

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0859137	(X3) Date Survey Completed 04/18/2022
Name of Provider or Supplier Galen Medical Group Laboratory Pc	Street Address, City, State 4976 Alpha Lane, Hixson, TN	
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:</p> <p>===== Based on review of patient test audit for 10/5/2021 for ABO Type and Antibody Screen (Type and Screen), review of ABO Rh Blood Grouping MTS Gel Method policy, Antibody Screen/Indirect Antiglobulin Test (IAT): Ortho MTS-IgG Gel System policy and interview with the technical consultant, determined the laboratory failed to meet acceptable quality control guidelines prior to testing a total of 10 patients. The findings include: 1. A patient test audit for Type and Screen results on 10/5/2021 revealed lack of two levels of acceptable control materials prior to testing patients. 2. A review of the laboratory's ABO RH Blood Grouping MTS Gel Method policy stated, "Quality Control: Reagents are checked each day of use for expected positive and negative reactions using appropriate test cells." 3. A review of the laboratory's Antibody Screen/Indirect Antiglobulin Test (IAT): Ortho MTS-IgG Gel System policy stated, "Quality Control: To recognize reagent deterioration and to confirm reagent specificity/reactivity, reagents must be inspected and tested daily with appropriate controls and recorded in the computer." 4. An interview at approximately 12:30 p.m. April 18, 2022 with the technical consultant confirmed that no Type and Screen control materials were documented on 10/5/2021 with 10 patient Type and Screens tested and reported that day. =====</p>