

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1051831	(X3) Date Survey Completed 03/15/2022
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 03/15/2022. The findings were reviewed with the director of out-patient operations and regional manager at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the regional manager, the laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process for ESR testing for three of four lot numbers. Findings include: (1) On 03/15/2022 at 09:45 am, the regional manager stated the following to surveyor #1: (a) Automated ESR (Erythrocyte Sedimentation Rate) testing was performed using the Polymedco Sedimat analyzer; (b) Two levels (Normal and Abnormal) of Polymedco Sed-Chek 2 controls materials were performed each day of patient testing. (2) Surveyor #1 reviewed the package insert for the control materials which stated, "Results depend on differences in equipment, reagents, supplies, and techniques. Therefore, a lab should establish its own acceptable ranges"; (3) Surveyor</p>

#1 reviewed QC records for four lot numbers of control materials used from 03/01/2021 through the current date and identified that, although the laboratory had established their own acceptable ranges, they were utilizing the package insert guideline ranges to determine patient acceptability for three of four lot numbers as follows: (a) Normal control lot #11003201N and Abnormal control lot #11003201A - In use from 03/01/2021 through 02/28/2022 (i) Abnormal control - The laboratory had established a range of 44.27-57.59 but was using the package insert range of 35-65. (b) Normal control lot #11002211N and Abnormal control lot #11001211A - Put into use on 03/01/2022 and was currently in use (i) Normal control - The laboratory had established a range of 3.1-4.7 but was using the package insert range of 1-11; (ii) Abnormal control - The laboratory had established a range of 43.6-48 but was using the package insert range of 39-67. (4) Surveyor #1 reviewed the records with the regional manager who stated on 03/15/2022 at 12:00 pm, the laboratory had used the manufacturer's ranges to determine patient acceptability instead of using their established ranges as shown above.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the regional manager, the technical consultant failed to ensure an initial training included complete documentation of all moderate complexity testing performed for one of one person. Findings include: (1) On 03/15/2022 at 09:45 am, the regional manager stated to surveyor #1 the following testing were performed in the laboratory: (a) CBC (Complete Blood Count) testing using the Sysmex XS-1000i analyzer; (b) Microscopic Urine Sediment analysis; (c) ESR (Erythrocyte Sedimentation Rate) testing using the Polymedco Sedimat analyzer; (d) Specific Gravity testing using a refractometer. (2) Surveyor #2 then reviewed 2020 and 2021 personnel records for one person requiring initial training for the above testing, with the following identified: (a) Testing Person #2 - Although the initial training was completed by 03/30/2020, the initial training was not documented as performed until 03/03/2021. (3) Surveyor #2 reviewed the findings with the regional manager who stated on 03/15/2022 at 10:05 am that, the initial training had been performed but not signed until 03/03/2021 as indicated above.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the regional manager, the technical consultant failed to ensure a semiannual evaluation included complete documentation of all moderate complexity testing performed for one of one person. Findings include: (1) On 03/15/2022 at 09:45 am, the regional manager stated to surveyor #1 the following testing were performed in the laboratory: (a) CBC (Complete Blood Count) testing using the Sysmex XS-1000i analyzer; (b) Microscopic Urine Sediment analysis; (c) ESR (Erythrocyte Sedimentation Rate) testing using the Polymedco Sedimat analyzer; (d) Specific Gravity testing using a refractometer. (2) Surveyor #2 then reviewed 2020 and 2021 personnel records for one person requiring a semiannual competency for the above testing, with the following identified: (a) Testing Person #2 - The semiannual competency had been documented (03/20 - 08/20) as performed on 03/03/2021. (3) Surveyor #2 reviewed the findings with the regional manager who stated on 03/15/2022 at 10:05 am that, the semiannual competency had been performed but not signed until 03/03/2021 as indicated above.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the regional manager, the technical consultant failed to ensure an annual evaluation included complete documentation of all moderate complexity testing performed for one of two persons. Findings include: (1) On 03/15/2022 at 09:45 am, the regional manager stated to surveyor #1 the following testing were performed in the laboratory: (a) CBC (Complete Blood Count) testing using the Sysmex XS-1000i analyzer; (b) Microscopic Urine Sediment analysis; (c) ESR (Erythrocyte Sedimentation Rate) testing using the Polymedco Sedimat analyzer; (d) Specific Gravity testing using a refractometer. (2) Surveyor #2 then reviewed 2020 and 2021 personnel records for two persons requiring annual competencies for the above testing, with the following identified for one of two persons: (a) Testing Person #2 - 2020 annual competency had been dated as 03/03 /2021; (b) Testing Person #2 - 2021 annual competency had been dated as 01/14/2022. (3) Surveyor #2 reviewed the findings with the regional manager who stated on 03/15 /2022 at 10:05 am that, the 2020 annual competency had been performed but not signed until 03/03/2021 and the 2021 annual competency had been performed but not signed until 01/14/2022 as indicated above.