Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384673	07/25/2024
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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient test records, the laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 1:30 pm on 07/25 /2024, the laboratory failed to perform a positive and negative control with each new lot of Giardia/Cryptosporidium Quik Chek test kits for one out of one lot number (lot 062325, expiration 07/01/2024) used in February 2024. The findings include: 1. Patient A had Giardia/Cryptosporidium testing performed on 02/17/2024. 2. Review of the laboratory's IQCP indicated that the laboratory intended to perform QC with each new lot and shipment of Giardia/Cryptosporidium Quik Chek test kits. 3. The laboratory's records indicated that the laboratory began using lot 062325 (expiration 07 /01/2024) on 12/04/2023 but did not perform or document QC. 4. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not have additional QC records for lot 062325 (expiration 07/01/2024) of the Giardia/Cryptosporidium Quik Chek test kit.
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 patient testing records, quality control (QC) records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 11:31 am on 07/25/2024, the laboratory failed to perform negative QC each day of patient testing for one out of five days of unexpected antibody detection testing in February 2024. The findings include: 1. Patient B had unexpected antibody detection testing performed on 02/14/2024. 2. QC records indicated the laboratory performed a positive control on reagent Search-Cyte Plus I (lot 001, expiration 02/17 /2024) and reagent Search-Cyte Plus II (lot 001, expiration 02/17/2024) on 02/14 /2024. 3. At the time of the survey, the laboratory did not have records of a negative control being performed on reagent Search-Cyte Plus I (lot 001, expiration 02/17 /2024) and reagent Search-Cyte Plus II (lot 001, expiration 02/17/2024) on 02/14 /2024.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Biomeriuex Vitek 2 quality control (QC) records, the laboratory's microbiology QC policy, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 1:48 pm on 07/25/2024, the laboratory failed to use two or more substrates or reagents to check each lot number of identification (ID) cards for two out of two lots of ID cards. The findings include: 1. The day of the survey, the laboratory had in use lot 2422850403 (expiration 09/15/2025) of GP ID cards. The laboratory began using it on 05/24/2024. 2. The laboratory's microbiology QC policy stated, "Using streamline QC testing, the following organisms should be tested for Gram Positive Identification cards (GP): Enterococcus casseliflavus ATCC 700327 and Staphylococcus saprophyticus ATCC BAA-750. 3. On 05/24/2024, the laboratory performed QC on lot 2422850403 (expiration 09/15/2025) of GP ID cards with Staphylococcus saprophyticus ATCC BAA-750 only. 4. The day of the survey, the laboratory had in use lot 2412619503 (expiration 01/17/2025) of GN ID cards. The laboratory began using it on 05/24/2024. 5. The laboratory's microbiology QC policy stated, "Using streamline QC testing, the following organisms should be tested for Gram Negative Identification cards (GP): Enterobacter hormaechei ATCC 700323 and Stenotrophomonas maltophilia ATCC 17666. 6. On 05/24/2024, the laboratory performed QC on lot 2412619503 (expiration 01/17/2025) of GN ID cards with

	Stenotrophomonas maltophilia ATCC 17666 only. 7. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not have additional QC records for the GP and GN ID cards listed above.
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 alarm check records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 11:31 am on 07/25/2024, the laboratory failed to document the high and low activation temperatures and nurse response notes as part of the alarm system inspection for six out of six time periods from 01/01/2023- 06/30 /2024. The findings include: 1. The laboratory's policy stated that the blood bank alarm system would be checked on a quarterly basis by an outside company. It also stated, "Record both the low and high activation temperatures, the date, and the name or initials of the person performing the test. Document nursing personnel verified that the remote alarm rang at the nurse's station." 2. Review of the blood bank refrigerator alarm check documentation from the outside company indicated the checks were performed on 02/07/2023, 05/23/2023, 07/19/2023, 11/13/2023, 03/13/2024, and 05/22 /2024. 3. The records 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.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the New Hampton 2024 CLIA Volumes form, lack of comparison activity records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at 12:53 pm on 07/25/2024, the laboratory failed to perform and document comparison activities twice annually for the analytes, sodium, potassium, chloride, glucose, lactate, and creatinine, for three out of three time periods from 01/01/2023 - 07/25/2024. The findings include: 1. The laboratory performed the following analytes on the Beckman Coulter DxC600i test system: sodium, potassium, chloride, glucose, lactate, and creatinine. 2. As a backup method, the laboratory performed the analytes listed above on the Siemens EPOC test system. 3. At the time

	of the survey, personnel identifier #2 confirmed that comparison testing had not been performed between the Beckman Coulter DxC600i and Siemens EPOC test systems for the analytes, sodium, potassium, chloride, glucose, lactate, and creatinine, from 01 /01/2023 - 07/25/2024.
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 identifier #2 (refer to the Laboratory Personnel Report) at 8:20 am on 07/25/2024, the technical supervisor failed to assess and document the competency of individuals performing high complexity testing at least annually for five out of eight testing personnel (laboratory personnel identifiers #2, #3, #5, #6, and #9) in 2023.