STATEMENT OF WORK

1. **Background**
    a. Veterans Integrated Service Network (VISN) 17 has a continuous need for urinalysis testing. The purpose of the CPRR contract will be to continue to provide urinalysis testing to patients and medical staff throughout VISN 17.
2. **Scope of Required Specifications:**
    a. VISN 17 requires urinalysis testing to accommodate in-house patient testing. Contractor shall provide urinalysis testing supplies and services on cost per reportable result (CPRR) basis. The CPRR includes all equipment, reagents, controls, calibrators, consumable supplies, shipping costs, maintenance services, labor, travel, training, replacement parts, and any ancillary items necessary for laboratories in VISN 17 to operate the systems and printers.
    b. The contractor shall provide urinalysis testing on leased equipment that meets all the following requirements:
        i. **Primary analyzer(s)**-
            A. Analyzer offered that shall fully support the scope of operations. Depending upon the technical functionality and the capabilities of the individual manufacturer's instrumentation, one analyzer or multiple analyzers may be required to meet the productivity specifications defined herein at each location in VISN 17. In those instances, the additional analyzer(s) shall, likewise, be considered primary instrumentation and shall meet all the technical specifications of this solicitation.
            B. Due to efficient and reliable operational needs, the 2nd analyzer must be completely redundant to the primary analyzer (provide chemistry and microscopic urinalysis).
            C. The desired instrumentation shall have the capability of performing or reporting the clinical parameters as defined herein for all urinalysis related testing. The instrument shall be capable of reflex testing from macroscopic to microscopic evaluations.
            D. The instrument shall be capable of simultaneously performing the complete profile as described below, meeting 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). The contractor shall identify if their test and specimen types are FDA cleared. All reagents, software and equipment/medical devices must be FDA cleared at the time of the solicitation.
        ii. **Industry Standards:** Unless otherwise stated, all equipment shall be held to current industry standards for such equipment is present in the current marketplace for Clinical urinalysis equipment, supplies, and related services.
        iii. Contractor must follow all applicable state, federal and local laws, and regulations related to laboratory testing.
        iv. All assays and equipment must be FDA cleared at the time of contract award.

3. **General Requirements**
    a. Period of Performance:

Ordering Period	Period Start	Period End
1	2/1/2027	1/31/2028
2	2/1/2028	1/31/2029
3	2/1/2029	1/31/2030
4	2/1/2030	1/31/2031

5	2/1/2031	1/31/2032

4. **Type of Contract:**
    a. VISN 17 requires an Indefinite Delivery Indefinite Quantity (IDIQ) contract for five (5) one-year ordering periods.

Please Note: Not all facilities listed in the "Primary Locations" section below are not guaranteed to require the supplies and services provided under this IDIQ for the entire contract period. Locations may be added or removed after award, as necessary, through bilateral modification, dependent upon the needs of the Government. If a primary location currently uses an instrument offered by the awardee, they may elect to continue use of that instrument until it has either reached the end of its useful life or the IDIQ has expired.

Primary Locations:

South Texas Veterans Healthcare System (STX)
Audie L. Murphy VA Hospital
Pathology & Laboratory Medicine Service
7400 Merton Minter Blvd.
San Antonio, TX 78229

Amarillo VA Healthcare System (AMA)
Thomas E. Creek VA Medical Center
Pathology & Laboratory Medicine Service
6010 Amarillo Blvd.
Amarillo, TX 79106

Amarillo VA Healthcare System (AMA)
Lubbock VA Clinic
Laboratory
6104 Avenue Q South Dr.
Lubbock, TX 79412

VA North Texas Healthcare System (NTX)
Dallas VA Medical Center
Pathology & Laboratory Medicine Service
4500 S. Lancaster Rd.
Dallas, TX 75216

VA North Texas Healthcare System (NTX)
Sam Rayburn Memorial Veterans Center
Laboratory
1201 E. 9th St.
Bonham, TX 75418

VA North Texas Healthcare System (NTX)
Fort Worth VA Clinic
Laboratory
2201 Southeast Loop 820
Fort Worth, TX 76119

Valley Coastal Bend VA Healthcare System (VCB)
VA Health Care Center (HCC) at Harlingen
Pathology & Laboratory Medicine Service
2601 Veterans Dr.
Harlingen, TX 78550

Valley Coastal Bend VA Healthcare System (VCB)
McAllen VA Clinic
Laboratory
901 East Hackberry Ave.
McAllen, TX 78501

Valley Coastal Bend VA Healthcare System (VCB)
Corpus Christi Specialty Clinic
Lab Department, B-144
205 S. Enterprise Parkway
Corpus Christi, TX 78405

