Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2163236	07/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
New Jersey Dermatology	479 County Road 520 Suite A 201, Marlboro, 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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on an in-office review of the laboratory's requirements for a New Jersey State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J.S.A. 45:9-42.28. License; necessity; categories, the laboratory failed to maintain a NJCLL for Potassium Hydroxide (KOH) testing in the calendar year 2025 or any prior years. The Office Manager (OM) confirmed on 7/22/24 at 1:30 pm that the laboratory did not maintain a NJCLL for KOH testing in the calendar year 2025 or any prior years.
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 surveyor review of the Procedure Manual (PM), Biannual Assessment (BA) records and interview with the Office Manager (OM), the laboratory failed to verify the accuracy and reliability of Histopathology testing twice a year from to 7/2/25. The finding includes: 1. The last documented evidence that a BA was performed was 3/5 /24. 2. The OM confirmed 7/22/25 at 1:10 pm, the laboratory did not verify the accuracy of Histopathology testing twice a year.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 Log (TL), Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to record the Cryostat temperature, room temperature and humidity where Histopathology tests are performed from 12/26/24 to 7/22/25. The finding includes. 1. The PM stated, "Console temperature is recorded daily. The cryostats should be maintained at -21 C to no colder than -30 C for best Mohs sectioning." 2. The last entry in the TL for Cryostat temperature, room temperature and humidity was entered on 12/26/24 . 3. The OM confirmed on 7/22/25 at 1:35 pm, the laboratory failed to record the Cryostat temperature, room temperature and humidity on each day of patient testing.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: A) Based on surveyor observation of Histopathology reagents and interview with the Office Manager (OM), the laboratory used expired Histopathology reagents from 9/30 /24 to 7/22/25. The findings include: 1. Adventek coverMount 3 D-Limonene based Lot # 157879 Expired 9/30/24 2. Adventek Tissue marking dyes were expired as follows: a) Blue marking day lot # 172404 expired 4/30/25 b) Red marking day lot # 171349 expired 4/30/25 2. Approximately 330 patients were tested with expired reagent. 3. The OM confirmed on 7/22/25 at 1:30 pm that the laboratory used expired reagents. B) Based on surveyor observation of Histopathology reagents and interview with the OM, the laboratory retained expired Histopathology reagents from 3/1/25 to the 7/22/25. The findings include: 1. EDM3 Solutions Toluidine Blue 1% Lot # 3060 Expiration 3/1/25 2. Microbiologics Potassium Hydroxide KOH 10% lot # 300145 Expiration 7/8/25 3. The OM confirmed on 7/22/25 at 1:30 pm that the laboratory retained expired reagents.
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. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to document Hematoxylin and Eosin (H&E) control slide reactions for Histopathology testing from 12/26/24 to 7/22/25. The findings include: 1. The laboratory did not document H&E stain QC reactions during the time period stated above. 2. The laboratory read and reported approximately 330 patients in the above time period. 3. The OM confirmed on 7/22 /25 at 1:30 pm that the laboratory did not document H&E QC stain reaction.
D5603	HISTOPATHOLOGY CFR(s): 493.1273(b)(f) (b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under 493.1449(b), (f), or (g). This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) Histopathology slides and interview with the Office Manager (OM), the laboratory failed to retain QC Histology Slides (HS) from 10/25/23 to 7/22/25. The OM confirmed on 7/2/25 at 1:15 pm that QC HS were not retained.
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 and interview with the Office Manager (OM) the laboratory failed to ensure the TR included all the required information from 10/25/23 to 7/22/25. The findings include: 1. TR did not include the name address of the laboratory where the professional component of Histopathology testing was performed. 2. The OM confirmed on 7/22/25 at 1:00 pm, the laboratory failed to ensure the TR included all the required information.
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 surveyor review of a Procedure Manual (PM) and interview with the Office Manager (OM)), the Laboratory Director (LD) failed to have an approved PM for Histopathology testing from March 2024 to 7/22/25. The findings include; 1. The OM stated the LD changed in March of 2024. 2. The name of the LD listed in the PM was not listed on the CMS form 209. 3. The address of the laboratory in the PM was 621 South Ballas Road, Ste 597a Marlboro, New Jersey (NJ), 07746 4. The current address of the laboratory was 479 County Road 520 Suite A 201 Marlboro NJ 07746. 5. The PM was not approved by the LD. 6. The OM confirmed on 7/22/25 at 1:10 pm that the LD did not ensure an approved PM was available.