

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0385140	(X3) Date Survey Completed 01/28/2021
Name of Provider or Supplier Orange City Municipal Hospital	Street Address, City, State 1000 Lincoln Circle Se, Orange City, 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
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 (QC) records and confirmed by laboratory personnel #1 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 1/28/2021, the laboratory failed to perform negative QC on one out of one day of ABO group patient testing on 8/7/2020. The findings include: 1. On 8/7/2020, the laboratory perform ABO group testing on four patients. 2. QC records indicated the laboratory performed a positive control on Reagent Anti-A (Lot number 101935, expiration date 12/20/20) and on Reagent Anti-B (Lot number 203810, expiration date 5/9/21) on 8/7/2020. 3. At the time of the survey, the laboratory did not have records of a negative control being performed on Reagent Anti-A and Anti-B.</p>