Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1054775	07/19/2024
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 07/18,19/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with technical consultant #3 at the conclusion of the survey.
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 records, policies and procedures, and interview with technical consultant #3, the laboratory failed to follow their written policy for establishing the means for new lot numbers of control materials prior to implementation for nine of 15 lot numbers used during the review period of 11/15/2023 through 06/28/2024. Findings include: (1) On 07/18/2024 at 08:35 am, technical consultant #3 stated the following: (a) The laboratory performed CBC (complete blood count) testing using the Abbott Cell-Dyn Ruby analyzer; (b) Three levels of Cell-Dyn 26 Plus Control QC (quality control) materials were performed each day of patient testing. (c) Laboratory established means and historic SD's (standard deviations) were used to determine acceptability of quality control results. (2) A review of the procedure manual titled, "Complete Blood Count Abbott Cell-Dyn Ruby" on page 4, under the section "X. Quality Control" stated the following: (a) "F. Run the new controls twice a day for 5 days." (3) A review of records for 15 control lot numbers used from 11/15/2023 through 06/28/2024 identified the laboratory did not follow their policy as follows: (a) Lot #L3303, Lot #N3303, and Lot #H3303 - The controls had been tested thirteen times over three days as follows: (i) Four times on 11/15/2023 (ii) Four times on 11/16 /2023 (iii) Five times on 11/17/2023 (b) Lot #L3359, Lot #N3359, and Lot #H3359 -

	The controls had been tested ten times over one day as follows: (i) Ten times on 01/12 /2024 (c) Lot #N4106 - The control had been tested thirteen times over two days as follows: (i) Twice on 04/30/2024 (ii) Eleven times on 05/01/2024 (d) Lot #N4106, and Lot #H4106 - The controls had been tested twenty times over four days as follows: (i) Five times on 04/30/2024 (ii) Fifteen times on 05/01/2024 (4) The findings were reviewed with technical consultant #3 who stated on 07/19/2024 at 10: 00 am, the laboratory did not follow their written policy.
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 #3, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly for one of two annual function checks performed during the review period of June 2022 through the current date. Finding include: (1) On 07/18/2024 at 11:00 am, technical consultant #3 stated the following: (a) Urine sediment examinations were performed by the laboratory; (b) The specimens were processed in a Unico centrifuge at a speed of 1500 rpm (revolutions per minute) for 5 minutes. (2) A review of the procedure titled, " Microscopic Urine Analysis", stated "Place 10 to 12 milliliters (ml) of a well mixed urine into a labeled urine tube. Cap the tube and place it in the centrifuge for 5 minutes at 1500 revolutions per minute (RPM)"; (3) A review of centrifuge function check records from June 2022 through the current date identified on 04/03/2024 the centrifuge speed been checked at 2000 (RPM's), rather than 1500 (RPM's); (4) The records were reviewed with technical consultant #3, who stated on 07/18/2024 at 11:00 am, the laboratory had not followed their policy.