

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2290677	(X3) Date Survey Completed 07/29/2024
Name of Provider or Supplier Laura M Wake Md	Street Address, City, State 7 East Lake Ave, Baltimore, MD	
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 observation and interview with the laboratory director (LD), the laboratory did not have an approved standard operating procedure manual (SOPM). Findings: 1. The laboratory performed remote evaluations of histopathology slides that were processed and stained at another facility. 2. There was no SOPM that included the procedures for: a. Specimen transportation, acceptability, rejection, and storage b. Microscopic examination, including the detection of inadequately prepared slides c. Microscope maintenance d. Entering results into the patient record e. Documenting corrective actions when issues were identified f. Performing proficiency testing g.</p>

Quality assurance monitoring h. Any additional activities performed 3. During the survey on 07/29/2024 at 10:00 AM, the LD confirmed that there was no approved SOPM for laboratory operations.