

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2119195	(X3) Date Survey Completed 02/13/2019
Name of Provider or Supplier Dr Brandon Lingenfelter	Street Address, City, State 411 12th Street Ext, Princeton, WV	
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 review of the laboratory's records and interview with testing personnel, the laboratory failed to include the following required components in its procedures: (b) (1) specimen acceptability/rejection criteria as described in 493.1242 Findings: 1. Review of the Urinalysis procedure in the binder titled "Laboratory Policy and Procedure Manual," demonstrated that the procedure was missing specimen acceptability and rejection criteria. 2. Interview with testing personnel on 2/13/19 at approximately 1:00PM confirmed the findings.</p>

D5405

PROCEDURE MANUAL

CFR(s): 493.1251(c)

Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's records and interview with testing personnel, the laboratory failed to include the following required components of a procedure manual when using a manufacturer's procedure: (b)(10) Reference values (normal values) (b) (13) 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/alert values (b)(14) Description of the course of action to take if a test system becomes inoperable Findings: 1. Review of the binder titled, "Laboratory Policy and Procedure Manual," demonstrated the manufacturer-provided procedure for Cepheid CT/NG was missing normal values for (b)(10) and the reporting policy for (b)(13). 2. Review of the manufacturer-provided Qualigen Vitamin D procedure in the same binder demonstrated there was no policy for how to proceed if the system becomes inoperable for (b)(14). 3. Interview with testing personnel on 2/13/19 at approximately 1:00PM confirmed the findings.