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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 16D0384673 | (X3) Date Survey Completed 03/31/2026 |
| Name of Provider or Supplier Mercyone New Hampton Medical Center | Street Address, City, State 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 |
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| D5545 | <p>HEMATOLOGY CFR(s): 493.1269(b)(d)</p> <p>(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed.</p> <p>This STANDARD is not met as evidenced by: Based on review of ACL TOP coagulation quality control (QC) records, activated partial thromboplastin time (APTT) TOP procedure, patient test records, and confirmed by interview with the general supervisor (GS) identifier #1 at 11:27 am on 3/31/2026, the laboratory failed to perform two levels of QC every 8 hours for six out of eleven patients that had APTT testing performed between 1/1/2026 - 1/31/2026. The findings include: 1. The APTT TOP procedure stated, "QC frequency is every 8 hours before a patient result. Controls need to be tested and acceptable before reporting patient results." 2. On 1/2/2026, the laboratory reported a patient APTT result at 2:59 am. 3. On 1/5/2026, the laboratory reported a patient APTT result at 11:52 pm. 4. On 1/8/2026, the laboratory reported a patient APTT result at 04:57 am. 5. On 1/19/2026, the laboratory reported a patient APTT result at 7:37 pm and another patient APTT result at 8:40 pm. 6. On 1/30/2026, the laboratory reported a patient APTT result at 11:03 pm. 7. GS #1 confirmed the laboratory routinely performed two levels of APTT QC once per day between 7:00 - 8:00 am, and the laboratory did not perform APTT QC every 8 hours of patient testing.</p> |