Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0669880	02/06/2018
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
D0000	The findings were reviewed with the laboratory director/technical consultant at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 1. 493.1215; D5024: Hematology 2. 493.1403; D6000: Laboratory Director, Moderate Complexity 3. 493.1409; D6033: Technical Consultant
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director/technical consultant, the laboratory failed to ensure proficiency testing attestation statements had been signed by the analyst. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed 2016 and 2017 proficiency testing records. The following was identified for 4 of 29 proficiency testing events: (a) 2016 Hematology 2nd Event - The attestation statement had not been signed and dated by the analyst performing the wet prep analysis (VA-02); (b) 2016 Hematology 3rd Event - The attestation statement had not been signed and dated by the analyst performing the wet prep analysis (VA-03); (c) 2017 Hematology 2nd Event - The attestation statement had not been signed and dated by the analyst performing the wet prep analysis (VA-02); (d) 2017

	Hematology 3rd Event - The attestation statement had not been signed and dated by the analyst performing the wet prep analysis (VA-03). (2) The surveyors reviewed the records with the laboratory director/technical consultant, who stated the attestation statements, as indicated above, had not been signed and dated by the analyst performing the wet prep analysis.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory director/technical consultant, the laboratory failed to ensure the requirements were met for the specialty of Hematology. Findings include: (1) The laboratory failed to follow the manufacturer's instructions for verifying flagged results. Refer to D5411; (2) The laboratory failed to ensure control materials were not used beyond the expiration date. Refer to D5417; (3) The laboratory failed to perform maintenance procedures as required by the manufacturer. Refer to D5429; (4) The laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process, and would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for CBC testing. Refer to D5441; (5) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791; (6) The laboratory failed to ensure patient test reports included the name of the laboratory location. Refer to D5805.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director/technical consultant, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed 2016 and 2017 proficiency testing records. The following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program) were identified: (a) 2017 Chemistry Core - 2nd event (i) ALT (Alanine Amino Transferase) - 5 of 5 results exhibited a negative bias (aa) CH-06- SDI -1.9 (bb) CH-07- SDI -3.1 (cc) CH-08- SDI -2.6 (dd) CH-09- SDI -2.4 (ee) CH-10 - SDI -1.5 (ii) Triglycerides - 5 of 5 results exhibited a negative bias (aa) CH-06- SDI -3.9 (bb) CH-07- SDI -4.6 (cc) CH-08- SDI -4.5 (dd) CH-09- SDI -3.9 (ee) CH-10 - SDI -3.0 (b) 2017 Chemistry Core - 3rd event (i) Bilirubin - 5 of 5 results exhibited a negative bias (aa) CH-11 - SDI -2.7 (bb) CH-12 - SDI -2.8 (cc) CH-13 - SDI -2.4 (dd) CH-14 - SDI -2.0 (ee) CH-15 - SDI -2.2 (ii) Glucose - 4 of 5 results exhibited a negative bias (aa) CH-11 - SDI -2.4 (bb) CH-12 - SDI -2.0 (cc) CH-13 - SDI -2.1 (dd) CH-15 - SDI -2.1 (iii) Triglycerides - 3 of 5 results exhibited a negative

	bias (aa) CH-11 - SDI -3.6 (bb) CH-12 - SDI -3.8 (cc) CH-15 - SDI -2.6 (c) 2017 Hematology - 3rd event (i) MCV (Mean Corpuscular Volume) - 5 of 5 results exhibited a negative biasis (aa) ABT-11 - SDI -2.6 (bb) ABT -12 - SDI -2.6 (cc) ABT-13 - SDI -2.7 (dd) ABT -14 - SDI -2.8 (ee) ABT -15 - SDI -2.8 (2) The surveyors reviewed the above findings with laboratory director/technical consultant who stated the biases had not been thoroughly addressed. NOTE: D5211 was cited on the previous recerrtification survey performed on 01/21/16.