

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0972445	(X3) Date Survey Completed 12/13/2023
Name of Provider or Supplier Grace Medical Clinics, Pa	Street Address, City, State 2317 Concord Lake Road, Concord, NC	
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
D6040	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)</p> <p>The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Based upon the review of verification records and interview with the TC (Technical Consultant) on 12/13/23, the TC failed to verify the performance characteristics of the Medonic hematology analyzer implemented in the laboratory in November of 2023. Findings: Review of verification records for the Medonic Hematology analyzer revealed the performance of a calibration and one run of external quality controls prior to patient testing. There was no documentation of a study to verify the accuracy, precision and reportable range of the instrument at this laboratory. In interview at approximately 10:45 a.m., the TC confirmed that prior to patient testing, he calibrated the instrument and ran external quality controls. The TC also stated that the analyzer was previously in use at a different laboratory and the verifications that were performed at the other laboratory have been retained.</p>