| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 16D0648043 | 05/22/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| St Anthony Regional Hospital | 311 South Clark Street, Carroll, 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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| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:<br><br>This STANDARD is not met as evidenced by:<br>Based on review of rapid plasma reagin (RPR) records, the RPR manufacturer package insert, and confirmed by interview with General Supervisor #1 (GS #1) at 3: 10 pm on 05/21/2026, the laboratory failed to retain needle drop delivery and rotator speed check records for six out of six days of patient testing reviewed from 12/01 /2025- 12/31/2025. The findings include: 1. The laboratory performed patient RPR testing on the following dates in December 2025: 12/01/2025, 12/03/2025, 12/05 /2025, 12/15/2025, 12/17/2025, and 12/23/2025. 2. The laboratory uses the BD Macro-Vue RPR Card test system to perform patient RPR testing. 3. The BD Macro-Vue RPR package insert stated the RPR needle should deliver 29-31 drops of antigen per 0.5 mL when held in a vertical position. 4. The BD Macro-Vue RPR package insert also stated to rotate the cards for eight minutes at 98-102 RPMs. 5. GS #1 stated the laboratory performs needle drop delivery and rotator speed checks each day of patient testing and records the results in their Meditech Laboratory Information System (LIS). The following month, a cumulative report is ran and saved from the LIS with the RPR needle drop delivery and rotator speed checks for the previous month; however, the laboratory did not have a record of the report from December 2025. 6. At the time of the survey, GS #1 confirmed the laboratory failed to retain needle drop delivery and rotator speed check records for the dates listed above from 12/01/2025- 12/31/2025. |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g) |

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| | (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Ortho Vitros 7600 chemistry quality control (QC) records and confirmed by interview with General Supervisor #1 (GS #1) at 9:30 am on 05/22 /2026, the laboratory failed to perform two levels of QC at least once each day of patient testing for 2 out of 31 days reviewed from 12/01/2025- 12/31/2025 for the analyte, low-density lipoprotein (LDL). The findings include: 1. The laboratory performs chemistry testing on two Ortho Vitros 7600 instruments identified as Regina (serial # 7602320) and Karen (serial # 7602332). 2. On 12/03/2025, the laboratory performed LDL patient testing on the instrument identified as Regina, but only ran the MAS CORE 2 control. 3. On 12/05/2025, the laboratory performed LDL patient testing on the instrument identified as Regina, but only ran the MAS CORE 2 control. 4. At the time of the survey, GS #1 confirmed the laboratory failed to perform two levels of QC at least once each day of patient testing for the analyte, LDL, on the dates listed above from 12/01/2025- 12/31/2025. |
| **D5783** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(2)<br><br>(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Ortho Vitros 7600 chemistry quality control (QC) records, the laboratory's QC policy/procedure, and confirmed by interview with General Supervisor #1 (GS #1) at 9:30 am on 05/22/2026, the laboratory failed to take and document corrective action when chemistry QC fell outside the laboratory's established criteria for acceptability for 8 out of 31 days of patient testing reviewed from 12/01/2025- 12/31/2025 for the following analytes: ammonia, prostate specific antigen (PSA), blood alcohol (ETOH), lipase, vancomycin (VANC), albumin (ALB), alkaline phosphatase (ALP), aspartate aminotransferase (AST), and sodium (NA). The findings include: 1. The laboratory performs chemistry testing on two Ortho Vitros 7600 instruments identified as Regina (serial # 7602320) and Karen (serial # 7602332). 2. The laboratory's Quality Control Program policy/procedure stated the following: *1-2s Rule: QC results are acceptable if one level is within 2 standard deviations (SD) and the other level is between 2 SD and 3 SD. *1-3s Rule: QC is not acceptable if any level is greater than 3 SD. Patient testing cannot be performed for that assay. *Remedial action must be taken for any deficiencies that are identified through the quality control program. Documentation of remedial action should be made in the LIS when verifying QC or on the monthly QC reports. 3. Review of chemistry QC records revealed "1-2s" QC rule failure flags for the following dates, analytes, instrument, and QC levels: * 12/02/2025- ALB (Regina); level 1 and level 2 (1-2s flags) * 12/19/2025- PSA (Regina); level 1 (1-3s flag) and level 2 (1-2s flag) * 12/23/2025- Ammonia (Regina); level 1 (1-2s flag) and level 2 (1-3s flag) * 12/24 |

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| | /2025- Lipase (Regina); level 1 and level 2 (1-2s flags) 4. Review of chemistry QC records revealed "1-3s" QC rule failure flags for the following dates, QC levels, analytes, and instrument: * 12/11/2025- level 3, AST (Karen) * 12/12/2025- level 1, ALP (Karen) * 12/16/2025- level 3, ETOH (Regina) * 12/19/2025- level 3, VANC (Regina) * 12/19/2025- level 2, ALB (Regina) * 12/19/2025- level 2, Lipase (Regina) * 12/19/2025- level 1, PSA (Regina) * 12/23/2025- level 1, ALP (Karen) * 12/23 /2025- level 2, Lipase (Regina) * 12/23/2025- level 2, PSA (Regina) * 12/31/2025- level 3, NA (Karen) 5. At the time of the survey, GS #1 confirmed that the laboratory failed to take and document corrective action for the unacceptable QC results listed above. |