

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0906177	(X3) Date Survey Completed 04/02/2025
Name of Provider or Supplier Absentee Shawnee Tribal Health System -	Street Address, City, State 15951 Little Axe Drive, Norman, 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 04/01,02/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and laboratory manager at the conclusion of the survey.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory manager, the laboratory failed to label three of three containers with the identity, expiration date, and lot number of the contents. Findings include: (1) On 04/01/2025 at 10:20 am, the laboratory manager stated the laboratory stained peripheral blood smears to perform manual differential testing; (2) Observation on 04/01/2025 at 10:22 am identified three unlabeled Coplin jars, appearing to contain materials used to stain peripheral blood smears; (3) The findings were reviewed with the laboratory manager who on 04/01/2025 at 10:25 am stated the Coplin jars contained staining materials had not been labeled with the identity, expiration date, and lot numbers.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>(b)(2)(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. (b)(2)(ii) Perform and document the function checks, including</p>

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, policy and procedure, and interview with the laboratory manager, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly during the review period of April 2023 through the current date. Finding include: (1) On 04/01/2025 at 10:30 am, the laboratory manager stated the laboratory performed microscopic urine sediment examination and the specimens were processed using the Drucker Diagnostics model 642-VES centrifuge at a speed of 1500 rpm (revolutions per minute) for 5 minutes; (2) A review of the centrifuge function check policy titled, "Instrument Maintenance & Repair" under section II required the urine centrifuge speed and time checks to be performed bi-annually at the speed of 1500 RPM + 5% for 5 minutes + 20 seconds; (3) On 04/01/2025, a review of the centrifuge records from April 2023 through the current date identified the following: (a) Function check performed on 04/02/2024 - The centrifuge record identified speed and timer check had been reported as "Passed" - The actual speed and time that had been obtained had not been recorded. (4) The records were reviewed with the laboratory manager who stated on 04/01/2025 at 04:30 pm, the laboratory had not followed their policy for ensuring the centrifuge was functioning properly as stated above.