| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 37D0669880 | 02/13/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Eufaula Indian Health Center | 500 Eunice Burns Rd, Eufaula, OK | |

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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| **D0000** | The recertification survey was performed 02/12/20-02/13/20. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with technical consultant #1 and technical consultant #2 at the conclusion of the survey. |
| **D5211** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(a)<br><br>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with technical consultant #1, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, technical consultant #1 stated to the surveyors the laboratory performed chemistry testing (e.g., Albumin, LDL (Low Density Lipoprotein) Cholesterol (measured), Total Cholesterol, Total Protein, etc.) and immunoassay testing (e.g., TSH (Thyroid Stimulating Hormone), etc.) using the Architect Ci4100 analyzer; (2) The surveyors reviewed proficiency testing records from 2018 through the first day of the survey in 2019. The surveyors identified in the First 2019 Chemistry Event, the laboratory's proficiency testing results obtained biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program). The findings follow: (a) Albumin - 5 of 5 results exhibited a Positive bias: (i) CH-01: SDI 2.9 (ii) CH-02: SDI 4.4 (iii) CH-03: SDI 3.2 (iv) CH-04: SDI 2.7 (v) CH-05: SDI 3.5 (b) LDL Cholesterol - 5 of 5 results exhibited a Negative bias: (i) CH-01: SDI -7.2 (ii) CH-02: SDI -6.3 (iii) CH-03: SDI -6.9 (iv) CH-04: SDI -5.6 (v) CH-05: SDI -4.8 (c) Total Cholesterol - 3 of 5 results exhibited a Negative bias: (i) CH-01: SDI -3.9 (ii) CH-02: SDI -2.7 (iii) CH-03: SDI -2.3 (d) Total Protein - 3 of 5 results exhibited a Positive bias: (i) CH-01: SDI 3.6 (ii) CH-02: SDI 2.9 (iii) CH-03: SDI 2.8 (e) TSH - 3 of 5 results exhibited a Negative |

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| | bias: (i) CH-01: SDI 2.4 (ii) CH-02: SDI 2.2 (iii) CH-03: SDI 2.3 (3) The surveyors reviewed the records again. There was no documentation that proved at the time the results were received, the laboratory identified the biases or had taken corrective action (i.e., reviewed maintenance, quality control results, calibration records, reagent stability, reviewed patient results, etc.) to determine the cause of the biased proficiency results listed above; (4) The surveyors reviewed the findings with technical consultant #1 and asked if there was documentation to prove the biases listed above had been reviewed and that corrective action had been taken. Technical consultant #1 stated to the surveyors the proficiency testing was reviewed by the previous technical consultant, but there was no documentation that the biases listed above had been reviewed and there was no documentation correction had been taken. NOTE: D5211 was cited at the previous recertification survey performed 02/06/18. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, procedure manual, and interview with technical consultant #1 and technical consultant #2, the laboratory failed to include the correct reportable range for Platelet Count testing in the procedure. Findings include: (1) On the first day of the survey, technical consultant #1 and technical consultant #2 stated to the surveyors CBC testing (Complete Blood Count), which included Platelet Count, was performed on the Cell Dyn Ruby analyzer. Technical consultant #2 also stated to the surveyors, the Cell Dyn Ruby analyzer was put into use on 04/27/18 at the laboratory's previous location; (2) On the second day of the survey, the surveyors reviewed the laboratory's reportable range studies performed on the new Cell Dyn Ruby CBC analyzer put into use on 04/27/18 at the laboratory's previous location. The reportable range verified during the implementation for the analyte, Platelet Count, was 6.8-1989.0; (3) The surveyors reviewed the laboratory's "Complete Blood Count Abbott Cell Dyn Ruby" policy and procedure. Under "XVI. Limitation," the surveyors identified the following: (a) The reportable range for the Cell Dyn Ruby Platelet Count was 0.9-2175.0; (b) Patient samples with results outside these ranges were to be sent to the reference lab for special testing. (4) The surveyors then reviewed the findings with technical consultant #1 and technical consultant #2, who stated to the |

