

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0906177	(X3) Date Survey Completed 04/17/2023
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 04/17/2023. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the executive director, laboratory director, and laboratory manager during an exit conference performed at the conclusion of the survey.
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory manager, the laboratory failed to follow their written function check protocol to ensure the urine centrifuge was functioning properly for two of two function checks performed during the review period of March 2022 through March 2023. Findings include: (1) On 04/17/2023 at 09:40 am, the laboratory manager stated the following: (a) The laboratory performed urine microscopic testing; (b) The urine specimens were processed at a speed of 1500 rpm (revolutions per minute) for 5 minutes using the Horizon 642 VES centrifuge. (2) A review of the policy titled, "Instrument Maintenance & Repair" under the section titled, "Centrifuge RPM Checks" stated, "Every six months we need to make sure the Centrifuges are operating at an optimal speed and time"; (3) A review of centrifuge maintenance records from March 2022 through March 2023 identified the centrifuge had not been check every</p>

six months and identified the following: (a) 03/2023 - The timer had been checked at ten minutes instead of five minutes; (b) 03/2023 - Although the speed and timer check had been performed, there was no documentation of the actual speed and time obtained and the documentation stated, "pass". (4) The records were reviewed with the laboratory manager who stated on 04/17/2023 at 03:50 pm, the laboratory did not follow their policy and did not ensure the urine centrifuge was functioning properly as shown above.