

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2188290	(X3) Date Survey Completed 07/22/2021
Name of Provider or Supplier Quest Diagnostics - Milwaukee Rrl	Street Address, City, State 4852 S 6th St, Milwaukee, WI	
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
D6070	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1)</p> <p>Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and calibration records and interview with the laboratory director, testing personnel did not follow the laboratory's procedure for calibration verification on the Sysmex XN550 hematology analyzer. Findings include: 1. Review of the "Sysmex XNL-Series Operation for CBC" procedure revealed calibration verification was required every six months. Further review revealed, "Daily data provided by the BeyondCare Quality Monitoring (BCQM) program does not currently replace the 6-month requirement but is used as an additional tool to assess instrument performance." 2. Review of the Sysmex XN550 hematology analyzer's calibration records showed no documentation of six month calibration verification after August 2020. 3. Interview with the laboratory director on July 22, 2021 at 1:00 PM confirmed the testing personnel did not follow the laboratory's procedures for calibration verification on the Sysmex XN 550 hematology analyzer.</p>