

**36C25919Q0204 - URINALYSIS COST PER REPORTABLE RESULT  
ATTACHMENT A - STATEMENT OF WORK**

**A. Scope:**

Contractor shall provide all equipment, reagents, standards, controls, supplies, consumable/disposable items, parts, accessories and any other item required for the proper operation of its' contractor owned automated urinalysis testing instruments and peripherals necessary for the generation of automated urinalysis reportable patient test result (CPRR) services on behalf of participating VISN 19 Pathology & Laboratory Medicine (P&LMS) departments. A services component will also be included in the contract, to provide all maintenance, repairs, upgrades, trainings and a Quality Control program. Equipment, supplies and services shall be provided to the following facilities:

1. Rocky Mountain Regional VA Medical Center (VAMC): 1700 Wheeling Street, Aurora, CO 80045
2. Grand Junction VAMC: 2121 North Ave. Grand Junction, CO 81501
3. Fort Harrison VAMC: 3687 Veterans Drive, P.O. Box 1500, Fort Harrison, MT 59636
4. Billings Community Based Outpatient Clinic (CBOC): 1766 Majestic Lane, Billings, MT 59102
5. Cheyenne VAMC: 2360 East Pershing Blvd, Cheyenne, WY 82001
6. Loveland CBOC: 5200 Hahn's Peak Drive, Loveland, CO 80538
7. Sheridan VA Healthcare System: 1898 Fort Road, Sheridan, WY 82801
8. Salt Lake City Health Care System: 500 South Foothill Drive, Salt Lake City, UT 84148
9. Oklahoma City VA Health Care System: 921 NE 13<sup>th</sup> Street, Oklahoma City, OK 73104
10. Lawton CBOC: Bldg. 4303, Pitman Street, Fort Sill, OK 73507
11. Eastern Oklahoma VA (Jack C. Montgomery VAMC): 1011 Honor Heights Drive, Muskogee, OK 74401
12. Ernest Childers CBOC: 9322 E.41<sup>st</sup> Street, Tulsa, OK 74146
13. Fort Collins CBOC: 2509 Research Blvd., Fort Collins, CO 80526

**B. Definitions:**

Cost Per Reportable Result (CPRR): Contractors are required to provide a price for each patient test that can be performed on its equipment. The per reportable patient test price shall include costs covering (a) equipment use, (b) all reagents, calibrators, 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 patient test result, (c) all necessary maintenance to keep the equipment in good operating condition (This element includes both preventive maintenance and emergency repairs and (d) training for Government personnel. Contractors are required to provide delivery, installation and removal of equipment at no additional charge. All

hard drives are to be removed and handed over to the facilities for destruction when equipment is removed.

### **C. General Requirements:**

1. Offered models of clinical laboratory urinalysis instruments shall be capable of producing accurate and reproducible assays on urine specimens for both automated urine dipstick chemistries and automated urine microscopic analysis by established *in vitro* diagnostic methods and Body Fluid analysis. Models shall provide accurate test assay result for sample specimens up to the manufacturer's defined maximum test per hour without excessive malfunctions, breakdowns, or service calls. Current waste stream analysis and SDS (Safety Data Sheets) shall be provided to this site.
2. Offered equipment shall be new equipment. Remanufactured and discontinued models will not be accepted.
3. The awarded contractor shall provide all upgrades to the equipment hardware and operating system software, at no additional cost to the Government. These enhancements shall be delivered and installed the medical facility within 60 days of issuance to the commercial market.
4. The 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 manufactured as new equipment and is currently available on the offerors existing FSS contract for CPRR. Discontinued models that are only being made available as remanufactured equipment are not acceptable.
5. An operator's manual shall be furnished with each instrument supplied to VA and updates to manual shall be provided in a timely manner.
6. Editable electronic copy in CLSI (Clinical and Laboratory Standards Institute) format of operating procedures shall be furnished with each instrument supplied to all participating facilities.
7. Contractors offered urinalysis system shall conform to each of the participating facility's existing space and structural parameters in terms of delivery, installation and lab space. (i.e. equipment size, weight, packaged size for delivery, electrical/voltage).
8. Laboratory assays currently performed shall include, but may not be limited to the following assays.
  - a. Urinalysis Assays:
    - i. Automated Dipstick Urine and/or Microscopic Urinalysis and Body Fluid analysis.
    - ii. Provide identical walk-away, automated sampling and testing for urinalysis chemistry testing only for backup purposes.
    - iii. A single vendor must provide both the automated chemical and the microscopic analysis for urinalysis testing.