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| | surveyors, the laboratory's reportable range for Platelet Count included in the CBC policy and procedure, did not match the reportable range verified by the laboratory during the implementation studies. In addition, the surveyors explained to technical consultant #1 and technical consultant #2 the reportable range in the policy and procedure would allow patient Platelet Counts to be reported, which were lower and higher than the laboratory's verified reportable range. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, and interview with technical consultant #1, the laboratory failed to follow the manufacturer's instructions for 2 of 5 CBC's that obtained flags. Findings include: (1) On the first day of the survey, technical consultant #1 and technical consultant #2 stated to the surveyors CBC testing (Complete Blood Count) (i.e. WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, WBC automated differentials reported in percents and number, etc.) was performed on the Cell Dyn Ruby analyzer. Technical consultant #1 also stated to the surveyors, the Cell Dyn Ruby analyzer was put into use at the new laboratory site on 08/16/18; (2) On the second day of the survey, surveyor #1 reviewed the manufacturer's operator's manual for information regarding flagged CBC results. The following was identified: (a) NWBC: Review a smear for platelet clumps, giant platelets or low levels of NRBC (Nucleated Red Blood Cells) and follow your laboratory's review criteria; (b) BAND: Review a stained smear for the presence of bands and follow the laboratory's review criteria; (c) SUSPECT PARAMETER FLAGS: These flags are generated after the instrument evaluates the measured data. The results may be suspect due to interfering substances or the inability of the instrument to measure a particular parameter due to a sample abnormality. (3) Surveyor #1 then reviewed the laboratory's, "Manual Differential Count and Slide Review" policy, which listed the laboratory's criteria for performing a manual WBC differential or a slide review: (a) A manual differential or slide review is indicated when any parameter result obtains a flag such as NWBC and BAND; (b) All patient samples suspected to be abnormal that need examination under the microscope to verify the results, should also have a manual differential performed. (4) Surveyor #1 reviewed 5 patient records with results that obtained flags. For 2 of the 5 reports, the laboratory failed to ensure a manual differential had been performed, as required by the manufacturer's instructions. The findings follow: (a) Patient #120460003 - Testing performed 09/10/2019 at 10:41 PM: An NWBC flag was obtained on the results of the Monocytes count (both percent and number); (b) Patient #C619254144 - Testing performed 09/11/2019 at 08:04 AM: A BAND flag was obtained on the results of the Neutrophil count (both percent and number). (5) Surveyor #1 reviewed the findings with technical consultant #1, who stated to surveyor #1, the flagged CBC results listed above had not been verified as required by the manufacturer. NOTE: D5411 was cited at the previous recertification survey performed 02/06/18. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1) |

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| | Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, and interview with technical consultant #1 and technical consultant #2, the laboratory failed to ensure the accuracy, precision, and reportable range data had been reviewed and evaluated for new analyzers prior to use. Findings include: CELL DYN RUBY APPROVAL OF VERIFICATION OF PERFORMANCE SPECIFICATIONS (1) On the first day of the survey, technical consultant #1 and technical consultant #2 stated to the surveyors CBC testing (Complete Blood Count) (i.e. WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, Platelet Count, etc.) was