Central Texas Veterans Healthcare System (CTX)
Olin E. Teague Veterans' Center
1901 Veterans Memorial Dr.
Temple, TX 76504

Central Texas Veterans Healthcare System (CTX)
Doris Miller Department of Veterans Affairs Medical Center

Central Texas Veterans Healthcare System (CTX)
Austin VA Clinic
7901 Metropolis Drive

4800 Memorial Drive
Waco, TX 76711

Austin, TX 78744

VA West Texas Healthcare System (WTX)
George H. O'Brien, Jr., VA Medical Center
300 Veterans Blvd.
Big Spring, TX 79720

VA El Paso Healthcare System (ELP)
El Paso VA Clinic
5001 N. Piedras St.
El Paso, TX 79930

5. **Annual Estimated Test Volumes:**

Location	Estimated Urinalysis	Estimated Microscopic	Estimated Body Fluid
All STX Locations	84,000	84,000	128
All AMA Locations	35,236	18,624	0
All NTX Locations	143,004	74,712	756
All VCB Locations	37,500	13,500	0
All CTX Locations	126,000	63,000	0
All WTX Locations	16,700	8,900	0
All ELP Locations	44,000	44,000	0
Total Annual Estimated Testing	442,400	306,736	884

a. Breakdown of Annual Estimated Testing by Location. (Orders may have quantities that are different than those listed below).

Location	Urinalysis	Microscopic	Body Fluid
STX – San Antonio	84,000	84,000	128
AMA – Amarillo	26,136	13,068	0
AMA – Lubbock	11,100	5,556	0
NTX – Dallas	96,000	49,200	756
NTX – Fort Worth	2,417	17,004	0
NTX – Bonham	1,500	8,508	0
VCB – Harlingen	16,500	8,000	0
VCB – McAllen	11,000	2,500	0
VCB – Corpus Christi	10,000	3,000	0
CTX – Temple	84,000	42,000	0
CTX – Waco	18,000	9,000	0
CTX – Austin	24,000	12,000	0
WTX – Big Spring	16,700	8,900	0
ELP – El Paso	44,000	44,000	0

6. **Testing Requirements:**
   a. Urinalysis analyzers must be capable of performing urine chemistry to include the following: Urine color, appearance, glucose, bilirubin, ketones, specific gravity, blood pH, protein, urobilinogen, nitrite, leukocyte esterase, and clarity.
   b. Microscopic analysis to recognize and identify 13 urine sediment particles: RBC, WBC, WBC clumps, squamous epithelial cells, non-squamous epithelial cells, hyaline casts, unclassified casts, crystals, bacteria, yeast, sperm, and mucus.
      i. In addition, microscopic analysis must be able to subclassify unclassified casts: granular, cellular, waxy, broad, RBC, WBC, epithelial cells and fatty cast, crystals (calcium phosphate, uric acid, calcium carbonate, leucine, cystine, tyrosine, amorphous calcium

oxalate, triple phosphate) and place other particles as questionable for the technician to identify and quantify to complete reports.

c. Perform automated body fluid cell count analysis to include cerebrospinal, pleural, peritoneal, peritoneal dialysate, peritoneal lavage, pericardial, general serous fluids, synovial fluids, and bronchoalveolar lavage specimens. Instrument must be able to differentiate between white and red blood cells.