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory director/technical consultant, the laboratory failed to follow the manufacturer's instructions for verifying flagged results. Findings include: (1) At the beginning of the survey, the laboratory director/technical consultant verified the following to the surveyors: (a) CBC (Complete Blood Count) testing, which included a 5 part automated differential, was performed on the Cell Dyn Ruby analyzer; (b) The laboratory did not perform manual differential testing in house, therefore when a manual differential was indicated, the patient sample would be sent to the reference laboratory. (2) The surveyors reviewed the manufacturer's operator's manual for information regarding flagged results. The following was identified: (a) For RBC MORPH flags, the instructions stated, "Review a stained smear for abnormal RBC or PLT morphology and follow your laboratory's review criteria"; (b) For NWBC flags, the instructions stated, "Review smear for platelet clumps, giant platelets or low levels of NRBC and follow your laboratory's review criteria"; (c) For BAND flags, the instructions stated, "Review a stained smear for the presence of bands and follow your laboratory's review criteria"; (d) VAR LYM flags, the instructions stated, "Review a stained smear for the presence of variant lymphocytes and follow your laboratory's review criteria." (3) The surveyors asked the laboratory director/technical consultant if the laboratory had a policy for addressing flagged results. The laboratory director /technical consultant obtained the policy for the surveyors. The policy stated, "A manual differential or slide review is indicated when any parameter results, such are NRBC, DFLT, LRI, URI, BAND, BLAST, VAR LYM, or RBC MORPH are displayed." In addition, the policy stated, "Refer to Section 3 of the Operator's Manual for a complete listing of the Operational Messages and Data Flagging as well as the suggested actions"; (4) Surveyor #2 then reviewed 10 patient records containing flags. For 5 of 10 records, the laboratory did not send the specimen to the reference laboratory to verify the results when the flags were obtained as follows: (a) Patient #17 - BAND flag obtained and reported on 06/05/17 at 10:04 am; (b) Patient #18 - RBC MORPH flag obtained and reported on 06/15/17 at 09:50 am; (b) Patient #19 - NWBC flag obtained and reported on 06/15/17 at 08:39 am; (c) Patient #20 - BAND flag obtained and reported on 06/23/17 at 12:35 pm; (d) Patient #21 - VAR LYM flag obtained and reported on 06/28/17 at 09:47. (5) The findings were discussed with the laboratory director/technical consultant who stated the laboratory did not ensure the flags that were obtained above had been verified. NOTE: D5411 was cited on the previous recerrtification survey performed on 01/21/16.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director/technical consultant, the laboratory failed to ensure control materials were not used beyond the expiration date. Findings include: (1) At the beginning of the survey, the laboratory director/technical consultant stated the following to the surveyors: (a) CBC (Complete Blood Count) testing was performed on the Cell Dyn Ruby analyzer; (b) Three levels of Cell Dyn 26 Plus quality control (QC) materials were performed each day of patient testing. (2) Later during the survey, surveyor #1 reviewed QC records for 7 lot numbers of QC materials used from 12/20/16 through the day of the survey. It was identified controls had been used beyond the manufacturer's expiration date for 2 of 7 lot numbers reviewed as follows: (a) Low, Normal, and High controls (lot #7086) used from 04/11/17 through 06/16/17. The manufacturer's expiration date was 06/09 /17; (b) Low, Normal, and High controls (lot #7254) used from 09/25/17 through 12 /12/17. The manufacturer's expiration date was 11/24/17. (3) Surveyor #1 reviewed the records with the laboratory director/technical consultant who stated the controls had been used beyond the expiration date; (4) The following were examples of patient CBC testing performed when the laboratory used expired QC materials to assess the acceptable performance of the analyzer: (a) Patient #1 - Testing performed on 06/12 /17 (b) Patient #2 - Testing performed on 06/13/17 (c) Patient #3 - Testing performed on 06/14/17 (d) Patient #4 - Testing performed on 06/15/17 (e) Patient #5 - Testing performed on 06/16/17 (f) Patient #6 - Testing performed on 11/27/17 (g) Patient #7 - Testing performed on 11/28/17 (h) Patient #8 - Testing performed on 11/29/17 (i) Patient #9 - Testing performed on 11/30/17 (j) Patient #10 - Testing performed on 12 /01/17 (k) Patient #11 - Testing performed on 12/04/17 (l) Patient #12 - Testing performed on 12/05/17 (m) Patient #13 - Testing performed on 12/06/17 (n) Patient #14 - Testing performed on 12/07/17 (o) Patient #15 - Testing performed on 12/08/17 (p) Patient #16 - Testing performed on 12/12/17 NOTE: D5417 was cited on the previous recerrtification survey performed on 01/21/16. 