Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D0688237	**(X3) Date Survey Completed** 02/23/2021
Name of Provider or Supplier Advanced Dermatology And Cosmetic	**Street Address, City, State** 28212 Kelly Johnson Pkwy Ste 245, Valencia, CA	
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**
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 review of the laboratory's policies & procedures, eight (8) random patients biopsies and Mohs reports, quality control records, proficiency testing records, and interview with the laboratory staff on February 23 2020 at 11:45 a.m.; it was determined that the laboratory failed to verify, at least twice annually, the accuracy of its biopsies and Mohs test for the years 2019 and 2020. The findings included: 1. The laboratory did not have any documentation showing that it had verified its biopsies and Mohs test accuracy for the years 2019 and 2020. Therefore, the accuracy of the laboratory's test results to the patients for biopsies and Mohs procedures, cannot be assured. 2. The laboratory staff affirmed on 2/23/2020 at approximately 1:00 p.m., that the laboratory did not have any record to verify its biopsy and Mohs test accuracy for the years 2019 and 2020. 3. The laboratory's testing declaration form signed by the laboratory director, stated that the laboratory performs 5,000 Histopathology tests including biopsies and Mohs tests annually.
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 review of eight (8) random patient sampling covering a period from 07/5 /2018 to 01/14/2021, review of quality control documents, lack of the current practice laboratory policies and procedures, and interview with the laboratory personnel; it was determined that 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 general laboratory systems. The findings included: 1. On the day of the survey 02/23/2021 at approximately 12:00 p.m. no documentation could be retrieved to show that the laboratory had written policies and procedures for the current practice. This correction process involves records retention and storage policies, peer review, quality assessment, and policies for preventing problems that have been identified. 2. The laboratory personnel confirmed on 02/23/2021 at approximately 1:20 p.m. that the laboratory did not have written policies and procedures that reflect the current practice for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. 3. The annual testing declaration submitted on 02/23/2021 estimated 5,100 tests resulted and reported.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the lack of documentation of the Cryostat temperature used by Mobile Mohs, review of maintenance records, and interview with the laboratory staff; it was determined that the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer for the Cryostat used to process samples for the Mohs procedure. The findings included: 1. The laboratory contracts Mobile Mohs Company to process samples for the Mohs procedure. 2. For two (2) out of four (4) random selected Mohs samples processed, no records of temperature and preventive maintenance of the cryostat used to process Mohs samples were found for the following dates: 11/03/2018 and 06/04/2019. 3. The laboratory staff confirmed on 02/23/2021 at approximately 12:30 p.m. that the laboratory failed to follow manufacturer's instruction to document the Cryostat temperature at the time of processing samples for the Mohs procedure on the dates indicated in 1.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on the lack of established policies and procedures reflecting the current practice (D5291), failure to establish and follow a peer review policy for the verification at

	least twice annually the accuracy of the biopsies and Mohs procedure for the years 2019 and 2020 (D5217), and the lack of preventive maintenance and temperature records for the cryostat (D5429) it was determined that the laboratory director failed to ensure that testing systems developed and used for each of the biopsies and the Mohs tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.