

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0469836	(X3) Date Survey Completed 06/02/2022
Name of Provider or Supplier Goddard Health Center / Ou Health Services	Street Address, City, State 620 Elm Ave, 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 06/01,02/2022. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and laboratory manager during an exit conference performed at the conclusion of the survey.
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for two of four Hematology events reviewed. Findings include: (1) On 06/01/2022, proficiency testing records were reviewed for 2021 and to date in 2022. The following was identified for two of four Hematology events: (a) First 2021 Event (i) Blood Cell ID (Educational) - One of five results (ECI-03) stated, "See Commentary" under "Expected Results". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (b) Second 2021 Event (i) Blood Cell ID - One of five results (BCI-07) stated, "See Data Summary" under "Expected Results". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (ii) Blood Cell ID (Educational) - One of five results (ECI-07) stated, "See Commentary" under "Expected Results". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (2) The records were reviewed with the</p>

laboratory manager who stated on 06/02/2022 at 02:10 pm, the laboratory had not evaluated the results that were not graded by the proficiency testing program.

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 laboratory manager, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly for one of three function checks performed. Findings include: (1) On 06/01/2022 at 10:30 am, the laboratory manager stated the the following: (a) Urine sediment examinations were performed in the laboratory; (b) The specimens were processed in the McKesson Variable Speed centrifuge at a speed of 1750-2250 rpm (revolutions per minute) for 5 minutes. (2) The policy titled "Centrifuge Operation, Cleaning/Disinfection, and Maintenance" was reviewed which stated, "The McKesson has a preset range of 1750-2250 RPM for 5 minutes" and "Verification or calibration is to be done.....Twice a year-preferably at 6-month intervals"; (3) A review of the centrifuge maintenance records for 2021 and to date in 2022 revealed the centrifuge timer had not been checked at the time urine specimens were processed for one of three checks as follows: (a) 03/08/2022 - The centrifuge timer had been checked at 10 minutes instead of five minutes. (4) The findings were reviewed with the laboratory manager who stated on 06/01/2022 at 02:15 pm, the timer had not been checked at the time urine specimens were processed.