Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0259401	11/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Emory Medical Laboratories	1364 Clifton Road Northeast, Atlanta, GA	

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	An unannounced onsite complaint investigation was conducted from 11/04/2024 through 11/07/2024. The allegations were substantiated, and condition-level non-compliance was identified, as follows: D3000 CFR 493.1100 Facility Administration D6108 CFR. 493.1447 Laboratories performing high complexity testing; technical supervisor
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of the facility's blood product transfusion procedures, facility transfusion training materials, laboratory procedure, patient transfusion records, and staff interview, the facility administration failed to meet the requirements specified in 493.1101 through 493.1105, as evidenced by: 1. The facility failed to follow their own policies to promptly identify and report blood transfusion reactions to the laboratory. Refer to D3025.
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 review of the facility's blood product transfusion procedures, facility transfusion training materials, laboratory procedure, patient transfusion records, and staff interview, the facility failed to follow their own policies to promptly identify and report blood transfusion reactions for five of seven patient transfusions. Findings included: 1. The facility procedure titled, "Blood and blood product transfusion" stated "...Implementation ...Obtain the patient's vital signs immediately before initiating the transfusion to serve as a baseline for comparison ...Remain near the patient during the first 15 minutes to monitor for signs and symptoms of a transfusion reaction ...If a reaction occurs, stop the transfusion immediately and notify transfusion services and the patient's practitioner ...At the completion of the blood product administration, obtain the patient's vital signs and compare them with the baseline measurements to detect signs of a possible transfusion reaction ...Continue to assess and monitor the patient for signs and symptoms of a delayed transfusion reaction for 4 to 6 hours after the transfusion ..." 2. The facility procedure titled, "Blood and Blood Product Transfusion-Adverse Reactions" stated "...Introduction ...Any suspected adverse reaction to the transfusion of blood products must be reported to the Transfusion Service for evaluation and to the patient's physician to facilitate appropriate treatment for the patient ...Acute Transfusion Reactions Listed below are signs and symptoms that may be associated with acute transfusion reactions: All symptoms should be evaluated by a physician. Fever, with or without chills, defined as a temperature of >/= 38C and an increase of at least 1C from pre-transfusion value ...hypotension or hypertension, Respiratory distress, including wheezing, coughing, dyspnea, tachypnea, bronchospasm, or hypoxemia, Tachycardia, cardiac arrhythmia, cardiac arrest, urine color changes (hematuria/hemoglobinuria) ..." The facility's procedures failed to provide specific criteria to assess hypotension, hypertension, respiratory distress, or tachycardia. 3. The facility's blood product transfusion training material titled, "Blood Product Safety" stated "...Adverse Reaction Regulations ... AABB and CAP require annual continuing education for all clinicians involved in blood transfusions. Possible S/S of Transfusion Reactions Fever, with or without chills, defined as a temperature of >/= 38C and an increase of at least 1C from pre-transfusion value ...hypotension or hypertension ...Respiratory distress, including wheezing, coughing, dyspnea, tachypnea, bronchospasm, or hypoxemia, Shock Tachycardia, cardiac arrhythmia, cardiac arrest, urine color changes (hematuria /hemoglobinuria) ..." The facility transfusion training material failed to provide specific criteria to assess hypotension, hypertension, respiratory distress, or tachycardia. 4. In an interview on 11/05/2024 at 2:15pm in the conference room, the Corporate Director of Accreditation and Policy Management was asked what patient vital signs were documented before initiation of a blood product transfusion. She stated blood pressure, pulse, temperature, and respiration rate were taken prior to a transfusion. The Corporate Director of Accreditation and Policy Management was also asked to provide documentation of blood transfusion continuing education for all clinicians that included providers/ practitioners. No documentation was provided. 5. The laboratory procedure titled CTCT Transfusion Reactions stated "...Process: Nursing responsibilities 1. If any signs or symptoms suggestive of an immediate transfusion reaction occur, the personnel attending that patient are to promptly interrupt the transfusion and notify the blood bank and the patient's physician. a. Signs

