (reportable range), calibration verification, verification of reference

interval, and determination of sensitivity and specificity at no cost to the Government. The Contractor shall perform all of the statistical analysis as stated in the Method Performance/Validation section above and report data in an organized, clearly comprehensible format.

3. Training. The Contractor shall provide an instrument training program that is coordinated with and timely to the equipment installation, sufficient to the size and scope of the Wilkes-Barre VAMC Laboratory services and minimally equivalent to the terms and conditions for training required to operate the equipment. This shall include training on the operation of the system, data manipulation, and basic trouble shooting and repair. Thereafter, the Contractor shall provide training for minimally one operator per facility per year at the discretion of the Government for each model of instrumentation placed. Utilization of the training slots shall be mutually agreed upon between the VA and the Contractor. A training program that involves off-site travel shall include the cost of airfare, room and board for each participant.
4. The Contractor shall provide all necessary procedures manuals, troubleshooting manuals, operator manuals (also available on computer disc format). Procedures should be in Clinical and Laboratory Standards Institute (CLSI) format.

Equipment Preventative Maintenance/Repair Service. The Contractor shall be able to provide emergency equipment repair and preventative maintenance on all primary and back-up instrumentation and any incremental support equipment, e.g. water system, offered according to the following terms:

4.4.4.17 **Service Requirements**

1. A technical assistance center shall be available by telephone 24 hours per day, 7 days per week with a maximum callback response time of 30 minutes

2. Equipment repair service shall be provided during business hours Monday through Friday on site service as needed. However, if both analyzers are down,

then service will be provided 24 hours/ 7 days per week. All arrangements shall be coordinated between the Contractor and VA laboratory personnel.

3. Equipment repair response time at the site shall be no more than 2 hours for service personnel.

4. Preventative maintenance will be performed as frequently as published in manufacturer's operators manual and within 2 weeks of the scheduled due date. Scheduled maintenance times should be flexible to minimize interruptions during peak workload times.

a. A malfunction incident report shall be furnished to the Laboratory upon completion of each repair call. The report should include, as a minimum, the following:
    i. date and time notified
    ii. date and time of arrival
    iii. serial number, type and model number of equipment
    iv. time spent for repair, and
    v. proof of repair that includes documentation of a sample run of quality control verifying acceptable performance.
    vi. Each notification for an emergency repair service call shall be treated as a separate and new service call.
    vii. Assist the user in setting up and maintaining/troubleshooting user-defined assays.
    viii. If the equipment provided by the contractor is requiring repair and is down in excess of 24 hours and the second analyzer goes down, the Contractor is to bear the cost of testing at an alternative location until the equipment is returned to a fully functional level.

5. 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 Government. These shall 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, correction of hardware defect, upgrade offered to commercial customers at no additional charge, upgrade to replace model of equipment no longer Contractor supported, etc. This does not refer to replacing the original piece of equipment provided under the contract; however, it does refer to significant changes in the hardware operational capability.

6.Ancillary support equipment - The Contractor shall provide, install and maintain through the life of the contract , as indicated, any and all ancillary support equipment to fully operate the analyzer as defined in these specifications, e.g. cabinetry to support/house the analyzer (if necessary), water systems (including consumable polishers, filters, etc.), and universal interface equipment, etc. In addition, the Contractor shall include all ancillary components that are customarily sold or provided with the model of equipment proposed, e.g. starter kits, tables/stands, etc.

4.4.4.18.The Contractor will notify, within 24 hours, all participating facilities of any recalled reagents or equipment components. This must be accomplished by telephone, email, and/or certified mail. The contractor will provide sufficient replacement items to resolve the problem so no break in service is realized.

4.4.4.19.In the case of a company merger and/or acquisition, the contractor will immediately notify the Contracting Officer for this contract and provide a contingency plan of services to assure that no break in services is realized by the Wilkes-Barre VAMC Laboratory.

4.4.4.20.The Contractor shall provide a directory with the names and telephone numbers of all contact persons to be used by the participating facilities to inquire about billing issues, reagent shipments, service concerns, etc.

4.4.4.21.The contractor is encouraged to quote a spectrum of value added incentives. Such incentives may include customer and professional service programs (i.e. PACE approved continuing education programs for clinical laboratory staff) and new innovations to assist the Wilkes-Barre VAMC with the usage of the contractor's products/services in the most efficient manner.

4.4.4.22.Interface Requirements

1. The Contractor shall be responsible for providing all hardware required for the connection, implementation, and operation of the interface to the universal interface and any incremental fee that is required each time an instrument is added to an existing universal interface system (see Attachment A).