7. **Instrumentation Requirements:**
   a. **Analyzer(s)** –Contractor shall provide Clinical Urinalysis analyzers that meet the following requirements:
      i. Equipment must be fully automated, semi-automated for ELP, with the ability to continuously load patient samples.
      ii. Sample throughput for urine microscopy must be up to 80 samples per hour.
      iii. Sample throughput for urine chemistry must be up to 210 samples per hour.
      iv. System should be either cap piercing or provide a decapper as part of the walkaway integrated system.
      v. The system must have the capability to be directly plumbed for analyzer waste.
      vi. The system must be capable of producing a specific gravity result, color, and clarity.
      vii. System must hold up to 300 test strips.
      viii. Specimen volume for urine microscopy must be a minimum of 2.0 mL of unspun urine with aspiration of approximately 1.3mls.
      ix. Specimen volume for urine chemistry must be a minimum: 2.0 mL of un-spun urine, 40mm
      x. Operating environment temperature should be 64-82°F (18-28°C) with a humidity of 20-80%, non-condensing. All reagents storage should also fall within this range for room temperature.
      xi. Electrical power requirement for Microscopy module must be 90-240 VAC, 50-60 Hz; Chemistry module must be 100-240 VAC, 50-60 Hz.
      xii. Sample capacity must be a 10-tube rack system with up to five racks for 10-tube rack system.
      xiii. The chemistry urinalysis analyzer and the microscopic analyzer should be integrated into one system for true walk away abilities. System must have walk away capacity with up to five sample rack sampling.
      xiv. Preferred (not required and will not be evaluated) use of fluorescent flow cytometry methodology in identifying and quantifying cells. Utilizing side scatter detection technology to differentiate similarly sized crystals and RBC.
      xv. Both primary and secondary (back-up) instruments are required to be validated to demonstrate that chlorhexidine present in our current BD VACUTAINER PLUS UA Preservative tubes will not have any adverse effect on the routine urinalysis parameters. Both instruments should have excellent agreement within one grade (ex-Negative/Rare).
      xvi. Instrument must not introduce additional chemicals or other fluids to a sample that would contaminate the sample which would preclude additional testing if needed.
      xvii. Ability to detect when manual review of automated microscopic is required.
      xviii. Analyzer must be able to bypass microscopic testing when urine strip is negative or as defined/ programmed by the user.
      xix. Ability to track/inventory reagent and consumables (i.e., lot numbers, expiration dates) using bar code technology or other technology eliminating the need to manual enter reagent/consumable information.
      xx. Analyzer must be able to accurately monitor reagent use and alert operator of low reagent and consumable levels.

xxi. Contractor must provide installation of all equipment at no additional cost to the Government.

b. **Other Primary Hardware Features:** Contractor shall provide Clinical urinalysis equipment that meets the following requirements:
   i. Analyzer(s) that is fully capable of performing macroscopic analysis as defined in section 6(a).
   ii. Analyzer(s) that is fully capable of performing microscopic analysis as defined in section 6(b).
   iii. Analyzer that is fully capable of performing body fluid testing as defined in section 6(c).
   iv. The contractor shall provide a laboratory grade bench or instrument cart if the installation of the instrument is not freestanding.
   v. Provide a digital and hard copy of the operations manual for all equipment provided.
   vi. Capable of accepting both conical (i.e., KOVA and various style tubes) and round-bottom sample tubes (including varying sizes of evacuated tubes). Requirement can be met by use of different carriers or inserts, supplied by the Contractor at no additional charge.
   vii. Preferred (not required and will not be evaluated) use of fluorescent flow cytometry methodology in identifying and quantifying cells. Utilizing side scatter detection technology to differentiate similarly sized crystals and RBC.
   viii. Preferred (not required and will not be evaluated) use of an on board warmer that dissipates urates and phosphate material thus eliminating an additional step to reduce amorphous interference. The on board warmer will reduce manual technical intervention and improve workflow.

c. **Barcoding** – Contractor shall provide barcoding stations located at user monitoring stations along the line or track system and must have the following capabilities:
   i. The accuracy of the barcode reading must have less than a 1.0 % failure rate.
   ii. Equipment must be able to support multiple barcode formats (Code 39, Code 128) that may be enabled concurrently.
   iii. Equipment shall accept, at minimum, 10 characters in specimen identifier that is alpha and/or numeric.
   iv. Sample identification must have auto-ID barcode and keyboard entry for sample identification.

d. **Printers and Other Support Items (Support Items):** Contractor shall provide printer and other support equipment that meets the following requirements:
   i. Printers that have the capability of printing a patient report with patient demographic information that includes the patient's name, medical record number (SSN) and accession or unique identifier number (UID).
   ii. An uninterruptible power supply (UPS) with line conditioner for each instrument provided. (This includes UPS units for sites with automation lines, specimen management systems, data management systems, refrigerated storage, etc. Each UPS must provide electrical power for a minimum of 15 minutes after electrical power fails and the system must allow for an automatic controlled shutdown to prevent damage to the instrument and data records.
   iii. If there are upgrades/repairs/maintenance to the printer during the life of the contract, the Contractor is responsible for seeing that the printers are repaired or replaced to avoid disturbance in workflow at no additional cost to the Government.

e. **Software, Connectivity and Conformance Standards:** The instrument software shall have capability to connect to other equipment and software systems that meet the following requirements:

i. **Instrument Software** – Internal testing instrumentation software that provides/maintains the following:

A. Ability to monitor instrument performance.

B. Continuous monitoring of vital functions with immediate operator notification of failure(s) and on-board storage of these records.

C. Capability to detect and alert operator of out-of-range quality control results via flagged results on QC printout and visual alerts on display monitor.

D. System shall have a data management system capable of storing quality control (QC) results and performing QC statistical analysis.

