

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2313576	(X3) Date Survey Completed 03/25/2026
Name of Provider or Supplier Dermatology Center Of North Jersey	Street Address, City, State 401a South Van Brunt St, Englewood, 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
D3041	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6)</p> <p>(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. In addition, retain the following: (a)(6)(i) Immunohematology reports as specified in 21 CFR 606.160(d). (a)(6)(ii) Pathology test reports for at least 10 years after the date of reporting</p> <p>This STANDARD is not met as evidenced by: Based on review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to have a retention policy from 11/04/24 to 3/25/26. The finding includes: 1. There was no procedure to maintain histopathology slides performed in Mohs testing for the required 10 years. 2. The TP confirmed on 3/25/26 at 1:30 pm that he was there was no procedure to maintain histopathology slides.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to establish a detailed procedure for Biannual Assessment (BA) from 11/04/24 to 3/25/26. The findings include: 1 The laboratory</p>

did not have a procedure for BA. 2. The TP confirmed on 3/25/26 at 1:15 pm that the laboratory did not have a procedure for BA.

D5391

PREANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1249(a)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:

Based on review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems from 11/04/24 to 3/25/26. The TP confirmed on 3/25/26 at 1:30pm that the laboratory failed to establish the aforementioned procedures.

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 review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to have per-analytical, analytical and post-analytical procedures. The findings include: 1) the laboratory failed to have the following procedures. a) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection. b) Procedures for Microscopic examination, including the detection of inadequately prepared slides. c) Procedures for Preparation of slides, solutions, reagents, stains, and other materials used in testing. d) Control procedures. e) Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. f) Description of the course of action to take if a

test system becomes inoperable. 2) The TP confirmed on 3/25/26 at 1pm the laboratory failed to have the above mentioned procedures..

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to establish a maintenance protocol for the, Microscope, and Cryostat used for Histopathology tests from 11/04/24 to 3/10/26 The findings include: 1. The PM did not have a maintenance protocol for the Microscope, and Cryostat used for Histopathology tests. 2. The TP confirmed on 3/25/26 at 1:30 pm, the laboratory did not have the above mentioned maintenance protocols.