Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2004723	10/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology Of Nj Pc	700 Paramus Park, Paramus, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on surveyor observation of the laboratory reagents and interview with the Officwe Manager (OM), the laboratory failed to ensure protection from chemical and physical hazards at the time of survey. The findings include: 1. Observation of the flammable cabinet and undersink cabinet revealed that all flammable and inhalation risk reagents were not kept in the flammable cabinet. 2. Five containers of 100% Reagent Alcohol were stored in the laboratory undersink cabinet. 3. The OM confirmed on 10/20/22 at 1:35 pm that the laboratory did not ensure protection from chemical and physical hazards.
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 Office Manager (OM), the laboratory failed to perform a CA on two out of two testing

	personnel for the calendar years 2020, 2021 and 2022. The OM confirmed on 10/20 /22 at 1:30 pm that the CA was not performed as stated above. Note: This was previously cited: 1/22/20
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 surveyor review of the Procedure Manual (PM), and interview with the Office Manager (OM), the laboratory failed to have a procedure written for the preparation of Toluidin Blue reagent from 1/22/20 to the date of the survey. The OM confirmed on 10/20/22 at 1:30 pm that the laboratory did not have the aforementioned written procedure.
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 Log (TL) and interview with the Office Manager (OM), the laboratory failed to define an acceptable Room temperature and humidity range where Histopathology tests are performed from 1/22/19 to the date of the survey. The finding include: 1. The TL did not have an acceptable range for Temperature or Humidity. 2. The OM confirmed on 10/20/22 at 1:35 pm that an acceptable range was not defined.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: a) Based on surveyor observation of the laboratory Cabinet and interview with the Office Manager (OM), the laboratory failed to appropriately label Toluidine Blue

	reagent used for Histopathology testing from 1/22/20 to the date of the survey. The finding includes: 1. There were no preparation and expiration dates on the container containing Toluidine Blue. 2. The OM confirmed on 10/20/22 at 1:35 pm that all reagents were not labeled correctly. b) Based on surveyor observation of the Staining Station and interview with the OM, the laboratory failed to label the identity of all staining jars used for Histopathology testing from 1/22/20 to the date of the survey. The OM confirmed on 10/20/22 at 1:35 pm that all staining jars were not labeled.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: Based on surveyor observation of the Flammable Cabinet and interview with the Office Manager (OM), the laboratory used expired Eosin Y Alcoholic Working Solution reagent for Histopatholgy testing on 11/15/21. The findings include: 1. Eosin Y Alcoholic Working Solution Lot # 063019 expired 10/8/21. 2. Approximately 5 patients were tested with the expired reagent. 3. The OM confirmed on 10/20/22 at 1: 30 pm that the laboratory used expired reagent.
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 Cryostat Maintenance Log (CML) and interview with the Office Manager (OM), the laboratory failed to take and document Corrective Action (CA) when the Cryostat Temperature (CT) was out of range from 10/28/20 to the date of survey. The finding includes: 1. A review of the CML revealed that CT was outside the established range on 10/28/20, 11/1120, 11/17/20, 11/25/20, 1/20/21, 2/3/21, 2/4/21, 2/17/21, 3/17/21, 4/26/21, 4/18/21, 5/3/21, 5/12/21, 5/16/21, 6/29/21, 7/7/21, 7/19/21, 8/4/21, 8/18/21, 9/1/21, 10/27/21, 11/15/21, 12/8/21, 1/19/21, 2/2/21, 4/13/22, 5/15/22, 6/8/22, 7/6/22, 9/28/22. 2. There was no documented evidence of corrective action taken. 3. Approximately 150 patient samples were prepared in the Cryostat. 4. The OM confirmed on 10/20/22 at 1:45 pm the laboratory did not document corrective action. Note: This deficiency was previously cited on 1/22/20
D5805	TEST REPORT CFR(s): 493.1291(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 Final Report (FR) and interview with the Office Manager (OM), the laboratory failed to ensure that the FR included all the required information from on the date of survey. The finding include: 1. A review of ten FR revealed that the name and address of the laboratory performing Mohs testing was incorrect on the FR. 2. The current address of the laboratory is 700 Paramus Park, Paramus NJ 07652. 3. The address on the FR was 1200 East Ridgewood ave, Suite 211, Ridgewood NJ 07450. 4. The OM confirmed on 10/20/22 at 1:45 pm that FR did not have all the required information.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on the lack of Personnel Records (PR) and interview with the Office Manager (OM), the Laboratory Director (LD) failed to ensure that the education and training records were available on the date of the survey. The finding includes: 1. Education and training records were not available for two out of two Testing Personnel. 2. The OM confirmed on 10/20/22 at 1:39 pm that all education and training records were not available.