E. On-board quality control (QC) data management system which includes Levy-Jennings graphs and Gaussian statistical analysis. The analyzer must have the ability to transfer QC data to external media.

F. Ability to store and retransmit patient records to the VA Laboratory Information system for a minimum 72 hours in case of interface outage.

G. Capability to record, store, and print the following information in accordance with current CLSI guidelines and related documents, College of American Pathologists (CAP) Standards, The Joint Commission, and federal regulations.

1. Quality control, calibration, and instrument maintenance information.
2. Patient demographic information and specimen results.

H. The capability to program a test as a repeat with interfacing of results to overlay initial result.

I. Ability to retransmit patient records to the Laboratory Information System (including contractor provided middleware) in case of interface outage.

ii. **Customization**

A. Contractor shall provide equipment with technology to automatically direct additional specimen testing based on customer-configurable testing criteria (reflex technology).

B. Contractor shall collaborate with each lab to write/develop protocols to establish customer configurable rules to enhance workflow management and productivity.

iii. **Interface**

A. Interface Requirements:

1. The Contractor shall provide 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.
2. The Contractor hardware and software proposed solution meets all VA Information Security, Hardware, Software and Network requirements (VA 6500). Any wireless equipment must be FIPS 140-2 compliant with certificate of compliance.
3. The Contractor supplies responses to required documents to add systems to the VA network including but not limited to the VA

Form 6550, Ports Protocols Services, MSD2, network Topological diagram and Equipment Inventory hardware/software list.

4. Communication interface must be bidirectional with host query.

B. If there are 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 Laboratory Interface Middleware.

C. If the Operating System (OS) and/or Firmware is updated or the OS reaches end of life during the contract period, the Contractor shall update OS and/or Firmware at no additional cost. Additionally, if the hardware requires an update or replacement to support the OS/Firmware, the Contractor shall update/provide the needed hardware at no additional cost.

D. Sufficient memory to store patient information and test records with downloading capability to an external medium for long term storage of patient records and other information.

1. Data onboard storage must be up to 10,000 patient results.
2. Data Storage patient sample results and the ability to export results to external storage media for acceptable review by regulatory agencies.

E. Patient status display for technologist review and workflow management for all integrated (linked) testing instrumentation.

F. Ability to retransmit patient records to universal interface system in case of interface outage.

G. Technology to automatically repeat testing based on customer configurable testing criteria (repeat testing).

H. Technology to automatically direct additional specimen testing based on customer-configurable testing criteria (reflex technology).

I. Technology must interface to VA licensed Data Innovations Instrument Manager sending all appropriate information to complete auto verification rules processing within the VA licensed IM. Preferred, but not required, that no additional middleware be necessary to connect instruments beyond the VA licensed DI IM.

J. Contractor shall collaborate with each lab to write/develop protocols to establish customer configurable rules to enhance workflow management and productivity.

K. Contractor shall assist customer with optimizing operation and utilization of the data management system to fully integrate desired testing instrumentation enhancing productivity and management of workflow. This shall include sending personnel back on site to optimize the analyzer, automation and data management work flows six months and twelve months after the system has gone live.

L. Contractor must have existing VA MOU/ISA or agrees to establish an MOU/ISA upon award to provide remote monitoring and support meeting all VA Security Requirements. Contractor should use remote monitoring to prevent instrument or testing issues as possible in addition to troubleshooting and support. The Contractor shall include a copy of the MOU/ISA as part of their quote with the file named “VA MOU/ISA”. The Contractor shall provide all hardware and software to implement the remote support system.

iv. **Connectivity and Conformance**

A. Contractor must have a Memorandum of Understanding/Information Security Agreement (MOU/ISA) with the VA in sufficient time to meet the installation timeframes in section 3.
B. Contractor shall meet VA OI&T information security requirements IAW VA Directive 6500.
C. Contractor shall provide remote monitoring and support of the urinalysis system while the manufacturer's warranty is active. Contractor shall use remote monitoring to prevent instrument or testing issues, when possible, in addition to troubleshooting and support. The Contractor shall provide all hardware and software to implement the remote support system.
D. The urinalysis system's operating software version must be approved for use on the VA network (Windows 10 and Server 2012/2016).
E. The urinalysis system must be capable of connecting to an HL7 interface and must comply with the VHA Lab HL7 Interface Specifications Document.
    1. https://www.va.gov/vdl/application.asp?appid=71
    2. https://www.va.gov/vdl/application.asp?appid=75
F. Any software and hardware solutions supplied and installed on VA workstations by the contractor must appear as an approved technology on the most current VA Technical Reference Model (TRM) or must appear on a TRM that is within 2 lifecycles of the most recent TRM approved version. For software or hardware solutions that do not meet these requirements at the time of contract award, Contractor shall obtain the required TRM approval without impacting installation timeframes.
    1. https://www.oit.va.gov/Services/TRM/TRMHomePage.aspx.

v. **Support Features**

A. Training

1. Training. The Contractor shall provide an instrument off site training program that is coordinated with and timely to the equipment installation, sufficient to the size and scope of the facility's services and minimally equivalent to the terms and conditions for training. This shall include training on the operation of the system, data manipulation, and basic trouble shooting and repair. Offsite training should be for minimally one operator per facility 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.