performed on the Cell Dyn Ruby analyzer. Technical consultant #2 also stated to the surveyors, the Cell Dyn Ruby analyzer was put into use on 04/27/18 at the laboratory's previous location; (2) On the second day of the survey, the surveyors reviewed the implementation records for the new analyzer. There was no evidence the accuracy, precision, and reportable range data had been evaluated, reviewed, and signed by the laboratory as acceptable for use; (3) The surveyors reviewed the findings with technical consultant #1 and technical consultant #2, who stated to the surveyors the data had not been signed as reviewed by the laboratory prior to putting into use. RELOCATION OF ANALYZER (1) The surveyors reviewed CBC testing records from 03/01/18 through 02/12/20 and identified the laboratory had relocated to a new location on 08/06/18. The surveyors identified accuracy and precision of the analyzer had been verified after the relocation, but could not find documentation the laboratory verified that the reportable range had not been affected by the relocation of the analyzer; (2) The surveyors asked technical consultant #1 and technical consultant #2 if there was documentation which proved the reportable range of the CBC testing had not been affected by relocation of the analyzer. Technical consultant #1 and technical consultant #2 stated to the surveyors, there was no documentation available that showed the reportable range had not been affected by the relocation from the old laboratory location to the new location. CLINITEK ADVANTUS APPROVAL OF VERIFICATION OF PERFORMANCE SPECIFICATIONS (1) Technical consultant #1 and technical consultant #2 stated to the surveyors the Clinitek Advantus urine reagent dipstick reader was put into use for patient testing on 10/17/18; (2) The surveyors reviewed the verification of the performance specifications of accuracy and precision for the dipstick reader and identified the laboratory had not approved the dipstick reader for patient testing, until 11/27/18, after patient testing had begun; (3) The findings were reviewed with technical consultant #1 and technical consultant #2, who stated to the surveyors, the data had not been signed as reviewed by the laboratory prior to putting into use. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at |

least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on a review of records, manufacturers' instructions, and interview with technical consultant #1 and technical consultant #2, the laboratory failed to perform maintenance procedures as required by the manufacturers. Findings include: ARCHITECT CI4100 ANALYZER: CHEMISTRY MODULE (1) On the first day of the survey, technical consultant #1 stated to the surveyors the laboratory performed Chemistry testing (i.e., Albumin, Carbon Dioxide, Glucose, Direct Bilirubin, Total Protein, etc.) using the Architect Ci4100 analyzer (composed of a chemistry module and an immunoassay module) put into use on 08/27/18; (2) The surveyors reviewed the manufacturer's required maintenance procedures. The manufacturer required the following procedures be performed: (a) Daily: (i) Check 1 ml (milliliter) syringes (ii) Check DI (deionized) water purity (iii) Daily maintenance procedures, which included: (aa) Flush sample and reagent lines (bb) Inspect sample and reagent syringes for bubbles and leaks (cc) Replace sample wash solutions (dd) Change water in bath (ee) Add Water Bath Additive (ff) Wash ICT (Integrated Chip Technology) probe with ICT Cleaning Fluid and ICT Reference Solution (gg) Drain and fill ICT reference cup (hh) Clean sample probe exterior (whole blood only) (ii) Verify that a backup has been performed in last 30 days. If not, perform backup (jj) Check the database integrity (b) Weekly: (i) Check ICT components (ii) Clean mixers (iii) Clean sample/reagent probes (iv) Clean cuvettes with detergent (v) Check HC (High-Concentration) Pump tubing (c) Monthly: (i) Check Dispense components (ii) Clean cuvette washer nozzles (iii) Check syringes and valves (iv) Clean ICT drain tip (d) Quarterly (each 3 months): (i) Change lamp (ii) Clean sample syringe (iii) Wash syringe (iv) Reagent syringe (v) Change 