Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384673	09/10/2020
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's immunohematology procedures and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 12:30 pm on 09/10/2020, the laboratory failed to have a written procedure defining the criteria for when it is appropriate for the laboratory to perform an electronic crossmatch.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of performance specification records and confirmed by Laboratory Personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 3:00 pm on 09/10/2020, the laboratory failed to verify the performance specifications of accuracy and precision for the Cardinal Human Chorionic Gonadotropin (HCG) serum qualitative test system. The findings include: 1. The laboratory began using the Cardinal HCG serum qualitative test system in July 2018. 2. At the time of the survey, the laboratory did not have performance specification records for this test system.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 laboratory's blood bank alarm check policy, blood bank temperature records and charts, and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 12:30 pm on 09/10/2020, the laboratory failed to document the high and low activation temperatures and nurse response notes as part of the alarm system inspection for three out of three time periods from 01/01/2020 to 08/31/2020. The findings include: 1. The laboratory's policy stated that the blood bank alarm system would be checked on a quarterly basis. It also stated that the high and low activation temperatures would be documented as well as the time at which the nursing station responded to the alarm. 2. Review of the blood bank refrigerator recorder chart wheels indicated that alarm checks were performed 01/2020, 04/2020, and 08/2020. 3. The recording chart wheels did not indicate at what temperature the high and low alarm activation occurred nor at what time the nursing station responded to the alarm. 4. At the time of the survey, the laboratory did not have additional blood bank alarm check records.
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 #5 (refer to the Laboratory Personnel Report) at approximately 9:30 am on 09/10/2020, the technical consultant failed to assess and document the competency of individuals performing moderate complexity testing at least annually for three out of five testing personnel (laboratory personnel identifiers #16- #18) in 2019. The findings include: 1. Personnel identifier #5 stated that personnel identifiers #8, #9, #16, #17, and #18 perform urine sediment examinations, potassium hydroxide (KOH) preparations, and wet mount examinations in the clinic laboratory attached to the hospital. 2. At the time of the survey, the laboratory did not have 2019 annual competency evaluations for personnel identifiers #16- #18.
D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of testing personnel records, lack of performance specification records, and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 3:00 pm on 09/10/2020, the technical consultant failed to document training for the Cardinal Human Chorionic Gonadotropin (HCG) serum qualitative test system prior to reporting patient test results for eight out of eight testing personnel (laboratory personnel identifiers #5- #12). The findings include: 1. The laboratory began using the Cardinal HCG serum qualitative test system in July 2018. 2. At the time of the survey, the laboratory did not have training records for testing personnel identifiers #5- #12.