Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0993510	06/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology Inc	412 18th Ave, Monroe, WI	

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 surveyor review of laboratory records and interview with the laboratory director, the laboratory did not document twice annual verification of accuracy for two of two histology procedures not included in Subpart I. Findings include: 1. Review of laboratory quality records showed the laboratory last documented accuracy verification for Mohs testing in August 2022. Record review showed no documented evidence of twice annual accuracy verification for diagnostic interpretations of frozen sections performed in the laboratory in 2023 or 2024. 2. Review of the patient log from May 1 through May 10, 2025, showed the laboratory reported 28 diagnostic interpretations of frozen section tissue samples. 3. Interview with the laboratory director on June 9, 2025, at 1:45 PM confirmed the laboratory performed Mohs and diagnostic interpretation of tissue frozen section specimens and confirmed the laboratory did not document twice annual accuracy verification for either procedure during 2023 or 2024.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) (b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records for three Mohs cases that required more than one stage and interview with Testing Personnel (Staff A), the laboratory

	had not documented the time they received subsequent tissue specimens for three of the three cases. Findings include: 1. Review of maps for three Mohs cases that required more than one stage showed no record of the time the laboratory received subsequent tissue specimens after the first stage. 2. Interview with Staff A on June 9, 2025, at 1:00 PM confirmed testing personnel did not document the time of specimen receipt for each subsequent tissue received in the laboratory for processing during Mohs procedures when the procedure required more than one stage. This is a repeat deficiency previously cited on August 3, 2023.
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 surveyor review of laboratory procedures and interview with the Laboratory Director, testing personnel occasionally perform potassium hydroxide (KOH) tests and a procedure was not available in one of one procedure manuals reviewed. Findings include: 1. Review of procedures showed no evidence of a procedure for performing KOH testing on dermatologic specimens. 2. Interview with the Laboratory Director on June 9, 2025, at 1:05 PM revealed the laboratory occasionally performed KOH testing on dermatologic samples. Further interview confirmed an approved procedure was not available for the KOH test.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and This STANDARD is not met as evidenced by: Based on surveyor observation in the laboratory, review of manufacturer specifications and environmental records, and interview with Testing Personnel (Staff A), the Laboratory Director did not ensure that the environmental conditions of the laboratory were appropriate for use of the Tanner TN50 cryostat, one of two cryostats in use in the laboratory. Findings include: 1. Observation in the laboratory on June 9, 2025, at 12:45 PM revealed two cryostats, both were operating with tissue samples in the freezing chambers. 2. Review of manufacturer's specification for the Tanner TN50 cryostat showed the manufacturer allowed a maximum 60% relative humidity, non-condensing. 3. Review of environmental records in the laboratory showed no evidence the laboratory monitored the relative humidity of the laboratory when personnel used the Tanner TN50 cryostat. 4. Interview with Staff A on June 9, 2025, at 1:50 PM confirmed personnel did not monitor the relative humidity of the laboratory, and that the director had not ensured the laboratory could maintain humidity levels appropriate for the Tanner TN50 operation.