

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1051831	(X3) Date Survey Completed 01/29/2020
Name of Provider or Supplier Labcorp Oklahoma, Inc Royal Ave	Street Address, City, State 4229 Royal Avenue, Suite100, Oklahoma City, 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 01/29/2020. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with technical consultant #3 and the outreach operations director during an exit conference performed at the conclusion of the survey.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with technical consultant #3, the laboratory failed to have a written technical supervisor, technical consultant, and general supervisor competency policy based on the position responsibilities as listed in Subpart M. Findings include: (1) During the survey, the surveyor reviewed the competency assessment policy. It did not include guidance for assessing the competency of the technical supervisor, technical consultant, and general supervisor; (2) The surveyor then reviewed personnel records for competency assessments performed during 2018 and 2019. There was no evidence of competencies performed for the technical supervisor, technical consultant #3, and general supervisor, based on their job responsibilities; (3) The surveyor asked technical consultant #3 if a written policy to evaluate the technical supervisor, technical consultant, and general supervisor based on job responsibilities was available. Technical consultant #3 stated a policy had not been written and the above competencies had not been performed.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p>

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with technical consultant #3, the laboratory failed to review and evaluate proficiency testing results for 1 of 6 events. Findings include: (1) During the survey, the surveyor reviewed 2018 and 2019 proficiency testing records. The following failure was identified, in which there was no evidence of corrective action: (a) Second 2019 Hematology Event (i) Blood Cell Identification - The laboratory failed the result for 1 of 5 samples and attained a score of 80%. The result for sample BCI-07 had failed. (2) The surveyor reviewed the records with technical consultant #3, who stated corrective action had not been taken for the above failure.

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 technical consultant #3, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly for 1 of 2 function checks performed. Findings include: (1) At the beginning of the survey, technical consultant #3 stated to the surveyor urine sediment examinations were performed in the laboratory. The specimens were processed in the Horizon Premier centrifuge at a speed of 1500 rpm for 5 minutes; (2) The surveyor reviewed the policy titled "Centrifuges". It stated, "Measure and record the RPM (revolutions per minute) using the hand digital tachometer. The speed should be checked at the setting or settings used under normal operating circumstances. The speed of the centrifuge should be checked on an annual basis"; (3) The surveyor reviewed the centrifuge maintenance records for 2018 and 2019. The records showed the centrifuge speed check that had been performed on 05 /21/19, had been checked at 3000 rpm, which was not the speed the laboratory processed urine specimens; (4) The surveyor reviewed the findings with technical consultant #3, who stated the centrifuge speed had not been checked at the speed urine specimens were processed.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a review of records and interview with technical consultant #3, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 3 of 6 events. Findings include: (1) During the survey, the surveyor reviewed 2018 and 2019 proficiency testing records. It was identified for 3 of 6 events, the attestation statements had been signed approximately 1-3 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Second 2018 Hematology Event - The sample testing had been completed on 07/30/18 and the attestation statement had not been signed by the laboratory director until 10/29/18; (b) Third 2018 Hematology Event - The sample testing had been completed on 11/30/18 and the attestation statement had not been signed by the laboratory director until 01/28/19; (c) First 2019 Hematology Event - The sample testing had been completed on 03/29/19 and the attestation statement had not been signed by the laboratory director until 04/22/19; (2) The surveyor reviewed the findings with technical consultant #3 and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.