

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1007238	(X3) Date Survey Completed 03/12/2025
Name of Provider or Supplier Ira Davis Md Plc Mohs Laboratory	Street Address, City, State 280 North Central Park Avenue Suite 114, Hartsdale, NY	
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>(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 Standard Operating Procedures (SOPs), lack of thermometer calibration records, as well as interview with the Testing personnel (TP), the laboratory failed to draft and approve procedures for thermometer calibration. FINDINGS: 1. There was no calibration certificate documentation for the thermometer utilized for laboratory room temperature and humidity monitoring where patient specimen processing occurred. 2. The current, approved SOPs did not include</p>

instructions for thermometer calibration and calibration certificate retention. 3. The TP confirmed the findings on March 12, 2025, at approximately 12:45 P.M.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

(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 SOPs as well as interview with the TP, the laboratory failed to document approval and date of approval by the current Laboratory Director (LD).
FINDINGS: 1. There was no documentation of LD approval and date of approval for 2022, 2023, and 2024 SOPs. 2. The TP confirmed the findings on March 12, 2025, at approximately 12:45 P.M.