

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0386206	<b>(X3) Date Survey Completed</b>  07/24/2024
<b>Name of Provider or Supplier</b>  Mercyone Elkader Medical Center	<b>Street Address, City, State</b>  901 Davidson Street Nw, Elkader, IA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5435</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(2)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, pipette function check records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 11:31 am on 07/24/2024, the laboratory failed to establish a function check policy for pipettes used in the laboratory, including the frequency for performing pipette function checks. The laboratory also failed to perform and document pipette function checks for three out of four pipettes used in the laboratory from 11/29/2022- 07/24/2024. The findings include: 1. The laboratory uses the following pipettes: *ID Tipmaster (12.5 uL, 25.0 uL, and 50 uL), Reference #YO2481 *Adjustable Eppendorf, reference #K38350F *Adjustable Eppendorf, reference #N11315F *Thermoscientific FinnPipette, Reference #05201 2. The laboratory performed a function check on the pipettes listed above in November 2022. In addition, the laboratory serviced the Thermoscientific FinnPipette (Reference #05201) pipette in October 2023. 3. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not have a function check policy for pipettes or documentation of function checks performed for the ID Tipmaster and two Adjustable Eppendorf pipettes listed above from 11/29/2022- 07/24/2024.</p>

**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, the Micro Typing Systems (MTS) Anti-Human Globulin Anti-IgG manufacturer's package insert, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 12:27 pm on 07/24/2024, the laboratory failed to perform a negative and positive control material each day of patient testing for three out of three days of patient testing from 02/01/2024- 02/29/2024. The findings include: 1. The laboratory uses the MTS Anti- Human Globulin Anti- IgG card to perform unexpected antibody detection testing. 2. The MTS Anti- Human Globulin Anti- IgG Card instructions for use state, "To confirm the specificity and reactivity of the MTS Anti- IgG card, it is recommended that each lot be tested each day of use with known positive and negative antibody samples with the appropriate red blood cells." 3. The laboratory performed unexpected antibody detection testing on the following dates: \*02/08/2024- 1 patient \*02/12/2024- 1 patient \*02/22/2024- 1 patient 4. Personnel identifier #1 confirmed that the laboratory routinely performs a positive control on the MTS Anti- Human Globulin Anti-IgG card each day of patient testing, but not a negative control. 5. At the time of the survey, the laboratory did not have negative control records for the dates of patient testing listed above.