Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0667030	10/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Kickapoo Tribal Health Center Laboratory	105365 S Hwy 102, Mcloud, 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 10/05/2020. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant The findings were reviewed with the laboratory director at the conclusion of the survey.
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 the laboratory director, the laboratory failed to have a written clinical consultant competency policy based on the position responsibilities as listed in Subpart M. Findings include: (1) During the survey, the surveyor reviewed the competency assessment policy. It did not include guidance for assessing the competency of the clinical consultant; (2) The surveyor then reviewed personnel records for competency assessments performed during 2019 and 2020. There was no evidence of competencies performed for the clinical consultant, based on their job responsibilities; (3) The surveyor asked the laboratory director if a written policy to evaluate the clinical consultant based on job responsibilities was available. The laboratory director stated to the surveyor on 10/05 /2020 at 12:40 pm, a policy had not been written and the above competencies had not been performed.
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 and interview with the laboratory director, the laboratory failed to ensure the demonstrated reportable ranges were utilized for 5 of 6 new test methods. Findings include: ORTHO VITROS 350 ANALYZER (1) At the beginning of the survey, the laboratory director 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 06/09/2019. (2) The surveyor reviewed the performance specification records for ALT-V and identified the laboratory had demonstrated a reportable range of 6.0-761 U/L; (3) The surveyor then requested documentation to show the reportable range that had been programmed into the analyzer, which showed the laboratory was using a reportable range of 4.0-750 U/L; (4) The surveyor reviewed the findings with the laboratory director, who stated to the surveyor 10/05/2020 at 2:50 pm, the laboratory was not using the reportable range that had been demonstrated by the laboratory. ORTHO VITROS ECiQ ANALYZER (1) At the beginning of the survey, the laboratory director stated to the surveyor, the laboratory began using the Ortho Vitros ECiQ analyzer to perform Free T4 (Thyroxine), TSH (Thyroid Stimulating Hormone), PSA (Prostate Specific Antigen), Vitamin B12 and Vitamin D testing on 02/01/2019; (2) The surveyor reviewed the performance specification records for the above analytes and identified the following for the reportable ranges for 4 of 5 of the analytes: (a) Free T4 - The laboratory had demonstrated a reportable range of 0.02-6.52 ng/dl (b) TSH - The laboratory had demonstrated a reportable range of 0-94.2 mIU/L (c) PSA - The laboratory had demonstrated a reportable range of 0.01-92.6 ng/mL (d) Vitamin D - The laboratory had demonstrated a reportable range of 21.9-99.1 ng/mL (3) The surveyor then requested documentation to show the reportable ranges that had been programmed into the analyzer. The following was identified: (a) Free T4 - The laboratory was using a reportable range of 0.07-6.99 ng/dl (b) TSH - The laboratory was using a reportable range of 0.015-100 mIU/L (c) PSA - The laboratory was using a reportable range of 0.064-100 ng/mL (d) Vitamin D - The laboratory was using a reportable range of 12.8-126 ng/mL (4) The surveyor reviewed the findings with the laboratory director, who stated to the surveyor on 10/05/2020 at 2:50 pm, the laboratory was not using the reportable ranges that had been demonstrated by the laboratory.
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 laboratory director, the laboratory failed to perform calibration verification procedures, to include a maximum value, once every 6 months for 5 of 7 calibration verifications reviewed for Vitamin B12 and Vitamin D testing; and failed to perform calibration verification procedures once every 6 months for Vitamin B12 testing. Findings include: MAXIMUM VALUES NOT INCLUDED IN CALIBRATION VERIFICATION (1) At the beginning of the survey, the laboratory director stated to the surveyor the laboratory began using the Ortho Vitros ECiQ analyzer to perform Vitamin B12 and Vitamin D testing on 02/01 /2019; (2) Later during the survey, the surveyor reviewed calibration verification records for the analytes (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 3 calibration verification procedures for Vitamin B12; and 2 of 4 calibration verification procedures for Vitamin D, included a maximum value near the upper limit of the reportable range as follows: (a) Vitamin B12 - The laboratory reportable range was 159-1000 pg/mL (i) 05/15/2019 - The procedure performed included 3 specimens, resulting in values within the minimal and mid-point values (215,331,460). A maximum value near the upper limit of the reportable range had not been performed; (ii) 10/11/2019 - The procedure performed included 3 specimens, resulting in values within the minimal and mid-point values (223,360,463). A maximum value near the upper limit of the reportable range had not been performed; (iii) 08/06/2020 - The procedure performed included 3 specimens, resulting in values within the minimal and mid-point values (221,326,467). A maximum value near the upper limit of the reportable range had not been performed. (b) Vitamin D - The laboratory reportable range was 21.9-99.1 ng/mL (i) 05/29/2020 - The procedure performed included 3 specimens, resulting in values within the minimal and mid-point values (28.9,45.4,60.1). A maximum value near the upper limit of the reportable range had not been performed; (ii) 01/17/2020 - The procedure performed included 3 specimens, resulting in values within the minimal and mid-point values (26.8,42.7,59.9). A maximum value near the upper limit of the reportable range had not been performed. (3) The surveyor reviewed the records with the laboratory director, who stated on 10/05/2020 at 2:25 pm, calibration verification had not been performed to include a maximum value, once every 6 months as indicated above. CALIBRATION VERIFICATION NOT PERFORMED EVERY 6 MONTHS (1) During the review of calibration verification records, the surveyor was not able to locate a calibration verification record for Vitamin B12 between 10/11/2019 and 08/06 /2020 (due 04/2020); (2) The surveyor reviewed the records with the laboratory director and asked if the calibration verification that had been due in 04/2020 for Vitamin B12 had been performed. The laboratory director stated on 10/05/2020 at 2:

	25 pm calibration verification had not been performed for Vitamin B12 between 10/11 /2019 and 08/06/2020.
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 and interview with the laboratory director, 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 individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for 1 of 3 competency evaluations performed. Findings include: (1) During the survey, the surveyor reviewed records for 3 persons performing moderate complexity testing in 2019 (laboratory director, who is also listed as testing person #1, testing person #2, and testing person #3). The records showed the evaluation for 1 of 3 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #1 (laboratory director) - The 09/30/2019 evaluation had been performed by testing person #2 (this person had earned an associate degree in science). (2) The surveyor explained to the laboratory director that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). The laboratory director stated to the surveyor on 10/05/2020 at 12:30 pm, the evaluation had been performed by an individual who did not meet the educational qualifications of a technical consultant.