2. The Contractor shall provide any and all necessary software support for insuring that successful interfacing has been established. Specific requirements for the communication of the data streams will be unique to the instrument system involved and dictated by the manufacturer itself. Information necessary to make the type and amount of interfacing equipment is supplied in Attachment A.

3.If the Wilkes-Barre VAMC Laboratory already has a universal interface box, the Contractor is responsible for everything leading up to the box including any incremental fee required to add additional equipment (e.g. licenses, ports/cards, cables, software, etc.) to the universal interfacing system.

4. If the Wilkes-Barre VAMC laboratory does not have a universal interface and one is needed to optimally interface the instrument, then the Contractor is responsible for the acquisition of the universal interface box and everything else needed to connect with VA computerized hospital information system.

5. 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 computerized hospital information system.

4.4.4.23. **Commercial offerings** - The Contractor shall provide any additional support material that is routinely provided to equivalent commercial customers and assists in regulatory compliance, e.g. Computer disc containing their procedure manual in CLSI format and/or an on-line procedure manual in the instrument software.

4.4.4.24. **Characterization of waste** – The Contractor shall provide documentation that it has characterized the hazardous nature of all wastes produced by all equipment, devices, reagents, and discharges in accordance with the requirements of the Code of Federal Regulations Title 40 "Protection of the Environment" Part 261 et seq. and applicable state and local requirements. Documentation shall include a description of the characteristics of the hazardous waste produced as a byproduct of the instrument operations, Safety Data Sheets (SDS) meeting the requirements of the Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA), the analytical process used to determine the hazardous nature and characteristics of the waste, and the analytical test results. Testing of hazardous waste is to be done in accordance with testing protocol specified for each individual waste as described in the Code of Federal Regulations Title 40 to make a determination if the waste is a hazardous waste or otherwise regulated.

a. The determination and description shall address the following:
    i. Waste toxicity (Reference 40 CFR §261.11 and 40 CFR §261.24)
    ii. Waste ignitability (Reference 40 CFR §261.21)
    iii. Waste corrosivity (Reference 40 CFR §261.22)

iv. Waste reactivity (Reference 40 CFR §261.23)
v. Hazardous waste from non-specific sources (F-listed) (Reference 40 CFR §261.31)
vi. Discarded commercial products (acutely toxic or P-listed and toxic or U-listed) (Reference 40 CFR §261.33)
vii. Solid Waste (Reference 40 CFR §261.2)
viii. Exclusions (Reference 40 CFR §261.4)

b. The contractor will provide written instructions and training material to ensure VHA laboratory staff are trained as needed to properly operate devices with special emphasis to managing and disposing of hazardous waste in accordance with EPA and state requirements. Additionally, the training provided by the contractor must fulfill Resource Conservation and Recovery Act (RCRA) requirements for training as applicable to devices.

c. Contractor shall provide a description of all wastes the process or equipment may discharge so that the facility can determine whether the discharge meets Local Publicly Owned Treatment Works (POTW), State and Federal discharge requirements. At a minimum the characteristics of ignitability, corrosivity, reactivity and toxicity as defined in 40 CFR §261 must be determined and documented. Any mercury containing reagents must be identified in any concentrations. All test results shall be provided. All listed chemicals (F, U, K and P) found in 40 CFR §261 shall be provided in product information and their concentrations documented. For those materials with positive hazardous waste determination, a mechanism for the laboratory to meet local discharge requirements (i.e. mercury, thimerosol

and formaldehyde) must be developed and SDS sheets must be provided in advance for review. At a minimum, documentation shall include, but not be limited to the concentration/measures of the elements and parameters listed below and must be included with vendor response:

i. Barium (Total)
ii. Cadmium (Total)
iii. Chromium (Total)
iv. Copper (Total)
v. Cyanide (Total)
vi. Lead (Total)
vii. Mercury (Total)
viii. Nickel (Total)
ix. Silver (Total)
x. Zinc (Total)
xi. Arsenic (Total)
xii. Selenium (Total)
xiii. Tin (Total)
xiv. pH
xv. Flash point (to higher than 200□F)
xvi. BOD; biochemical oxygen demand

d. The documentation the contractor provides will be used to work with the VAMC and the public and/or private organization (e.g., POTW) to determine whether or not the waste from each device can legally be disposed of via the sewerage system

4.4.4.25. .**Implementation/transition timeframe** - The implementation of the services/requirements described in this solicitation shall be completed no later than 90 days after the award of the contract. This timeline is based on a reasonable attempt of the Contractor to complete all of the necessary implementation requirements within the stated timeframe. Contractor shall not be penalized for implementation timelines that extend beyond the 90 day timeframe, if the extension is through no fault of the Contractor and is a result of delays due to the Government.

a. Upon award of a contract, the transition period for the awarded contract to have all equipment and peripherals installed and operational shall be from date of award through 90 days. During this same period all initial training of VA personnel in the operation and maintenance of said award shall also be completed.

b. Contractor shall provide with its quotation and implementation plan for installation of new equipment. Contractor's submitted plan shall not exceed 90 days for the transition of all services under the awarded contract including installation and training of personnel, transition of all testing materials, reagents and supplies, etc., performance of all correlations and validations. Failure of the Contractor to conform to the transition period shall be considered as sufficient cause to terminate contract for cause under the Termination for Cause clause of the contract.

