# LANGUAGE

* 1. INTENT: It is the intent of the Department of Veterans Affairs to establish an Indefinite Delivery/Indefinite Quantity (IDIQ) contract for Automated Urinalysis Instrumentation. The IDIQ shall be Cost per Test (CPT)/ Cost per Reportable Result (CPRR), Clinical Laboratory Analyzers. The Government will award a CPRR IDIQ to a single Contractor for Automated Urinalysis Instrumentation. Contractor agrees to the following terms of the IDIQ exclusively with the Atlanta VA Medical Center and awarded in the final IDIQ. Additional tests/reagents/instrumentation may be added to the IDIQ as new technology becomes available on the market.
  2. PRICES AND TERMS: Pricing is based on the AVERAGE daily test volume. The Government estimates a volume of 80,000 urine analysis per year; this is an estimate ONLY.
  3. TERM OF AGREEMENT: This will be a single award, firm-fixed price IDIQ with one base year, and three one year options. The Contractor is required to immediately notify the CO (Government Contracting Officer), in writing, if at any time there is a need to be a change in the contract. Please price a six months extension after the end of the base and option years in case one is needed. If the Contractor fails to perform in a manner satisfactory to the CO, this IDIQ may be canceled with thirty days written notice to the Contractor by the CO. The Contractor shall also reserve the right to terminate this contract with 30 days notification to the CO. This IDIQ shall be reviewed annually.
  4. ORDERING METHOD: The participating facilities may order products via Electronic Data Interchange (EDI), telephone, facsimile or other written communication, identifying the products by number, quantity, purchase price, address for delivery, and any special instructions.

# DESCRIPTION/SPECIFICATIONS

# SCOPE OF PROCUREMENT:

* + 1. The desired instrumentation shall have the capability of performing or reporting the clinical parameters as defined in the performance work statement. The instrument shall have random access capability (if discrete testing is required) and be able to simultaneously perform the complete profile as described below 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).
    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. 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~~.~~
    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.

* 1. DEFINITIONS:
     1. Cost per Patient Reportable Result (CPRR)- The per patient reportable result price shall include costs covering: (1) 5 year equipment use, (2) all reagents, standards, quality controls, supplies, consumable/disposable items, parts, accessories and any other item required for the proper operation of the Contractor’s equipment and 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 (his element includes both preventive maintenance and emergency repairs) and (4) training for Government personnel. Contractors shall provide delivery, installation and removal of equipment at no additional charge.
     2. Cost per Test (CPT) -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) five year equipment use, (2) all reagents, standards, quality controls, supplies, consumable/disposable items, parts, accessories and any other item required for the proper operation of the Contractor’s equipment and 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. Contractors are required to provide delivery, installation and removal of equipment at no additional charge.
     3. Parameter definitions
        1. Automated Urine Macroscopic – Chemical analysis of urine to include color, clarity, specific gravity, pH and the presence/absence of leukocytes esterase, nitrites, total protein, glucose, blood/hemoglobin, ketone, ascorbic acid, urobilinogen and bilirubin.
        2. Automated Urine Microscopic- Analysis to determine the presence/absence of sediment constituents, such as but not limited to red blood cells, white blood cells, casts, crystals, bacteria, etc. Must be able to analyze body fluids. Instrument must be able to display particle images to provide high confidence in the classification of such elements.
  2. GENERAL REQUIREMENTS:
     1. Primary analyzer(s) – Base equipment offered that shall fully support the scope of operations (minimal requirements). 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. In those instances, the additional analyzer(s) shall, likewise, be considered primary instrumentation and shall meet all of the technical specifications of this solicitation. 
     2. Contractor shall provide quality control material at a minimum of two levels; normal and elevated/abnormal levels.
     3. Operational Features**-** The instrumentation offered shall have the following:
        1. Sufficient capacity and throughput to meet the volume and service demands of Atlanta VAMC.
        2. 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.
        3. 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.
           1. The accuracy of the barcode reading must have less than a one percent failure rate.
           2. Equipment must be able to support multiple barcode formats (Code 39, Code 128) that may be enabled concurrently.
        4. Ability to prioritize STAT testing without compromising existing programmed testing.
        5. Minimal daily, monthly, and periodic maintenance.
        6. Ability to store and retransmit records (24 hours of maximal instrument throughput) in case of interface outage.
        7. On board reagent stability sufficient to accommodate both high and low volume use. Contractor to provide expiration dates of at least six months for reagents.
        8. Capable of analyzing small sample volumes (less than 3 ml).
        9. Capability to detect out of range quality control.
        10. Ability to accept various types of sample containers.
        11. Ability to store and retransmit records (24 hours of maximal instrument throughput) in case of interface outage.
        12. Ability to select either numeric or semi-quantitative result format (i.e., mg/dL or large/4+).
        13. Ability to set facility developed flags for reflex to automated microscopic testing.
     4. Technical Features-The instrumentation must be approved by the Food and Drug Administration (FDA) and shall have the following:
        1. On-board QC data management system. QC files and includes Levy-Jennings graphs. Analyzer must have the ability to capture, store and electronically transfer QC data.
        2. Ability to monitor instrument performance.
        3. On board reagent inventory system.
        4. Minimal reagent, calibrator, and control preparation.
        5. Minimal carryover.
        6. Long calibration stability.
     5. Hardware Features-The instrumentation shall have the following:
        1. A total equipment footprint that when installed in the laboratory shall not impact the functionality/operations of that laboratory.
        2. An on-board monitor/screen that is easily readable.
        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. An uninterruptible power supply with line conditioner for each instrument provided.
        5. Primary tube sampling.
     6. 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. One of the following protocols shall be used:
        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 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.
        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.
        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.
     7. 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 included on the list of supplies defined in the Federal Supply Schedule contract and 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 facility’s services and minimally equivalent to the terms and conditions for training defined in the Cost-Per-Test Clinical Laboratory Analyzers contract. 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. 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:
        5. Service Requirements
           1. Preventative maintenance will be performed as frequently as published in manufacturer’s operator’s manual and within two weeks of the scheduled due date.
           2. A technical assistance center shall be available by telephone 24 hours per day, seven days per week with a maximum call back response time of 0.5hour(s).
           3. Equipment repair service 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.
           4. Equipment repair response time shall be no more than one hour.
           5. 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:

