| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 16D0383015 | 05/13/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Newton Clinic Pc | 300 N Fourth Avenue E, Newton, 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 TOSOH G8 patient test records, TOSOH G8 quality control (QC) records, and confirmed by interview with Testing Personnel #1 (TP #1) at 12:00 pm on 05/13/2026, the laboratory failed to retain instrument printouts for daily QC and patient test results for 162 out of 162 days of testing from 11/01/2025- 05/13/2026. The findings include: 1. The laboratory began using the TOSOH G8 chemistry analyzer to perform patient testing in November 2025. 2. The laboratory recorded patient test results and daily QC results on paper log sheets. 3. TP #1 stated that the TOSOH G8 instrument prints all patient, QC, and calibration records and that the laboratory only keeps the calibration printouts. The laboratory discards patient and QC instrument printouts. 4. At the time of the survey, TP #1 confirmed that the laboratory failed to retain instrument printouts for daily QC and patient test results for the TOSOH G8 from 11/01/2025- 05/13/2026. |
| **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 |

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| | patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Ortho Vitros XT 3400 quality control (QC) records, the laboratory's QC procedures, patient test records, and confirmed by interview with Testing Personnel #1 (TP #1) at 12:15 pm on 05/13/2026, the laboratory failed to take and document corrective action when chemistry QC fell outside the laboratory's established criteria for acceptability for 1 out of 31 days of patient testing reviewed in December 2025. The findings include: 1. The laboratory performs chemistry testing on the Ortho Vitros XT 3400 instrument. 2. TP #1 stated that the laboratory performs three levels of QC each day of patient testing for all analytes on the Vitros XT 3400 instrument and that two of the three levels must be acceptable before performing patient testing. The laboratory did not have a written policy including the number, type, and frequency of testing control materials or the acceptability criteria including two of three acceptable controls. 3. On 12/10/2025, the laboratory performed three levels of BioRad Liquid Assayed Multiqual QC: level 1 (lot 46041, exp. 05/31/2028), level 2 (lot 46042, exp. 05/31/2028), and level 3 (lot 46043, exp. 05/31/2028); and received the following QC results for the analyte, aspartate aminotransferase (AST): *Level 1: 40.4 U/L (reference range 37.8- 51.4 U/L) *Level 2: 104.9 U/L (reference range 110-143 U/L) *Level 3: 251.6 U/L (reference range 258-334 U/L) 4. The laboratory reported AST results for a total of 41 patients on 12/10/2025. 5. At the time of the survey, TP #1 confirmed that the laboratory failed to take and document corrective action for the unacceptable QC results listed above. In addition, TP #1 confirmed that the laboratory failed to have a written policy including the number, type, and frequency of testing control materials or the acceptability criteria including two of three acceptable controls. |