4.4.4.26.At the end of 90 days from award of the contract, the awarded Contractor shall have full and sole responsibility for services under the awarded contract.

4.4.4.27.Standard and Quality of Performance- This paragraph establishes a standard of quality performance that shall be met before any equipment listed on the delivery order [or contract] is accepted by the Government. This also includes replacement, substitute machines and machines that are added or field modified after a system has demonstrated successful performance. The acceptance period shall begin on the installation date. It shall end when the equipment has met the standard of performance for a period of 30 consecutive calendar days by operating in conformance with the Contractor's technical specification or as quoted in any contract at an effectiveness level of 90% or more.

a. In the event that equipment does not meet the standard of performance during the initial 30 consecutive calendar days, the standard of performance tests shall continue on a day-by-day basis until the standard of performance is met for a total of 30 consecutive days.

b. If the equipment fails to meet the standard of performance after 90 calendar days from the installation date, the user may, at his/her option, request a

replacement or terminate the order in accordance with the provisions of FAR 52.212-4 entitled “Termination for cause.” (The Contractor shall receive revenue for tests reported during the 90-day acceptance period.)

c. Operational use time for performance testing for a system is defined as the accumulated time during which the machine is in actual use. System failure downtime is that period of time when any machine in the system is inoperable due to equipment failure. Downtime for each incident shall start from the time the Government makes a bona fide attempt to contact the Contractor’s designated representative at the prearranged contact point until the system or machine(s) is returned to the Government in proper operating condition.

4.4.4.28.During the performance period for a system, a minimum of 100 hours of operational use time with productive or simulated work shall be required as a basis for computation of the effectiveness level. However, in computing the effectiveness level, the actual number of operational use hours shall be used when in excess of the minimum of 100 hours

4.4.4.29.The Government will maintain daily records to satisfy the requirements of the Standard and Quality of Performance section and shall notify the Contractor in writing of the date of the first day of the successful period of operation. Operations use time and downtime shall be measured in hours and whole minutes

4.4.4.30.During the term of the contract, should the repair record of any individual piece of laboratory equipment reflect a downtime of 10% or greater of the normal working days in one calendar month, a determination shall be made by the COR to replace the malfunctioning equipment with new equipment. The responsibility for maintaining the equipment furnished in good condition in accordance with manufacturer’s instructions, shall be solely that of the Contractor. Each instrument provided by the Contractor shall maintain an uptime of 90% in each month of the term of the agreement for equipment.

ii. **Government’s Responsibility-** The user will perform routine maintenance and cleaning as required in the manufacturer’s operation and maintenance instructions. The user shall maintain appropriate records to satisfy the requirements of this paragraph.

iii. **Ownership of Equipment-** Title to the equipment shall remain with the Contractor. All accessories (unused consumables, etc.) furnished by the Contractor shall accompany the equipment when returned to the Contractor. The Contractor, upon expiration of order(s), at termination and/or replacement of equipment, shall remove the equipment. The Contractor shall disconnect the analyzer (gas, water, air, etc.) and shall be responsible for all packing and shipping required to remove the analyzer.

iv. The Contractor will identify if removable media is required to perform their duties. The Clinical Engineering Department will ensure the removable media is scanned with anti-virus software running current virus definitions prior to connection to any medical device/system. Any Contractor with patient sensitive information that is imported into the removable media device for any reason must purge all patient sensitive information prior to departure from the facility.

v. Prior to termination or completion of this contract, Contractor/subcontractor must not destroy information received from VA, or gathered/created by the Contractor in the course of performing this contract without prior written approval by the VA. Any data destruction done on behalf of VA by a Contractor/subcontractor must be done in accordance with National Archives and Records Administration (NARA) requirements as outlined in VA Directive 6300, *Records and Information Management* and its Handbook 6300.1 *Records Management Procedures*, applicable VA Records Control Schedules, and VA Handbook 6500.1, *Electronic Media Sanitization*. Self-certification by the Contractor that the data destruction requirements above have been met must be sent to the VA Contracting Officer within 30 days of termination or completion of the contract.

