Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2088219	09/12/2024
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 09/09,10,11,12/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager, lead technologist, director of clinical operations, and the laboratory director during an exit conference performed at the conclusion of the survey.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on a review of records, nursing policy, and interview with the laboratory manager, the facility failed to ensure written policies were followed for documenting vital signs for five of five units of packed red blood cells; and failed to administer three of five units of packed red blood cells according to policy. Findings include: VITAL SIGNS (1) On 09/11/2024 at 2:30 pm, the laboratory manager stated that blood transfusions were performed by nursing staff; (2) A review of the hospital policy titled, "Blood Product Administration" defined vitals as temperature, blood pressure, pulse and respirations and stated: (a) "Baseline vital signs should be taken within 30 minutes before initiation of transfusion"; (b) "Check vitals for the first 15 minutes after initiation (plus or minus five minutes) of the transfusion and then every hour (plus or minus ten minutes) during the transfusion until transfusion is complete"; (c) "A post vital sign should be documented within 20 minutes of stop time". (3) A review of transfusion records for five units identified the policy had not been followed for five units as follows; (a) Unit #W091024188491 - The unit was started at 08:30 am and vital signs were not taken between 8:45 am and 10:15 am; (b) Unit

	#W091024163657 - The unit was started at 10:50 am and vital signs were not taken following the completion of the transfusion; (c) Unit #W091024286815 - The unit was started at 06:00 am and vital signs were not taken at the completion of the unit at 08:30 am; (d) Unit #W091024180672 - The unit was started at 9:25 am and vital signs were not taken before or after the completion of the transfusion; (e) Unit #W091024178186 - The unit was started at 2:45 pm and vital signs were not taken after the conclusion of the transfusion. (4) The records were reviewed with the laboratory manager who stated on 09/11/2024 at 02:30 pm, the vital signs had not been documented according to policy. BLOOD ADMINISTRATION (1) On 09/11 /2024 at 2:30 pm, the laboratory manager stated that blood transfusions were performed by nursing staff; (2) A review of the hospital policy titled, "Blood Product Administration" defined the procedure to administer blood products and stated: (a) "Blood components must be started within 30 minutes of issue from the blood bank and must be completed within four hours"; (3) A review of transfusion records for five units identified the policy had not been followed for three units as follows; (a) Unit #W091024163657 - The unit was issued at 10:12 am and was started at 10:50 am; (b) Unit #W091024180672 - The unit was started at 9:25 am and ended at 1:30 pm; (c) Unit #W091024178186 - The unit was started at 2:45 pm and ended at 7:45 pm. (4) The records were reviewed with the laboratory manager who stated on 09/11 /2024 at 02:30 pm, the blood had not been administered according to policy.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on a review of policy, observation, and interview with testing person #3 the laboratory failed to follow the policy for preparing platelet poor plasma (PPP) for coagulation testing to ensure optimum integrity of patient specimens. Findings include: (1) On 09/11/2024 at 11:00 am, testing person #3 stated that platelet poor plasma (PPP) was obtained, for coagulation testing performed on the ACL TOP 300 analyzer, by using the Cardinal 24V centrifuge; (2) A review of the policy "Procedure for Verifying Platelet Poor Plasma Using Sysmex XN-100r" stated that the specimens should be spun at 3500 revolutions per minute (RPM) for ten minutes and the platelet count should be less than 10,000; (3) A review of the Platelet Poor Plasma Worksheet revealed that the centrifuge was last checked on 06/12/2024 at the appropriate speed and time of 3500 RPM for 10 minutes; (4) Observation of the laboratory on 09/11 /2024 revealed that the Cardinal 24V centrifuge speed was set at 3350 RPM's; (5) The findings were reviewed with testing person #3 who stated on 09/11/2024 at 11:00 am, the laboratory could not provide evidence the specimens were centrifuged at the appropriate speed to obtain PPP.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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.