39088 Based on a review of records, observation, and interview with the laboratory director/technical consultant, the laboratory failed to ensure testing supplies were not available for use beyond the open stability expiration date. Findings include: (1) At the beginning of the survey, surveyor #2 observed the following control materials contained in the laboratory refrigerator: (a) Dipper Urinalysis Diptick Control Level 1 (lot#44291) dated as opened on 01/04/18 & Level 2 (lot# 44292) dated as opened on opened 01/04/18 (2) Surveyor #2 asked laboratory director/technical consultant to explain what the controls were used for. The laboratory director/technical consultant explained the following: (a) Dipper Urinalysis Dipstick controls were used to perform daily quality control procedures for urinalysis testing performed on the Clinitek Advantus analyzer. (3) Surveyor #2 reviewed the manufacturer's open date stability instructions, which required the following: (a) After initial use each tube of control is stable for 3 months or 20 dipstick immersions, whichever occurs first. (4) Surveyor #2 reviewed the instructions, the date on the control bottles, and the quality control records between 01 /04/18 through 02/06/18 with the laboratory director/technical consultant. The review

	verified the controls had been used for 23 dipstick immersions; (5) The laboratory director/technical consultant stated the controls had been used beyond 20 dipstick immersions;
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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, manufacturer's instructions, and interview with the laboratory director/technical consultant, the laboratory failed to perform maintenance procedures as required by the manufacturer. Findings include: (1) At the beginning of the survey, the laboratory director/technical consultant stated to the surveyors CBC (Complete Blood Count) testing was performed on the Cell Dyn Ruby analyzer; (2) Surveyor #1 reviewed the manufacturer's maintenance instructions for the analyzer which were: (a) Weekly (i) Clean Loader Components (b) Monthly (i) Inspect Syringes (ii) Replace Transfer Pump Tubing (iii) Clean Shear Valve (iv) Replace Dil /Sheath (v) Extended Auto Clean (3) Maintenance records were reviewed by surveyor #1 for 13 months (January 2017 through January 2018) with the following identified: (a) The weekly maintenance had not been documented as performed between: (i) 01 /18/17 and 01/30/17 (ii) 05/05/17 and 05/18/17 (iii) 05/26/17 and 06/22/17 (iv) 06/22 /17 and 07/05/17 (v) 10/13/17 and 10/23/17 (vi) 11/17/17 and 11/27/17 (vii) 12/12/17 and 12/27/17 (viii) 01/04/18 and 01/15/18 (b) The following monthly maintenance procedures had not been documented as performed: (i) April 2017 - Clean Shear Valve and Extended Auto Clean (ii) May 2017 - Replace Dil/Sheath and Replace Transfer Pump Tubing (iii) June 2017 - Replace Dil/Sheath and Extended Auto Clean (iv) November 2017 - Extended Auto Clean (4) Surveyor #1 reviewed the records with the laboratory director/technical consultant, who stated there was no evidence the above maintenance procerdures had been performed as required; (5) The following were examples of patient CBC testing performed when maintenance had not been performed as required by the manufacturer: (a) Patient #27 - Testing performed on 01 /24/17 (b) Patient #28 - Testing performed on 01/26/17 (c) Patient #35 - Testing performed on 04/11/17 (d) Patient #36 - Testing performed on 04/13/17 (e) Patient #37 - Testing performed on 04/17/17 (f) Patient #38 - Testing performed on 04/19/17 (g) Patient #39 - Testing performed on 04/28/17 (h) Patient #40 - Testing performed on 05/02/17 (i) Patient #41 - Testing performed on 05/11/17 (j) Patient #42 - Testing performed on 05/16/17 (k) Patient #43 - Testing performed on 05/24/17 (l) Patient #44 - Testing performed on 05/30/17 (m) Patient #45 - Testing performed on 06/01/17 (n) Patient #46 - Testing performed on 06/05/17 (o) Patient #47 - testing performed on 06/07/17 (p) Patient #48 - Testing performed on 06/20/17 (q) Patient #49 - Testing performed on 06/28/17 (r) Patient #50 - Testing performed on 06/30/17 (s) Patient #64 - Testing performed on 10/19/17 (t) Patient #70 - Testing performed on 11/22/17 (u) Patient #6 - Testing performed on 11/27/17 (v) Patient #16 - Testing performed on 12 /12/17 (w) Patient #71 - Testing performed on 01/09/18 (x) Patient #72 - Testing performed on 01/10/18 (y) Patient #73 - Testing performed on 01/12/18 (z) Patient #74 - Testing performed on 01/15/18
