Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2043828	03/10/2026
Name of Provider or Supplier	**Street Address, City, State**	
Nj Certified Dermatology Pc	668-670 Broadway, Bayonne, 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	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) (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 This STANDARD is not met as evidenced by: Based on the lack of a Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to have a retention policy from 5/29/24 to 3/10/26. The finding includes: 1. There was no procedure to maintain histopathology slides performed in Mohs testing for the required 10 years. 2. The OM confimed on 3/10/26 at 1:30 pm that he was there was no procedure to maintain histopathology slides.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on the review of the Biannual Assessments (BA) records and interview with the Office Manager (OM) the laboratory failed to verify the accuracy of Histopathology testing biannually in the calendar year 2025. The finding includes: 1. There was no documented evidence the laboratory verified the accuracy of histopathology testing in the calendar year 2025. 2. The OM confirmed on 3/10/26 2pm, the laboratory did not verify the accuracy of Histopathology testing in the calendar year 2025.

D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the lack of a Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to establish a detailed procedure for Biannual Assessment (BA) from 5/29/24 to 3/10/26. The findings include: 1. The laboratory did not have a procedure manual. 2 The laboratory did not have a procedure for BA. 3. The OM confirmed on 3/10/26 at 1:15 pm that the laboratory did not have a procedure for BA.
D5309	TEST REQUEST CFR(s): 493.1241(e) (e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on surveyor review of Test Reports (TR), Electronic Medical Records (EMR), lack of a Procedure Manual and interview with the Office Manager (OM), the laboratory failed to have an ongoing mechanism to ensure the accuracy of manual entries by personnel into the EMR from 5/29/24 to 3/10/26. The findings include: 1. The laboratory failed to have a procedure for TR and other pertinent information manually scanned into the EMR. 2. The OM confirmed on 3/10/26 at 1:10pm the laboratory failed to verify the accuracy of manual entries by personnel into the EMR.
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 the lack of a Procedure Manual (PM) and interview with Office Manager (OM) 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 5/29/24 to 3/10/26. The OM confirmed on 3 /10/26 at 1:30pm that the laboratory failed to establish the aforementioned procedures.
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: Based on lack of Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to have a PM from 5/29/24 to 3/10/26. The OM confirmed on 3/10/26 at 12:45 PM the laboratory did not have a PM for all tests and procedures performed in the laboratory.
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 the lack of a Procedure Manual (PM), and interview with the Office Manager (OM) the laboratory failed to have per-anytical, 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 OM confirmed on 3/10/26 at 2pm 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 the lack of a Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to establish a maintenance protocol for the Auto Stainer , Microsope, and Cryostat used for Histopathology tests from 5/29/24 to 3/10/26 The findings include: 1. The PM did not have a maintenance protocol for the Auto Stainer, Microsope, and Cryostat used for Histopathology tests. 2. The OM confirmed on 3/10 /26 at 1:30 pm, the laboratory did not have the above mentioned maintenance protocols.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Reports (TR) for Histopathology testing and interview with the Office Manager (OM) the laboratory failed to ensure TR included all the required information from 5/29/24 to 3/10/26. The findings include: 1. TR did not include the address of the laboratory where Histopathology testing was performed. 2. The OM confirmed on 3/10/26 at 2:00 pm, the laboratory failed to ensure the TR included all the required information.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor review of the Laboratory records lack of a Procedure Manual (PM) and interview with the Office Manager (OM), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory from 5/29/24 to 3/10/26. The findings include: 1. The LD failed to ensure Biannual Assessment (BA) was performed to evaluate the laboratory's performance accurately in the calendar year 2025. Cross refer to D6091. 2. The LD failed to ensure Quality Control (QC) and Quality Assessment (QA) programs are established and maintained. Cross refer to D6093. 3. The LD failed to have an approved PM for Histopathology testing. Cross refer to D6106. 4. The LD failed to specify in writing the responsibilities and duties of laboratory personnel engaged in the performance of the pre--analytical, analytic, and post-analytical phases of testing. Cross refer to D6107

D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on the lack of Biannual Assessment (BA) records and interview with the Office Manager (OM), the Laboratory Director (LD) failed to ensure BA was performed to evaluate the laboratory's performance accurately in the calendar year 2025. The findings include: 1) There was no documented evidence that a BA was performed in the calendar year 2025. 2) The OM confirmed on 3/10/26 at 1:00 pm the BA was not performed to evaluate the laboratory's performance in the calendar year 2025. Cross refer to D5217
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment 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 the lack of a laboratory Procedure Manual (PM) and interview with the Office Manager the Laboratory Director (LD) failed to ensure Quality Control (QC) and Quality Assessment (QA) programs are established and maintained from 5/29/24 to 3/10/26. The findings include: 1. The LD failed to have written procedures for QC and QA programs. 2. The OM confirmed on 3/10/26 at 2:00 pm, the LD failed to ensure QC and QA procedures were established.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on lack of a Procedure Manual (PM) and interview with the Office Manager (OM), Laboratory Director (LD) failed to have an approved PM for Histopathology testing from 5/29/24 to 3-10-26. The finding includes: 1) The laboratory have an approved PM for Histopathology testing. 2) The OM confirmed on 3/10/26 at 1:10 pm that the LD did not ensure an approved PM was available. Cross refer 5401
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and

	procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the lack of a Procedure Manual (PM) and interview with the Office Manager (OM) the Laboratory Director (LD) failed to specify in writing the responsibilities and duties of laboratory personnel engaged in the performance of the pre--analytical, analytic, and post-analytical phases of testing, from 5/29/24 to 3/10/26. The finding includes: 1) The laboratory did not have have an approved PM for Histopathology testing. 2) The OM confirmed on 3/10/26 at 1:20 pm that the LD failed to specify in writing the responsibilities and duties of the aforementioned staff.