

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D0679889	(X3) Date Survey Completed 09/16/2024
Name of Provider or Supplier Wyoming State Hospital Laboratory	Street Address, City, State 831 Highway 150 South #733b, Evanston, WY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5403	<p>PROCEDURE MANUAL 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 3 procedure manuals reviewed (microalbumin/creatinine ratio). The findings were: 1. Review of the 8/16/24 policy and procedure for the DCA Vantage microalbumin/creatinine ratio assay showed the procedure failed to include the reference intervals and the reportable range. 2. Interview with the laboratory manager on 9/16/24 at 11:23 AM confirmed the procedure manual did not contain all of the required elements.</p>

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on new instrument and new test method verification study review, lack of documentation, staff interview, and review of the manufacturer's instructions, the laboratory failed to confirm the reference values were appropriate for the patient population for 1 of 3 microalbumin/creatinine ratio) new instrument verification studies reviewed. The findings were: 1. Review of the DCA Vantage verification study for the determination of the microalbumin/creatinine ratio showed the laboratory director approved the precision, accuracy, and reportable range study on 8/15/24. There was no evidence the laboratory director had verified that the reference intervals were appropriate for the laboratory's population. 2. Review of the DCA Vantage manufacturer's instructions showed "...EXPECTED VALUES: The reference ranges suggested by the study shown below should be regarded as guidelines only. Because of differences which may exist between laboratories and locales with respect to population, diet, laboratory technique and selection of reference groups, it is important for each laboratory to establish by similar means the appropriateness of adopting the reference ranges suggested by this study..." 3. Interview with the laboratory manager on 9/16/24 at 11:26 AM confirmed there was no evidence the reference ranges had been reviewed and approved by the laboratory director.