Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0386618	06/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Compass Memorial Healthcare	300 West May Street, Marengo, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), at approximately 10:00 am on 6/20/2018; the laboratory director failed to attest to the routine integration of PT samples into the patient workload for four out of five proficiency testing events (2017 events 1, 2, and 3 and 2018 event 1) from 1/1/2017 - 6/20/2018. The findings include: 1. For 2017 testing event 1, the laboratory director did not sign the bacteriology attestation statement. 2. For 2017 testing event 2, the laboratory director did not sign the non-chemistry, chemistry, and bacteriology attestation statements. 3. For 2017 testing event 3, the laboratory director did not sign the bacteriology attestation statement. 4. For 2018 testing event 1, the laboratory director did not sign the non-chemistry and chemistry attestation statements.
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 Ortho Anti-Human Globulin

	Anti-IgG manufacturer's package insert, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12:30 pm on 6/20/2018; 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.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the Ortho immunohematology performance specification records, immunohematology procedures and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 6/20/18, the laboratory failed to establish a function check policy for the Ortho immunohematology dispenser, including the frequency for performing volume checks. The laboratory also failed to perform a volume check on the Ortho dispenser from 3/1/2017 - 6/20/2018. The findings include: 1. The laboratory implemented the Ortho immunohematology test system to perform unexpected antibody detection and compatibility testing in March 2017. 2. The laboratory used the Ortho dispenser to deliver specific volumes of diluent when performing immunohematology procedures. 2. At the time of the survey, the laboratory did not have a policy for performing volume checks on the Ortho dispenser. In addition, the laboratory had not performed a volume check on the dispenser since its implementation.
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 Ortho Anti-Human Globulin Anti-IgG manufacturer's package insert, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12:30 pm on

	6/20/2018, 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 two out of two patients (Patient identifiers A and B) performed in March 2018. The findings include: 1. Patient identifier A had compatibility testing performed on four units of packed red blood cells on 3/18/2018. 2. Patient identifier B had compatibility testing performed on two units of packed red blood cells on 3/26 /2018. 3. The laboratory performed the compatibility testing on both patients using Ortho Anti-Human Globulin Anti-IgG gel cards. 4. The manufacturer's package insert for the Ortho 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." 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.