Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2150768	07/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
Nj Certified Dermatology, Pc	111 West Water St, Toms 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the lack of Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to follow written procedures to perform a CA on one of one TP for the calendar years 2019 and 2020. The TP confirmed on 7 /29/21 at 1:30 pm that the CA procedure was not followed .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP) the laboratory failed to have all applicable procedures for Histopathology tests from 12/14/2018 to the date of the survey. The finding includes: 1. The laboratory did not have a procedure for slide retention. 2. The TP confirmed on 7/29/2021 at 1:15 pm that the PM did not have all applicable procedures.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the temperature logs and interview with the Testing Personnel (TP), the laboratory did not document corrective action taken when the Cryostat Temperature (CT) was out of range in January through July 2021. The findings include: 1. A six month review of the CT log revealed that the temperature was outside the established range as below: a. January 2021: 4 out of 4 days b. February 2021: 1 out of 2 days c. March 2021: 4 out of 4 days d. April 2021: 3 out of 3 days e. May 2021: 3 out of 3 days f. June 2021: 2 out of 2 days g. July 2021: 2 out of 3 days 2. There was no documented evidence of Corrective Action (CA) taken. 3. The TP confirmed on 7/29/21 at 12:45 pm the laboratory did not document CA when the CT was out of range.