

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2180540	(X3) Date Survey Completed 03/16/2021
Name of Provider or Supplier Dermatopathology Associates	Street Address, City, State 119 14th St Nw, Suite 230, New Brighton, MN	
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
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review and interview with laboratory personnel, the laboratory failed to establish and follow a procedure for function checks of general laboratory equipment. Findings are as follows: 1. A tour of the laboratory on 3/16/21, at 9:05 a.m., revealed the presence of a Frigidaire Refrigerator / Freezer, with a Taylor Analog Alcohol Thermometer, Model 5925 (no serial number) located in the refrigerated compartment. 2. In an interview on 3/16/21, at 9:15 a.m., Testing Personnel 3 (TP3) indicated that the refrigerator was used for storage of Immunohistochemical (IHC) special stains. 3. The Equipment procedure, located in the Quality manual, did not include instructions for assuring the accuracy of this thermometer on a periodic basis. 4. Function check records from 2020 and 2021 for the thermometer noted above could not be located in the laboratory's files. The laboratory was unable to provide the missing procedure or records upon request. 5. In an interview on 3/16/20, at 10:20 a.m., TP3 confirmed the above findings. .</p>