

Statement of Work

Automated Urinalysis Analyzers CPT

Reference No.:

626-17-1-066-0011 (Nashville)

626-17-1-2065-0010 (Murfreesboro)

626-17-1-2065-0015 (Chattanooga)

Service: Pathology & Laboratory Medicine Service

Service Period: 10/01/016-09/30/2017

General: The Pathology and Laboratory Medicine Service (P&LMS) of Tennessee Valley Healthcare System (TVHS) requires automated urine chemistry and urine cell analyzers to process a high volume of testing, and requests a year-long cost per test contract with a vendor that meets each requirement described in the Statement of Work (SOW). These requirements have been determined to ensure high quality care is rendered to patients through accurate and reliable test results, while integrating effectively with current P&LMS staffing and VHA regulations. The contractor shall furnish three (3) primary automated urinalysis analyzers, three (3) back-up analyzers that use identical methodology as the primary analyzer, three (3) printers, an operator's manual, accessory kit, all reagents, all calibrators, necessary to operate the analyzers for the contracted tests.

The instrument's test menu must meet the needs of P&LMS of TVHS, with an industry acceptable throughput of the analyzer (how many tests can it do in an hour), the contractor will provide analyzers to meet the testing needs of our facility. The analyzer, instrument methodology and results shall be in accordance with the requirements of professional standards of the College of American Pathologists (CAP) and the Joint Commission (TJC) and any applicable Directives from the Department of Veterans Affairs (VA), Department of Veterans Health Administration (VHA) or Office of the Air Force Surgeon General Standards or requirements. Requirements and standards are incorporated in this SOW. The Contractor shall submit reports and documentation as identified throughout the SOW.

The period of performance will be from 1 Oct 2016 through 30 Sep 2017.

The primary analyzer should have automation capable of processing a large volume of samples; the back-up analyzer must possess identical methodology as the primary analyzer. The instrument should interface with our existing Hospital Computer System

(through Dawning, now Data Innovations) and be capable of producing reliable ketones, urobilinogen, creatinine, glucose, leukocytes, nitrite, protein, occult blood, pH, bilirubin, and specific gravity test results. Also essential is urine color and clarity determination.

PRICING TO BE BASED ON ANNUAL USAGE BETWEEN MURFREESBORO NASHVILLE AND CHATTANOOGA OF 62,378 URINALYSIS/YEAR AND 25,252 URINE MICROSCOPICS/YEAR. (NASHVILLE - URINALYSIS/YEAR AND URINE MICROSCOPICS/YEAR; ACY – 27,513 URINALYSIS/YEAR AND 10,899 URINE MICROSCOPICS/YEAR; COPC – 13,284 URINALYSIS/YEAR AND 4,596 URINE MICROSCOPICS/YEAR)

PAYMENTS WILL BE MADE FROM THREE SEPARATE PURCHASE ORDER NUMBERS.

ESTIMATED VALUE: \$

The period of performance is 01 October 2016 through 30 September 2017.

Contract Period
CLIN 0001 Quantity Unit Total Clinical Laboratory Urine Analyzers 12 Months IAW the attached Statement of Work (POP 01 Oct 2016 - 30 Sep 2017)

(VI) Full description of requirement as follows:

1. Analyzer Requirements:

Primary Analyzer: The analyzer should have dry pad testing methodology (reagent test strips) capable of producing reliable tests for ketones, urobilinogen, creatinine, glucose, leukocytes, nitrite, protein occult blood, pH, bilirubin, protein. The instrument should also determine urine color, and clarity.

The analyzer must possess a specimen bar code reader to eliminate patient information input while providing continuous specimen access and STAT testing slots.

The analyzer must possess built-in liquid level sensing for short samples and the ability to determine if a specimen needs microscopic analysis based on set result parameters.

The analyzer should have a small enough platform to fit into our laboratory and use our existing (power) facility capabilities. For the Chattanooga location only, the analyzer must fit in a space that is equal to or smaller than 53.5" in width and 29" in depth.

The integrated urine analyzers will offer the following features:

- Automatic sample transport from one workstation to another to enable more efficient work processes
- Automatic verified results directly reportable to the LIS, to minimize technician follow up
- Automated Body Fluid analysis with white blood cell and red blood cell enumeration. Linearity capabilities down to 100 blood cells/mm³
- High on-board sample and reagent capacity to deliver the walkaway capability needed in busy lab environments
- Loading up to 100 samples
- Complete of up to 80 UA tests per hour
- Ability to cross-check with urine chemistry leukocyte and nitrite results to increase confidence in UTI assessments

Back-up Analyzers- semi-automated bench top urine chemistry dipstick analyzer. This analyzer will serve as the back-up to the provided fully automated urinalysis analyzers. This back-up analyzer must be compatible and be able to interface through our Data Innovation system to provide seamless delivery of patient results in the event of the primary instrument malfunction.

Analyzer must have:

- 50 tests per hour output potential
- Throughput of 7seconds/sample
- Urine color input
- Automated internal calibration verification
- Automated QC analysis
- Built in thermal printer
- High degree of specificity
- Barcoded samples managed with a handheld barcode reader (reader will be included)
- Simple maintenance and clean-up is an important factor

Urinalysis Instrument software

Software must be provided that allows the following benefits to optimize the use of a fully integrated urinalysis testing system:

- Auto-validation of results
- Real-time data checking and automatic reflex testing
- Delta checking and tracking of patient historical data by medical record numbers

- Operator management function for validation and security access
- Customized reports for audit trail

2. Maintenance and Repair:

Service includes: INITIAL SERVICE (MON-FRI 8AM-5PM EXCLUDING HOLIDAYS), EXTENDED SERVICE (MON-FRI 8AM-5PM EXCLUDING HOLIDAYS) AND 24 HR UNLIMITED TECHNICAL PHONE SUPPORT.

The contractor will provide 24/7 technical phone support. The contractor will provide 24/7 emergency and routine maintenance service and all reagents, calibrators, controls, and consumables required to perform urinalysis testing. The contractor will provide all tools, parts and labor needed for emergency or preventive maintenance and incur all associated travel costs

3. Billings:

A cost per test will be established for the instrument to include all reagents test packs, calibrators, rinse additive kit and controls. The ability to establish drop shipments of supplies will be available.

Billings for three urine analyzers will be arranged on three separate purchase orders.

4. Training Support:

TRAINING COSTS FOR THREE TO BE COVERED BY VENDOR INCLUDING AIRFARE IF REQUIRED, ON-SITE TESTING PERFORMED FOR CROSSOVER STUDIES, NORMAL RANGE AND CORRELATION STUDIES, LIS INTERFACE ALLOWANCE UP TO \$ 15,000.

On-site technical service specialist will provide setup, method validation, and correlations with new analyzers. This does not apply to existing instruments. The technical service specialist will also provide on-site training per instrument for each completed year of customer agreement when a new instrument is installed.

5. Orientation:

The contractor will be responsible for providing an orientation program to the clinical laboratory staff.

(VII) Place of performance is located at three locations of the Tennessee Valley Healthcare System;

(1) 1310 24th Ave south, Nashville, TN 37212 and

(2) Alvin C. York Campus, 3400 Lebanon Pike, Murfreesboro, TN 37129-1236

(3) VA Medical Lab Chattanooga, 150 Debra Rd. 6200 Building Suite 5200,
Chattanooga, TN 37411