

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2043116	(X3) Date Survey Completed 10/08/2018
Name of Provider or Supplier University Of Minnesota Genomics Center	Street Address, City, State 1-210 Ccrb 2231 6th St Se, Minneapolis, 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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on observation, document review and interview with laboratory personnel, the laboratory failed to establish a function check procedure and maintain function check records for all laboratory equipment. Findings are as follows: The laboratory performed Molecular Diagnostics testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/8/18 at 9:35 a.m. A. Refrigerator and Freezer 1. A Frigedaire refrigerator (S/N = FFRU17B2qw) and a Frigedaire freezer (S/N = FFFh20F2qW) were observed as present and available for use during a tour of the laboratory. 2. Fisher Brand In-outdoor digital electronic temperature monitors were observed as attached to each of the refrigerator and freezer to display internal temperatures. A monitor unit serial number and manufacturer calibration expiration date label was not affixed to either unit. 3. The laboratory was unable to provide a function check procedure or calibration records for the above equipment upon request. 4. In an interview on 10/8/18 at 10:50 a.m., GS confirmed that the above findings B. Timers 1. The following digital timers were observed as present and available for use during a tour of the laboratory.: Fisher Scientific Color = Black Unit serial number = Illegible Manufacturer Calibration Expiration Date = 10/19/11 Fisher Scientific Traceable Color = White Unit serial number = 160570811 Manufacturer Calibration</p>

Expiration Date = 7/16/15 3. The laboratory was unable to provide a function check procedure or calibration records for the above equipment upon request. 4. In an interview on 10/8/18, at 10:50 a.m., GS confirmed that the above findings