Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1063032	07/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
Nj Certified Dermatology, Pc	26 Highway 35 North, Neptune, 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 9:30 am 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 10/30/2018 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 10:15 am that the PM did not have all applicable procedures.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor review of the Temperature Charts (TC) and interview with the Testing Personnel (TP), the laboratory failed to monitor and document Room Temperature (RT) and Cryostat Temperature (CT) on each day of Mohs testing from January 2019 to the date of the survey. The finding includes: 1. Review of TC revealed that the laboratory did not monitor and RT and CT from January 2019 to the date of the survey on days patient testing was performed. 2. The TP confirmed on 7/29 /21 at 10:00 am that the RT and CT was not monitored and recorded each day of Mohs testing.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to document Hematoxylin and Eosin (H&E) control slide reaction from January 2019 to the date of survey. The findings include: 1. The laboratory did not document H&E stain QC reaction for reading of biopsy slides. 2. The laboratory read and reported approximately 300 patient slides. 3. The TP confirmed on 7/29/21 at 10:45 am that the laboratory did not document H&E QC stain reaction.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director failed to maintain a Quality Control (QC) program for Hematoxilyn and Eosin (H&E) stain reaction from January 2019 to the date of survey. The TP confirmed on 7/29/21 at 10:45 am that a QC program was not maintained.