

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0385441	(X3) Date Survey Completed 02/10/2023
Name of Provider or Supplier Osceola Regional Health Center	Street Address, City, State 600 9th Avenue North, Sibley, 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 Ortho MTS ID-Micro Typing System instructions for use and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 9:00 am on 2/10/2023, the laboratory failed to perform a negative control on three MTS gel cards used to perform ABO, D (Rho) typing and unexpected antibody screen testing on one out of one patient performed on 11/21/2022. The findings include: 1. On 11/21/2022, the laboratory used the A/B/D monoclonal and reverse grouping gel card (lot number 050622037-12, expiration date 2/20/23) to perform patient ABO and D(Rho) typing on patient identifier #1. 2. On 11/21/2022, the laboratory used A/B/D monoclonal grouping gel card (lot number 062022053-02, expiration date 4/18/23) to perform donor unit ABO and D(Rho) typing confirmation. 3. On 11/21/2022, the laboratory used Anti-IgG (Rabbit) gel card (lot number 101822001-05, expiration date 7/25/23) to perform unexpected antibody identification testing on patient identifier #1. 4. The Ortho MTS ID-Micro Typing System instructions for use for each of the gel cards state that a positive and negative control must be testing each day of use. 5. On 11/21/2022, the laboratory did not perform a negative control for the above listed gel cards.</p>