

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0997934	(X3) Date Survey Completed 04/11/2022
Name of Provider or Supplier Lake Pointe Medical Center	Street Address, City, State 20912 Se 29th Street, Harrah, 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 04/11/2022. The findings were reviewed with the medical assistant at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the medical assistant, the laboratory failed to verify the accuracy of Wet Prep testing at least twice annually. Findings include: (1) On 04/11/2022 at 10:00 am, the medical assistant stated: (a) The laboratory performed Wet Prep testing. (2) A review of 2021 records revealed the testing had not been verified for accuracy twice annually during the review period; (3) The records were reviewed with the medical assistant. The medical assistant stated on 04/11/2022 at 11:00 am, the laboratory had not verified the accuracy twice annually as indicated above.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
Based on a review of records, manufacturer's storage instructions, and interview with the medical assistant, the laboratory manager failed to ensure the humidity was monitored where the testing equipment was maintained for 15 of 15 months. Findings include: (1) On 04/11/2022 at 10:00 am the medical assistant stated: (a) CBC (Complete Blood Count) testing was performed on the Beckman Coulter AcT2 Diff analyzer. (2) A review of the manufacturer's environmental requirements for the analyzer identified the manufacturer required the relative humidity be maintained between 20%-85%. (3) A review of laboratory records from January 2021 through March 2022 revealed there was no evidence the humidity of the laboratory had been monitored during the review period; (4) The records were reviewed with the medical assistant. The medical assistant stated on 04/11/2022 at 10:55 am the laboratory had not documented the humidity as indicated above.

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, policies and procedures, and interview with the medical assistant, the laboratory failed to follow their written function check protocol to ensure the urine centrifuge was functioning properly for one of one function checks. Findings include: (1) On 04/11/2022 at 10:00, the medical assistant stated: (a) The laboratory performed urine microscopic testing; (b) The urine specimens were processed at a speed of 1500-1900 rpm (revolutions per minute) for 5 minutes using the Ultra Select centrifuge. (2) A review of the laboratory's written procedures titled, "policy and procedure manual" under the procedure titled, "CENTRIFUGE POLICY PROCEDURE" stated: (a) THE CENTRIFUGE WILL BE INSPECTED AND A FUNCTION CHECK TEST WILL BE PERFORMED ANNUALLY AND DOCUMENTED IN THE POLICY AND PROCEDURE MANUAL AFTER BEING REVIEWED AND SIGNED BY THE LABORATORY DIRECTOR"; (3) A review of the 2021 function check records revealed there was no documentation to prove the laboratory had performed an annual function check; (4) The findings were reviewed with the medical assistant who stated on 04/11/2022 at 11:05 am that the laboratory did not follow their written function check protocol for the urine centrifuge.