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory director/technical consultant, the laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process, and would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for CBC testing. Findings include: (1) At the beginning of the survey, the laboratory director/technical consultant stated the following to the surveyors: (a) CBC (Complete Blood Count) testing was performed on the Cell Dyn Ruby analyzer; (b) Three levels of Cell Dyn 26 Plus quality control (QC) materials were performed each day of patient testing; (c) The laboratory established their own means and 2 standard deviation ranges for new lot numbers of QC material before putting into use for patient testing. (2) Surveyor #1 reviewed the manufacturer's instructions contained in the QC package insert which stated, "The Mean Range does not represent standard deviations (SD)"; (3) Surveyor #1 then reviewed QC records for 7 lot numbers of QC material used for patient testing performed from January 2016 through January 2018 for the CBC analytes WBC (White Blood Count), Hemoglobin, and Platelet. For 4 of 7 lot numbers, it was identified there were no outliers (approximately 1 out of every 20 control results should be defined as unacceptable and there were no results that were beyond the laboratory's established range). Upon further review, it was identified the laboratory had used QC ranges that were wider than the manufacturer's QC package insert range of means (and not a 2 SD range) as follows: (a) Control lot #6340 - Used from 12/20/16 through 02/16/17 (i) Normal Level (aa) WBC - The package insert range of means was 6.7-8.1. A range of 4.72-10.4 had been used to evaluate QC results; (bb) Hemoglobin - The package insert range of means was 11.6-12.8. A range of 11.4-13.8 had been used to evaluate QC results; (cc) Platelet - The package insert range of means was 184-244. A range of 148-326 had been used to evaluate QC results. (b) Control lot #7086 - Used from 04 /11/17 through 06/16/17 (i) Normal Level (aa) WBC - The package insert range of means was 6.9-8.3. A range of 5.60-9.00 had been used to evaluate QC results; (bb) Hemoglobin - The package insert range of means was 11.6-12.8. A range of 9.29-14.9 had been used to evaluate QC results; (cc) Platelet - The package insert range of means was 178-238. A range of 161-275 had been used to evaluate QC results. (ii) High Level (aa) WBC - The package insert range of means was 14.8-19.8. A range of 9.18-23.2 had been used to evaluate QC results; (bb) Hemoglobin - The package insert range of means was 15.6-17.2. A range of 11.6-20.4 had been used to evaluate QC results; (cc) Platelet - The package insert range of means was 426-546. A range of 367-617 had been used to evaluate QC results. (c) Control lot #7142 - Used from 06 /20/17 through 08/03/17 (i) Normal level (aa) WBC - The package insert range of means was 6.3-7.7. A range of 4.37-9.13 had been used to evaluate QC results; (bb) Hemoglobin - The package insert range of means was 11.3-12.5. A range of 8.48-15.5

had been used to evaluate QC results; (cc) Platelet - The package insett range of means was 182-242. A range of 186-260 had been used to evaluate QC results. (ii) High level (aa) WBC - The package insert range of means was 13.3-18.3. A range of 10.7-20.5 had been used to evaluate QC results; (bb) Hemoglobin - The package insert range of means was 15.4-17.0. A range of 11.1-21.3 had been used to evaluate QC results; (cc) Platelet - The package insert range of means was 454-574. A range of 358-688 had been used to evaluate QC results. (d) Control lot #7254 - Used from 09 /25/17 through 12/12/17 (i) High level (aa) WBC - The package insert range of means was 13.7-18.7. A range of 12.1-19.7 had been used to evaluate QC results; (bb) Hemoglobin - The package insert range of means was 14.9-16.5. A range of 13.0-18.8 had been used to evaluate QC results; (cc) Platelet - The package insert range of means was 461-581. A range of 355-697 had been used to evaluate QC results. (4) Surveyor #1 reviewed the findings with the laboratory director/technical consultant, and explained the QC ranges used by the laboratory did not monitor the accuracy and precision of the complete analytic process, and did not detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance. The laboratory director/technical consultant stated the laboratory was not aware the established ranges were wider than the package insert range of means; (5) Examples of patient CBC testing performed when the laboratory did not have QC ranges to monitor the accuracy and precision of the analytic process: (a) Patient #22 - Testing performed on 01/03/17 (b) Patient #23 - Testing performed on 01/05/17 (c) Patient #24 - Testing performed on 01/10/17 (d) Patient #25 - Testing performed on 01/13/17 (e) Patient #26 - Testing performed on 01/17/17 (f) Patient #27 - Testing performed on 01/24/17 (g) Patient #28 - Testing performed on 01/26/17 (h) Patient #29 - Testing performed on 01/31/17 (i) Patient #30 - Testing performed on 02/02/17 (j) Patient #31 - Testing performed on 02/08/17 (k) Patient #32 - Testing performed on 02/10/17 (l) Patient #33 - Testing performed on 02/14/17 (m) Patient #34 - Testing performed on 02/16/17 (n) Patient #35 - Testing performed on 04/11/17 (o) Patient #36 - Testing performed on 04/13/17 (p) Patient #37 - Testing performed on 04/17/17 (q) Patient #38 - Testing performed on 04/19/17 (r) Patient #39 - Testing performed on 04/28/17 (s) Patient #40 - Testing performed on 05/02/17 (t) Patient #41 - Testing performed on 05/11/17 (u) Patient #42 - Testing performed on 05/16/17 (v) Patient #43 - Testing performed on 05/24/17 (w) Patient #44 - Testing performed on 05/30/17 (x) Patient #45 - Testing performed on 06/01/17 (y) Patient #46 - Testing performed on 06/05/17 (z) Patient #47 - Testing performed on 06/07/17 (aa) Patient #1 - Testing performed on 06/12/17 (bb) Patient #2 - Testing performed on 06/13/17 (cc) Patient #3 - Testing performed on 06/14/17 (dd) Patient #4 - Testing performed on 06/15/17 (ee) Patient #5 - Testing performed on 06/16/17 (ff) Patient #48 - Testing performed on 06/20/17 (gg) Patient #49 - Testing performed on 06/28/17 (hh) Patient #50 - Testing performed on 06/30/17 (ii) Patient #51 - Testing performed on 07/06/17 (jj) Patient #52 - Testing performed on 07/11/17 (kk) Patient #53 - Testing performed on 07/18/17 (ll) Patient #54 - Testing performed on 07/26/17 (mm) Patient #55 - Testing performed on 07/31/17 (nn) Patient #56 - Testing performed on 08/01/17 (oo) Patient #57 - Testing performed on 08/03/17 (pp) Patient #58 - Testing performed on 09/25/17 (qq) Patient #59 - Testing performed on 09/27/17 (rr) Patient #60 - Testing performed on 09/29/17 (ss) Patient #61 - Testing performed on 10/02/17 (tt) Patient #62 - Testing performed on 10/04/17 (uu) Patient #63 - Testing performed on 10/09 /17 (vv) Patient #64 - Testing performed on 10/19/17 (ww) Patient #65 - Testing performed on 10/25/17 (xx) Patient #66 - Testing performed on 10/31/17 (yy) Patient #67 - Testing performed on 11/03/17 (zz) Patient #68 - Testing performed on 11/09 /17 (aaa) Patient #69 - Testing performed on 11/15/17 (bbb) Patient #70 - Testing performed on 11/22/17 (ccc) Patient #6 - Testing performed on 11/27/17 (ddd) Patient #7 - Testing performed on 11/28/17 (eee) Patient #8 - Testing performed on 11/29/17

(fff) Patient #9 - Testing performed on 11/30/17 (ggg) Patient #10 - Testing performed on 12/01/17 (hhh) Patient #11 - Testing performed on 12/04/17 (iii) Patient #12 - Testing performed on 12/05/17 (jjj) Patient #13 - Testing performed on 12/06/17 (kkk) Patient #14 - Testing performed on 12/07/17 (lll) Patient #15 - Testing performed on 12/08/17 (mmm) Patient #16 - Testing performed on 12/12/17 NOTE: D5441 was cited on the previous recerrtification survey performed on 01/21/16. 39088 Based on a review of records, manufacturer's package insert, and interview with the laboratory director/technical consultant, the laboratory failed to have control procedures that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for chemistry testing. Findings include: QUALITY CONTROL RANGES (1) At the beginning of the survey, the laboratory director/technical consultant verified the following to the surveyors: (a) The laboratory used the Ortho Vitros 250 analyzer to perform testing for the analytes Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CO2, Creatinine, Glucose,LDL (Low Density Lipoprotien), HDL (High Density Lipoprotein) Cholesterol, Potassium, Sodium, Total Bilirubin, Total Cholesterol, Total Protein, and Triglycerides; (b) Two levels of Vitros Performance Verifier quality control (QC) materials were performed each day of patient