2. The contractor shall provide operator training on-site for all operators on all shifts.
3. Additional onsite training shall be provided 60-90 days after instrumentation's go live date.

B. Contractor shall provide example policies and procedures such as standard operating procedure templates.

vi. **Waste**

A. The Contractor shall provide documentation demonstrating that it has characterized the hazardous nature of all wastes produced by all equipment, devices, reagents, and discharges Contractor provides 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 decide if the waste is a hazardous waste or otherwise regulated. The determination and description shall address the following:

1. Waste toxicity (Reference 40 CFR §261.11 and 40 CFR §261.24)
2. Waste ignitability (Reference 40 CFR §261.21)
3. Waste corrosivity (Reference 40 CFR §261.22)
4. Waste reactivity (Reference 40 CFR §261.23)
5. Hazardous waste from non-specific sources (F-listed) (Reference 40 CFR §261.31)
6. Discarded commercial products (acutely toxic or P-listed and toxic or U-listed) (Reference 40 CFR §261.33)
7. Solid Waste (Reference 40 CFR §261.2)
8. 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 equipment or process 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, thimerosal and formaldehyde) must be developed and SDS sheets must be provided in advance for review.

D. The documentation the contractor provides will be used to work with the medical center, CBOCs, and the public or private organization (e.g., POTW) to determine whether the waste from each device can legally be disposed of via the sewerage system.

E. Ability to separate alcohol waste from other waste for appropriate environmental disposal.

8. **PACKAGING & MARKING**

a. **Packaging**

i. All equipment shall be adequately packaged to prevent damage during shipping, handling, and storage. Bags or packages shall be whole, intact, and not otherwise torn or damaged. Upon delivery, the Government shall examine all packages. The Contractor shall be required to replace unacceptable or damaged products at the Contractor's expense.

b. **Marking**

i. All items shall be marked clearly with the Contract Number, Obligation number, and delivery location within the facility, i.e., Pathology & Laboratory Services.

9. **INSPECTION AND ACCEPTANCE / DELIVERIES & PERFORMANCE**

a. **Installation/Implementation**

i. **Implementation/transition timeframe:** All sites shall have complete installation and go live of their system within 60 days from award of this contract.

ii. **Contractor shall execute an implementation plan which includes:**

A. Installation - Contractor shall make every effort to conduct a concurrent implementation at all sites with weekly collaborative meeting. Contractor shall provide a dedicated project manager throughout the entire implementation. Installation shall also include conversion of all current data minimally including operator profiles.

B. Testing- Shall include at minimum a test of all analytes in addition through all testing phases (pre- analytical, analytical, and post-analytical). In addition, training must be provided to all sites.

C. Acceptance must meet the approval requirements of accrediting agencies and VA Pathology & Laboratory Medicine Services (P&LMS) approval at each facility to meet accreditation standards.

D. Post Go-Live follow-up thirty day after go-live date.

E. Start-Up Reagents. The Contractor shall provide all reagents, calibrators, consumable/disposable items, parts, accessories, and any other item required to establish instruments for operation for performance of acceptance testing. This applies to equipment as well as additional or replacement equipment placed under the terms and conditions of this contract. The Contractor shall perform 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 statistical analysis as stated in the Method Performance/Validation section below and provide a hard copy of data in an organized, clearly comprehensible format.

F. Onsite Go live Instrument, Automation and technical support Requirements shall consist of 48 hours of continuous support. Daily onsite support for a total of five business days for each phase of implementation.

iii. **Method Performance / Validation**

A. Method performance/comparison shall be at the expense of the Contractor, shall include linearity material and reagents as required or recommended based on manufacturer's specifications, and be consistent with current CLSI guidelines and related documents, College of American Pathologists (CAP) standards and Federal regulations. The Method Validation will include the following

1. Correlation studies for each analyte. A minimum of 20 samples spanning the reportable range, shall be run by the present and the proposed method. Contractor shall analyze results and provide statistical data to support acceptance of the new method. Statistics shall meet current standards defined by CLSI.
2. 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 (may be run twice a day) for a total of 20 values per level of control. Where applicable, intra-VISN facility variations should be kept at an absolute minimum.
3. Carryover Studies. Successful carryover studies shall be completed 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, formerly NCCLS). The program(s) shall be provided to each laboratory at no charge.

