

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1092055	(X3) Date Survey Completed 01/15/2021
Name of Provider or Supplier Absentee Shawnee Tribal Health System -	Street Address, City, State 2029 S Gordon Cooper Dr, Building 17, Shawnee, 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 01/15/2021 The findings were reviewed with the laboratory manager/testing person #1 and the laboratory director during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
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, policy and procedure manual, and interview with the laboratory manager/testing person #1, the laboratory failed to follow their written function check protocol to ensure the urine centrifuge was functioning properly for 1 of 1 years. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyor: (a) The Unico (serial# 6788) centrifuge was used to process urine specimens for urine microscopic testing at a speed of 1500 rpm (Revolutions Per Minute) and a time of 10 minutes. (2) The surveyor reviewed the written centrifuge check policy (#GL17) titled, "Instrument Maintenance & Repair", which required 6 month speed checks be performed on the centrifuge; (3) The surveyor reviewed the centrifuge maintenance record for 2020. The speed had not been checked at the speed the urine specimens were processed, to ensure the</p>

centrifuge was functioning properly at that speed, for 2 of 2 checks performed as follows: (a) 02/17/2020 - The speed had been checked at 2000 rpm; (b) 06/12/2020 - The speed had been checked at 2000 rpm. (4) The surveyor reviewed the findings with the laboratory manager/testing person #1. The laboratory manager/testing person #1 stated on 01/15/2020 at 11:15 am the centrifuge speed had not been checked at the speed used to process urine specimens as indicated above.