

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0382831	(X3) Date Survey Completed 10/29/2020
Name of Provider or Supplier Greene County Medical Center	Street Address, City, State 1000 W Lincoln Way, Jefferson, IA	
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
D5026	<p>IMMUNOHEMATOLOGY CFR(s): 493.1217</p> <p>If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1271, and 493.1281 through 493.1299.</p> <p>This CONDITION 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 11:50 am on 10/29/20, the laboratory failed to perform a negative control material each day of patient testing as specified in D5449.</p>
D5449	<p>CONTROL PROCEDURES 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 11:50 am on 10/29/20, the laboratory failed to perform a negative control material each day of patient testing for one patient who had ABO group, D (Rho) typing and unexpected antibody</p>

detection testing performed on 3/7/2020. The findings include: 1. Patient identifier A had ABO group, D (Rho) typing and unexpected antibody detection testing performed on 3/7/2020. The laboratory used the MTS A/B/D Monoclonal and Reverse Grouping Card to perform the ABO group and D (Rho) typing, and the MTS Anti-IgG card to perform the unexpected antibody detection testing. 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. The MTS Anti-IgG Card instructions for use state, "To confirm the specificity and reactivity of the MTS Anti-IgG card, it is recommended that each lot be tested each day of use with known positive and negative antibody samples with the appropriate red blood cells." 4. Laboratory personnel identifier #1 confirmed the laboratory routinely performed a positive control on the the MTS A/B/D Monoclonal and Reverse Grouping card and on the MTS Anti-IgG card each day of patient testing, but not a negative control.