

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1028878	(X3) Date Survey Completed 03/15/2023
Name of Provider or Supplier Academic Dermatology & Cosmetic Surgery Center	Street Address, City, State 51189 Shelby Pkwy, Shelby Township, MI	
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
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:</p> <p>. Based on observation, lack of documentation, and interview with the Office Manager and a staff member, the laboratory failed to perform and document the thermometer calibration checks as required by the manufacturer before the expiration for 2 (Digi-Sense) of 2 thermometers in use. Findings include: 1. During a tour of the laboratory on 3/15/2023 at 9:17 am, the surveyor observed a thermometer in the histopathology processing laboratory and another by the microscope in the Laboratory Director's office in use past their expiration dates as follows: a. histopathology lab - S/N 192161185 expired 5/07/2021. b. Laboratory Directors office - S/N 192161221 expired 5/07/2021. 2. A record review of the procedure manual revealed no maintenance procedure for the frequency of thermometer calibrations and/or replacement prior to expiration dates noted on the thermometer. 3. A record reviewed revealed a lack of documentation for the calibration of the 2 thermometers and/or replacement by the expiration dates noted on the serial tags. 4. A interview on 3/15 /2023 at 9:28 am, the Office Manager and a staff member confirmed the 2 thermometers were not calibrated and/or replaced before their expiration.</p>