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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>16D0383015  | <b>(X3) Date Survey Completed</b><br><br>05/07/2024 |
| <b>Name of Provider or Supplier</b><br><br>Newton Clinic Pc  | <b>Street Address, City, State</b><br><br>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. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
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| <b>D2000</b>              | <p>ENROLLMENT AND TESTING OF SAMPLES<br/>CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on review of American Proficiency Institute (API) proficiency testing records and the Laboratory Test List &amp; Annual Volume form (IA-CLIA-PS01), observations during the survey and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at 10:04 am on 05/07/2024, the laboratory failed to enroll in an HHS approved proficiency testing program for the analyte, quantitative human chorionic gonadotropin (hCG) testing for two out of two years from 1/1/2023 - 5/8/2024. The findings include: 1. The Laboratory Test List &amp; Annual Volume form stated the laboratory performed quantitative hCG testing using the Tosho analyzer. 2. Tour of the laboratory confirmed quantitative hCG reagent in the laboratory refrigerator. 3. The laboratory did not enroll in proficiency testing for the analyte, quantitative hCG in 2023 or 2024.</p> |
| <b>D5429</b>              | <p>MAINTENANCE AND FUNCTION CHECKS<br/>CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at</p>  |

least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on lack of Cepheid GeneXpert maintenance records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at 11:22 am on 05/07/24, the laboratory failed to perform and document daily, weekly, monthly, and quarterly maintenance on the Cepheid GeneXpert instrument for 128 out of 128 days, 19 out of 19 weeks, five out of five months and one out of one quarter from 1/1/2024 - 5/7/2024. The findings include: 1. The GeneXpert Maintenance log stated the laboratory must daily perform the following: \*Clean the work area \*Close all module doors \*Discard used cartridges 2. The GeneXpert Maintenance log stated the laboratory must weekly perform the following: \*Power down the GeneXpert instrument \*Power down the GeneXpert computer 3. The GeneXpert Maintenance log stated the laboratory must monthly perform the following: \*Archive tests \*Purge tests 4. The GeneXpert Maintenance log stated the laboratory must quarterly perform the following: \*Clean plunger rod and cartridge bay \*Clean the instrument surfaces 5. At the time of the survey, the laboratory did not perform and document any of the above daily, weekly, monthly or quarterly maintenance from 1/1/2024 - 5/7/2024.

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on review of Cepheid GeneXpert calibration certificates and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 11:22 am on 5/7/2024, the laboratory failed to perform annual calibrations on the Cepheid analyzer for one out of two years from 5/7/2022 - 5/7/2024. The findings include: 1. The Cepheid GeneXpert needs to be calibrated annually. 2. On 11/1/2022, the laboratory performed a calibration on the Cepheid GeneXpert. 3. At the time of the survey, the laboratory had not performed a calibration on the Cepheid GeneXpert since 11/1/2022.