Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1054775	10/20/2020
Name of Provider or Supplier	**Street Address, City, State**	
Koweta Indian Health Facility	31870 East State Highway 51, Coweta, 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 10/20/2020. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with technical consultant #2 and testing person #2 at the conclusion of the survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory director or designee and testing person failed to sign a proficiency testing attestation statement for 1 of 13 events. Findings include: (1) The surveyor reviewed 2019 and 2020 proficiency testing records and identified the following for 1 of 13 events: (a) First 2020 Chemistry Miscellaneous Event - The attestation statement had not been signed by the laboratory director or designee and by the person performing the test. (2) The surveyor reviewed the findings with technical consultant #2, who stated to the surveyor on 10/20/2020 at 11:55 am, the attestation statement had not been signed by the laboratory director or designee and the person performing the test.
D5435	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with technical consultant #2, the laboratory failed to ensure the urine centrifuge was functioning properly for 1 of 5 function checks. Findings include: (1) On 10/20/2020 at 09:30 am, technical consultant #2 stated the following to the surveyor: (a) Urine sediment examinations were performed in the laboratory; (b) The specimens were processed in the Unico Centrifuge (denoted by the laboratory as #78896) at a speed of 1500 rpm (revolutions per minute) for 5 minutes. (2) The surveyor reviewed the policy titled, "Maintenance and Function Checks", which stated, "Function checks for RPM and accuracy are performed by the MCNDH Net Facilities Department twice a year"; (3) The surveyor reviewed the centrifuge maintenance records for 2019 and to date in 2020. The speed had not been checked at the speed the urine specimens were processed, to ensure the centrifuge was functioning properly at that speed, for 1 of 5 checks performed as follows: (a) 09/03/2020 - The speed had been checked at 3916 rpm. (4) The surveyor reviewed the findings with technical consultant #2, who stated on 10/20/2020 at 12:42 pm, the centrifuge speed had not been checked at the speed used to process urine specimens.