

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0050504	(X3) Date Survey Completed 05/08/2025
Name of Provider or Supplier Mary Mahoney Memorial Health Center	Street Address, City, State 12716 Ne 36th Street, Spencer, 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 05/08/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and testing person #1 at the conclusion of the survey.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with testing person #1, the laboratory failed to ensure expired supplies were not available for use. Findings include: (1) Observation of the laboratory on 05/08/2025 at 10:20 am, identified the following expired supplies that appeared to be available for use: (a) 25 Microtainer Brand EDTA Tubes, lot #23C4336, expired 03/31/2025; (b) 35 Vacutainer Brand Sodium Citrate Tubes, lot 4198275, expired 04/30/2025. (2) Interview with testing person #1 on 05/08/2025 at 10:20 am confirmed the expired supplies were available for use.</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 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>

This STANDARD is not met as evidenced by:

Based on a review of records, policies and procedures, and interview with testing person #1, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly for two of two annual function checks performed during the review period of July 2023 through the current date. Finding include: (1) On 05/08/2025 at 11:00 am, testing person #1 stated the following: (a) Urine sediment examinations were performed by the laboratory; (b) The specimens were processed in the McKesson 602 centrifuge at a speed of 1500 - 2000 rpm (revolutions per minute) for 5 minutes. (2) A review of the procedure titled, "Centrifuge Calibration" stated, "Centrifuges will be calibrated annually for the RPM's and Timer to ensure the speed and times are within acceptable limits and to ensure the quality of testing is not compromised"; (a) "Acceptable RPM's will be between 1500 - 2000 RPM's"; (b) "Acceptable time limit will be 4.9-5.0 minutes". (3) A review of centrifuge function check records from July 2023 through the current date identified the speed check was not within the acceptable limits as follows: (a) On 10/27/2023 the centrifuge speed check was documented at 2202 (RPM); (b) There were no function checks documented in 2024. (4) The records were reviewed with testing person #1, who stated on 05/08/2025 at 11:00 am, the laboratory had not followed their policy for function checks.