

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2108423	(X3) Date Survey Completed 08/19/2025
Name of Provider or Supplier Diagnostic Dermatopathology Associates, Llc	Street Address, City, State 2101 Brookstone Centre Parkway, Suite 300, Columbus, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) Recertification Survey was completed on August 19, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D3003	<p>FACILITIES CFR(s): 493.1101(a)(2)</p> <p>(a)(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.</p> <p>This STANDARD is not met as evidenced by: A tour of the laboratory confirmed that the laboratory failed to minimize the risk of cross contamination for patient specimens, equipment, instruments, reagents, materials, and personnel. THE FINDINGS INCLUDE: 1. A tour of the laboratory revealed that a separate clean sink was not available in the clinical laboratory on the date of inspection. 2. A tour of the laboratory revealed that the sink-mounted eyewash station was mounted on the faucet of the dirty sink used for the disposal of biohazard waste. 3. An exit interview, with the LD and the HT, on August 19, 2025, at 11:30am confirmed that the laboratory failed to minimize the risk of cross contamination for patient specimens, equipment, instruments, reagents, materials, and personnel.</p>
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</p>

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:

A review of 2023 - 2025 Temperature and Humidity Records and a tour of the laboratory confirmed that the laboratory personnel failed to monitor the temperature and humidity in the laboratory to ensure that the manufacturers' required operating environment for the equipment were met. THE FINDINGS INCLUDE: 1. A tour of the laboratory revealed that there was no thermometer available to monitor the temperature and the humidity in the testing area. 2. A review of the 2023 - 2025 Temperature and Humidity Records confirmed that there were no logs that documented the room temperature or room humidity levels in the testing area. 3. A review of the Leica Bond-Max Stainer, the Tissue-Tek VIP5A Tissue Processor, the Tissue-Tek TEC Embedding Console, Leica AutoStainer XL Stainer revealed an operating temperature requirement of 10C - 35C (50F - 95F) and an operating humidity requirement of 30% - 80%. 4. An exit interview, with the Laboratory Team, on August 19, 2025, at 11:30am confirmed that laboratory personnel failed to monitor the temperature and humidity in the laboratory to ensure manufacturers' required operating environment for the equipment were met.

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:

A review of 2023 - 2025 Maintenance Records revealed that the required manufacturer maintenance was not documented and/ or not performed for the Nikon Eclipse microscope, Leica Autostainer XL, Tissue-Tek TEC, Airflotronix Air System, and Captive Aire System. THE FINDINGS INCLUDE: 1. A review of the 2023 - 2025 Maintenance Records confirmed that maintenance records for the Nikon Eclipse microscope, Leica Autostainer XL, Tissue-Tek TEC, Airflotronix Air System, and Captive Aire System were not available at the time of survey. 2. A review of the 2023 - 2025 Maintenance Records and equipment during the tour of the laboratory confirmed that the annual preventive maintenance, required by the manufacturers, were not performed for the following analyzers: a. Nikon Eclipse Microscope required annual maintenance was last performed on July 19, 2023. b. Leica Autostainer XL stainer required annual maintenance was last performed on July 19, 2023. c. Tissue-Tek TEC Embedding Console required annual maintenance was last performed on July 19, 2023. d. Tissue-Tek VIP5A Tissue Processor required annual maintenance was last performed on July 19, 2023. e. Captive Aire Air Systems required semiannual maintenance was not performed per interview with the Laboratory Director (LD) and Histology Technician (HT). f. The Airflotronix Air System required annual recertification was not performed per interview with LD and HT. 3. An exit interview, with the LD and HT, on August 19, 2025, at 11:30am confirmed that the manufacturer required maintenance was not documented and/ or not performed for the Nikon Eclipse microscope, Leica Autostainer XL, Tissue-Tek TEC, Airflotronix Air System, and Captive Aire System.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

A review of 2023 - 2025 Maintenance Records, 2023 - 2025 Quality Control Records, 2023 - 2025 Temperature Records, and a tour of the laboratory confirmed that Laboratory Director (LD) failed to provide oversight of the administration of the laboratory operations. Refer to D3003, D5413, D5429, D6020

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

A review of 2023 - 2025 Maintenance Records, 2023 - 2025 Quality Control Records and 2023 - 2025 Temperature Records, confirmed that the Laboratory Director (LD) failed to ensure that the quality control and quality assessment programs were established and maintained to assure the quality of laboratory services provided. THE FINDINGS INCLUDE: 1. A review of the aforementioned 2023 - 2025 records confirmed that the maintenance, quality control, and temperature documentation was not reviewed by the LD to assure the quality services of the laboratory. 2. An exit interview, with the LD and HT, on August 19, 2025, at 11:30am, confirmed that the LD failed to ensure that quality control and quality assessment programs were established and maintained.