	This STANDARD is not met as evidenced by: Based on a review of records, written policies, and interview with the laboratory manager, the laboratory failed to follow their written policy to assess the competency of the technical consultants, based on the position responsibilities as listed in Subpart M, for two of three persons. Findings include: (1) A review of the laboratory policy titled, "Education and Competency Assessment" required the competency of technical consultants be assessed annually; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of January 2023 through the current date identified competencies, based on job responsibilities, had not been performed for two of three persons listed as technical consultants on Form CMS-209; (3) The findings were reviewed with the laboratory manager who stated on 09/10/2024 at 10:15 am, the policy had not been followed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, written procedure, observation, and interview with the director of clinical operations, laboratory manager, and lead technologist, the laboratory failed to follow their written procedure for coagulation reagent lot change studies for two of two lot numbers; and failed to follow their written procedure for QC (quality control) lot changes for two of two lot numbers. Findings include: REAGENT LOT CHANGES (1) On 09/11/2024 at 09:45 am, the lead technologist stated PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed using the ACL TOP 300 analyzer; (2) On 09/11/2024 at 01:00 pm, the laboratory manager stated the following reagents were put into use on 03/30/2024: (a) PT Reagent - HemosIL Recombiplastin 2G, lot #N1026877 (b) PTT Reagent - HemosIL SynthasIL, lot #N1036542 (3) A review of the procedure titled, "Annual Reagent Lot Change and Quality Control Lot Changes" identified the following: (a) The section titled, "Annual Lot Conversion - Correlation Between Reagent Lots" under "Normal Specimen Collection" stated, "Collect at a minimum, 20 ideally unfrozen specimens for PT and PTT normal reference range verification over a period of 1-3 days. The following criteria for the normal patients must be documented:" (i) "Age - Includes ages that span the population reflecting patient diversity"; (ii) "Sex - Approximately equal numbers of males and females"; (iii) "Drug History - patients excluded if taking the following drugs: Birth control or estrogen containing products, Coumadin, Heparin, Direct Thrombin Inhibitors, Antibiotics"; (iv) "Conditions - Patients excluded if they are pregnant or have any known immunologic disease". (4) A review of the implementation records for the new PT and PTT reagent lot numbers identified the written procedure had not been followed for the normal specimen collection as follows: (a) Although 20 donors had been tested, there was no documentation of the age, gender, health status and medication history of the donors. (5) The records were reviewed with the laboratory manager and lead technologist. Both stated on 09/11/2024 at 01:55 pm, the laboratory

	had not followed their procedure for the PT and PTT lot change studies. QC LOT CHANGES (1) On 09/11/2024 at 03:00 pm, the director of clinical operations and laboratory manager stated the following QC materials used for PT and PTT testing were put into use on 11/23/2023: (a) HemosIL Normal Control 1, lot #N0330178 (b) HemosIL Abnormal Control 3, lot #N0330391 (2) A review of the procedure titled, "Annual Reagent Lot Change and Quality Control Lot Changes" identified the following: (a) The section titled, "Quality Control (QC) Lot Changes" stated: (i) "The minimum number of data points need to establish this site's QC ranges is 30 (30 points for the normal control and 30 points for the abnormal control)"; (ii) "This testing protocol applies to all testing performed on the ACL TOP 300"; (iii) "After new QC means and ranges are calculated, all data points and calculations, after being signed off by the site's Medical Director, should be stored in the appropriate files"; (iv) "The new means and target ranges will be entered into the instrument's QC files when ready to start using the new QC lots". (3) A review of QC records identified the following for PT and PTT testing: (a) No evidence the QC means and ranges had been established for each level of QC materials prior to putting into use; (b) The means and ranges for the new lot numbers were identical to the previous lot numbers that had been in use until 11/22/2023 (Normal control lot #N320752 and Abnormal control lot#N0925651). (4) Interview with the director of clinical operations and laboratory manager confirmed the laboratory had carried over the means and ranges that had been used for the previous lot numbers instead of establishing new means and ranges for the new lot numbers of QC materials. 47979 Based on a review of records, policies and procedures, and interview with the laboratory manager and lead technologist, the laboratory failed to follow their written procedure for performing manual differentials for two of five patient reports. Findings include: (1) On 09/09 /2024 at 02:50 pm, the lead technologist stated CBC (Complete Blood Count) testing was performed on the Sysmex XN-1000 hematology analyzer; (2) A review of the laboratory policy and procedure manual titled" Criteria for Scans and Manual Differentials" stated the following as guidance for when to perform a manual differential or slide review: (a) "Manual Differential are indicated when:" (i) "C. If >2. 