testing for the analytes listed above. (2) The surveyors reviewed the package inserts for the control materials. The manufacturer provided a standard deviation (SD) for the laboratory to utilize for each level of control and analyte; and a range of means for the laboratory to use as a guide when establishing their means; (3) The surveyors reviewed QC records for testing performed from September 2017 through November 2017 for the analytes BUN, Cholesterol, Chloride and CO2. The review verified the laboratory was using SD's that were greater than the package insert provided SD's as follows: (a) Vitros Performance Verifier level 1 (lot #N5113) (i) BUN (aa) Level 1 - The package insert SD was 0.60. A SD of 7.3 had been used to evaluate (ii) Cholesterol (aa) Level 1 - The package insert SD was 4.33. A SD of 4.5 had been used to evaluate QC results; (iii) Chloride (aa) Level 1 - The package insert SD was 1.10. A SD of 1.20 had been used to evaluate QC results; (iv) CO2 (aa) Level 1 - The package insert SD was 1.30. A SD of 1.47 had been used to evaluate QC results; (b) Vitros Performance Verifier level 2 (lot #P5115) (i) Glucose (aa) Level 2 - The package insert SD was 4.72. A SD of 4.86 had been used to evaluate QC results; (4) The surveyors reviewed the findings with the laboratory director/technical consultant, who stated the manufacturer provided SD had not been utilized for the above analytes. NOTE: D5441 was cited on the previous recertification survey performed on 01/21/16. QUALITY CONTROL VARIANCES Based on a review of records and interview with the laboratory manager /technical consultant, the laboratory failed to have control procedures that monitored the accuracy of the analytic process. Findings include: (1) At the beginning of the survey, the laboratory manager/technical consultant stated the following to surveyors: (a) The laboratory used the Ortho Vitros 250 analyzer to perform testing for the analytes Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CO2, Creatinine, Glucose,LDL (Low Density Lipoprotien), HDL (High Density Lipoprotein) Cholesterol, Potassium, Sodium, Total Bilirubin, Total Cholesterol, Total Protein, and Triglyceride; (b) Two levels of Vitros Performance Verifier quality control (QC) materials were performed each day of patient testing for the analytes listed above. (2) Later during the survey, the surveyors reviewed quality control records for testing performed during September 2017 through November 2017. The following biases were identified as follows: (a) Vitros Performance Verifier level 1 (lot #N5113) (i) Albumin (aa) September 2017 - 18 of 18 control results were above the mean (bb) October 2017 - 19 of 19 control results were above the mean (cc)

	November 2017 - 14 of 15 control results were above the mean (ii) Calcium (aa) September 2017 - 17 of 18 control results were below the mean (bb) October 2017 - 19 of 19 control results were below the mean (b) Vitros Performance Verifier level 2 (lot #P5115) (i) AST (aa) September 2017 - 15 of 18 control results were below the mean (bb) October 2017 - 19 of 19 control results were below the mean (cc) November 2017 - 14 of 15 control results were above the mean (ii) Calcium (aa) September 2017 - 16 of 18 control results were below the mean (bb) November 2017 - 12 of 15 control results were below the mean (iii) ChloridE (aa) September 2017 - 16 of 18 control results were below the mean (bb) October 2017- 13 of 19 control results were above the mean (iv) Cholesterol (aa) September 2017 - 17 of 18 control results were below the mean (bb) October 2017 - 18 of 19 control results were below the mean (cc) November 2017 - 15 of 15 control results were below the mean (v) Glucose (aa) September 2017 - 12 of 18 control results were below the mean (bb) October 2017 - 18 of 19 control results were below the mean (cc) November 2017 - 15 of 15 control results were above the mean (3) There was no evidence in the records that the control biases had been identified and addressed; (4) The surveyors reviewed the records with the laboratory director/technical consultant and asked if there was documentation to prove the biases had been identified and addressed. The laboratory director/technical consultant stated the biases had not been addressed; (5) Since the above biases had not been identified and addressed, the surveyors determined the laboratory failed to have control procedures that monitored the accuracy of testing for the above analytes.
