

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0384085	<b>(X3) Date Survey Completed</b>  03/23/2022
<b>Name of Provider or Supplier</b>  Franklin General Hospital	<b>Street Address, City, State</b>  1720 Central Avenue East, Hampton, IA	
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>D5449</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of immunohematology quality control records, Micro Typing Systems (MTS) instructions for use and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 3/23 /2022, the laboratory failed to perform a negative control material each day of patient testing for one patient who had ABO group and D (Rho) typing performed on 11/11 /2021. The findings include: 1. Patient identifier A had ABO group and D (Rho) typing performed on 11/11/2021. The laboratory used the MTS A/B/D Monoclonal and Reverse Grouping Card to perform the ABO group and D (Rho) typing. 2. The MTS A/B/D Monoclonal and Reverse Grouping Card instructions for use state, "To confirm the reactivity and specificity of the microtubes containing Anti-A and Anti-B, it is recommended that each lot of cards be tested each day of use with antigen positive and antigen negative red blood cells." 3. Laboratory personnel identifier #1 confirmed the laboratory routinely performed a positive control on the the MTS A/B /D Monoclonal and Reverse Grouping card each day of patient testing, but not a negative control. 4. The laboratory did not perform a negative control for ABO group and D (Rho) typing on 11/11/2021.</p>