

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2059976	(X3) Date Survey Completed 12/28/2020
Name of Provider or Supplier M Health Fairview Dermatology Bloomington	Street Address, City, State 600 W 98th St E Ste 315, Bloomington, 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, interview, and email communications 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 12/28/20, at 8:05 a.m., revealed the presence of a Panasonic Refrigerator (Serial Number = 130100097), with an integrated digital temperature display. 2. In an interview on 12/28/20, at 8:15 a.m., the histotechnician (HT) stated that the refrigerator was used to store MART-1 immunohistochemical stains. 3. The Equipment Checks and Maintenance Policy procedure, located in the Lab Manual, did not include instructions for assuring the accuracy of the refrigerator temperature display on a periodic basis. 4. Function check records for the refrigerator temperature display from 2018, 2019, and 2020 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 12/28/20, at 8:45 a.m., the HT stated that the refrigerator had been previously equipped with a NIST* traceable thermometer unit, which could not be located on the day of the survey. 6. In an email on 12/30/20, the HT confirmed that calibration records for the refrigerator digital temperature display could not be located. In an email on 1/4/21, the HT stated that it could not be determined when, or by whom, the NIST traceable thermometer unit had been removed from the refrigerator. * NIST = National Institute of Standards and Technology .</p>