

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0383015	(X3) Date Survey Completed 05/23/2018
Name of Provider or Supplier Newton Clinic Pc	Street Address, City, State 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
D5016	<p>ROUTINE CHEMISTRY 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: Based on review of the Ace Alera chemistry analyzer quality control (QC) records, the Ace Alera QC package inserts, laboratory procedure manual, calibration verification records, and confirmed by laboratory personnel identifiers #2 and #3 (refer to the Laboratory Personnel Report), the laboratory failed to meet chemistry requirements for: having a quality control procedure with acceptable result criteria as specified in standard D5403; performing and documenting calibration verification procedures as specified in the standard D5439; taking corrective action when the quality control results failed to meet the laboratory's established criteria for acceptability as specified in the standard D5783; and failing to establish a system for ensuring package insert data is entered correctly into the laboratory's quality control computer program as specified in standard D5791.</p>
D5403	<p>PROCEDURE MANUAL 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 at approximately 12:00 pm on 05/23/2018 and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 11:15 am on 05/30/2018, the laboratory failed to have a written procedure defining quality control acceptability criteria for the Ace Alera chemistry instrument. The findings include: 1. Review of the procedure manual on the day of the survey revealed that the laboratory did not have a written procedure that defined quality control (QC) acceptability for the Ace Alera chemistry instrument. 2. On 05/30/2018, laboratory personnel identifier #3 verbally confirmed that the laboratory does not have a written procedure defining QC acceptability criteria.

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:

A. Based on review of the Ace Alera calibration verification records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 11:50 am on 05/23/2018, the laboratory failed to perform calibration verification every six months for three out of four time periods for all analytes

performed on the Ace Alera chemistry test system in 2016-2017. The findings include: 1. The laboratory performed calibration verification for all analytes performed on the Ace Alera chemistry test system on 01/27/2017. 2. At the time of the survey, the laboratory did not have calibration verification records for any analytes performed on the Ace Alera chemistry test system from 2016 or for the time period between 07/01/2017 and 12/31/2017. B. Based on review of the TOSOH calibration verification records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 11:25 am on 05/23/2018, the laboratory failed to perform calibration verification every six months for four out of four time periods for prostate specific antigen (PSA) testing performed on the TOSOH chemistry test system in 2016-2017. At the time of the survey, the laboratory did not have PSA calibration verification records from 2016 and 2017.

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 Ace Alera quality control (QC) records, Ace Alera QC package inserts, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 12:00 pm on 05/23/2018 and laboratory personnel identifier #3 at approximately 11:15 am on 05/30/2018, the laboratory failed to take and document corrective action when chemistry QC failed to meet the laboratory's established criteria for acceptability for six out of 41 days of patient testing from 08/24/2017- 10/20/2017. The findings include: 1. The Ace Alera chemistry control package insert for lot number 889UNCM (expiration 2018-02) listed the acceptable range for the analyte, alanine aminotransferase (ALT), as 29- 47 U/L. 2. On 10/13/2017, the laboratory recorded the ALT QC result as 26.0 U/L for QC lot number 889UNCM. 3. The Ace Alera chemistry control package insert for lot number 889UNCM (expiration 2018-02) listed the acceptable range for the analyte, aspartate aminotransferase (AST), as 38- 56 U/L. 4. The laboratory recorded the following AST QC results for lot number 889UNCM: *09/19/2017- 36.0 U/L *09/21/2017- 36.0 U/L *10/16/2017- 34.0 U/L 5. The Ace Alera chemistry control package insert for lot number 889UNCM (expiration 2018-02) listed the acceptable range for the analyte, carbon dioxide (CO2), as 14.2- 21.2 mEq/L. 6. The laboratory recorded the following CO2 QC results for lot number 889UNCM: *09/01/2017- 14.0 mEq/L *09/26/2017- 14.0 mEq/L 7. At the time of the survey, the laboratory did not have a written policy defining the laboratory's established criteria for QC acceptability. Refer to D5403. 8. On 05/30/2018, laboratory personnel identifier #3 verbally confirmed that the laboratory operates within the manufacturer's established three standard deviation (SD) range for each of the Ace Alera analytes performed in the laboratory. 8. At the time of the survey, the laboratory did not have documented corrective action for QC results that fell outside the established ranges on the dates listed above.

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 the Ace Alera quality control (QC) records, the Ace Alera QC package inserts, and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 11:15 am on 05/30/2018, the laboratory failed to establish a system for ensuring package insert data is entered correctly into the laboratory's QC computer program. The findings include: 1. For the analyte, alanine aminotransferase (ALT), the Ace Alera chemistry control package insert for lot number 889UNCM (expiration 2018-02) listed the mean as 38 U/L and one standard deviation (SD) as 3.1. 2. Review of QC records indicated that the laboratory recorded the ALT mean as 38.0 U/L and 1 SD as 4.00 in the QC computer program for lot number 889UNCM. 3. For the analyte, aspartate aminotransferase (AST), the Ace Alera chemistry control package insert for lot number 889UNCM (expiration 2018-02) listed the mean as 47 U/L and one SD as 3.1. 4. Review of QC records indicated that the laboratory recorded the AST mean as 47.0 U/L and 1 SD as 4.50 in the QC computer program for lot number 889UNCM. 5. For the analyte, carbon dioxide (CO₂), the Ace Alera chemistry control package insert for lot number 889UNCM (expiration 2018-02) listed the mean as 17.7 mEq/L and one SD as 1.18. 6. Review of QC records indicated that the laboratory recorded the CO₂ mean as 17.7 mEq/L and 1 SD as 1.75 in the QC computer program for lot number 889UNCM. 7. For the analyte, ALT, the Ace Alera chemistry control package insert for lot number 677UECM (expiration 2018-02) listed the mean as 116 U/L and one SD as 7.7. 8. Review of QC records indicated that the laboratory recorded the ALT mean as 116.0 U/L and 1 SD as 8.20 in the QC computer program for lot number 677UECM. 9. Laboratory personnel identifier #3 confirmed that the laboratory did not have a system in place to ensure package insert data is entered correctly into the laboratory's QC computer program.