Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2088219	07/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Labcorp Oklahoma, Inc Cityplex	2408 E 81st St, Ste 105, Tulsa, 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 07/26,27,28,29/2022. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with technical consultant #1, technical consultant #2, and laboratory support at the conclusion of the survey.
D2179	COMPATIBILITY TESTING CFR(s): 493.863(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, technical consultant #2, and laboratory support, the laboratory failed to take corrective action for an unacceptable proficiency testing score for one of four Immunohematology events. Findings include: (1) On 07/26/2022, a review of 2021 and 2022 proficiency testing records revealed the following failure: (a) Second 2021 Immunohematology Event (i) Compatibility Testing - The laboratory failed the result for one of five samples, resulting in a score of 80%. There was no evidence corrective action had been taken for the failed result. (2) The records were reviewed with technical consultant #1, technical consultant #2, and laboratory support. All stated on 07/27 /2022 at 10:30 am, there was no documentation to prove corrective action had been taken for the failed result.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)

	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 #1, technical consultant #2, and laboratory support, the laboratory failed to review and evaluate proficiency testing results for two of 13 events. Findings include: (1) On 07/26/2022, a review of 2021 and 2022 proficiency testing records revealed the following failures: (a) First 2021 Chemistry Core Event (i) ALT (Alanine Aminotransferase) - The laboratory failed the result for one of five samples. There was no evidence corrective action had been taken for the failed result; (ii) pCO2 (Blood Gas) - The laboratory failed the result for one of five samples. There was no evidence corrective action had been taken for the failed result. (b) Second 2021 Chemistry Core Event (i) AST (Aspartate Aminotransferase) - The laboratory failed the result for one of five samples. There was no evidence corrective action had been taken for the failed result; (ii) BUN - The laboratory failed the result for one of five samples. There was no evidence corrective action had been taken for the failed result; (iii) pO2 (Blood Gas) - The laboratory failed the result for one of five samples. There was no evidence corrective action had been taken for the failed result. (2) The records were reviewed with technical consultant #1, technical consultant #2, and laboratory support. All stated on 07/27/2022 at 10:30 am, there was no documentation to prove corrective actions had been taken for the failed results.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) 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). This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, technical consultant #2, and laboratory support, 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 07/26/2022, a review of 2021 and 2022 proficiency testing records revealed the following 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 Result". 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 technical consultant #1, technical consultant #2, and laboratory support. All stated on 07/27/2022 at 10:20 am, the laboratory had not evaluated the results that were not graded by the proficiency testing program.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with technical consultant #1 and technical consultant #2, the laboratory failed to follow the manufacturer's instructions for implementing one of four coagulation reagents. Findings include: (1) On 07/28/2022 at 02:30 pm, techical consultant #2 stated the following: (a) The ACL TOP analyzer was used to perform PTT (Partial Thromboplastin Time) testing; (b) HemosIL SynthasIL APTT reagent, lot N0614092 was currently in use and had been put into use on 01/06/2022. (2) A review of the manufacturer's instructions contained in the "Hemostasis Performance Verification Manual" for implementing new reagents, under the section titled, "Establishing a Normal Reference Interval" stated, "Donors should be healthy and have no known pathological conditions. Don't use samples from in-patients (due to medical conditions and treatment regiments). Donors should not be on medication affecting coagulation, including (but not limited to) oral contraceptives, estrogen therapy (HRT), anticoagulants, high-does aspirin, etc."; (3) A review of the implementation records for the reagent lot change revealed that, although the laboratory had used 20 donors, there was no evidence of the medical history and health status of the donors; (4) The findings were reviewed with technical consultant #1 and technical consultant #2. Both stated on 07/28/2022 at 04:20 pm the manufacturer's instructions had not been followed as specified above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to ensure the performance specification of reference range had been verified for one of two new test systems reviewed. Findings include: (1) On 07/27/2022 technical consultant #1 stated two EPOC analyzers were put into use to perform Sodium, Potassium, Chloride, CO2, BUN, Creatinine, Ionized Calcium, Glucose, Blood Gas (pH, pCO2, pO2), Hemoglobin, and Hematocrit testing on 08/11/2021 as follows: (a) Serial number 28949 was used for patient testing in the laboratory; (b) Serial number 28939 was used for patient testing in the ICU (Intensive Care Unit). (2) A review of the performance specification records for the new test system revealed no

