Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2190007	07/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Imperial Dermatology	3000 E Imperial Hwy Ste 150, Brea, 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
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 the surveyor's observation during the laboratory tour, review of the laboratory's policy and procedure, and interviews with office manager (OM) and laboratory director (LD), the laboratory failed to establish safety procedures to ensure protection from physical, chemical, and biochemical materials. The findings include: 1. Based on the survey on July 22, 2025, at approximately 12:20 p.m. the laboratory failed to provide a written policy and procedure for laboratory safety. 2. Based on the observations during the laboratory tour where the Mohs processing and staining of samples took place, it was found that the laboratory lacked an eye wash. 3. The OM and LD affirmed by interviews July 22, 2025, at approximately 12:45 p.m. that the laboratory lacked safety procedures and eyewash in the Mohs processing area. 4. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 07/21/2025, the laboratory processed and reported annually approximately 100 Mohs patients' test samples.
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 surveyor's review of the laboratory's policies and procedures, peer review records, six (6) randomly selected patient records, and interviews with the office manager (OM); the laboratory failed to verify the accuracy of any test or procedure performed at least twice annually for the years 2023 and 2024. The findings include: 1. The laboratory's policy and procedure for proficiency testing stated that two cases are sent to another facility to verify the accuracy of results for Dermatopathology. However, only one case per year was available for review for the years 2023 and 2024. Therefore, the accuracy of patient results could not be assured. 2. The OM confirmed by interview the day of the survey July 22, 2025, at approximately 11:30 a.m., that the laboratory failed to verify the accuracy of the dermatopathology Mohs procedure at least twice per year as stated in #1. 3. The laboratory's testing declaration form submitted at the time of the survey stated that 100 tests Dermatopathology Mohs were processed and reported annually during the time that laboratory failed to verify the accuracy of the Mohs test results.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 surveyor's review of the laboratory's policies and procedures, preventive maintenance (PM) documentation, six (6) patient records, and interviews with the laboratory's office manager (OM); the laboratory failed to follow an established policy and procedure in place for the preventive maintenance (PM) as defined by the manufacturer, with at least the frequency recommended for the laboratory's equipment prior to patient testing for the microscope. The findings include: 1.The laboratory failed to provide PM documentation for the year 2023 for the microscope according to manufacturer's requirements, to be performed annually. 2. No corrective action report was available for review at the time of survey. 3. The OM affirmed by interviews on July 22, 2025, at approximately 12:00 p.m., that the laboratory missed the PM for the year 2023 for the Olympus BH-2 microscope used for patient Mohs sample microscopic examination and diagnosis. 4. According to the testing volume declaration submitted at the time of the survey, the laboratory performed and reported approximately 100 tests annually for Histopathology- Mohs during the time annual equipment PM for the microscope was missed to be performed and documented.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) 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 surveyor's review of the laboratory's policies and procedures, randomly selected patient test records, preventive maintenance documentation, direct observation during the laboratory tour, and interviews with the laboratory's Office manager on July 22, 2025, the laboratory director is herein cited due to failure to

	ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. The findings include: 1. Peer review not performed twice a year for the years 2023 and 2024. See D5217. 2. Fail to have a Safety Plan for the laboratory and accessible eye wash area during sample processing for Mohs. See D3011. 3. Failure to conduct preventive maintenance annually for th microscope for 2023. D 5429.