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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>10/21/2020 |
| <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>D5016</b>              | <p>ROUTINE CHEMISTRY<br/>CFR(s): 493.1210</p> <p>If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on review of the procedure manual, prostate specific antigen calibration verification records, VITROS chemistry verifier I and II instructions for use, the VITROS performance verifier I and II assayed quality control (QC) package inserts, VITROS QC results, monthly quality assurance checklist and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), the laboratory failed to meet the chemistry requirements for having procedures as specified in D5403; performing calibration verification as specified in D5439; correctly defining the analyte-specific mean and acceptable QC ranges as specified in D5469, taking corrective action when QC fails to meet the laboratory's criteria for acceptability as specified in D5783, and having a quality assessment program that identifies QC problems as specified on D5791. The is a repeat deficiency from the previous survey.</p> |
| <b>D5403</b>              | <p>PROCEDURE MANUAL<br/>CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other</p>  |

materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 1:00 pm on 10/21/2020, the laboratory failed to have a procedure for: defining the analyte-specific mean and acceptable ranges for assayed chemistry quality controls (QC), programming the analyte-specific mean and standard deviation of chemistry QC into the laboratory information system, and general chemistry quality control procedures including the acceptability criteria of QC and the course of action to take when QC results fail to meet the laboratory's criteria for acceptability. This is a repeat deficiency from the previous survey.

**D5439**

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

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of the prostate specific antigen (PSA) calibration verification records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 12:30 pm on 10/21/2020, the laboratory failed to perform calibration verification procedures every six months for one out of three time periods for the analyte, PSA from 1/1/2019 - 10/21/2020. The findings include: 1. The

laboratory performed calibration verification for the analyte, PSA on 5/12/2019 and 4/3/2020. 2. At the time of the survey, the laboratory did not have calibration verification records for the time period between 5/12/2019 and 04/3/2020.

**D5469**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of VITROS chemistry verifier I and II instructions for use, the VITROS performance verifier I and II assayed quality control (QC) package inserts, and VITROS QC results and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 10/21/2020, the laboratory failed to correctly define the analyte-specific mean and acceptable range for the chemistry assayed controls for four out of four lot numbers of QC ( N7648, L7425, R7909 and T7911) performed from 2/1/2020 - 2/28/2020 and 10/1/2020 - 10/21/2020. The findings include: 1. The VITROS chemistry verifier I and II instructions for use states: "\*Each laboratory should establish its own analyte-specific mean \*Each laboratory should evaluate and, if necessary, update the mean for each reagent lot change \*The within-lab standard deviation (SD) published on the assay sheet for a given analyte may be used as the laboratory's baseline SD for any reagent lot" 2. The VITROS performance verifier assayed QC package insert states, "Range of Means. The analyzer mean value should fall within this range". 3. Laboratory personnel identifier #1 confirmed the laboratory did not establish their own analyte-specific mean. Instead the laboratory would use the range of means values listed on the VITROS QC package insert to calculate the mean. 4. The laboratory entered the calculated mean and the SD from the VITROS QC package insert into the laboratory information system (LIS) control program, and the LIS would calculate the acceptable QC range at 2SDs. Since the laboratory did not use the correct analyte-specific mean, the laboratory did not have the correct QC range. 5. For lot numbers N7648, L7425, R7909 and T7911 the laboratory did not correctly define the analyte-specific mean and acceptable QC range for the following analytes: albumin, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, direct bilirubin, indirect bilirubin, blood urea nitrogen, calcium, cholesterol, chloride, creatinine, high density lipoprotein, carbon dioxide, gamma-glutamyl transpeptidase, glucose, potassium, lactic acid dehydrogenase, sodium, total bilirubin, total protein, triglyceride, and uric acid.

**D5783**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (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.

This STANDARD is not met as evidenced by:

Based on review of VITROS chemistry verifier I and II instructions for use, the VITROS performance verifier I and II assayed quality control (QC) package inserts, and VITROS QC results and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 10/21/2020, the laboratory failed to take corrective action when chemistry QC results failed to meet the laboratory's established criteria for acceptability for four out of four lot numbers of QC ( N7648, L7425, R7909 and T7911) performed from 2/1/2020 - 2/28/2020 and 10/1/2020 - 10/21/2020. The findings include: 1. The laboratory did not have chemistry quality control procedures. Refer to D5403. 2. The laboratory did not have the correct analyte-specific mean and acceptable range programmed into the laboratory information system. Refer to D5469. 3. Laboratory personnel identifier #1 stated at the survey, "If the chemistry QC fell outside the established ranges the laboratory would compare the QC results to the range of means on the VITROS performance verifier I and II assayed QC package inserts. If the QC results fell within the range of means the laboratory would accept the results." 4. The laboratory did not document corrective action when chemistry QC results fell outside the VITROS range of means. Refer to Table 1. This is a repeat deficiency from the previous survey.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of VITROS chemistry verifier I and II instructions for use, the VITROS performance verifier I and II assayed quality control (QC) package inserts, VITROS QC results, monthly quality assurance checklist and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 10/21/2020, the laboratory's quality assessment program failed to identify problems related to chemistry quality control issues for February 2020. The findings include: 1. The laboratory performed a monthly quality assurance checklist. 2. The monthly quality assurance checklist stated: "Our QUALITY CONTROL POLICIES were performed as specified: \*Any necessary remedial action was performed and documented. \*All quality control/calibrations were performed and were within acceptable limits before patient test results were reported. \*Quality control results were examined for possible problems." 3. Laboratory personnel #1 and #2 indicated "yes" the laboratory successfully completed the above activities and signed the checklist on 2/28/2020. 4. The laboratory did not have the correct analyte-specific