	evidence the reference ranges (normal ranges) had been verified; (3) The records were reviewed with technical consultant #1 who stated on 07/27/2022 at 02:39 pm, the laboratory had not verified the reference ranges for each analyte.
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 and interview with technical consultant #1, the laboratory failed to have a function check protocol that ensured a new centrifuge was functioning properly prior to putting into use for patient testing. Findings include: (1) On 07/26/2022 at 10:40, technical consutlant #1 stated the following: (a) The laboratory began using the Grifols system to perform patient Antibody Screen testing on 05/27/2021; (b) The test system included the Grifols D spin centrifuge which was used at a speed of 980 -1000 rpm (revolutions per minute) for nine minutes. (2) On 07 /27/2022, a review of the policy titled, "Timer and RPM Calibration Check" required the centrifuge speed and timers in the laboratory be checked at least annually. The policy did not address ensuring new centrifuges were checked prior to putting into use prior to using for patient testing: (3) On 07/28/2022, a review of speed and timer checks for the Grifols D spin centrifuge revealed that, although the centrifuge speed and timer had been checked on 08/02/2021 and 07/25/2022, it had not been checked for proper performance before it had been put into use for patient testing on 05/27 /2021; (4) The records were reviewed with technical consultant #1 who stated on 07/28 /2022 at 01:34 pm, the centrifuge speed and timer had not been checked prior to putting into use for patient testing.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control

	materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, technical consultant #2, and laboratory support, the laboratory failed to perform calibration verification procedures at least once every 6 months for one of four analyzers reviewed. Findings include: (1) On 07/26/2022 at 12:40 pm, technical consultant #1 stated the laboratory performed Troponin I testing using the Siemens Stratus analyzer; (2) On 07/27/2022, a review of calibration verification records from January 2021 through the current date revealed that calibration verification had not been performed between 06/21/2021 and 02/02/2022 (due December 2021); (3) The records were reviewed with technical consultant #1, technical consultant #2, and laboratory support. All stated on 07/27/2022 at 01:00 pm, calibration verification procedures had not been performed every six months.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1 and technical consultant #2, the laboratory failed to perform negative and positive control materials seven of 48 days of patient qualitative serum pregnancy testing reviewed. Findings include: (1) On 07/26/2022 at 12:30 pm, technical consultant #1 stated the following: (a) The laboratory performed qualitative serum pregnancy testing using the Cardinal Health hCG Combo test kit; (b) Positive and negative serum quality control (QC) materials were performed each day of patient testing. (2) On 07/27/2022, a review of QC and patient testing records during September 2021, March 2022, and May 2022 revealed that negative and positive QC materials had not been documented as performed each day of patient testing reviewed as follows: (a) September 2021 - Three of 15 days of patient testing reviewed. The specific days were 09//02,03,07 /2021; (b) March 2022 - Three of 17 days of patient testing reviewed. The specific days were 03/01,02,03/2022; (c) May 2022 - One of sixteen days of patient testing reviewed. The specific days were 05/07/2022. (3) The records were reviewed with technical consultant #2 who stated on 07/27/2022 at 11:26 am, negative and positive QC materials had not been performed as shown above.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures

	necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records, email correspondence, and interview with technical consultant #1, technical consultant #2, and laboratory support, the laboratory failed to document problems obtaining supplies for ACT (Activated Clotting Time) testing performed on the Hemochron Signature analyzer in quality assessment records. Findings include: (1) On 07/26/2022 at 10:45 am, technical consultant #1 stated ACT testing was performed by nursing staff in the Cath Lab using the Hemochron Signature analyzer; (2) On 07/27/2022, a review of QC (Quality Control) and patient testing records from 01/05/2022 through 04/30/2022 revealed that two levels of QC materials had not been performed ten of 37 days of patient testing reviewed. The review confirmed that one level of QC material had been performed on the following days of patient testing instead of two levels as required at 493.1269: (a) 02/15/2022 (b) 02/28/2022 (c) 03/01/2022 (d) 03/04/2022 (e) 03/07/2022 (f) 03/09/2022 (g) 03/10 /2022 (h) 03/28/2022 (i) 03/31/2022 (j) 04/06/2022 (3) Interview with technical consultant #1 on 07/29/2022 at 01:00 pm and email correspondence with the previous laboratory supervisor and the manufacture's representative confirmed the following: (a) The manufacturer of the control materials experienced an inventory shortage which affected shipments of materials from October 2021 through the second quarter of 2022; (b) Due to the shortage the laboratory did not have control level three in stock from 02/15/2022 through 04/06/2022. (4) Interview with technical consultant #1, technical consultant #2, and laboratory support on 07/29/2022 at 04:27 pm revealed the laboratory had not documented an explanation for performing one level of QC on the days specified above, including remediation of the patient testing that had been performed to ensure there was not an affect on patient testing during this time.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of patient reports and interview with technical consultant #1, technical consultant #2, and laboratory support, the laboratory failed to ensure reference intervals were available to the authorized person who ordered the tests for three of three patient reports. Findings include: (1) On 07/26/2022 at 10:35 am, technical consultant #1 stated the laboratory performed CBC (Complete Blood Count) testing, which included the automated differential parameters of % Neutrophils, % Lymphocytes, % Monocytes, % Eosinophils, and % Basophils, using the Siemens Sysmex XN-1000 analyzer; (2) On 07/29/2022, a review of three patient CBC reports with test dates of 07/27/2022 at 09:40 am, 07/27/2022 at 10:00 am, and 07/27/2022 at 02:28 pm revealed the reports did not include the reference intervals (normal ranges) for % Neutrophils, % Lymphocytes, % Monocytes, % Eosinophils, and % Basophils;

	(3) The reports were reviewed with technical consultant #1, technical consultant #2, and laboratory support. All stated on 07/29/2022 at 02:30 pm, the reports did not include the reference intervals as stated above.
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 #1, technical consultant #2, and laboratory support, 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 one of four events. Findings include: (1) On 07/26/2022, a review of 2021 and 2022 proficiency testing events revealed for one of 1 four Immumohematology events, the attestation statement had been signed approximately 14 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): (a) First 2021 Event - The sample testing had been completed on 04/12/2021 and the attestation statement had not been signed by the laboratory director until 06/08/2022. (2) The findings were reviewed with technical consultant #1, technical consultant #2, and laboratory support. All stated on 07/27 /2022 at 10:30 am, the attestation had been signed approximately 14 months after the proficiency samples had been tested.
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 technical consultant #1 and technical consultant #2, the technical consultant failed to ensure evaluations included all moderate complexity testing for three of 11 competency evaluations reviewed. Findings include: (1) On 07/26/2022 at 12:30 pm, technical consultant #1 stated Troponin I testing was performed using the iSTAT 1 analyzer as the back-up method to the Abbott Architect Plus c4000 analyzer; (2) A review of personnel records for six persons in the laboratory performing Troponin I testing using the iSTAT 1 analyzer revealed that three of 11 evaluations did not include an assessment of Troponin I testing performed on the iSTAT 1 analyzer: (a) Testing Person #1- Performed on 07/22 /2022 (b) Testing Person #2 - Performed on 07/18/2022 (c) Testing Person #4 - Performed on 06/30/2022 (3) The findings were reviewed with technical consultant #2 who stated on 07/26/2022 at 02:45 pm the above evaluations did not include Troponin I testing performed on the iSTAT 1 analyzer.