Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384673	06/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mercyone New Hampton Medical Center	308 North Maple Avenue, New Hampton, 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
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of coagulation reagent studies, observations of the coagulation analyzer and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 06/22/2022, the laboratory fails to meet the hematology (coagulation) requirements for test system/equipment/reagent verification as specified in the standard D5411.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observations made during the survey, review of coagulation reagent studies, and confirmed by laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at approximately 10:00 am on 06/22/2022, the laboratory failed to enter the correct normal patient mean into the coagulation analyzer; perform patient poor plasma studies; and verify the manual calculation of the international normalized ratio (INR) for lot number N0320573, expiration date 2024-03 of prothrombin time

	reagent. The findings include: 1. The laboratory started using lot number N0320573, expiration date 2024-03 of prothrombin time reagent on 6/1/2022. 2. The laboratory established a normal patient mean of 10.7 seconds for lot number N0320573, expiration date 2024-03 of prothrombin time reagent. 3. Observations made the day of the survey, indicated the laboratory programmed the normal patient mean of 11.8 seconds into the coagulations analyzer. 4. At the time of the survey, the laboratory did not have documentation of platelet poor plasma studies or a manual check of the INR.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: A. Based on review of the Sysmex hematology procedure and calibration records and interview with laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at approximately 9:45 am on 06/22/2022, the laboratory failed to calibrate the hematology analyzer according to the manufacturer's instructions for three out of four time periods from 1/1/2021 - 6/22/2022. The findings include: 1. The Sysmex hematology procedure states that the hematology analyzer will be calibrated every six months according to manufacturer's instructions. 2. The laboratory calibrated the Sysmex hematology analyzer on 5/12/2021. 3. At the time of the survey, the laboratory did not have records indicating that calibrations had been performed any other time between 1/1/2021 - 6/22/2022. B. Based on review of the Cepheid bacteriology analyzer operator's manual, lack of calibration records and interview with laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 6/22/2022, the laboratory failed to calibrate the Cepheid bacteriology analyzer annually in 2021. The findings include: 1. The Cepheid operator's manual stated the analyzer must be calibration annually. 2. At the time of the survey, the laboratory did not have calibration records from 2021.
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 individualized quality control plans (IQCP), quality control (QC)

	records and confirmed by laboratory personnel identifier #2 (refer to Laboratory Personnel Report) at approximately 2:30 pm on 06/22/2022, the laboratory failed to perform a negative and positive control for one out of one lot number of Cryptosporidium and Giardia test kits in March 2022. The findings include: 1. On 3/9 /2022 the laboratory performed cryptosporidium and giardia testing using lot number 0921033, expiration date 2/1/2023 of test kit. 2. The IQCP for the Cryptosporidium and Giardia test kit stated QC would be performed with each lot and or shipment of test kits. 3. At the time of the survey, the laboratory did not have QC records for lot number 0921033, expiration date 2/1/2023 of Cryptosporidium and Giardia test kit.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifiers #1 and #2 (refer to the Laboratory Personnel Report) at approximately 8:30 am on 06/22/2022, the technical supervisor failed to assess and document the complete competency of individuals performing high complexity testing at least annually for four out of eight testing personnel in 2021. The 2021 annual competencies for testing personnel #2 - #5 did include each test system.