

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2109579	(X3) Date Survey Completed 04/03/2024
Name of Provider or Supplier Carlisle Dermatology Group Llc	Street Address, City, State 41 Eastgate Drive, Carlisle, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the clinical manager (CM), the laboratory failed to ensure that reagents and supplies used for macroscopic dermatopathology examinations were not used beyond the expiration dates from 12/31/2023 to the date of the survey. Findings Include: 1. On the date of the survey, 04/03/2024 at 12:10 pm, a laboratory tour revealed the following reagent used for macroscopic dermatopathology examinations from 12/31/2023 to 04/03/2024 was expired: - 1 of 1 Tissue Marking Dye-Green CR2056 GN- Lot 138465, Expiration Date 12/31/2023. 2. The CM confirmed the findings above on 04/03/2024 at 12:30 pm.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the clinical manager (CM), the laboratory failed to perform and document maintenance on 1 of 1 thermometer used to ensure proper working conditions were maintained when macroscopic</p>

dermatopathology examinations were performed from 08/01/2023 to the day of the survey. Findings Include: 1. On 04/03/2024, at 12:15 pm, an observation of the laboratory revealed that 1 of 1 Thermo Scientific (S/N 150253534) thermometer used to monitor room temperature (RT) and humidity to maintain proper working condition for 2 of 2 Avantik QS 12 cryostats was expired on 11/27/2017. 2. According to Avantik QS 12 Cryostat manufacturer's instructions the environmental operating temperature should be between 5C to 35C and the humidity should be less than 60%. 3. The laboratory performed 1,797 dermatopathology examinations in 2023 (CMS 116 annual test volume) 4. The CM confirmed the findings above on 04/03/2024 at 12:30 pm.