

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0399264	(X3) Date Survey Completed 07/19/2022
Name of Provider or Supplier La Clinica (Mcc) Rrl - Quest Diagnostics	Street Address, City, State 153 Cesar Chavez St, Saint Paul, 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: . Based on observation and interview with laboratory personnel, the laboratory failed to perform and document function checks for 1 of 2 centrifuges in 2021. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory on 07/13/22, at 1:00 p.m. 2. A Horizon centrifuge was observed as present and available for use in the laboratory during the tour. 3. The laboratory's Centrifuge Maintenance procedure, found in the policy software SmartSolve, indicated the centrifuge tachometer and timer functions were verified annually. 4. Documentation of 2021 laboratory centrifuge function check was not found during review of laboratory records. 5. During an interview at 4:45 p.m. on 07/13/22, the LD confirmed the above finding. The laboratory was give five business days to provide the function check documentation. 6. In an email received at 4:06 p.m. on 07/19/22, the LD indicated the 2021 laboratory centrifuge function check records were not found.</p>