Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0705524	09/21/2020
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 recertification survey was performed on 09/18,21/2020. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant at the conclusion of the survey.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on a review of records, procedure manual, and interview with the technical consultant, the laboratory failed to ensure the demonstrated reportable range and the verified reference range were utilized for a new test method. Findings include: (1) On the first day of the survey, the technical consultant stated the following to the surveyor: (a) The laboratory performed ALT (Alanine Aminotransferase) testing using the Vitros Ortho 350 analyzer; (b) ALT-V (a new ALT reagent), was put into use on 05/02/2019. (2) On the second day of the survey, the surveyor reviewed the performance specification records for ALT-V and identified the following: (a) Reportable Range - The laboratory had demonstrated a reportable range of 6.0-750 U/L; (b) Reference Range - The laboratory had verified a reference range of 6.0-50 U/L. (3) The surveyor then requested documentation to verify the reportable range that had been programmed into the analyzer; and requested a patient report to verify the reference range that was being utilized by the laboratory. The following was

	identified: (a) Reportable Range - The laboratory was using a reportable range of 4.0-750 U/L; (b) Reference Range - The reference range on the patient report was 4.0-50 U/L. (4) The surveyor reviewed the findings with the technical consultant, who stated the following on 09/21/2020 at 11:30 am; (a) The laboratory was not using the reportable range that had been demonstrated by the laboratory; (b) The patient report did not reflect the reference range that had been verified by the laboratory.
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 technical consultant, the laboratory failed to perform maintenance procedures as required by the manufacturers. Findings include: SYSMEX XS 1000i ANALYZER (1) On the first day of the survey, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XS1000i analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance instructions for the analyzer which were: (a) Weekly - Power Down IPU (3) Maintenance records were reviewed by the surveyor for 20 months (January 2019 through August 2020). The weekly maintenance had not been documented as performed between: (a) 03/22/2019 and 04/05/2019 (b) 03/20/2020 and 04/03/2020 (c) 05/22/2020 and 06/05/2020 (d) 07/24/2020 and 08/07/2020 (4) The surveyor reviewed the records with the technical consultant who stated on 09/21/2020 at 10:00 am, there was no evidence the above maintenance had been performed as required. SIEMENS DCA VANTAGE ANALYZER (1) On the first day of the survey, the technical consultant stated to the surveyor Urine Microalbumin and Urine Creatinine testing were performed on the Siemens DCA Vantage analyzer (serial number S025387); (2) The surveyor reviewed the manufacturer's maintenance instructions, which were: (a) Weekly (i) Clean the Barcode Window (ii) Clean the Exterior (3) The surveyor then reviewed maintenance records for 14 months (August 2019 through September 2020). There was no evidence the maintenance had been performed as follows: (a) Weekly - Not performed between: (i) 08/19/2020 and 09/02/2020 (4) The surveyor reviewed the records with the technical consultant, who stated on 09/18/2020 at 1:05 pm, there was no evidence the maintenance, as indicated above, had been performed as required.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the technical consultant, the laboratory failed to perform calibration verification procedures, to include a minimal value and a maximum value, once every 6 months. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor Chloride, Potassium, and Sodium testing were performed using the Ortho Vitros 350 analyzer; (2) On the second day of the survey, the surveyor reviewed calibration verification records for Chloride, Potassium, and Sodium (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). There was no evidence that 3 of 7 calibration verification procedures for Chloride; 4 of 8 calibration verification procedures for Potassium; and 4 of 8 calibration verification procedures for Sodium; included a minimal value and a maximum value near the upper limit of the reportable range as follows: (a) Chloride - The laboratory reportable range was 50-175 mmol/L (i) 11/15/2020 - The procedure performed included 5 specimens, resulting in values within the mid-point value (95,96,103,105,110). A minimal value and a maximum value near the upper limit of the reportable range had not been performed; (ii) 03/11/2020 - The procedure performed included 5 specimens, resulting in values within the mid-point value (90,91,99,106,119). A minimal value and a maximum value near the upper limit of the reportable range had not been performed; (iii) 08/19/2020 - The procedure performed included 5 specimens, resulting in values within the mid-point value (99,102,104,107,112). A minimal value and a maximum value near the upper limit of the reportable range had not been performed. (b) Potassium - The laboratory reportable range was 1.0-14.0 mmol/L (i) 01/15/2020 - The procedure performed included 5 specimens, resulting in values within the mid-point value (2.9,3.4,4.6,5.0,5.9). A minimal value and a maximum value near the upper limit of the reportable range had not been performed; (ii) 02/12/2020 - The procedure performed included 5 specimens, resulting in values within the mid-point value (2.9,3.4,4.6,5.0,5.8). A minimal value and a maximum value near the upper limit of the reportable range had not been performed; (iii) 08/05/2020 - The procedure performed included 5 specimens, resulting in values within the mid-point value (2.6,2.9,4.1,5.5,7.5). A minimal value and a maximum value near the upper limit of the reportable range had not been performed; (iv) 08/19/2020 - The procedure performed included 5 specimens, resulting in values within the mid-point value (3.9,4.6,5.1,5.5,6.5). A minimal value and a maximum value near the upper limit of the reportable range had not been performed. (c) Sodium - The laboratory reportable range was 75-250 mmol/L (i) 01/15/2020 - The procedure performed included 5 specimens, resulting in values within the mid-point value (130,134,147,151,161). A minimal value and a maximum value near the upper limit of the reportable range had not been performed; (ii) 02/12/2020 - The procedure performed included 5 specimens,

	resulting in values within the mid-point value (131,135,148,152,161). A minimal value and a maximum value near the upper limit of the reportable range had not been performed; (iii) 08/05/2020 - The procedure performed included 5 specimens, resulting in values within the mid-point value (123,135,136,150,170). A minimal value and a maximum value near the upper limit of the reportable range had not been performed; (iv) 08/19/2020 - The procedure performed included 5 specimens, resulting in values within the mid-point value (132,134,139,148,157). A minimal value and a maximum value near the upper limit of the reportable range had not been performed. (3) The surveyor reviewed the records with the technical consultant, who stated on 09/21/2020 at 1:10 pm, calibration verification had not been performed to include a minimal value and a maximum value, once every 6 months as indicated above.