

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  53D2254056	<b>(X3) Date Survey Completed</b>  05/31/2022
<b>Name of Provider or Supplier</b>  Cheyenne Urological Lab	<b>Street Address, City, State</b>  2003 Bluegrass Circle, Cheyenne, WY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation, and staff interview, the laboratory failed to ensure the procedure manual contained all the required elements for 1 of 1 procedure manual reviewed (UTI and Method SOP). The findings were: 1. Review of the UTI and Method SOP procedure manual failed to include the following requirements: a. A step-by-step performance of the procedure, including test calculations, and interpretation of results for specimen types other than urine. b. The threshold values established for the test system for specimen types other than urine. c. The laboratory's system for entering results in the patient record. d. A description of</p>

the course of action to take if a test system becomes inoperable. 2. Interview with the general supervisor on 5/31/22 at 10:29 AM confirmed the procedure manuals failed to include the required elements.

**D5407**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of the CMS-116 form, procedure manual review, and staff interview, the laboratory director failed to sign, and date as approved, the laboratory's standard operating procedure and microbiology manuals. The findings were: 1. Review of the CMS-116 form showed an initial application for a certificate of compliance was received on 2/16/22 and approved on 2/28/22. 2. Review of the microbiology and standard operating procedure manuals failed to include the laboratory director's signature and date of approval. 3. Interview with general supervisor on 5/31/22 at 10:04 AM confirmed the laboratory director had not reviewed and approved the procedure manuals.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on observation, review of patient test records, review of the "UTI with Antibiotic Resistance" method validation study, and staff interview, the laboratory failed to establish performance specifications using specimen types other than urine. The laboratory performed 25 tests using rectal swabs and 1 prostatic specimen since 3/16/22. The findings were: 1. Observation of the laboratory on 5/31/22 at 9:15 AM showed the laboratory used the Applied Biosystems QuantStudio PCR system which had not been approved by the FDA. 2. Review of the "UTI with Antibiotic Resistance" method validation study showed urine was the only specimen used to establish the performance specifications for the test system. 3. Review of the patient test requisition showed, in addition to urine, prostatic specimens, vaginal swabs, urethral swabs, and rectal swabs were listed as specimen sources. 4. Interview with the general supervisor on 5/31/22 at 11 AM confirmed the validation study did not include specimen types other than urine.