Date and Time Notified

Date and Time of Arrival

Serial Number, Type and Model Number of Equipment

Time spent for Repair, and

Proof of Repair that includes documentation of a sample run of quality control verifying acceptable performance.

* + - * 1. Each notification for an emergency repair service call shall be treated as a separate and new service call.
      1. 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.
      2. 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.
      3. 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.
      4. 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.
         1. 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.
         2. 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.
      5. 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.
      6. 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 IDIQ. 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.
         1. Upon award of contract, the transition period for the awarded IDIQ 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.
         2. Contractor shall provide with its quotation an 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 IDIQ for cause under the Termination for Cause clause of the contract.
         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 IDIQ.
    1. 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 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.
       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.
       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.)
       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. 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.
       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.
       6. During the term of the IDIQ, 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.
    2. 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.
    3. 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. 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.
    5. 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.
    6. 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.
    7. 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.
    8. Due to the highly specialized and sometimes proprietary hardware and software associated with medical equipment/systems, if it is not possible for the VA to retain the hard drive, then;
       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.
       3. A statement needs to be signed by the Director (System Owner) that states that the drive could not be removed and that (a) and (b) controls above are in place and completed. The Information Security Officer (ISO) needs to maintain the documentation.

1. **CONTRACTOR PERSONNEL SECURITY REQUIREMENTS**

3.1 All contractor employees who require access to the Department of Veterans Affairs’ computer systems shall be the subject of a background investigation and must receive a favorable adjudication from the VA Office of Security and Law Enforcement prior to contract performance. This requirement is applicable to subcontractor personnel requiring the same access.

* + 1. Position Sensitivity – The position sensitivity has been designated as Low Risk.
    2. Background Investigation – The level of background investigation commensurate with the required level of access is minimum background investigation.
  1. Contractor Responsibilities
     1. The contractor shall prescreen all personnel requiring access to the computer systems to ensure they maintain a U.S. citizenship, and are able to read, write, speak and understand the English language.
     2. The contractor shall submit or have their employees submit the required forms (SF 86 or SF 85P, SF 85P-S, FD 258, Contractor Fingerprint Chart, VA Form 0710, Authority for Release of Information Form, and Optional Forms 306 and 612) to the VA Office of Security and Law Enforcement within 30 days of receipt.
     3. The contractor, when notified of an unfavorable determination by the Government, shall withdraw the affected employee from working under the contract.
     4. Failure to comply with contractor personnel security requirements may result in

termination of the contract for default.

* 1. Government Responsibilities
     1. The VA Office of Security and Law Enforcement will provide the necessary forms to

the contractor, or to the contractor’s employees, after receiving a list of names and addresses.

* + 1. Upon receipt, the VA Office of Security and Law Enforcement will review completed

forms for accuracy, and forward the forms to the office of Personnel Management (OPM) to conduct background investigations.

* + 1. The VA Office of Security and Law Enforcement will notify the CO, and contractor, of

adjudication results received from OMB.

* 1. Training
     1. All contractor employees and subcontractor employees requiring access to VA

information and VA information systems shall complete the following before being granted access to VA information and its systems:

* + - 1. Sign and acknowledge (either manually or electronically) understanding of and

responsibilities for compliance with the Contractor Rules of Behavior, Appendix E relating to access to VA information and information systems;

* + - 1. Successfully complete the VA Cyber Security Awareness and Rules of Behavior

training and annually complete required security training;

* + - 1. Successfully complete the appropriate VA privacy training and annually complete

required privacy training; and

* + - 1. Successfully complete any additional cyber security or privacy training, as required for VA personnel with equivalent information system access [to be defined by the VA program official and provided to the contracting officer for inclusion in the solicitation document - e.g., any role-based information security training required in accordance with NIST Special Publication 800-16, Information Technology Security Training Requirements.]
    1. The contractor shall provide to the contracting officer and/or the COR a copy of the

training certificates and certification of signing the Contractor Rules of Behavior for each applicable employee within 1 week of the initiation of the contract and annually thereafter, as required.

* + 1. Failure to complete the mandatory annual training and sign the Rules of Behavior

annually, within the timeframe required, is grounds for suspension or termination of all physical or electronic access privileges and removal from work on the contract until such time as the training and documents are complete.