B. 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. This linearity analysis shall be performed for each measured test parameter provided.

C. Sensitivity may be validated concurrently with the linearity verifications.

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

E. A verification of the manufacturer's suggested reference range may be performed if the suggested range is based on a comparable population of test subjects with medical director approval. The manufacturer shall 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.

F. 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.

G. 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.

b. **Delivery:** The Contractor shall deliver all urinalysis analyzers to participating VA medical facilities and CBOCs.

i. The delivery location is subject to change as required by the designated authority or authorized personnel at the receiving facility. The Point of Contact (POC) will notify the Contractor when delivery locations have been changed.
ii. All deliveries shall be made from 8:00 a.m. to 4:00 p.m., Monday through Friday, and a copy of the packing list/slip shall be provided at time of delivery. The packages packing list/slip shall contain the complete contract number, purchase order number, shipping address, delivery location, items/quantity ordered, and items/quantity shipped. Standard orders shall be delivered no more than 30 working days after receipt or placement of order.
iii. Contractor must provide replacement reagents/supplies/consumables at no additional cost to the Government due to improper handling (i.e., items do not arrive at proper temperature for storage/ use).
iv. Any shortages causing delay in delivery of reagents to the Government shall be provided to the COR, POCs, and Contracting Officer as soon as the shortage is identified. If testing is required to be sent to a third party, the Contractor shall reimburse the Government through credits or invoicing discounts.

c. **Reports-** The Contractor shall provide to the designated individuals (designated post-award) a copy of a **<u>quarterly report of sales</u>, by ordering facility, within 30 calendar days after the close of each quarter's business.** Reports are to reflect, at a minimum, total net sales amounts before discount, and discount amounts by ordering facility as well as the raw data used to develop these reports. These reports shall be used to monitor the commitment of each facility, reporting the savings realized and shall be shared with each participating facility, personnel associated with acquiring the products, and respective laboratory personnel. Additional invoice charges associated with reagent and/or supply wastage or repair parts included at no charge shall not be accepted. There will be no additional charges for any reports required as part of the IDIQ.

d. **Equipment Preventative Maintenance/Repair Service-**
   i. 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:
      A. Service Requirements-
      B. A technical assistance center shall be available by telephone 24 hours per day, 7 days per week with a maximum callback response time of 2 hours.
      C. Once a service call is placed to the contractor for equipment repair, primary field-based engineer must be onsite within 24 hours of service call.
      D. Equipment repair services shall be provided during core business hours. Certain circumstances may dictate the need for repair service to be conducted outside routine business hours. All such arrangements shall be coordinated between the Contractor and VA laboratory personnel.
      E. Equipment repair response time shall be no more than 24 hours.
      F. Preventative maintenance will be performed as frequently as published in manufacturer's operator's manual and within 2 weeks of the scheduled due date.
      G. A malfunction incident report shall be furnished to the Laboratory upon completion of each repair call. The report shall include, as a minimum, the following:
         1. Date and time notified
         2. Date and time of arrival
         3. Serial number, type and model number of equipment

4. Time spent for repair, and
5. Proof of repair that includes documentation of a sample run of quality control verifying acceptable performance.

H. Each notification for an emergency repair service call shall be treated as a separate and new service call.

ii. **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 IDIQ; however, it does refer to significant changes in the hardware operational capability.

iii. **Ancillary support equipment** - The Contractor shall provide, install and maintain through the life of the IDIQ, 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.

iv. **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 or an on-line procedure manual in the instrument software.

v. **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:
1. Waste toxicity (Reference 40 CFR §261.11 and 40 CFR §261.24)
2. Waste ignitability (Reference 40 CFR §261.21)
3. Waste corrosivity (Reference 40 CFR §261.22)
4. Waste reactivity (Reference 40 CFR §261.23)
5. Hazardous waste from non-specific sources (F-listed) (Reference 40 CFR §261.31)
6. Discarded commercial products (acutely toxic or P-listed and toxic or U-listed) (Reference 40 CFR §261.33)
7. Solid Waste (Reference 40 CFR §261.2)

8. 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 a positive hazardous waste determination, a mechanism for the laboratory to meet local discharge requirements (i.e., mercury, thimerosal 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 Contractor response:

1.	Barium	(Total)	9.	Silver	(Total)
2.	Cadmium	(Total)	10.	Zinc	(Total)
3.	Chromium	(Total)	11.	Arsenic	(Total)
4.	Copper	(Total)	12.	Selenium	(Total)
5.	Cyanide	(Total)	13.	Tin	(Total)
6.	Lead	(Total)	14.	pH	
7.	Mercury	(Total)	15.	Flash point(to higher than 200°F)	
8.	Nickel	(Total)	16.	BOD; biochemical oxygen demand	

vi. 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 the waste from each device can legally be disposed of via the sewerage system.