1 ml syringes (vi) Change ICT Asp Check Valve (vii) Check ICT Ref Check Valves (viii) Check/clean HC waste sensor (3) Maintenance records from 09/01/18 through 12/31/19 were reviewed. The surveyors identified the maintenance procedures had not been performed as required by the manufacturer. The findings follow: (a) Daily: The daily maintenance records from 335 days of testing were reviewed: (i) Check 1 ml syringes had not been documented as performed on 1 day: 8/07/19; (ii) Check DI water purity had not been performed on 2 days: 03/05/19 and 08/07/19; (iii) Daily maintenance procedures had not been performed: (aa) 2018: On 1 of 81 days reviewed: (i) December: On 1 of the 20 days of testing: Day 28 (bb) 2019: On 6 of 254 days reviewed: (i) June: On 1 of the 20 days of testing: Day 11 (ii) August: On 4 of the 22 days of testing: Days 2,5,6,7 (iii) October: On 1 of the 23 days of testing: Day 17 (b) Weekly maintenance procedures: (i) Check ICT components had not been performed between: (aa) 09/28/18 through 10/11/18 (bb) 01/04/19 through 01/28/19 (cc) 09/26/19 through 10/01/19 (ii) Clean mixers had not been performed between: (aa) 09/28/18 through 10/11/18 (bb) 11/09/18 through 11/20/18 (cc) 12/27/18 through 01/28/19 (dd) 09/26/19 through 10/07/19 (iii) Clean sample/reagent probes had not performed between: (aa) 09/28/18 through 10/11/18 (bb) 11/09/18 through 11/20/18 (cc) 12/27/18 through 01/28/19 (dd) 09/26/19 through 10/07/19 (iv) Clean cuvettes with detergent had not been performed between: (aa) 09/28/18 through 10/11/18 (bb) 11/09/18 through 11/20/18 (cc) 12/27/18 through 01/28/19 (dd) 09/26/19 through 10/07/19 (v) Check HC Pump tubing had not been performed between: (aa) 10/01/18 through 10/11/18 (bb) 01/04/19 through 01/28/19 (cc) 09/26/19 through 10/07/19 (c) Monthly: (i) Check Dispense components had not been performed between 01/28/19 and 03/07/19 (ii) Clean cuvette washer nozzles had not been performed between 01/28/19 and 03/07/19 (iii) Check syringes and valves had not been performed between 12/27/18 and 03/07/19 (iv) Clean ICT drain tip had not been performed between 11/28/18 and 03/07/19 (d) Quarterly: (i) Change lamp:

Second quarter of 2019 (January through March) (ii) Third quarter of 2019 (July through September): (aa) Clean sample syringe (bb) Wash syringe (cc) Reagent syringe (dd) Change 1 ml syringes (ee) Change ICT Asp Check Valve (ff) Check ICT Ref Check Valves (gg) Check/clean HC waste sensor (4) The surveyors reviewed the findings with technical consultant #1 and technical consultant #2, who stated to the surveyors the manufacturer's required maintenance procedures had not been performed, as listed above. ARCHITECT CI4100 ANALYZER: IMMUNOASSAY MODULE (1) The laboratory performed Immunoassay testing (i.e., Total PSA (Prostatic Specific Antigen), TSH (Thyroid Stimulating Hormone), HgbA1C (Glycosolated Hemoglobin, FT4 (Free Thyroxine), Vitamin D 25-OH, and Vitamin B12) using the Immunoassay module of the Architect Ci41000; (2) The surveyors reviewed the manufacturer's required maintenance procedures, which were: (a) Daily: (i) Clean the outside of the probes in the wash zone (ii) Mix the microparticle bottles on the reagent carousel (iii) Dry the vacuum pump filter (iv) Flush and prime the wash zone, pre-trigger, and trigger manifolds (v) Check the database integrity (b) Weekly: (i) Manual probe cleaning (ii) Pipettor/WZ (Wash Zone) probe cleaning (iii) Wash Cup cleaning (c) Monthly: (i) Air filter cleaning (3) The maintenance records from 09 /01/18 through 12/31/19 were reviewed. The surveyors identified the maintenance procedures had not been performed as required by the manufacturer, as follows: (a) Daily: (i) 2018: On 9 of the 81 days reviewed: (aa) September: On 1 of the 19 days of testing: Day 28 (bb) October: On 6 of the 23 days of testing: Days 15,16,17,18,19,25 (cc) December: On 2 of the 20 days of testing: Days 27,28 (ii) 2019: On of 23 of the 254 days reviewed: (aa) January: On 2 of the 22 days of testing: Days 9,14 (bb) February: On 1 day of the 21 days of testing: Day 21 (cc) March: On 9 of the 21 days of testing: Days 1,8,11,12,13,14,15,27,28 (dd) August: On 4 of the 22 days of testing: