Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1075013	10/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology	230 Newport Center Dr Ste 200, Newport Beach, 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
D5315	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c) (c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. This STANDARD is not met as evidenced by: Based on review of specimen grossing records, an interview with the Laboratory Director (LD), and review of seven (7) randomly selected patient test results on October 16, 2025, it was determined that the laboratory failed to ensure that the reference laboratory maintains a current CLIA certificate. The findings included: 1. It was the practice of the laboratory to perform histopathology testing. 2. On October 16, 2025, at approximately 10:30 a.m., the laboratory director confirmed that specimen grossing is referred to Harris Histology Service, which handles both grossing and quality control. 3. Harris Histology Service does not hold a current CLIA certificate and is not qualified to perform specimen grossing. 4. The laboratory's testing declaration form, signed by the laboratory director on October 6, 2025, stated that the laboratory performed approximately 2124 histopathology tests annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 review of the laboratory's policies and procedures manuals and an interview

	with the Laboratory Director (LD) on October 16, 2025, it was determined that the laboratory failed to update the procedure manual when practice changes occurred. The findings included: 1. It was the practice of the laboratory to perform histopathology testing. 2. On October 16, 2025, at approximately 10:30 a.m., the LD confirmed that the laboratory had not updated the histopathology procedure manual to reflect current practices. The laboratory director stated that they do not follow the quality control procedures and refer specimen grossing to Harris Histology Service, which performs both the grossing and quality control. 3. On the day of survey, it was noted that the laboratory did not follow the Quality Control (QC), Quality Assurance, and grossing procedures outlined in the existing manual. The manual also lacks sections on referring grossing and quality control to another laboratory. 4. The laboratory's testing declaration form, signed by the laboratory director on October 6, 2025, stated that the laboratory performed approximately 2124 histopathology tests annually. See D5407 and D5315.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (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 review of the laboratory's policies and procedures manuals and an interview with the Laboratory Director (LD) on October 16, 2025, it was determined that the laboratory director failed to update the procedure manual when practice changes occurred. The findings included: 1. It was the practice of the laboratory to perform histopathology testing including Mohs Micrographic Surgery. 2. On October 16, 2025, at approximately 10:30 a.m., the LD confirmed that the laboratory director did not update and sign and date the policies and procedure manuals to reflect the current practice offered by the laboratory. The last update and signature on the manual were dated October 3, 2007. 3. The laboratory's testing declaration form, signed by the laboratory director on October 6, 2025, stated that the laboratory performed approximately 2124 histopathology tests annually.