9. VISN 19 Facility Requirements:

- a. ECHCS, Denver, CO/RMR, Aurora, CO:
  - i. Walk-away automated sampling for urinalysis chemistry and microscopic testing.
  - ii. Minimum capacity of 20 samples loaded at once.
  - iii. Direct, automated specimen pathway between the chemistry urinalysis specimen sampling and testing and the microscopic urinalysis sampling and testing.
- b. Grand Junction VAMC, CO:
  - i. Walk-away automated sampling for urinalysis chemistry and microscopic testing.
  - ii. Minimum capacity of 10 samples loaded at once.
  - iii. Direct, automated specimen pathway between the chemistry urinalysis specimen sampling and testing and the microscopic urinalysis sampling and testing.
- c. Fort Harrison VAMC, MT:
  - i. One walk-away sampling for urinalysis chemistry and microscopic testing. a minimum of 10 samples at once.
  - ii. Direct, automated specimen pathway between the chemistry urinalysis specimen sampling and testing and the microscopic urinalysis sampling and testing.
  - iii. One backup unit, standard UA chemistry testing, manual feed of strips by operator is acceptable or identical walk-away sample for urinalysis chemistry and microscopic testing.
- d. Billings CBOC, MT:
  - i. One walk-away sampling for urinalysis chemistry and microscopic testing. a minimum of 10 samples at once.
  - ii. Direct, automated specimen pathway between the chemistry urinalysis specimen sampling and testing and the microscopic urinalysis sampling and testing.
  - iii. One backup unit, standard UA chemistry testing, manual feed of strips by operator is acceptable or identical walk-away sample for urinalysis chemistry and microscopic testing.
- e. Cheyenne VAMC Cheyenne WY:
  - i. Walk-away automated sampling for urinalysis chemistry and microscopic testing.
  - ii. Minimum capacity of 10 samples loaded at once.
  - iii. Direct, automated specimen pathway between the chemistry urinalysis specimen sampling and testing and the microscopic urinalysis sampling and testing.
  - iv. One Primary and one Backup instrument. Backup may be dipstick only.

- f. Loveland CBOC, Loveland, CO:
  - i. Walk-away automated sampling for urinalysis chemistry
  - ii. Minimum capacity of 5 samples loaded at once.
  - iii. One instrument required
- g. Sheridan VA Healthcare System
  - i. Walk-away automated sampling for urinalysis chemistry and microscopic testing.
  - ii. Minimum capacity of 10 samples loaded at once.
  - iii. Direct, automated specimen pathway between the chemistry urinalysis specimen sampling and testing and the microscopic urinalysis sampling and testing.
  - iv. One Primary and one Backup instrument. Backup may be dipstick only.
- h. Salt Lake City VAMC
  - i. Walk-away automated sampling for urinalysis chemistry and microscopic testing.
  - ii. Minimum capacity of 10 samples loaded at once.
  - iii. Direct, automated specimen pathway between the chemistry urinalysis specimen sampling and testing and the microscopic urinalysis sampling and testing.
  - iv. One Primary and one Backup instrument.
- i. Oklahoma City VA Health Care System
  - i. Walk-away automated sampling for urinalysis chemistry and microscopic testing.
  - ii. Minimum capacity of 40 samples loaded at once.
  - iii. Direct, automated specimen pathway between the chemistry urinalysis specimen sampling and testing and the microscopic urinalysis sampling and testing.
  - iv. Body Fluid testing to include all serous, CSF and Synovial with dilution protocols in place for various degrees of Turbidity.
  - v. Backup system must be identical to primary system minus Body Fluids
- j. Lawton Outpatient Clinic
  - i. Walk-away automated sampling for urinalysis chemistry and microscopic testing.
  - ii. Minimum capacity of 20 samples loaded at once.
  - iii. Direct, automated specimen pathway between the chemistry urinalysis specimen sampling and testing and the microscopic urinalysis sampling and testing.
  - iv. No backup required.

