Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0472320	(X3) Date Survey Completed 11/14/2024
Name of Provider or Supplier Mangum Regional Medical Center	**Street Address, City, State** 1 Wickersham Drive, Mangum, 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 11/12,13,14/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager, technical consultant, and hospital administrator at the conclusion of the survey.
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, policy and procedure, and interview with the technical consultant and 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 11/12/2024 at 11:00 am, the technical consultant and laboratory manager stated the laboratory performed microscopic urine sediment examination and the specimens were processed using the Unico PowerSpin LX centrifuge at a speed of 2000-25000 rpm (revolutions per minute) for 5 minutes; (2) A review of the centrifuge function check policy titled, "Blood and Urine Centrifuges" stated "It is recommended that the centrifuge's RPM and timer be checked and calibrated at least every 6 months. The variable speed centrifuge will be set at 2,000-2500 RPM for 5 minutes which is for the urine specimens." (3) On 01/18/2024 a review of the centrifuge records from April 2023

	through the current date identified the following: (a) Function check performed on 10 /23/2023 - The centrifuge speed had been checked at 2015 rpm and the timer had been checked at 10 minutes instead of five minutes; (b) Function check performed on 04/29 /2024 - The centrifuge record identified speed and timer check had been reported as "Pass - Max rpm accuracy" and "Pass Timer accuracy" - The actual speed and time that had been obtained had not been recorded. (4) The records were reviewed with the technical consultant and laboratory manager who stated on 11/13/2024 at 01:00 pm, the laboratory had not followed their policy for ensuring the centrifuge was functioning properly as stated above.