Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0705524	04/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Citizen Potawatomi Nation Health Services	2307 S Gordon Cooper Drive, Suite N91-Lab, 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 findings were reviewed with the technical consultant at the conclusion of the survey.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure an analyzer was stored as required by the manufacturer. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XS-1000i analyzer, which was put into use on 02/17/17 to replace the Beckman Coulter AcT Diff 2 analyzer; (2) The surveyor then reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required the relative humidity be maintained within the range of 30-85%; (3) The surveyor reviewed laboratory humidity records for 5 months - April, November, and December 2017; January and February 2018. The surveyor identified on 18 days of the 100 days reviewed, the humidity was less than 30%, as follows: (a) December 2017: (i) On 9 of the 19 days reviewed, the humidity was less than 30%: Days 6,7,11,12,13,14,27, 28,29 (ii) On 2 of the 19 days reviewed, the humidity was less than 30%: Days 8 and 26. Although corrective action had been taken (turned on

	humidifier), the laboratory failed to ensure the corrective action taken was effective and the humidity was still below 30% when checked. (b) January 2018: (i) On 6 of the 22 days reviewed, the humidity was less than 30%: Days 2,3,12,16,17,31 (c) February 2018: (i) On 1 of the 20 days reviewed, the humidity was less than 30%: Day 2 (4) The surveyor reviewed the findings with the technical consultant who stated to the surveyor the laboratory failed to maintain the humidity as required by the manufacturer.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the technical consultant, the laboratory failed to ensure a function check performed on pipettes was acceptable. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor the laboratory performed Chemistry testing (e.g., Glucose, Creatinine, Cholesterol, etc.) using the Ortho Vitros 350 analyzer; (2) Later in the survey, the surveyor asked the technical consultant how the laboratory performed pipette function checks. The technical consultant explained to the surveyor the laboratory utilized a pipette verification service once a year to ensure the pipettes used in the laboratory, accurately delivered the volume selected. The surveyor observed the following multidelivery pipettes available for use on the day of the survey: (a) Finnipette (V666520), which delivered volumes of 1000ul (microliters), 500ul, or 100ul (b) Oxford (A9X023702), which delivered volumes of 1000ul, 500ul, or 100ul (c) Finnipette (V69381), which delivered volumes of 100ul, 50ul, or 10ul (3) The surveyor asked the technical consultant how the laboratory used the pipettes listed above. The technical consultant stated to the surveyor the pipettes were used in the following situations: (a) To manually dilute analytes for testing when they could not be autodiluted by the analyzer (b) To mix equal volumes of the low and high calibrators in order to make a midpoint calibrator for calibration verification purposes (c) To make up the bleach solution used in analyzer maintenance procedures (4) The surveyor then reviewed the documents provided by the pipette verification service. The "Result Sheet" stated the following: (a) The acceptable "per cent recovery" should be "100% +/- 3%" (97.0%-103.0%); (b) "If the Percent Recovered is outside the acceptable performance limits: 1. Review maintenance procedures. 2. Verify that correct operators procedures were followed. 3. If the above procedures have been followed, refer to the pipette instruction manual for recalibration recommendations." (5) The surveyor reviewed records which showed the function checks were performed on 02/26/16 and 10/11/17. The surveyor identified that the function check performed on 10/11/17 failed for the 1000ul volume dispensed by the Oxford (A9X023702) pipette. The % Recovery was unacceptable at 94.17%; (6) The surveyor reviewed the findings with the technical consultant who stated to the surveyor the annual pipette function check listed above was unacceptable and the laboratory failed to ensure pipettes used for testing in the laboratory, dispensed accurately.
D5785	CORRECTIVE ACTIONS

	CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to take corrective action for unacceptable environmental conditions. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XS-1000i analyzer, which was put into use on 02/17/17 to replace the Beckman Coulter AcT Diff 2 analyzer; (2) The surveyor then reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required the relative humidity be maintained within the range of 30-85%; (3) The surveyor reviewed laboratory humidity records for 5 months - April, November, and December 2107; January and February 2018. The surveyor identified on 18 of the 100 days reviewed, the humidity was less than 30%, as follows: (a) December 2016: (i) On 9 of the 19 days reviewed, the humidity was less than 30%: Days 6,7,11,12,13,14,27, 28,29; (ii) There was no documentation found which proved the laboratory took corrective actions (e.g., turn on humidifier, etc.) for the unacceptable humidity; (iii) On 2 of the 19 days reviewed, the humidity was less than 30%: Days 8 and 26. Although corrective action was taken (humidifier turned on), the laboratory failed to ensure the corrective action was effective and the humidity was still less than 30% when checked. (b) January 2018: (i) On 6 of the 22 days reviewed, the humidity was less than 30%: Days 2,3,12,16,17,31; (ii) There was no documentation found which proved the laboratory took corrective actions. (c) February 2018: (i) On 1 of the 20 days reviewed, the humidity was less than 30%: Day 2; (ii) There was no documentation found which proved the laboratory took corrective actions. (4) The surveyor reviewed the findings with the technical consultant who stated to the surveyor, the laboratory failed to take corrective action for unacceptable humidity as listed above, and failed to ensure the corrective taken, was effective in maintaining the manufacturer's humidity requirement.