0% IG or IMGR or IG PRESENT flag: perform manual diff. If you see >1% Meta, Myelos, or Pros, report the manual differential" (3) A review of five patient records meeting the criteria for a manual differential identified no evidence the laboratory followed their written procedure for two of the five patient records as follows: (a) Patient tested on 06/14/2024 at 04:32 pm with a WBC IP Message of "IG Present" and 3.5% obtained. A slide had been scanned and documented as "Few bands and metas"; (b) Patient tested on 06/15/2024 at 05:51 pm with a WBC IP Message of "IG Present" and 3.6% obtained. A slide had been scanned and documented as "Few immatures seen metas". (4) The findings were reviewed with the laboratory manager who stated on 09/11/2024 at 01:45 pm that the procedure had not been followed as indicated above. 48517 Based on a review of policies and procedures and interview with the laboratory manager, the laboratory failed to have a written procedure that explained the current practices and procedures for issuing blood and blood products. Findings include: BLOOD BANK (1) On 09/11/2024 at 3:30 pm, the laboratory manager stated the laboratory performed blood and blood product transfusions; (2) A review of documentation and interview with the laboratory manager revealed no policy for blood and blood product administration; (3) The findings were reviewed with the laboratory manager, who stated on 09/22/2024 at 3:30 pm, the blood bank did not have a written policy for blood and blood product administration.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	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. This STANDARD is not met as evidenced by: Based on observation and interview with the lead technologist, the laboratory failed to ensure one of one EPOC test card was being stored as required; and failed to ensure blood collection tubes were stored as required in two of two areas observed in the hospital. Findings include: EPOC TEST CARD STORAGE (1) On 09/10/2024 at 09: 45 am, the lead technologist stated Blood Gas (pH, pCO2, pO2), Sodium, Potassium, Chloride, CO2, BUN (Urea Nitrogen), Creatinine, Ionized Calcium, Hemoglobin, and Hematocrit testing were performed in the ICU (Intensive Care Unit) using the BGEM test card and the EPOC analyzer; (2) Observation of the ICU testing area identified one BGEM card stored in the refrigerator (2-8 degrees Centigrade-C); (3) Review of the manufacturer's storage requirements, as stated on the test card, showed a storage requirement of 15-30 degrees C; (4) The findings were reviewed with the lead technologist who stated on 09/10/2024 at 11:25 am, the test card was not being stored as required by the manufacturer. ICU SUPPLY ROOM (1) Observation of the ICU supply room on 09/10/2024 at 10:15 am identified the following examples of blood collection tubes with the manufacturer's storage requirement, in the room: (a) Ten BD Vacutainer Lithium Heparin tubes, lot #401167; storage requirement of 4-25 degrees C; (b) 13 BD Vacutainer K2 EDTA 7.2 mg tubes, lot #4135162; storage requirement of 4-25 degrees C; (c) 13 BD Vacutainer Buff Na Citrate 3.2% tubes, lot #3352647; storage requirement of 4-25 degrees C. (2) Interview with the lead technologist on 09 /10/2024 at 10:30 am confirmed the temperature of the ICU supply room was not being monitored. NINTH FLOOR STORAGE AREA (1) Observation of the ninth floor storage area on 09/10/2024 at 10:20 am identified the following examples of blood collection tubes with the manufacturer's storage requirement, in the room: (a) 200 BD Vacutainer SST tubes, lot #4130825; storage requirement of 4-25 degrees C; (b) 100 BD Vacutainer K2 EDTA 7.2 mg tubes, lot #4102827; storage requirement of 4-25 degrees C; (c) 200 BD Vacutainer Buff Na Citrate 3.2% tubes, lot #4045029; storage requirement of 4-25 degrees C. (2) Interview with the lead technologist on 09 /10/2024 at 10:30 am confirmed the temperature of the ninth floor storage area was not being monitored. 48517 Based on a review of records, observation, and interview with the laboratory manager, the laboratory failed to ensure 40 of 40 boxes of Liquid Assayed Multiqual quality control materials were stored as required by the manufacturer. Findings include: (1) On 09/10/2024 at 11:00 am observation of the contents of the laboratory freezer #3 identified the following materials: (a) 40 boxes of Liquid Assayed Multiqual quality control material, master lot # 45950; (2) The storage requirement, as stated on the box for the materials was -20 degrees C (Celsius) or colder; (3) Observation of the freezer temperature log from 07/01/2024 through 07 /31/2024 identified the following: (a) The temperatures were warmer than -20 degrees C for two of 31 days reviewed. (4) The findings were reviewed with the laboratory manager who stated on 09/10/2024 at 11:00 am, the freezer temperatures were not within the manufacturer's storage requirements.