

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0399264	(X3) Date Survey Completed 05/30/2024
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
D0000	The La Clinica (MCC) RLL - Quest Diagnostics laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on May 30, 2024. The following standard-level deficiencies were cited: 493.1254 Maintenance and function checks .
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, record review, and interview with laboratory personnel, the laboratory failed to take corrective action when a centrifuge function check failed for one of two centrifuges in use in 2023. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 10:05 a.m. on 05/30/24. 2. A Horizon 642E centrifuge was observed as present and available for use during the tour. 3. The Horizon 642E centrifuge failed the 11/16/23 function check as indicated in the Excel spreadsheet documentation for the task. See below. Spreadsheet documentation did not include corrective actions for the failure or indicate the centrifuge was removed from service. 11/16/23 Horizon 642E 220113HF323 Tachometer reading 3343 Centrifuge reading 3492 Acceptable range 3392-3592 4. The laboratory's Policy for Centrifuge</p>

Maintenance and Function Checks procedure, found in the policy software SmartSolve, indicated removal from service and corrective action was required when centrifuge function check verification failed to meet performance requirements. 5. In an interview at 1:40 p.m. on 05/30/24, the LD confirmed the above finding.