10. **CONTRACT ADMINISTRATION DATA**

a. **Contractor Program Manager**

i. The Contractor shall provide a program manager who shall be responsible for the installation and go live of the work under the contract. In addition, the program manager shall act as the main focal point of communication between the Contracting Officer and the Contractor. The name of this person shall be designated in writing to the Contracting Officer. The program manager shall have full authority to act on behalf of the Contractor on all contract matters relating under the contract.

b. **Hours of work**

i. Contractor shall provide on-site repair services for all Contractor-provided equipment while the equipment is under standard manufacturer's warranty. Contractor shall also provide technical support via phone seven (7) days a week, twenty-four (24) hours a day. Contractor shall provide these services at no additional charge to the Government as they are included with standard manufacturer's warranty.

ii. **Holidays:** Only emergency service shall be provided on National Holidays and only if authorized by the POC in advance:

New Year's Day	January 1st
Martin Luther King's Birthday	Third Monday in January
President's Day	Third Monday in February
Memorial Day	Last Monday in May
Juneteenth	June 19th
Independence Day	July 4th
Labor Day	First Monday in September
Columbus Day	Second Monday in October
Veteran's Day	November 11th
Thanksgiving Day	Fourth Thursday in November
Christmas Day	December 25th

iii. When a National Holiday falls on a Sunday, the following Monday shall be observed as a National Holiday. When a National Holiday falls on a Saturday, the proceeding Friday is observed as a National Holiday by U.S. Government agencies. Also included in the definition of "Holidays" would be any other day, specifically declared by the President of the United States of America to be a National Holiday

11. **SPECIAL REQUIREMENTS**

a. **Physical Security and Facility Considerations**

i. **Identification, Parking, Smoking and VA Regulations (For any onsite services):** The Contractor employees and/or Subcontractors (collectively "Contractor personnel") shall always wear visible identification while on the premises of the facilities within the VISN. Identification shall include a company identification card, which shall include the company name, employee name, title, and a photograph of the employee. Contractor personnel shall maintain a professional appearance commensurate to their industry.

A. Contractor personnel shall park in the appropriate designated parking areas. Information on parking is available from the VA Police Section. The VA is not liable for parking violations of Contractor personnel under any conditions.

B. Any interior or exterior doors that are unlocked to gain access shall be kept locked during the performance of work unless it results in the creation of a safety hazard. In those instances, the Contractor is responsible to take necessary actions to maintain the same level of security prior to gaining access/performing work. Should any other devices need to be unlocked like an entry gate, those devices shall be locked immediately upon entry or exit. At no time shall the Contractor allow any person into a locked area or loan keys/access cards to another person. Contractor may be held in default for failure to comply with this requirement and subject the Contractor and its personnel to contractual and other legal remedies.

C. Contractor personnel are required to check into the facility Police & Security office at each visit to pick up a "contractor" badge prior to contacting the POC. The Contractor personnel shall also sign in and out each day at a designated location determined by the POC.

D. The Contractor agrees that none of its officers or employees shall use or reveal any research, statistical, medical, or security information which may be

obtained during the performance of the work or as a result their presence on Government premises without the written consent of the Government.

E. Smoking is prohibited inside any buildings at facilities within VISN 22.

F. Possession of weapons is prohibited. Enclosed containers, including tool kits, shall be subject to search. Violations of VA regulations may result in citation answerable in the United States (Federal) District Court.

G. The Contractor shall not allow its personnel to open desk drawers, cabinets, or to use office equipment, including the use of non-pay telephones for any purpose other than a local emergency call. The Contractor shall be responsible to provide all necessary equipment, tools, parts, and materials to perform the work. The Government shall not be obligated to provide any equipment, tools, parts, and materials to assist the Contractor in performing the work.

b. **Information Technology Security Considerations**

i. Contractor shall not destroy information received from VA, or gathered/created by the Contractor while performing this Contract without prior written approval by the VA. Any data destruction done on behalf of VA by a Contractor, or its subcontractors 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, all of which are incorporated herein by reference. 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 completion or termination of the Contract.

ii. System management middleware that is intuitive, provides direct operations control (e.g., over reflex testing), allows for a real test count, and allows for auto verification at the system level as required by the facility or LIS capability.