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|                     | <p>mean and acceptable ranges programmed into the laboratory information system. Refer to D5469. 5. The laboratory did not take corrective action when QC results fell outside the acceptable range. Refer to D5783. 6. At the time of the survey, the quality assurance checklist did not identify problems related to chemistry QC issues. This is a repeat deficiency from the previous survey.</p>   |
| <p><b>D6000</b></p> | <p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b><br/>CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on review of the procedure manual, prostate specific antigen calibration verification records, VITROS chemistry verifier I and II instructions for use, the VITROS performance verifier I and II assayed quality control (QC) package inserts, VITROS QC results, monthly quality assurance checklist and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), the laboratory director failed to ensure the laboratory performed calibration verification procedures as specified in D6014; ensure the laboratory correctly defined the analyte-specific mean and acceptable chemistry QC ranges as specified in D6020; ensure the laboratory had a quality control and quality assessment program that identified failures related to chemistry quality control as specified in D6022; and ensure the laboratory had chemistry procedures as specified in D6031.</p> |
| <p><b>D6014</b></p> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1407(e)(3)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the prostate specific antigen (PSA) calibration verification records and confirmed by laboratory personnel identifier #1 (refer to Laboratory Personnel Report) at approximately 12:30 pm on 10/21/2020, the laboratory director failed to ensure the laboratory performed calibration verification procedures every six months for one out of three time periods for the analyte, PSA from 1/1/2019 - 10/21/2020. Refer to D5439.</p>   |
| <p><b>D6020</b></p> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory</p>  |

director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of VITROS chemistry verifier I and II instructions for use, the VITROS performance verifier I and II assayed quality control (QC) package inserts, and VITROS QC results and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 10/21/2020, the laboratory director failed to ensure the laboratory's quality control program correctly defined the analyte-specific mean and acceptable ranges for chemistry assayed controls for four out of four lot numbers of QC ( N7648, L7425, R7909 and T7911) performed from 2/1/2020 - 2/28/2020 and 10/1/2020 - 10/21/2020. Refer to D5469.

**D6022**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of VITROS chemistry verifiers I and II instructions for use, the VITROS performance verifier I and II assayed quality control (QC) package inserts, and VITROS QC results and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 10/21/2020, the laboratory director failed to ensure the quality control program and quality assessment program identified failures related to chemistry quality controls for four out of four lot numbers of QC ( N7648, L7425, R7909 and T7911) performed from 2/1/2020 - 2/28 /2020 and 10/1/2020 - 10/21/2020. Refer to D5783 and D5791.

**D6031**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 1:00 pm on 10/21 /2020, the laboratory director failed to ensure the laboratory had a procedure for: defining the analyte-specific mean and acceptable ranges for assayed chemistry quality controls (QC), programming the analyte-specific mean and standard deviation of chemistry QC into the laboratory information system, and general chemistry quality

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|                     | <p>control procedures including the acceptability criteria of QC and the course of action to take when QC results fail to meet the laboratory's criteria for acceptability.</p>  |
| <p><b>D6033</b></p> | <p><b>TECHNICAL CONSULTANT-MODERATE COMPLEXITY</b><br/>CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on review of VITROS chemistry verifier I and II instructions for use, the VITROS performance verifier I and II assayed quality control (QC) package inserts, VITROS QC results and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report), the technical consultant failed to ensure the laboratory correctly defined the analyte-specific mean and acceptable chemistry QC ranges as specified in D6042 and ensure the laboratory took corrective action when QC failed to meet the laboratory's criteria for acceptability as specified in D6043.</p>  |
| <p><b>D6042</b></p> | <p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b><br/>CFR(s): 493.1413(b)(4)</p> <p>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of VITROS chemistry verifier I and II instructions for use, the VITROS performance verifier I and II assayed quality control (QC) package inserts, and VITROS QC results and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 10/21/2020, the technical consultant failed to ensure the laboratory correctly defined the analyte-specific mean and acceptable ranges for the chemistry assayed controls for four out of four lot numbers of QC ( N7648, L7425, R7909 and T7911) performed from 2/1/2020 - 2/28/2020 and 10/1/2020 - 10/21/2020. Refer to D5469.</p> |
| <p><b>D6043</b></p> | <p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b><br/>CFR(s): 493.1413(b)(5)</p> <p>(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of VITROS chemistry verifier I and II instructions for use, the VITROS performance verifier I and II assayed quality control (QC) package inserts, and VITROS QC results and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 10/21/2020, the</p>   |

technical consultant failed ensure the laboratory took corrective action when QC results failed to meet the laboratory's established criteria for acceptability for four out of four lot numbers of QC ( N7648, L7425, R7909 and T7911) performed from 2/1/2020 - 2/28/2020 and 10/1/2020 - 10/21/2020. Refer to D5783.