Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1092055	10/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Absentee Shawnee Tribal Health System -	2029 S Gordon Cooper Dr, Building 17, Shawnee, 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 recertification survey was performed on 10/16/18. The laboratory was found to be in compliance with standard-level deficiencies. The findings were reviewed with the laboratory director and the laboratory supervisor at the conclusion of the survey.
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 supervisor, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: (1) At the beginning of the survey, the surveyor reviewed the 2017 and 2018 proficiency testing records and identified the following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program): (a) First 2017 Chemistry Event (i) Glucose: 5 of 5 results exhibited a Negative bias (aa) CET-1: SDI -2.35 (bb) CET-2: SDI -2.31 (cc) CET-3: SDI -1.05 (dd) CET-4: SDI -2.50 (ee) CET-5: SDI -2.63 (2) There was no documentation found in the records the laboratory identified the biases, investigated to determine if a systematic failure had occurred, and failed to take corrective action (e. g., review quality control record, maintenance records, calibration, etc.) ; (3) The surveyor reviewed the findings with the laboratory supervisor and laboratory director who stated to the surveyor the biases had not been identified, or evaluated, and corrective action had not been taken.
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, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to have control procedures that detected immediate errors and monitored the accuracy and precision of the analytic process of CBC testing. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyor, the laboratory performed CBC (Complete Blood Count) (WBC-White Blood Count), RBC-Red Blood Count, Hgb (Hemoglobin), Hct (Hematocrit), Platelet Count, etc.) testing using the Sysmex XS-1000i hematology analyzer and the laboratory tested 3 levels (Level 1, Level 2, and Level 3) of Sysmex e-Check (XS) QC (Quality Control) materials each day of patient testing; (2) The surveyor reviewed QC records from 02/22/17 through 09/23/18 for each level of QC material for the analytes WBC, RBC, Hgb, Hct, and Platelet count. The laboratory utilized 21 lot numbers of QC materials during the period reviewed: (a) 01/05/17 to 03 /31/17: Level 1-Lot #63550804; Level 2-Lot #63550805; Level 3-Lot #63550806 (b) 02/22/17 to 04/07/17: Level 1-Lot #70450804; Level 2-Lot #70450805; Level 3-Lot #70450806 (c) 08/09/17 to 09/15/17: Level 1-Lot #72130804; Level 2-Lot #72130805; Level 3-Lot #72130806 (d) 11/29/17 to 12/27/17: Level 1-Lot #73250804; Level 2-Lot #73250805; Level 3-Lot #73250806 (e) 01/24/18 to 04/02 /18: Level 1-Lot #80160804; Level 2-Lot #80160805; Level 3-Lot #80160806 (f) 04 /02/18 to 04/27/18: Level 1-Lot #80720804; Level 2-Lot #80720805; Level 3-Lot #80720806 (g) 07/11/18 to 09/23/18: Level 1-Lot #81840804; Level 2-Lot #81840805; Level 3-Lot #81840806 (3) The surveyor identified 3 of the 21 QC lot numbers listed above, had no outliers (approximately 1 out of every 20 control results should be defined as unacceptable and there were no results beyond the laboratory's established ranges) for the analytes listed above. In addition, the LJ (Levey Jennings) graphs indicated the following: (a) 01/05/17 to 03/09/17: (i) Level 1: Lot #63550804 (aa) WBC: The mean used was 2.98. The upper limit or +2SD (Standard Deviation) was 5.96 and the lower limit or -2SD was 0.00 (bb) RBC: The mean was 2.28. The upper limit was 4.56 and the lower limit was 0.00; (cc) Hgb: The mean was 5.8. The upper limit was 11.6 and the lower limit was 0.0; (dd) Hct: The mean was 17.4. The upper limit was 34.8 and the lower limit was 0.0; (ee) Platelet: The mean was 63. The upper limit was 126 and the lower limit was 0. (ii) Level 2, Lot #63550805 (aa) WBC: The mean was 6.98. The upper limit was 13.96 and the lower limit was 0.00; (bb) RBC: The mean was 4.37. The upper limit was 8.74 and the lower limit was 0.00; (cc) Hgb: The mean was 12.5. The upper limit was 25.0 and the lower limit was 0.0; (dd) Hct: The mean was 36.3. The upper limit was 72.6 and the lower limit was 0.0; (ee) Platelet: The mean was 234. The upper limit was 468 and the lower limit was 0. (iii) Level 3, Lot #63550806 (aa) WBC: The mean was 16.35. The upper limit was 32.70 and the lower limit was 0.00; (bb) RBC: The mean was 5.17. The upper limit was 10.34 and the lower limit was 0.00; (cc) Hgb: The mean was 16.4. The upper limit was 32.8 and the lower limit was 0.0; (dd) Hct: The mean was 47.3. The upper limit

	was 94.6 and the lower limit was 0.0; (ee) Platelet: The mean was 548. The upper limit was 1096 and the lower limit was 0. (4) The surveyor asked the laboratory supervisor how the mean and limits listed above for each QC level and analyte were obtained. The laboratory supervisor explained prior to implementing new QC lot numbers, each level was repeated to obtain 20-25 data points. The mean was calculated from the data points and the ranges were set using the manufacturer's "Evidence Based Quality Control Limits," specific for each level and analyte. In addition, the laboratory supervisor explained the values listed on the LJ graphs were the values used to monitor the acceptability of the QC results. The laboratory supervisor stated it was discovered on 03/09/17, after the lots listed above had been utilized, the manufacturer's Evidence Based Quality Control Limits had been deleted and the manufacturer was contacted and the limits were re-entered; (5) The surveyor determined from the LJ graphs, the laboratory failed to utilize the manufacturer's Evidence Based QC Limits % for each level and analyte listed above. Therefore, the surveyor determined the laboratory did not have a method to detect immediate errors of the analytic process, and failed to monitor the accuracy and precision of CBC testing for the time period and QC lot numbers listed above; (6) The surveyor reviewed the findings with the laboratory supervisor and the laboratory director. Both stated to the surveyor the laboratory failed to use the manufacturer's Evidence Based QC Limits % for each analyte and level for the 3 QC lot numbers listed above, and the limits used to monitor the acceptability of QC results would not detect immediate errors and would not monitor the accuracy and precision of the testing.
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 supervisor, the laboratory failed to have an effective ongoing mechanism for performing analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing quality assessment due to the following issue identified during the survey: (a) The laboratory failed to have control procedures that detected immediate errors and monitored the accuracy and precision of the analytic process of testing. Refer to D5441.