Days 2,5,6,7 (ee) September: On 1 of the 20 days of testing: Day 27 (ff) October: On 3 of the 23 days of testing: Days 6,7,19 (gg) November: On 3 of the 18 days of testing: Days 9,20,21 (b) Weekly: (i) Manual probe cleaning had not been performed between: (aa) 09/21/18 and 10/11/18 (bb) 10/11/18 and 10/25/18 (cc) 11/09/18 and 11 /28/18 (dd) 12/18/18 and 03/07/19 (ee) 03/07/19 and 03/29/19 (ff) 09/26/19 and 10/10 /19 (gg) 10/24/19 and 11/04/19 (ii) Pipettor/WZ (Wash Zone) probe cleaning had not been performed between: (aa) 09/21/18 and 10/11/18 (bb) 10/11/18 and 10/25/18 (cc) 11/09/18 and 11/28/18 (dd) 12/18/18 and 03/07/19 (ee) 03/07/19 and 03/29/19 (iii) Wash Cup cleaning had not been performed between: (aa) 09/21/18 and 10/11/18 (bb) 10/11/18 and 10/25/18 (cc) 11/09/18 and 11/28/18 (dd) 12/18/18 and 03/07/19 (ee) 03 /07/19 and 03/29/19 (ff) 09/26/19 and 10/10/19 (gg) 10/24/19 and 11/04/19 (c) Monthly: The air filter cleaning had not been performed during 3 of the 15 months reviewed: (i) December 2018 (ii) January 2019 (iii) February 2019 (4) The surveyors reviewed the findings with technical consultant #1 and technical consultant #2, who stated to the surveyors the manufacturer's required maintenance procedures had not been performed, as listed above. CELL DYN RUBY HEMATOLOGY ANALYZER (1) Technical consultant #1 and technical consultant #2 stated to the surveyors a new Cell Dyn Ruby analyzer was put into use on 04/27/18 at the laboratory's previous location. The laboratory used the analyzer to perform patient CBC's (Complete Blood Count) (e.g., WBC-White Blood Count, RBC-Red Blood Count), Hemoglobin, Hematocrit, Platelet Count, WBC differential (i.e. Neutrophils, Lymphocytes, Monocytes, Eosinophils, and Basophis), etc.); (2) In addition, technical consultant #1 and technical consultant #2 stated to the surveyors the analyzer was moved to the laboratory's new location 08/06/18 and was put into use for patient testing on 09/24 /18; (3) The surveyors reviewed the manufacturer's required maintenance procedures as listed on the "Cell Dyn Ruby Maintenance Log" and identified the following procedures were required: (a) Daily: Run Auto-Clean (b) Weekly: Clean Loader Components (c) Monthly: (i) Inspect Syringes (ii) Clean Shear Valve (iii) Replace Dil

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| | /Sheath Filter (iv) Replace Transfer Pump Tubing (v) Extended Auto-Clean (4) Maintenance records from 05/06/18 through 01/31/20 were reviewed. It was identified the laboratory failed to perform the manufacturer's required maintenance procedures as follows: (a) Daily: (i) 2018: Had not been performed on 14 of the 166 days reviewed: (aa) August: On 3 of the 23 days of testing: Days 29,30,31 (bb) October: On 8 of the 23 days of testing: Days 15,16,17,18,19,22,26,29 (cc) December: On 3 of the 20 days of testing: Days 19,21,31 (ii) 2019: Had not been performed on 26 of the 254 days reviewed: (aa) January: On 8 of the 22 days of testing: Days 3,9,15,17,18,22,25,28 (bb) February: On 10 of the 21 days of testing: Days 4,7,11,13,14,15,18,20, 21,25 (cc) March: On 6 of the 21 days of testing: Days 1,4,6,21,25,29 (dd) April: On 2 of the 22 days of testing: Days 4,19 (b) Weekly: Had not been performed between: (i) 08/01/18 and 08/20/18 (ii) 09/04/18 and 09/14/18 (iii) 09/14/18 and 09/24/18 (iv) 10/10/18 and 11/05/18 (v) 11/15/18 and 11/28/18 (vi) 02/01/19 and 02/12/19 (vii) 02/22/19 and 03/05/19 (viii) 03/18/19 and 04/03/19 (ix) 04 /11/19 and 04/22/19 (c) Monthly: Had not been performed during 3 of the 21 months reviewed: (i) Replace Transfer Pump Tubing: (aa) October 2018 (bb) March 2019 (ii) Extended Auto-Clean: (aa) September 2018 (5) The surveyors reviewed the findings with technical consultant #1 and technical consultant #2, who stated to the surveyors the manufacturer's required maintenance procedures had not been performed, as listed above. NOTE: D5429 was cited at the previous recertification survey performed 02/06 /18. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with technical consultant #1 and technical consultant #2, the laboratory failed to perform calibration verification procedures at least once every 6 months. Findings include: (1) On the first day of the survey, technical consultant #1 stated to the surveyors the laboratory used the Architect Ci4100 analyzer (composed of a chemistry module and an immunoassay module) and performed chemistry and immunoassay (e.g., Total PSA (Prostatic Specific Antigen), |

