

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0399264	<b>(X3) Date Survey Completed</b>  03/03/2021
<b>Name of Provider or Supplier</b>  La Clinica (Mcc) Rrl - Quest Diagnostics	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5447</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure quality control (QC) was performed each day of Chemistry patient specimen testing. Findings are as follows: 1. The laboratory performed Chemistry testing as indicated on the Clinical Laboratory Improvement Amendment (CLIA) Application for Certification Form CMS-116, and confirmed by the Laboratory Director (LD) during a tour of the laboratory on 03/03/21, at 9:05 a.m. 2. External QC performance for a Chemistry 8 profile and Troponin were established in the Chem 8+ Cartridge on the Abbott i-STAT, and Cardiac Troponin I on the Abbott i-STAT procedures, both found in the on-line Procedure Manual. 3. Laboratory records revealed that external QC was performed every 30 days, with each new shipment, and each new lot number of reagents, as defined in the test method procedures noted. 4. Individualized Quality Control Plans (IQCP) for Chemistry 8 profile and Troponin, each on the Abbott i-STAT, were not found in laboratory records. The laboratory was unable to provide the IQCP's for either upon request. 5. In an interview on 03/03/21, at 11:15 a.m., the LD confirmed the above findings. .</p>