Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0669872	03/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Sapulpa Indian Health Center	1125 E Cleveland, Sapulpa, 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 03/10/2022. The findings were reviewed with the laboratory supervisor and technical consultant at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to review and evaluate proficiency testing results for one of 28 events. Findings include: (1) On 03/10/2022, the surveyor reviewed 2020 and 2021 proficiency testing records and identified the following failures: (a) First 2020 Chemistry Core Event (i) ALT (Alanine Aminotransferase) - The laboratory failed the results for one of five samples (CH-01); (ii) Total Iron - The laboratory failed the results for one of five samples (CH-03). (2) The surveyor could not locate evidence in the records proving the failure had been addressed; (3) The surveyor reviewed the records with the technical consultant, and asked if corrective action had been taken and documented for the failure. The technical consultant stated on 03/10/2022 at 11: 40 am corrective actions had not been taken.
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 and laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for performing daily maintenance procedures for 24 of 24 months. Findings include: (1) On 03/10/2022 at 10:00 am, the technical consultant stated to the surveyor the laboratory performs urinalysis testing on the Clinitek Advantus; (2) The surveyor reviewed the manufacturer's maintenance requirements as stated in the "Clinitek Advantus Operator's Guide". The daily requirements were as follows: (a) Clean the following parts at least once each day or after running 300 strips, whichever is more frequent: (i) Push Bar (ii) Fixed Platform (iii) Moving Table (iv) Reagent Strip Holddown Plate (b) Clean the display screen once a day if it is used to enter ID, color, or clarity during the run. (3) On 03/10/2022 at 01:15 pm, the surveyor asked the laboratory supervisor if the daily cleaning records for 2020 and 2021 were available for review; (4) The laboratory supervisor stated on 03/10/2022 at 01:25 pm, the daily maintenance had been performed but not been documented as performed as identified above.