- k. Jack C. Montgomery VAMC, Muskogee, OK
    - i. Walk-away automated sampling for urinalysis chemistry and microscopic testing.
    - ii. Minimum capacity of 10 samples loaded at once.
    - iii. Direct, automated specimen pathway between the chemistry urinalysis specimen sampling and testing and the microscopic urinalysis sampling and testing.
    - iv. One Primary and one Backup instrument.
  - l. Ernest Childers Outpatient Clinic, Tulsa, OK
    - i. Walk-away automated sampling for urinalysis chemistry and microscopic testing.
    - ii. Minimum capacity of 10 samples loaded at once.
    - iii. Direct, automated specimen pathway between the chemistry urinalysis specimen sampling and testing and the microscopic urinalysis sampling and testing.
    - iv. No back up required.
  - m. Fort Collins CBOC, Fort Collins, CO:
    - i. Urine Dipstick reader for urinalysis chemistry.
    - ii. One sample loading at a time is adequate
    - iii. One instrument required dipstick only.
10. Pricing: Offerors shall provide pricing for each test in accordance with the CPRR definition contained above, that can be performed on the quoted equipment. The CPRR shall include all costs for:
- a. Equipment use.
  - b. All consumables, reagents, calibrators, controls, supplies, consumable/disposable items, parts, accessories and any other items required for the proper operation of the contractor's equipment and necessary for the generation and reporting of a patient test result. All printers, computers and UPS power supplies, and water systems required to produce and store results shall be provided and maintained by contractor.
  - c. All necessary maintenance to keep equipment in manufacturer's operating conditions, both preventive maintenance, and emergency repairs.
  - d. Training for VA personnel operating equipment.
  - e. The awarded contractor is required to provide delivery, installation, set-up, validation and method comparison, including all supplies provided by the vendor, and removal of equipment at completion of this agreement at no additional charge to the Government.
11. Consumables
- a. All consumable supplies (reagents, standards, controls, disposables, parts, \ accessories, etc.) required for the proper operation of the contractor's equipment and necessary to perform tests on the equipment shall be included.

- b. In the event that the consumables 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 shall deliver the consumable supplies within a period of twenty-four hours after receipt of the verbal order for priority delivery from the Government activity. If either circumstance has occurred, the contractor shall deliver to the VA facility 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 Government site of the monthly standing order/routine supplies delivery. Failure to reserve adequate inventory may result in default.
12. Inventory - Controls, Calibrators, Reagents, Supplies, Disposables, Parts, Accessories: The contractor shall maintain on Government provided space a continuously stocked inventory of controls, calibrators, reagents, supplies, disposables, parts, accessories, and any other material required to properly perform tests on the offered equipment. These items shall be of the highest quality ensuring sensitivity, specificity and tested to assure precision and accuracy. The quality of the products shall be high enough to satisfy proficiency testing standards of the College of American Pathologists (CAP) and The Joint Commission (TJC).
13. Maintenance and Repairs:
- a. With the exception of the specific maintenance and repair requirements stated herein, which shall have precedence; preventive maintenance, emergency repair, maintenance credit for equipment malfunction, and replacement laboratory equipment shall be performed and provided in accordance with the terms, conditions, and provisions of contractor's existing Federal Supply Service Contract.
  - b. Emergency repairs shall be performed after initial telephone notification that the equipment fails any parameters. The contractor shall provide the Government with a designated point of contact and telephone number and shall make arrangements to enable vendor maintenance representative to receive such notification.
  - c. The contractor shall be on-site at the facility to perform emergency repair service within twenty-four (24) hours after receipt of initial telephone notification of a malfunction. Contractor shall provide maintenance coverage 24 hours per day, seven days per week including all Federal holidays. Exceptions are Billings CBOC, Lawton Clinic, Ernest Childers Outpatient Clinic and Sheridan VAHCS where services shall be from 8am to 5pm Monday through Friday. Contractor shall provide technical support service to assist in troubleshooting 24 hours per day, seven days per week including Federal holidays.

- d. In addition to above the contractor shall furnish a malfunction incident report to the installation upon completion of each repair call. The report shall include, as a minimum, the following:
  - i. date and time notified;
  - ii. date and time of arrival;
  - iii. serial number, type and model number(s) of equipment;
  - iv. time spent for repair;
  - v. description of malfunction and repair; and
  - vi. proof of repair that includes documentation of a sample run of quality control verifying acceptable performance and any other testing as needed.
- e. Should the repair record of any individual piece of laboratory equipment reflect a downtime of greater than 5% of the normal working days in one calendar month, a determination will be made by the designated representative of the Government at the using facility to replace the initial laboratory equipment with new equipment. The responsibility for maintaining the equipment furnished in good condition in accordance manufacturer's instruction, shall be solely that of the contractor. Each instrument provided by the contractor shall maintain an uptime of 95% in each month of the term of the agreement.
- f. The contractor shall not leave a service call open pending verification that repairs are completed by the contractor's maintenance personnel. For each instrument provided the contractor shall treat each notification for an emergency/repair service call from the Government as a separate and new service call.

