

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0384982	<b>(X3) Date Survey Completed</b>  11/11/2020
<b>Name of Provider or Supplier</b>  Chi Health Mercy Corning	<b>Street Address, City, State</b>  603 Rosary Drive, Corning, 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>D5026</b>	<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, patient immunohematology records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 11/11/20, the laboratory failed to perform a negative control material each day of patient testing as specified in D5449 and failed to meet immunohematology requirements for ensuring the laboratory performs compatibility testing following 21 CFR 606.151(a) through (e) as specified in D5551.</p>
<b>D5445</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on lack of Individualized Quality Control Plan (IQCP) records, review of quality control (QC) records, and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 9:45 am on 11/11/2020, the laboratory failed to perform a positive and negative control each day of patient testing for the following test systems: Cardinal Health serum human chorionic gonadotropin (hCG), BioRad ToxSee urine drug of abuse screen, and Cardinal Mono II serum infectious mononucleosis. The findings include: 1. The laboratory performed external controls monthly and with each new lot/shipment for the Cardinal Health hCG, BioRad ToxSee urine drug of abuse screen, and Cardinal Mono II serum infectious mononucleosis test system. 2. Laboratory personnel identifier #1 indicated that the laboratory intended to follow manufacturer's instructions for performing QC. 3. At the time of the survey, the laboratory's IQCP only included a risk assessment. The IQCP did not include a quality control plan, quality assessment plan or historical data for the Cardinal Health hCG, BioRad ToxSee urine drug of abuse screen, and Cardinal Mono II serum infectious mononucleosis test system.

**D5449**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(ii)(g)

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.

This STANDARD is not met as evidenced by:  
Based on review of immunohematology quality control and patient records, Micro Typing Systems (MTS) instructions for use and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 11/11/20, the laboratory failed to perform a negative control material each day of patient testing for six out of six days in May of 2020. The findings include: 1. The laboratory performed ABO group, D (Rho) typing and unexpected antibody detection testing on the following dates: \*5/2/2020 - one patient \*5/9/2020 - two patients \*5/11/2020 - one patient \*5/12/2020 - one patient \*5/14/2020 - one patient \*5/24/2020 - one patient 2. 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. 3. 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." 4. 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." 5. 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. 6. At the time of the survey, the laboratory did not have negative control records for the above dates of patient testing.

**D5551**

**IMMUNOHEMATOLOGY**  
CFR(s): 493.1271(a)(f)

(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of the MTS instructions for use, the Type and Crossmatch policy, patient comparability records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 11/11/2020, the laboratory failed to perform compatibility testing using procedures that demonstrate incompatibility between the donor's cell type and the recipient's serum or plasma type for two out of four patients (Patient identifiers A and B) performed in May of 2020. The findings include: 1. Patient identifier A had compatibility testing performed on two units of packed red blood cells on 5/9/2020. 2. Patient identifier B had compatibility testing performed on one unit of packed red blood cells on 5/9/2020. 3. The manufacturer's package insert for the MTS Anti-Human Globulin Anti-IgG gel cards stated, "IH-Card Anti-IgG consists of six microtubes containing a gel impregnated with rabbit polyclonal antihuman globulin AHG IgG that does not contain antibodies to complement components. The Anti-IgG is light chain specific (sera from hyperimmunised rabbits) and thus may also agglutinate IgA or IgM antibodies." 4. The Type and Crossmatch policy states, "An immediate spin crossmatch and AHG crossmatch should be completed on all units given." 3. The laboratory only performed AHG compatibility testing using MTS Anti-Human Globulin Anti-IgG gel cards on both patients. 4. The laboratory did not perform an immediate spin crossmatch on either patient. 5. At the time of the survey, the laboratory did not perform compatibility testing using a method that specifically demonstrated incompatibility for IgM antibodies between the donor's cell type and the recipient's serum or plasma.