

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1079089	(X3) Date Survey Completed 09/15/2026
Name of Provider or Supplier Nj Certified Dermatology, Pc	Street Address, City, State 540 Lacey Road, Forked River, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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. This STANDARD is not met as evidenced by: A) Based on surveyor review of the Procedure Manual (PM) and interview with the Office Manager (OM) the laboratory failed to have a complete procedure for Biannual Assesment.(BA) from 7-9-24 to 9-15-26. The finding includes: 1. The the BA procedure failed to have a procedure for third party review if the reviewing physicians assessment disagrees with the diagnosis. 2. The OM confirmed on 9-15-26 at 11:00 am the the laboratory did not have a complete procedure for BA. B) Based on surveyor review of the PM, Requisitions , Final Reports (FR) and interview with the OM the laboratory failed to follow the laboratories procedure "6.8 Turn Around Time" from 4-21-26 to 9-15-26. The findings include: 1. The PM stated "Standard of care: The goal for repotting patient results for routine cases is 5 days. Any lab delays are to be communicated to the laboratory director or pathology administrative staff". "80% of cases prepared in the NJ Certified Dermatology Laboratory should be within the determined Turn Around Time (TAT)". 2. Report dates exceeded five days from the specimen received date on seven out of ten RF reviewed . 3. The OM confirmed on 9-15-26 at 11:00 am the the laboratory did not follow the above mentioned procedure.
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 surveyor review of the Procedure Manual (PM), and interview with the Office Manager (OM) the laboratory failed to have a complete procedures for Histopathology tests from 7-9-24 to 9-15-26. The findings include: 1. There was no description of the course of action to take if a test system becomes inoperable. 2. There was no procedure on how to document Quality Control (QC) in the Lumea system. 3. The OM confirmed on 9/15/26 at 11:25 am that the PM did not have the aforementioned procedures.