

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0385677	(X3) Date Survey Completed 04/09/2025
Name of Provider or Supplier Manning Regional Healthcare Center	Street Address, City, State 1550 6th Street, Manning, 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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by interview with General Supervisor (GS) #1 at 8:37 am on 4/9/2025, the laboratory failed to perform a self evaluation when the laboratory received ungraded PT scores from six out of six testing events from 01/01/2023- 12/31/2024. The findings include: 1. For 2023 event 1, the laboratory received a not graded score for alanine aminotrasferase specimen CET-1. 2. For 2023 event 2, the laboratory received not graded scores for mean platelet volume specimens AF5-6, AF5-7, AF5-8, AF5-9, and AF5-10. 3. For 2023 event 3, the laboratory received not graded scores for red cell distribution width and mean platelet volume specimens AF5-11, AF5-12, AF5-13, AF5-14, and AF5-15. 4. For 2024 event 1, the laboratory received not graded scores for urine propoxyphene specimen UD-1 and Norovirus GI/GII (Biofire) specimen EP-5. 5. For 2024 event 2, the laboratory received not graded scores for Adenovirus F40/41 (Biofire) specimen EP-7, Salmonella species (Biofire) specimen EP-9, total iron binding capacity specimen CET-8, and serum osmolality specimens CET-6, CET-7, CET-8, CET-9, and CET-10. 6. For 2024 event 3, the laboratory received not graded scores for total iron binding capacity and serum osmolality specimens CET-11, CET-12, CET-13, CET-14, and CET-15. 7. At the time of the survey, GS #1 confirmed the laboratory failed to perform a self evaluation for the above ungraded PTscores.</p>
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records and confirmed by interview with General Supervisor (GS) #1 at 8:37 am on 4/9/2025, the laboratory failed to take and document corrective action for unacceptable PT scores from three out of six PT testing events from 01/01/2023- 12/31/2024. The findings include: 1. For 2024 testing event 1, the laboratory received an unacceptable score for Rota Virus (Biofire), specimen EP-04. 2. For 2024 testing event 2, the laboratory received the following unacceptable scores: *Creatinine 40% (specimens CET-6 and CET-9) *Total Iron Binding Capacity 80% (specimen CET-9) *Lactate 40% (CET-6, CET-7, and CET-9) *Magnesium 80% (CET-9) *Salicylate 60% (CET-6 and CET-9) *TSH 80% (CET-10) *Partial pressure carbon dioxide 80% (BG-07) *Calcium 80% (CET-9) 3. For 2024 testing event 3, the laboratory received the following unacceptable scores: *Platelet zero (AF5-11, AF5-12, AF5-13, AF5-14 and AF5-15) *Alcohol 80% (AM-15) *Urine sediment 50% (SU-3) 4. At the time of the survey, GS#1 confirmed the laboratory did not take and document corrective action for the above unacceptable PT scores.

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IMMUNOHEMATOLOGY

CFR(s): 493.1271(c)(f)

(c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's immunohematology policies, blood bank system alarm check records, and confirmed by interview with General Supervisor (GS) #1 at 12:10 pm on 4/9/2025, the laboratory failed to perform and document quarterly alarm system checks for the blood storage refrigerator for three out of eight time periods from 01/01/2023- 12/31/2024. The findings include: 1. The laboratory's blood bank alarm check policy states, "To be done quarterly by lab staff." 2. The laboratory performed blood bank alarm checks on 2/9/2023, 5/16/2023, 7/13/2023, 4/3/2024 and 12/31/2024. 3. At the time of the survey, GS #1 confirmed the laboratory did not perform alarm checks quarterly for the blood bank refrigerator.