Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0191111	08/19/2025
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Dermatology Associates Ltd	1259 South Cedar Crest Blvd Suite 100, Allentown, PA	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, and interview with the histotechnician, the laboratory failed to monitor and document room temperature and humidity to ensure test system operating conditions were met for instrumentation used when histopathology examinations were performed for 22 of 22 months from 10/06 /2023 to the date of survey. Findings include: 1. On the day of survey, 08/19/2025 during the tour of the laboratory at 12:01 pm, the surveyor discovered the following instrumentation in use: - 2 of 2 Leica 2255 rotary microtomes - 1 of 1 Tissue Tek processor - 1 of 1 Ventana Benchmark Ultra autostainer - 1 of 1 Leica autostainer XL - 1 of 1 Leica CV 5000 cover slipper - 10 of 11 microscopes (s/n 6G0372, s/n 1D77229, s/n 4J04836, s/n 160142, s/n 704966, s/n 702930, s/n 704905, s/n 219364, s /n 86998, s/n 282498). 2. On the day of survey, 08/19/2025, the laboratory failed to provide acceptable criteria and documentation for monitoring room temperatures and humidity to ensure operating conditions were met for the above instrumentation used when histopathology slide examinations were performed for 22 of 22 months from 10

	/06/2023 to 08/19/2025: 3. The laboratory performed 24,652 histopathology slide examinations in 2024 (CMS 116 estimated annual volume, dated 08/19/2025). 4. The histotechnician confirmed the findings above on 08/19/2025 at 12:08 pm.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Histotechnician, the laboratory failed to document a positive and negative control each day of patient testing for Potassium Hydroxide (KOH) and Scabies microscopic examinations performed for 22 of 22 months from 10/06/2023 to the day of survey. Findings include: 1. On the day of survey, 08/19/2025, the laboratory failed to provide documentation of the positive and negative control performed every day of patient testing for KOH and Scabies microscopic examinations performed from 10/06/2023 to 08/19/2025. 2. Review of the laboratory's KOH and Scabies testing procedures revealed the laboratory failed to include quality control instructions for each test. 3. The laboratory performed 922 KOH and 73 Scabies microscopic examinations from 05/17/2023 to 04/10/2025. 4. The Histotechnician confirmed the above findings on 08/19/2025 at 10:38 am.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: A. Based on review of the laboratory's quality control (QC) staining records and interview with the histotechnician, the laboratory failed to check for negative staining reactivity each time of use for immunohistochemical (IHC) stains used for microscopic histopathology slide examinations performed for 22 of 22 months from 10/06/2023 to the day of the survey. Findings Include: 1. On the day of the survey, 08/19/2025 at 10:33 am, review of the laboratory's Daily Stain QC records revealed the laboratory failed to document negative and positive staining reactivity each time of use for IHC stains used for microscopic histopathology slide examinations performed from 10/06/2023 to 08/19/2025. 2. The laboratory performed 5177 histopathology examinations using IHC stains from 10/06/2023 to 08/19/2025. 3. The histotechnician confirmed the findings above on 08/19/2025 at 12:08 pm. B. Based on review of laboratory policy, quality control (QC) staining records and interview with the histotechnician, the laboratory failed to establish and document the laboratory's criteria for intended reactivity to ensure acceptable staining characteristics of special stains used for microscopic histopathology examinations performed for 22 of 22 months from 10/06/2023 to the day of the survey. Findings include: 1. The laboratory's "Policy for Evidence of Daily Review of the Technical Quality of Histological Preparations by Pathologist" states, "The pathologist will initial a quality

	control log for routine Hematoxylin/Eosin (H&E), Special and Immunohistochemical (IHC) stains. If a stain or stains are not acceptable the pathologist will call the derm lab and initiate corrective action protocol." 2. On the day of survey, 08/19/2025 at 10: 33 am, review of the pathologist's Daily Stain QC logs revealed the laboratory failed to establish and document the laboratory's criteria for intended reactivity to ensure acceptable staining characteristics for special stains used when histopathology slides were examined from 10/06/2023 to 08/19/2025. 3. The laboratory performed 1950 histopathology examinations using special stains from 10/06/2023 to 08/19/2025. 4. The histotechnician confirmed the findings above on 08/19/2025 at 12:08 pm.