vi. All electronic storage media used on non-VA leased or non-VA owned IT equipment that is used to store, process, or access VA information must be handled in adherence with VA Handbook 6500.1, *Electronic Media Sanitization* upon: (i) completion or termination of the contract or (ii) disposal or return of the IT

equipment by the Contractor/subcontractor or any person acting on behalf of the Contractor/subcontractor, whichever is earlier. Media (hard drives, optical disks, CDs, back-up tapes, etc.) used by the Contractors/subcontractors that contain VA information must be returned to the VA for sanitization or destruction, or the Contractor/subcontractor must self-certify that the media has been disposed of per 6500.1 requirements. This must be completed within 30 days of termination or completion of the contract or disposal or return of the IT equipment, whichever is earlier

vii. Bio-Medical devices and other equipment or systems containing media (hard drives, optical disks, etc.) with VA sensitive information must not be returned to the Contractor at the end of lease, for trade-in, or other purposes. The options are:
    1. Contractor must accept the system without the drive;
    2. VA's initial medical device procurement includes a spare drive which must be installed in place of the original drive at time of turn-in; or
    3. VA must reimburse the company for media at a reasonable open market replacement cost at time of purchase.

viii. Due to the highly specialized and sometimes proprietary hardware and software associated with medical equipment/systems, if it is <u>not possible</u> for the VA to retain the hard drive, <u>then</u>;
    1. The equipment Contractor must have an existing BAA if the device being traded in has protected health information stored on it and hard drive(s) from the system are being returned physically intact; and
    2. Any fixed hard drive on the device must be non-destructively sanitized to the greatest extent possible without negatively impacting system operation. Selective clearing down to patient data folder level is recommended using VA approved and validated overwriting technologies/methods/tools. Applicable media sanitization specifications need to be pre-approved and described in the purchase order or contract.
    3. A statement needs to be signed by the Director (System Owner) that states that the drive cannot be removed and

that (a) and (b) controls above are in place and completed. The Information Security Officer (ISO) needs to maintain the documentation.

Pricing should be included for all tests that are currently available to be run on the instruments leaving open the possibility for the Wilkes-Barre VAMC to perform additional testing in the future.

Attachment A

TESTS REQUIRED with Estimated Annual Volume

TEST	ESTIMATED ANNUAL VOLUME
Glucose	**61471**
BUN	**61603**
Creatinine	**111285**
NA	**61380**
K	**61950**
Cl	**61585**
CO2	**61363**
Calcium	**61517**
Phosphorous	**12810**
Total Protein	**54510**
Albumin	**56191**
Alkaline Phosphatase	**24170**
AST	**54200**
LD	**795**
TBil	**54148**
DBIL	**4979**
Cholesterol	**33427**
TG	**33543**
HDLD	**33423**
ALT	**54182**

Amylase	835
Lipase	12636
Magnesium	19080
Uric acid	2990
ETOH	924
Carbamazepine	42
Digoxin	154
Phenobarbital	10
Dilantin	43
Theophylline	15
Valproic acid	360
Vancomycin	438
Amphetamine	5629
Barbiturate	5609
Benzodiazepine	5623
Cannabinoids	5597
Cocaine	5618
Methadone	5620
Opiate	5620
Phencyclidine	5596
Propoxyphene	5320
Ammonia	1934
GGT	690
CK	2601
Lactic Acid	2155
Micrototal Protein	5602
LDLD	33423
Oxycodone	5610
Lithium	196
Salicylate	48
Microalbumin	11245
Acetaminophen	58
CKMB	964
Troponin I	4393
PSA	9317
Free PSA	2632

BhCG	**153**
TSH	**27074**
FT4	**14891**
Procalcitonin	**890**
Vitamin D	**23720**
Fentanyl	**8254**
Parathyroid Hormone	**1364**
Buprenorphine	**2528**
Ferritin	**3380**
Trasferrin	**4196**
Body Fluids	**520**
Complete Blood Count with Automated Differential	**53869**
Reticulocyte Count	**591**

The vendor may have access to PHI when coming in for troubleshooting or fixing the instruments when they are down.

It has been determined that protected health information (PHI) may be used, disclosed, accessed, transmitted, created, stored/maintained, and/or destroyed (providing appropriate proof of destruction in compliance with VA Directive 6371) by the Contractor, and a signed Business Associate Agreement (BAA) will be required. The Contractor will adhere to the requirements set forth within the BAA, referenced in the solicitation, and will comply with all applicable VA/VHA Directives. Once awarded, Contractor and Contracting Officer will collaborate with the appropriate Facility Privacy Officer , Roxanne.Watson@va.gov to implement the appropriate BAA.

End of Document