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with the lead technologist, the laboratory failed to ensure testing materials had not exceeded their room expiration date for one of one Troponin I test cartridge observed; and failed to ensure expired blood collection tubes were not available for use in one of two areas observed in the hospital. Findings include: TROPONIN I TEST CARTRIDGE (1) On 09/10/2024 at 09:45 am, the lead technologist stated Troponin I testing was performed in the ICU (Intensive Care Unit) using the cTnI cartridge and the iSTAT 1 analyzer; (2) Observation of the ICU testing area on 09/10/2024 at 11:25 am, identified one cTnI test cartridge (lot #524077A) stored at room temperature, without documentation of when it had been removed from refrigeration; (3) Review of the manufacturer's storage requirements, as stated on the cartridge, showed the following: (a) Stability at 2-8 degrees C (Centigrade) until the expiration date listed on the box; (b) Stability at room temperature (18-30 degrees C) for 14 days. (4) Interview with the lead technologist on 09/10/2024 at 11:25 am, confirmed the cartridge had been placed at room temperature without a method to monitor if it exceeded the manufacturer's room temperature expiration date. EXPIRED BLOOD COLLECTION TUBES (1) Observation of the ninth floor storage area on 09/10/2024 at 11:45 am, identified the following expired supplies that appeared to be available for use: (a) 35 BD Vacutainer Buff. Na Citrate 0.109 M, 3.2% blood collection tubes, lot #3257661 with an expiration date of 06/30/2024. (2) Interview with the lead technologist on 09/10/2024 at 11:50 am confirmed the collection tubes had exceeded their expiration date and were available for use. 47979 Based on a review of manufacturer's instructions, observation, and interview with the lead technologist, the laboratory failed to ensure control materials had not been used beyond the modified expiration date for two of two lot numbers reviewed. Findings include: (1) One 09/09/2024 at 02:50 pm, the lead technologist stated the following: (a) The laboratory performed qualitative serum pregnancy testing using the Cardinal Health hCG Combo Rapid test kit; (b) Quidel positive and negative serum hCG quality control materials were tested monthly according to the IQCP. (2) Observation of the laboratory refrigerator on 09/10/2024 at 09:30 am, identified Quidel serum hCG quality control materials, lot 848A and lot 848B with an opened date of 08/23/2024; (3) A review of the manufacturer's package insert for the QC materials under the heading "Preparation of Controls" stated, "Write the date of reconstitution on the vial label. Controls can be used for two weeks after reconstitution. Store refrigerated."; (4) The findings were discussed with the lead technologist who stated on 09/10/2024 at 09:30 am, the expired positive and negative serum hCG controls were available for use beyond the modified expiration date.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by:

	Based on a review of records, manufacturer's instructions, and interview with the lead technologist and testing person #2, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for the ACL TOP 300 analyzer during the review period of August 2023 through July 2024. Findings include: (1) On 09/11/2024 at 10:00 am, the lead technologist stated PT/INR (Prothrombin Time/International Normalized Ratio), PTT (Partial Thromboplastin Time), and Anti Xa testing were performed using the ACL TOP 300 analyzer; (2) A review of the manufacturer's maintenance log showed the following required maintenance procedure: (a) Every Three Months - Change Bottles (3) A review of maintenance logs from August 2023 through July 2024 identified no documentation the maintenance had been performed between 01/24/2024 and 05/01/2024; (4) The records were reviewed with the lead technologist and testing person #2. Both stated on 09/11/2024 at 10:30 am, the maintenance procedure had not been documented as performed as shown above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 the lead technologist, the laboratory failed to perform QC (quality control) as stated in the IQCP (Individualized Quality Control Plan) for the qualitative serum pregnancy testing for one of nine months reviewed from January 2024 through the current date. Findings include: (1) On 09/09/2024 at 2:47 pm, the lead technologist stated the following: (a) The laboratory performed qualitative serum pregnancy testing using the Cardinal Health hCG Combo Rapid test kit; (b) Quidel positive and negative serum hCG quality control materials were tested monthly according to the IQCP. (2) A review of QC records from January 2024 through the current date identified no documentation to prove QC had been performed between 07/18/2024 and 09/10/2024; (3) The records were reviewed with the lead technologist who stated on 09/10/2024 at 02:35 pm, QC had not been performed as stated above.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by:

	Based on a review of records, written policy, and interview with the general supervisor, the laboratory failed to comply with 21 CFR 606.160(b)(3)(v). The laboratory failed to ensure that emergency release of blood forms had been signed by the physician for one of one emergency releases reviewed. Findings include: (1) On 09 /12/2024 at 9:00 am, the general supervisor stated the laboratory maintained units of (PRBC's) packed red blood cells. The units were to be used for patient transfusions; (2) On 09/12/2024 a review of the emergency transfusion tag stated, "I authorize the issuance of blood without Crossmatch as emergency since the life of the patient would be in danger without this blood" and includes a space for physician signature; (3) A review of documentation of emergency issue blood for one patient identified the following for one of one patient records: (a) Unit #W091024267879 was given emergent on 07/09/2024 and the emergency transfusion tag was not signed by the physician. (4) The findings were reviewed with the lab manager on 09/12/2024 at 9:00 am who confirmed that the form had not been signed by the physician.