Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2091714	(X3) Date Survey Completed 09/16/2024
Name of Provider or Supplier Advanced Dermatology Of Maryland	**Street Address, City, State** 14995 Shady Grove Rd Suite 150, Rockville, MD	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on laboratory patient electronic medical record (EMR) review and interview with the histotechnician, the laboratory did not follow the established policies and procedures to ensure positive identification of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. Findings: 1. The laboratory performs histopathology testing on patient specimens from Mohs surgery. The final patient record in the EMR includes a scanned copy of the Mohs map used to document the surgical process, as well as a copy of the letter sent to the patient's referring doctor (final report). 2. Random review of Mohs cases showed that for case # MR24-013, the date of birth of the patient was recorded as "4/17/24" on the Mohs map, however the date of birth in the final report was documented as "4/1/1952." 3. During an interview on 09/13/2024 at 11:45 AM, histotechnician #1 confirmed that the patient's date of birth was correct on the final report and that the laboratory failed to provide accurate information on the patient's Mohs map.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on procedure manual review and interview with the histotechnician, the laboratory failed to ensure that changes to the procedure manual were approved by the laboratory director (LD). Findings: 1. During an interview on 09/13/2024 at 11:50 AM, histotechnician #2 stated that the name of the laboratory changed to "Advanced Dermatology of Maryland" two years ago. 2. Procedure manual review showed that the outside of the procedure manual was labeled with the prior name of the laboratory; and 3. The name of the laboratory on the "Directory" page in the front of the procedure manual was a third, different laboratory name. 4. The "Directory" page was signed by the LD but not dated. 5. During an interview on 09/13/2024 at 12:00 PM, histotechnician #1 confirmed that the laboratory's procedure manual had not been updated with the current name of the laboratory or approved by the LD.

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 review of Mohs maps and final patient reports and interview with the histotechnicians, the laboratory failed to ensure that the final test report included the name and address of the laboratory where histopathology slides were interpreted. Findings: 1. During an interview on 09/13/2024 at 11:50 AM, histotechnician #2 stated that the name of the laboratory changed to "Advanced Dermatology of Maryland" two years ago. 2. Random review of Mohs maps and the letters that are sent to the patients' referring doctors (final reports) from two patients showed that for case # 23M-13 (testing performed 09/18/2023) the name of the laboratory on the Mohs map and the final report (dated 11/07/2023) was the name of the previous laboratory; and 3. Review of case # MR24-013 (testing performed 06/10/2024) showed that the Mohs map had the name of the current laboratory on it, however the final report (dated 08/22/2024) had the previous laboratory's name on the letterhead. 4. During an interview on 09/13/2024 at 12:00 PM, histotechnician #1 confirmed that the final reports provided to patients' referring doctors did not include the correct name of the laboratory where the testing was performed.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on procedure manual and temperature log record review and interview with the

histotechnician, the laboratory director (LD) failed to ensure that the acceptable temperature range for the cryostat was established for histopathology testing. Findings: 1. The "Mohs Procedure" in the laboratory's approved procedure manual states, "To begin a Moh's procedure the cryostat needs to be turned to -24C [celsius] to -29C." 2. The "Cryostat Calibration, Cleaning & Maintenance" procedure states that the "temperature range is -20 C TO -30 C". The acceptable temperature range listed on the cryostat temperature log was also "-20 C to -30 C". 3. During an interview on 09/13/2024 at 12:00 PM, histotechnician #1 confirmed that the LD failed to establish a consistent acceptable temperature range for the cryostat used for histopathology testing.