

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0863351	(X3) Date Survey Completed 01/09/2025
Name of Provider or Supplier Dermatology Center Of North Jersey	Street Address, City, State 1033 Clifton Ave, Clifton, NJ	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Biannual Assessments (BA) records and interview with the Mohs Technician, the laboratory failed to verify the accuracy and reliability of Mohs testing twice annually from 6/3/24 to 1/9/25. The findings include: 1. There were no statements of agreement from the Reviewing Pathologist and the Referring Pathologist documented on BA performed from 6/3/24 to 1/9/25. 2. The Mohs Technician confirmed on 1/9/25 at 10:30 am, there were not statements of agreement from the pathologists performing the BA.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), lack of reagent tracking logs and interview with the Mohs technician, the laboratory failed to follow all procedures for "Quality Control Policies and Documentation" from 5/10/23 to 1/9/25. The findings include: 1. The PM states "Reagent lot numbers and expiration dates must be recorded." 2. There was no documented evidence the procedure was</p>

followed. 3. The Mohs technician confirmed on 1/9/25 at 10:35 am, the laboratory did not follow the PM.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

(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.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual (PM) and interview with the Mohs technician, the laboratory failed to have all applicable procedures for Histopathology tests from 5/10/23 to 1/9/25. The findings include: 1. There was no procedure in the PM to perform coverslipping. 2. The Mohs technician confirmed on 1/9/25 at 10:40 am, the laboratory did not have a coverslipping procedure.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual (PM) and interview with the Mohs Technician , the Laboratory Director (LD) failed to establish a Competency Assessment (CA) procedure with all the required elements for Testing Personnel (TP) from 5/10/23 to 1/9/25. The finding includes: 1. There was no written procedure for performing CA on TP for initial training, six months after employment and annually with all the required elements. 2. The laboratory only had CA forms with no written procedures. 3. The Mohs Technician confirmed on 1/9/25 at 10:00 am that a written CA procedure was not established.