Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384720	08/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Community Memorial Hospital	909 West First Street, Sumner, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of proficiency testing records and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 08/08/2018, the laboratory failed to enroll in an approved proficiency testing program for the analytes: blood gas pH, blood gas partial pressure of oxygen (PO2), and blood gas carbon dioxide partial pressure (PCO2). The laboratory did not enroll in an approved proficiency testing program for 2018.
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 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. This CONDITION is not met as evidenced by: Based on review of patient compatibility records, the MTS Anti-Human Globulin

	Anti-IgG manufacturer's package insert, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 3:00 pm on 08/08/2018, the laboratory failed to meet immunohematology requirements for ensuring the laboratory performs compatibility testing following 21 CFR 606.151(a) through (e) as specified in D5551.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report) at approximately 10: 50 am on 08/08/2018, the laboratory failed to perform a self evaluation when it received a score of zero for one out of six testing events (2017 event 1) in 2016 and 2017. The findings include: 1. For 2017 testing event 1, the laboratory received a score of zero for failure to submit the PT results before the submission deadline for the following analytes: blood gas pH, blood gas partial pressure of oxygen (PO2), and blood gas carbon dioxide partial pressure (PCO2). 2. At the time of the survey, the laboratory did not have records indicating it had performed a self-evaluation for the failed PT scores.
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 patient compatibility records, the MTS Anti-Human Globulin Anti-IgG manufacturer's package insert, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 3:00 pm on 08/08/2018, 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 seven out of seven units of blood having compatibility testing performed from 02/06/2018- 02/19/2018. The findings include: 1. The laboratory performed compatibility testing on the following dates: *02/06/2018- two units of blood *02/09/2018- three units of blood *02/19/2018- two units of blood 2.

	The laboratory performed the compatibility testing using MTS Anti-Human Globulin Anti-IgG gel cards. 4. The "Limitations of the Procedure" section of the manufacturer's package insert for the MTS Anti-Human Globulin Anti-IgG gel cards stated, "There is the potential for IgM antibodies to react in this test. Some patient antibodies that are IgM in nature may react with corresponding antigens in the upper portion of the microtube and be trapped in the top portion of the gel at the time of centrifugation resulting in a positive reaction." 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 from 02/06/2018- 02/19/2018.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) reports from 2016 and 2017 and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 08/08/2018, the laboratory director failed to ensure the review of PT reports by the appropriate staff for four out of six testing events (2016 events 2 and 2; 2017 events 2 and 3) in 2016 and 2017. The findings include: 1. Review of PT reports revealed that the laboratory director did not document review and evaluation of the laboratory's performance with a signature and date. 2. Laboratory personnel identifier #6 confirmed that the laboratory director did not review and sign the PT reports for 2016 testing events 2 and 3 and 2017 testing events 2 and 3.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #6 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 08/08/2018, the technical consultant failed to assess and document the competency of individuals performing moderate complexity testing (arterial blood gases) at least annually for three out of three testing personnel (laboratory personnel identifiers #6, #7, and #8) in 2017. THIS IS A REPEAT DEFICIENCY FROM THE SURVEY PERFORMED ON 07/13/2016.