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 a review of records, manufacturer's instructions and interview with the laboratory director/technical consultant, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to follow the manufacturer's instructions for verifying flagged results. Refer to D5411; (b) The laboratory failed to ensure control materials were not used beyond the expiration date and failed to ensure testing supplies were not available for use beyond the open stability expiration date. Refer to D5417; (c) The laboratory failed to perform maintenance procedures as required by the manufacturer. Refer to D5429; (d) The laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process, and would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance. Refer to D5441. NOTE: D5791 was cited on the previous recerrtification survey performed on 01/21 /16.
D5805	TEST REPORT CFR(s): 493.1291(c)

	The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director/technical consultant, the laboratory failed to ensure patient test reports included the name of the laboratory location. Findings include: (1) At the beginning of the survey, the laboratory director/technical consultant verified to the surveyors the laboratory performed CBC (Complete Blood Count) using the Cell Dyn Ruby analyzer; CMP (Comprehensive Metabolic Panel) and Lipid Profile using the Vitros 250; (2) The surveyors then reviewed 2 patient reports: (a) Report #1 - CMP, Lipid Profile and CBC performed on 02/06/18 (b) Report #2 - CMP, Lipid Profile and CBC performed on 02/06/18 (3) It was identified that the name of the laboratory on the reports was "Creek Nation Hospital & Clinics", which did not match the name on the CLIA certificate. The name on the CLIA certificate was "Eufaula Indian Health Center"; (4) The surveyors reviewed the reports with the laboratory director/technical consultant who agreed the name on the reports did not match the name on the CLIA certificate. CMP - BUN (Blood Urea Nitrogen), Calcium, Creatinine, Glucose, Chloride, CO2, Potassium, Sodium, Albumin, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Alkaline Phosphatase, Total Bilirubin, Anion Gap, A/G Ration, Estimated Glomerular Filtration Rate, Osmolality and Total Protein Lipid Profile - Cholesterol, HDL (High Density Lipoprotein), Cholesterol, Triglycerides, LDL (Low Density Lipoprotein), VLDL (Very Low Density Lipoprotein) and Cholesterol/HDL Ratio
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 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. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory director/technical consultant, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to ensure test methods were performed as required to ensure accurate and reliable results were reported. Refer to D6014; (2) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (3) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021. NOTE: D6000 was cited on the previous recerrtification survey performed on 01/21/16.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(3)(iii) 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. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory director/technical consultant, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory director failed to ensure the manufacturer's instructions were followed for verifying flagged results. Refer to D5411; (2) The laboratory director failed to ensure control materials were not used beyond the expiration date. Refer to D5417; (3) The laboratory director failed to ensure maintenance procedures were performed as required by the manufacturer. Refer to D5429. NOTE: D6014 was cited on the previous recerrtification survey performed on 01/21/16.
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director/technical consultant, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed ensure control procedures monitored the accuracy and precision of the complete analytic process, and would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for CBC testing. Refer to D5441. NOTE: D6020 was cited on the previous recerrtification survey performed on 01/21/16.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions and interview with the laboratory director/technical consultant, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure there was an effective mechanism for performing quality assessment due to the issues identified during the survey. Refer to D5791. NOTE: D6021 was cited on the previous recerrtification survey performed on 01/21/16.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 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. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory director/technical consultant, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042; (2) The technical consultant failed to ensure a testing person performing moderate complexity testing had been evaluated at least annually. Refer to D6054. NOTE: D6033 was cited on the previous recerrtification survey performed on 01/21/16.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (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; This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory director/technical consultant, the technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure the manufacturer's instructions were followed for verifying flagged results. Refer to D5411; (2) The technical consultant failed to ensure control materials were not used beyond the expiration date. Refer to D5417; (3) The technical consultant failed to ensure maintenance procedures were performed as required by the manufacturer. Refer to D5429; (4) The technical consultant failed to ensure control procedures that monitored the accuracy and precision of the complete analytic process, and would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance. Refer to D5441.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with laboratory director/technical consultant, the technical consultant failed to evaluate testing persons performing moderate complexity testing at least annually. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed personnel records for 2 persons who performed testing in 2016 and 2017. For 1 of 2 persons there was no evidence annual evaluations had been documented as performed by the technical consultant. (a) 2017 (i) Testing Person #1 (2) The surveyors reviewed the findings with laboratory director/technical consultant, who stated the annual evaluation had not been documented as performed by the technical consultant in 2017 for the above testing person.