

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1072929	(X3) Date Survey Completed 07/10/2025
Name of Provider or Supplier Atlantic Dermatopathology Llc	Street Address, City, State 10 Industrial Highway Q3 Suite 1, Lester, 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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the Testing Personnel (TP), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 Olympus BX46 Microscopes used to perform histopathology slide examinations from 09/25 /2023 to the date of survey. Findings include: 1. The operating environment listed in the instruction manual for the Olympus biological microscope states: "microscope should be kept at temperatures between 5C-40C/41F-104F, with a maximum humidity of 80%." 2. On the date of the survey, 07/10/2025 at 09:40 am, the laboratory failed to provide documentation for monitoring room temperatures and humidity to ensure operating conditions were met for 1 of 1 Olympus BX46 microscope used to perform histopathology slide examinations from 009/25/2023 to 07/10/2025. 3. The laboratory performed 16 (CMS-116 estimated annual volume) histopathology slide examinations in 2024. 4. The TP confirmed the findings above on 07/10/2025 at 09:40 am.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p>

(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:

Based on review of quality control (QC) records, lack of documentation and interview with the Testing Personnel (TP), the laboratory failed to document positive and negative stain reactivity each time of use for 2 of 2 immunohistochemical stains (IHC) used for microscopic histopathology examinations from 09/25/2023 to 07/10/2025.

Findings include: 1. On the day of survey 07/10/2025 at 09:40 am, the laboratory failed to provide documentation for positive and negative reactivity each time of use for the following 2 of 2 immunohistochemical stains (IHC) used for microscopic histopathology examinations performed from 09/25/2023 to 07/10/2025: SOX10 MART 2. The laboratory performed 1 case for IHC staining in 2024. 3. The TP confirmed the findings above on 07/10/2025 at 9:40 am.