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| | TSH (Thyroid Stimulating Hormone), and Hemoglobin A1C) testing; (2) Surveyor #1 reviewed calibration verification records for testing performed from the last recertification survey on 02/06/18 through 02/12/20 (since routine calibration procedures were performed using less than three calibrators for the above analytes, calibration verification procedures, using three or more levels of calibration materials, were required every 6 months). Surveyor #1 identified calibration verification procedures for Total PSA, TSH, and Hemoglobin A1C had not been performed each 6 months between 08/28/18 and 09/09/19; (3) The surveyors reviewed the findings with technical consultant #1 and technical consultant #2, who stated to the surveyors, the laboratory failed to perform calibration verification procedures for the analytes Total PSA, TSH, and Hemoglobin A1C at least once every 6 months as listed above. |
| **D5479** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(5)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, and interview with technical consultant #1 and technical consultant #2, the laboratory failed to follow the manufacturer's specifications for control materials. Findings include: CHEMISTRY CONTROL MATERIALS (1) On the first day of the survey, technical consultant #1 stated to the surveyors: (a) Chemistry testing (i.e., Albumin, Glucose, Potassium, Lipase, etc.) was performed using the Architect Ci4100 analyzer (composed of a chemistry module and an immunoassay module); (b) The analyzer was put into use on 08/27/18 at the laboratory's new location; (c) Two levels (Level 1 and Level 3) of ThermoScientific MAS ChemTRAK Liquid Assayed Chemistry control materials were used each day to monitor acceptability of the testing process; (d) The lot numbers of QC (Quality Control) materials in use during the survey: Level 1, Lot #CHA 20111A and Level 3, Lot #CHA 20113A, put into use on 02/19/19. The new technical consultant (technical consultant #1) suspended chemistry testing from 03/27 /19 to 04/01/19 and established acceptable limits for the QC materials for each analyte. (2) The surveyors reviewed the manufacturer's instructions (package insert) for the QC materials. Under, "Control Ranges," it stated, "Instrument values provided are specific to this lot of control only and are intended to assist the laboratory in establishing its own means and ranges. Laboratory established means should fall within the assigned ranges although subsequent instrument, reagent or calibration modifications may invalidate assigned values;" (3) The surveyors then reviewed QC records from September 2018 through January 2020 for 4 analytes-Albumin, Glucose, Potassium, and Lipase. The surveyors identified the laboratory utilized 4 lot numbers of QC materials during the review period: (a) Level 1, Lot #CHA 19071A and Level 3, Lot #CHA 19073A: Used from 01/01/18 through 02/18/19; (b) Level 1, Lot #CHA 20111A and Level 3, Lot #CHA 20113A: Put into use on 02/19/19 and used through 02/13/20. (4) From the review, the surveyors identified the laboratory failed to establish its own established means and limits for the 4 analytes reviewed, but used the manufacturer's package insert mean, and the range of means as the acceptable limits for 2 of the 4 QC lot numbers (Level 1, Lot #CHA 20111A and Level 3, Lot #CHA 20113A) used from 03/01/19 through 06/30/19; (5) The findings were reviewed with technical consultant #1 and technical consultant #2, who stated to the |