14. Training:

- a. On-site training and key operator training for at least 2 operators per site. With the exception of the specific training requirements stated herein, which shall have precedence; contractor shall provide training in accordance with the terms, conditions, and provisions of contractor's existing Federal Supply Service Contract for performance of CPRR services.
- b. Provide initial in-depth training for two key operators at the facility and for each individual instrument provided. Provide annual training for one VA equipment operator, per each instrument, for the participating medical center.
- c. Provide on-site vendor operator training for all personnel who will run instrument with training provided for all applicable shifts.

15. Space Availability: All proposed equipment must fit the existing space at each VA P&LMS site, without the need for renovation work. Small scale re-arrangement of furniture is acceptable. Fitting existing space shall include conforming to the current structural parameters of each lab, in each facility, in terms of delivery, installation and lab space. (i.e. equipment size, weight, packaged size for delivery, electrical/voltage).

#### **D. Special Requirements:**

In addition to the general requirements for the Urinalysis CPRR requirements stated above, the contractor shall meet the following special requirements.

1. Equipment shall have a fully established VA VISTA computer system interface program via Dawning and/or Data Innovations Middleware, with all downloads / software necessary to transfer data into patient files in VA VISTA computer system via Dawning and/or Data Innovations Middleware, at no additional cost to VA.
2. Contractor shall provide automated, walk-away Urinalysis Chemistry analyzer with peripherals with direct, automated sample pathway to an automated, walk-away Microscopic Urinalysis analyzer with peripherals for sampling and testing.
3. Provide identical walk-away, automated sampling and testing for urinalysis chemistry testing only for backup purposes.
4. Provide Bi-directional interface with Dawning Middleware and/or Data Innovations and appropriate quality control analysis system and all components necessary to interface with VA VISTA computer system.
5. Provide Bi-directional interface with Data Innovations and appropriate quality control analysis system and all components necessary to interface with VISTA.
6. Shall be capable of operating at high altitudes with no interferences.
7. Shall provide data backup.
8. Systems shall provide ease of use (uncomplicated menus), with minimal maintenance required.
9. Shall provide flexibility in test volumes.
10. Shall be easy to troubleshoot.
11. All consumables, reagents, calibrators, controls, supplies, disposable items, parts, accessories and any other items required for the proper operation of the contractor's equipment and necessary for the generation and reporting of a patient test result shall be included in the CPRR.
12. Provide extended expiration date of supplies.
13. Uninterruptible power supply (surge protection, battery backup) provided by vendor for all associated electrical instruments and ancillary components excluding printer.
14. Provide a water system if required.
15. If a printer is required to produce patient or QC reports one shall be provided and replaced if needed by contractor.

#### **E. Transition Period:**

1. Upon award, the transition period for the awarded contractor to have all Urinalysis equipment and peripherals installed at the effected facility shall be 30 calendar days after award. During this same period all initial training of VA personnel in the operation and maintenance of said equipment shall also be completed.
2. Offerors shall provide with its quotation, a plan for transitioning equipment, supplies and services from the incumbent contractor to the new awarded contractor, with estimated dates and time to fully transition each participating facility. Contractor's



submitted transition plan shall not exceed 30 calendar days for installation and training of VA personnel.

3. No later than 60 calendar days after award, the contractor shall have completed full transition of all equipment, supplies and services under this agreement to include all correlation studies, validations, etc., and shall have full and sole responsibility for services.
4. Billing by Contractor starts on the first day of patient testing (also called Go-Live date) after all installation, training, and method validations have been completed and accepted in writing by the Contract Specialist (no later than 60 calendar days from time of award). At this time, the awarded contractor shall have completed full transition of all equipment, supplies and services and shall have full and sole responsibility.

**F. Cessation of Testing:**

If, for any reason, a contractor ceases testing of any Urinalysis assays, the contractor must notify the contracting specialist or equivalent 60 calendar days prior to the change. Until a new solicitation can be issued or the problem resolved, the contractor shall be held liable for all costs if performance is ceased, as the lab facility may have to resort to outsourcing the tests in order to continue patient care.