Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384694	09/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
Mercyone Oelwein Medical Center	201 Eighth Avenue Se, Oelwein, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the Laboratory Test List and Annual Volume form, review of proficiency testing (PT) records and confirmed by laboratory personnel identifiers #1 and #2 (refer to the Laboratory Personnel Report) at 9:42 am on 9/26/2023, the laboratory failed to twice annually verify the accuracy for the analyte, qualitative serum human chorionic gonadotropin (hCG) for three out of three time periods from 1 /1/2022 - 9/26/2023. The findings include: 1. The Laboratory Test List and Annual Volume form stated the laboratory performed 85 qualitative serum hCG tests annually. 2. The laboratory did not enroll in PT for qualitative serum hCG testing. 3. At the time of the survey, the laboratory did not have any additional records that the laboratory verified the accuracy twice annually for serum hCG testing.
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 blood bank procedures, lack of blood bank centrifuge function check records and confirmed by laboratory personnel identifiers #1 and #2 (refer to the Laboratory Personnel Report) at approximately 12:30 pm on 9/26/2023, the laboratory failed to define the frequency for performing the optimum spin time function check on the blood bank centrifuge. In addition, the laboratory failed to perform the optimum spin time function check on the blood bank centrifuge from 1/1 /2022 - 9/26/2023.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration and calibration verification records and the Dimension Hemoglobin A1C assay instructions for use, and confirmed by laboratory personnel identifiers #1 and #2 (refer to the Laboratory Personnel Report) at 10:20 am on 9/26 /2023, the laboratory failed to perform calibration verification procedures every six months for three out of three time periods for the analyte, hemoglobin A1C from 1/1 /2022 - 9/26/2023. The findings include: 1. The laboratory performed calibrations on the hemoglobin A1C reagent every 30 days as per the Dimension Hemoglobin A1C assay instructions for use. 2. The hemoglobin portion of the calibration used 2 calibrators and the hemoglobin A1C portion of the calibration used 5 calibrators. 3. At the time of the survey, the laboratory did not perform calibration verification procedures which included a minimal (zero) value, a mid-point value and maximum value for the analyte, hemoglobin A1C.