Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0668131	03/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Northeastern Tribal Health System	7600 S Hwy 69a, Miami, 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 validation survey was performed on 03/20/19 and 03/21/19. The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with technical consultant #2/laboratory supervisor, testing person #3 and testing person #4 at the conclusion of the survey.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2/laboratory supervisor, the laboratory failed to retain patient records for at least 2 years. Findings include: (1) On the first day of the survey, the technical consultant #2/laboratory supervisor stated CBC (Complete Blood Count) testing was performed on the Sysmex XS-1000i analyzer; (2) On the second day of the survey, the surveyor requested patient records which contained morphologic flags (i.e., Blasts?, Left Shift?, Atypical Lymph?). This was requested in order to determine if CBC morphologic flags obtained from testing on the analyzer had been verified according to the manufacturer's instructions and laboratory policy. Technical consultant #2/laboratory supervisor explained since patient information was transferred to their LIS, the instrument printouts were not maintained; (3) While searching in the analyzer's memory, technical consultant #2/laboratory supervisor stated that patient data could not be retrieved between 01/01/17 through 07/10/17. Therefore, the surveyor could not determine if morphology flags, obtained from patient testing between 01/01/17 through 07/10/17 had been evaluated; (4) The surveyor explained to technical consultant #2/laboratory supervisor that records of patient testing must be maintained for at least 2 years.

D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with technical consultant #2/laboratory supervisor, the laboratory failed to have a written technical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records for competency assessments performed during 2017, 2018, and 2019. There was no evidence competencies had been performed for the technical consultant, based on their job responsibilities; (2) The surveyor asked technical consultant #2/laboratory supervisor if a written policy to evaluate the technical consultant based on job responsibilities was available. Technical consultant #2/laboratory supervisor stated a policy to evaluate the technical consultant based on job responsibilities had not been written; and competencies had not been performed.
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 technical consultant #2/laboratory supervisor, the laboratory failed to review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, the surveyor reviewed the 2017, 2018, and 2019 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Second 2018 Chemistry Core Event (i) Alkaline Phosphatase - 3 of 5 results exhibited a negative bias (aa) Sample CH-06 - SDI of -2.3 (bb) Sample CH-08 - SDI of -2.0 (cc) Sample CH-10 - SDI of -2.4 (b) Second 2018 Hematology Event (ii) White Blood Cells- 3 of 5 results exhibited a negative bias (aa) Sample XE-06 - SDI of -2.5 (bb) Sample XE-09 - SDI of -2.5 (cc) Sample XE-10 - SDI of -2.1 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with technical consultant #2/laboratory supervisor who stated the biases had not been addressed.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

	This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with technical consultant #2/laboratory supervisor, the laboratory failed to evaluate the relationship of urinalysis testing performed on two different analyzers at least twice a year. Findings include: (1) On the first day of the survey, technical consultant #2/laboratory supervisor stated to the surveyor the laboratory performed routine urinalysis using two analyzers: (a) IRIS Diagnostics iCHEM/IRIS iChem VELOCITY/International Remote Imaging System IQ 200 (primary analyzer) (b) Siemens Clinitek Advantus (back-up analyzer) (2) The surveyor then reviewed 2018 records and identified that, although the laboratory had performed comparison testing between the two analyzers twice in 2018, using Proficiency Testing Verification samples, there was no evidence the results had been evaluated by the laboratory for acceptability; (3) The surveyor reviewed the laboratory's policy and procedure manual. A policy could not be located that explained how the test results obtained from both analyzers were to be compared and evaluated; (4) The findings were reviewed with technical consultant #2/laboratory supervisor who stated the following to the surveyor: (a) The data had not been evaluated using defined criteria; (b) A comparison testing policy had not been written.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2/laboratory supervisor, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population. Findings include: (1) On the first day of the survey, technical consultant#2/laboratory supervisor stated to the surveyor CBC (Complete Blood Count) testing was performed using the Sysmex XS-1000i analyzer; (2) On the second day of the survey, the surveyor reviewed two patient CBC reports - the first report was for an adult male patient with the testing performed on 08 /14/18 at 03:03 pm; the second report was for an adult female patient with the testing performed on 03/20/18 at 01:30 pm. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell), Hemoglobin, and Hematocrit which were: (a) RBC - 4.2 - 6.1 M/L (b) Hemoglobin - 12.0 - 18.0 g/dL (c) Hematocrit - 37.0 -52.0 % (3) The surveyor reviewed the findings with technical consultant #2/laboratory supervisor, who stated the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.