

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2063477	(X3) Date Survey Completed 03/20/2025
Name of Provider or Supplier Piedmont Plastic Surgery & Dermatology Dermlab	Street Address, City, State 1072 X-Ray Drive, Gastonia, NC	
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 procedure manual and operating manuals, review of 2022, 2023, 2024, and 2025 laboratory logs, and interview with the Technical Supervisor (TS) on 03/20/2025, the laboratory failed to ensure that the established humidity ranges were within the manufacturer's operating manual requirements from March 2022 to March 2025, a period of approximately 3 years. Findings: Review of "Laboratory Procedure Manual Histology" revealed on page 3, Section II.B.1., "Temperature, cleaning, and maintenance records for laboratory equipment are maintained daily for the laboratory and kept in range for all equipment within the lab according to the manufacturer's instructions." Review of four Operating Manuals revealed relative humidity ranges 30 - 85% (non-condensing): 1. "Tissue-Tek TEC 6 Cryo Module Operating Manual" Section 1.4.2 Specifications. 2. "Tissue-Tek TEC 6 Embedding Module Operating Manual" Section 1.4.2 Specifications. 3. "Tissue-Tek Prisma Plus Automated Slide Stainer Operating Manual" Section 1. Introduction. 4. "Tissue-Tek Film Automated Coverslipper Operating Manual" Section 1.8, Operating Conditions. Review of "Temp/Humidity and Eyewash Monitoring" laboratory logs, revealed "...Humidity Range 20 - 80%..." The laboratory established humidity range 20 - 80% does not meet the requirements listed in four of the manufacturer's operating</p>

manuals 30-85%. Laboratory logs revealed humidity ranges out of range for 212 days from March 23, 2022 to March 20, 2025: 1. 40 days from 03/23/2022 to 12/31/2022 2. 63 days in 2023 3. 62 days in 2024 4. 47 days from 01/01/2025 to 03/20/2025 During interview at approximately 2:13 p.m. TS confirmed the laboratory log humidity ranges do not match the operating manuals.

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:

Based on review of laboratory procedure manual, operating manual and guides, the absence of 2022, 2023, 2024, and 2025 equipment maintenance logs, and interview with the Technical Supervisor (TS) on 03/20/2025, the laboratory failed to document the required daily, weekly, monthly, and quarterly maintenance per operating manuals and guides from March 2022 to March 2025, a period of approximately three years. Findings: Review of "Laboratory Procedure Manual Histology" revealed on page 3, section II.B.1, "Temperature, cleaning, and maintenance records for laboratory equipment are maintained daily for the laboratory...according to the manufacturer's instructions..." Review of "Tissue-Tek TEC 6 Embedding Module Operating Manual" revealed on page 2, Chapter 5.2.2, "...Maintenance Action...Frequency...Clean the tissue tray after every use...Clean the paraffin drain tray and waste tray liner after every use..." Review of "Excelsior AS Tissue Processor Operator Guide" revealed on page 115, Chapter 5, "Daily and Weekly Cleaning Tasks...must be performed on a daily and weekly basis." Review of "Excelsior ES Reagent Management A1 Quality Rotation guide" revealed on page 62, Chapter 5.3, "Perform the following checks and maintenance at the intervals specified...Daily...Weekly...Monthly...Quarterly..." The absence of maintenance logs for 2022, 2023, 2024 and 2025 revealed no documentation of the performance of daily, weekly, monthly, or quarterly requirements per operating manuals and guides from 03/22/2022 to 03/20/2025. Interview with TS at approximately 3:00 p.m. confirmed no equipment maintenance logs available for review.