

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D0667030	<b>(X3) Date Survey Completed</b> 04/09/2024
<b>Name of Provider or Supplier</b> Kickapoo Tribal Health Center Laboratory	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The recertification survey was performed on 04/09/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director at the conclusion of the survey.
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory director, the laboratory failed to follow their written policy for verifying the stated values of control materials prior to implementation for three of three lot numbers used during the review period of January 2024 through the current date. Findings include: (1) On 04/09/2024 at 01:45 pm, the laboratory director stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XS-1000i analyzer; (b) Three levels of e-check QC (Quality Control) materials were tested each day of patient testing; (c) The manufacturer's provided ranges were a range of means, requiring the laboratory to determine acceptability of quality control results. (2) A review of the policy titled, "CLSI Procedure on the Sysmex XS-1000i Automated Hematology Analyzer" under section E titled "Starting a New Lot of Controls" stated, "Parallel test new controls by analyzing the three levels of controls a minimum of twice a day for 5 days prior to the expiration of the previous lot"; (3) A review of records for three control lot numbers used from April 2024 through the current date identified the laboratory had not followed their policy for three of three lot numbers as follows; (a) Lot #40640804, 40640805, and 40640806 used from 04/01/2024 through current date - The laboratory had tested the</p>

controls two times on 03/25/2024,three times on 03/26/2024, one time on 03/27/2024, and four times on 03/28/2024; (4) The findings were reviewed with the laboratory director 04/09/2024 at 1:45 pm, the laboratory did not follow their written policy.