Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0901216	06/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Okmulgee Indian Health Center	1313 E 20th St, Okmulgee, 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 initial survey was performed on 06/05/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director/technical consultant 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 and interview with the laboratory director/technical consultant, the laboratory failed to have a written clinical consultant and technical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) During the survey, the surveyor reviewed personnel records for competency assessments performed during 2017, 2018, and to date in 2019. There was no evidence competencies had been performed for the clinical consultant and technical consultant, based on their job responsibilities; (2) The surveyor asked the laboratory director/technical consultant if a written policy to evaluate the clinical consultant and technical consultant based on job responsibilities was available and if competencies had been performed during the review period. The laboratory director /technical consultant stated a policy to evaluate the clinical consultant and technical consultant based on job responsibilities had not been written; and competencies had not been performed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the

	laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual and interview with the laboratory director/technical consultant, the laboratory failed to have written procedures that explained the current practices and procedures being performed in the laboratory. Findings include: (1) At the beginning of the survey, the laboratory director /technical consultant stated to the surveyor microscopic urine sediment examinations were performed in the laboratory using the "Quick-Read Precision Cell Multi-Slide Urinalysis System"; (2) The surveyor reviewed the "Laboratory Policy and Procedure" manual. The procedure titled, "Microscopic Urine Analysis" did not explain the current procedure for performing microscopic urine sediment examinations. The procedure stated, "Mix the sediment thoroughly, place one drop on a microscope slide, add cover-slip and read"; (3) The surveyor reviewed the findings with the laboratory director/technical consultant who stated, the laboratory did not use the microscope slide and coverslip method and the procedure in the manual did not reflect the laboratory's current method of performing microscopic urine sediment examinations.
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/technical consultant, the laboratory failed to perform calibration verification procedures at least once every 6 months. Findings include: (1) At the beginning of the survey, the laboratory director/technical consultant stated to the surveyor Vitamin B12 testing was performed using the Ortho ECiQ analyzer: (2) The surveyor reviewed 2017, 2018, and 2019 calibration records and identified that calibration procedures for

	Vitamin B12 had been performed with two levels of calibrators. Since the calibration procedures included two levels, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) The surveyor could not locate records to verify calibration verification procedures had been performed for Vitamin B12 during 2017, 2018, and to date in 2019; (4) The surveyor asked the laboratory director/technical consultant if calibration verification procedures had been performed during the review period. The laboratory director/technical consultant stated calibration verification procedures had not been performed.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with laboratory director/technical consultant, the technical consultant failed to ensure evaluations were performed for all testing persons performing moderate complexity testing at least annually. Findings include: (1) During the survey, the surveyor reviewed personnel records for 2 persons who performed testing during 2017, 2018, and to date in 2019 (laboratory director /technical consultant and testing person #2). There was no evidence annual evaluations had been documented as performed for the laboratory director/technical consultant prior to 06/10/19; (2) The surveyor reviewed the findings with laboratory director/technical consultant, who stated annual evaluations had not been documented as performed for the laboratory director/technical consultant as a testing person prior to 06/10/19.