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

iv. Due to the highly specialized and sometimes proprietary hardware and software associated with medical equipment/systems, if it is not possible for Contractor to remove and the VA to retain the electronic storage, then the equipment contractor must have an existing BAA if the device being traded in has sensitive information stored on it and electronic storage media from the system are being returned physically intact; and any fixed electronic storage media 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 required using VA approved and validated overwriting technologies/methods/tools.

v. Contractor shall comply with all terms and conditions of VA Handbook 6500.6 Section C and VA Directive 6550.

12. **Records Management**

a. Contractor shall comply with all applicable records management laws and regulations, as well as National Archives and Records Administration (NARA) records policies, including but not limited to the Federal Records Act (44 U.S.C. chs. 21, 29, 31, 33), NARA regulations at 36 CFR Chapter XII Subchapter B, and those policies associated with the safeguarding of records covered by the Privacy Act of 1974 (5 U.S.C. 552a). These policies include the preservation of all records, regardless of form or characteristics, mode of transmission, or state of completion.
b. In accordance with 36 CFR 1222.32, all data created for Government use and delivered to, or falling under the legal control of, the Government are Federal records subject to the provisions of 44 U.S.C. chapters 21, 29, 31, and 33, the Freedom of Information Act (FOIA) (5 U.S.C. 552), as amended, and the Privacy Act of 1974 (5 U.S.C. 552a), as amended and must be managed and scheduled for disposition only as permitted by statute or regulation.
c. In accordance with 36 CFR 1222.32, Contractor shall maintain all records created for Government use or created while performing the contract and/or delivered to, or under the legal control of the Government and must be managed in accordance with Federal law. Electronic records and associated metadata must be accompanied by sufficient technical documentation to permit understanding and use of the records and data.
d. VISN 17 and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Records may not be removed from the legal custody of VISN 17 or destroyed except for in accordance with the provisions of the agency records schedules and with the written concurrence of the Head of the Contracting Activity. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. In the event of any unlawful or accidental removal, defacing, alteration, or destruction of records, Contractor must report to VISN 17. The agency must report promptly to NARA in accordance with 36 CFR 1230.
e. The Contractor shall immediately notify the appropriate Contracting Officer upon discovery of any inadvertent or unauthorized disclosures of information, data, documentary materials, records, or equipment. Disclosure of non-public information is limited to authorized personnel with a need-to-know as described in the [contract vehicle]. The Contractor shall ensure that the appropriate personnel, administrative, technical, and physical safeguards are established to ensure the security and confidentiality of this information, data, documentary material, records and/or equipment is properly protected. The Contractor shall not remove material from Government facilities or systems, or facilities or systems operated or maintained on the Government's behalf, without the express written permission of the Head of the Contracting Activity. When information, data, documentary material, records, and/or equipment is no longer required, it shall be returned to VISN 17 control, or the Contractor must hold it until otherwise directed. Items returned to the Government shall be hand carried, mailed, emailed, or securely electronically transmitted to the Contracting Officer or address prescribed in the [contract vehicle]. Destruction of records is EXPRESSLY PROHIBITED unless in accordance with Paragraph (4).
f. The Contractor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (sub-contractor) in support of this contract requiring the disclosure of information, documentary material and/or records generated under, or relating to, contracts. The Contractor (and any sub-contractor) is required to abide by Government and VISN 17 guidance for protecting sensitive, proprietary information, classified, and controlled unclassified information.
g. The Contractor shall only use Government IT equipment for purposes specifically tied to or authorized by the contract and in accordance with VISN 17 policy.
h. The Contractor shall not create or maintain any records containing any non-public VISN 17 information that are not specifically tied to or authorized by the contract.

i. The Contractor shall not retain, use, sell, or disseminate copies of any deliverable that contains information covered by the Privacy Act of 1974 or that which is generally protected from public disclosure by an exemption to the Freedom of Information Act.

j. VISN 17owns the rights to all data and records produced as part of this contract. All deliverables under the contract are the property of the U.S. Government for which VISN 17 shall have unlimited rights to use, dispose of, or disclose such data contained therein as it determines to be in the public interest. Any Contractor rights in the data or deliverables must be identified as required by FAR 52.227-11 through FAR 52.227-20.

k. Training. All Contractor employees assigned to this contract who create, work with, or otherwise handle records are required to take VISN 17provided records management training, Talent Management System (TMS) Item #10176, Privacy and Information Security, Rules of Behavior. The Contractor is responsible for confirming training has been completed according to agency policies, including initial training and an annual or refresher training.