surveyors the laboratory failed to follow the manufacturer's instructions to use their own established mean and limits of acceptability, as listed above. IMMUNOASSAY CONTROL MATERIALS (1) Technical consultant #1 stated to the surveyors, the following: (a) Immunoassay testing (i.e., Total PSA (Prostatic Specific Antigen), TSH (Thyroid Stimulating Hormone), etc.) was performed using the Architect Ci4100 analyzer (composed of a chemistry module and an immunoassay module); (b) The analyzer was put into use on 08/27/18 at the laboratory's new location; (c) Two levels (Level 1 and Level 3) of ThermoScientific MAS OmniIMMUNE Liquid Assayed Chemistry control materials were used each day to monitor acceptability of the testing process; (d) The lot numbers of QC materials in use during the survey were Level 1, Lot #OIM 2010A and Level 3, Lot #OIM 20103A, put into use on 08/24/19 and used through 02/13/20. The new technical consultant (technical consultant #1) stopped testing from 03/27/19 to 04/01/19 and established acceptable limits for the QC materials for each analyte; (2) The surveyors reviewed the manufacturer's instructions for the QC materials. Under, "Control Ranges," it stated, "Instrument values provided are specific to this lot of control only and are intended to assist the laboratory in establishing its own means and ranges." "Laboratory established means should fall within the assigned ranges although subsequent instrument, reagent or calibration modifications may invalidate assigned values;" (3) The surveyors then reviewed QC records from 08/27/18-01/31/20 for TSH and Total PSA and identified the following for 2 of the 2 QC lot numbers used: (a) TSH: (i) Level 1, Lot #OIM 2010A: (aa) 08/27 /18-11/30/18, the laboratory used the manufacturer's means, and range of means for their limits of acceptability; (bb) 12/01/18-12/31/18, the laboratory changed the mean and limits. There was no documentation to show the source of the new mean and limits; (cc) 01/01/19-01/31/19, the laboratory used the manufacturer's means, and range of means for their limits of acceptability; (dd) 02/01/19-04/30/19, the laboratory used their established mean and limits determined from the QC values from 01/01/19-01/31/19; (ee) 05/01/19-06/30/19, the mean was adjusted, but there was no documentation to show the source of the new mean. The same limits were used. (ii) Level 3, Lot #OIM 2013A: (aa) 08/27/18-11/30/18, the laboratory used the manufacturer's means, and range of means for their limits of acceptability; (bb) 12/01 /18-12/31/18, the laboratory changed the mean and limits. There was no documentation to show the source of the new mean and limits; (cc) 01/01/19-01/31 /19, the laboratory used the manufacturer's means, and range of means for their limits of acceptability; (dd) 02/01/19-04/30/19, the laboratory used their established mean and limits determined from the QC values from 01/01/19-01/31/19; (ee) 05/01/19-06 /30/19, the mean was adjusted, but there was no documentation to show the source of the new mean. The same limits were used. (b) Total PSA: (i) Level 1, Lot #OIM 20101A: (aa) 08/27/18-11/30/18, the laboratory used the manufacturer's means, and range of means for their limits of acceptability; (bb) 12/01/18-12/31/18, the laboratory changed the mean and limits. There was no documentation to show the source of the new mean and limits;; (cc) 01/01/19-1/31/19, the laboratory used the manufacturer's means, and range of means for their limits of acceptability; (dd) 2/01/19-06/30/19, the laboratory used their established mean determined from the QC values from 01/01/10-01/31/19. However, the manufacturer's limits were still used. (ii) Level 3, Lot #OIM 20103A: (aa) 08/27/18-11/30/18, the laboratory used the manufacturer's means, and range of means for their limits of acceptability; (bb) 12/01/18-12/31/18, the laboratory used their established mean and limits calculated from the QC values from 11/01/18-11/30/18; (cc) 01/01/19-01/31/19, the laboratory used the manufacturer's means, and range of means for their limits of acceptability; (dd) 02/01/19-06/30/19, the laboratory used their established mean and limits determined from the QC values from 01/01/10-01/31/19. (4) The findings were reviewed with technical consultant #1 and technical consultant #2, who stated to the surveyors the laboratory failed to follow the

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| | manufacturer's instructions to use their own established mean and limits of acceptability, as listed above. |