

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D1063889	(X3) Date Survey Completed 05/24/2023
Name of Provider or Supplier Middle Creek Medical Center	Street Address, City, State 4810 Bell Hill Road, Bessemer, AL	
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
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the Hematology quality control (QC) records for the Sysmex XP-300, the patient results log, and an interview with Testing Personnel #15, the laboratory failed to ensure at least two levels of quality control were run and acceptable prior to analyzing patient specimens and reporting the results. This was noted one day out of six months reviewed from September 2021 through April 2023. The findings include: 1. A review of the QC records for the Sysmex Hematology analyzer revealed on 09/14/2021 a) Low control was acceptable. b) Normal and High controls were unacceptable for Platelets. 2. A review of the cumulative patient log printed from the instrument revealed 12 patient CBC's (Complete Blood Counts) were performed on 09/14/2021. 3. During an interview on May 24th, 2023 at 1:00 PM, Testing Personnel #15 confirmed QC was outside acceptable ranges for the Normal and High controls on 09/14/2021.</p>