and symptoms of adverse reactions are described in the Lippincott Nursing Procedure: CTCT Nursing SOP: Blood and Blood Product Transfusion-Adverse Reactions. b. The transfusion reaction investigation will proceed whether or not the patient's physician deems it necessary ..." 6. Review of patient transfusion records revealed the following: Patient 9337343 02/17/2024 Specimen received. Patient typed as O positive, and a warm autoantibody was identified. All clinically significant alloantibodies were ruled out with alloabsorbed plasma. Four units were crossmatched and transfused. Units were phenotype matched as C, K, Fyb, and Jkb negative, however, antibodies to these antigens were not identified. Further review of Patient 9337343 transfusion records revealed: Unit number W201823626463 E0668, Leukoreduced Red Blood Cells, Vitals Documented 02/18/2024 at 09:32 am: Temp 37C (98.6F) Pulse 88 Resp 18 BP 124/68 mmHg Transfusion started: 02/18/2024 at 09:45 am Transfusion stopped: 02/18/2024 at 12:13 pm Vitals Documented 02/18 /2024 at 12:13 pm: Temp 38C (100.4F) Pulse 103 Resp 18 BP 135/71 mmHg At this time, the patient had a temperature increase of 1C from the pre-transfusion value. Unit number W201823626463 E0669, Leukoreduced Red Blood Cells, Vitals Documented 02/19/2024 at 08:11 am: Temp 36.3C (97.3F) Pulse 98 Resp 18 BP 116/67 mmHg Transfusion started: 02/19/2024 at 08:19 am Vitals Documented 02/19/2024 at 09:00 am: Temp 37.7C (99.9F) Pulse 88 Resp 18 BP 114/67 mmHg At this time, the patient had a temperature increase of 1.4C from the pre-transfusion value. Transfusion stopped: 02/19/2024 at 11:00 am Vitals Documented 02/19/2024 at 11:00 am: Temp 37.6C (99.4F) Pulse 84 Resp 20 BP 119/73 mmHg At this time, the patient had a temperature increase of 1.3C from pre-transfusion value. In an interview on 11/05 /2024 at 1:51pm, the Laboratory Quality Technical Specialist was asked to provide documentation of a transfusion reaction workup. No documentation was provided. The facility failed to identify and report a transfusion reaction, per their own policy, for a temperature increase from pre-transfusion value. This patient was discharged 02 /24/2024 and readmitted on 02/27/2024. Patient records stated, " ...The history and physical reports acute urinary retention and maroon colored urine with a large amount of blood was collected via Foley ..." Unit number W186624010973 E0332, Leukoreduced Red Blood Cells, Vitals Documented 02/28/2024 at 05:00 am: Temp No temperature documented at this time. Pulse 75 Resp 19 BP No blood pressure documented at this time. Transfusion started: 02/28/2024 at 05:14 am Unit number W186624005231 E0332, Leukoreduced Red Blood Cells, Vitals documented 02/28 /2024 at 07:00 am and at 07:05 am failed to include a temperature. Transfusion started: 02/28/2024 at 07:09 am The facility failed to document the required patient's vital signs (temperature and blood pressure) immediately before initiating the transfusion to serve as a baseline for comparison per their procedure. Review of the facility's incident documentation, "SAFE" report from 02/28/2024, stated, " ...After the start of the transfusion the patient was not responding well to commands and we suspected transfusion reaction by the resident and stopped the blood transfusion which was restarted after 20 minutes ..." The patient expired on 02/28/2024. In an interview on 11/05/2024 at 1:51pm, the Laboratory Quality Technical Specialist was asked to provide documentation of a transfusion reaction workup from the transfusions on 02 /28/2024. No documentation was provided. 7. Review of additional patient transfusion records revealed the following: Patient 19071637 Unit number W200323577756 E0668, Leukoreduced Red Blood Cells, No documented patient vital signs immediately before initiating the transfusion to serve as a baseline for comparison per their procedure. Transfusion started: 01/19/2024 at 06:12 am. The following vitals were documented at this time: Temp 36.6C (97.9 F) Pulse 67 Resp 17 BP 151/65 Vitals Documented 01/19/2024 at 06:39 am: Temp 36.9C (97.7F) Pulse 81 Resp 18 BP 116/72 mmHg At this time, the patient had a decrease in systolic blood pressure of 35 mmHg from the start of the transfusion. In an interview on 11/06/2024 at 1:24 pm

	in the conference room, the Clinical Nurse Specialist was asked if the decrease in blood pressure was significant. She stated yes and that any change in systolic blood pressure over 20 mmHg was significant. Patient 19044041 Unit number W180324135168 E0336, Leukoreduced Red Blood Cells Vitals Documented 11/04 /2024 at 3:30 pm: Temp 36.8C (98.2F) Pulse 114 Resp 25 BP 93/62 mmHg Transfusion started: 11/04/2024 at 3:36 pm Vitals were continuous monitored at regular intervals during the transfusion. Documented blood pressures during the transfusion: 11/04/2024 4:10 pm 112/64 mmHg 11/04/2024 4:20 pm 127/69 mmHg 11 /04/2024 4:30 pm 137/75 mmHg 11/04/2024 4:40 pm 153/84 mmHg At this time, the patient had an increase in systolic blood pressure of 60 mmHg from the pre-transfusion value. Transfusion stopped: 11/04/2024 at 5:20 pm Documented blood pressure at this time was 131/75. The patient had an increase in systolic blood pressure of 38 mmHg from the pre-transfusion value. In an interview on 11/06/2024 at 1:24 pm in the conference room, the Clinical Nurse Specialist was asked if the increase in blood pressure was significant. She stated that she would consider the increases significant. During the interview, the Laboratory Quality Technical Specialist was asked to provide documentation of a transfusion reaction workup for the patients 19071637 and 19044041. No documentation was provided. 8. Review of the facilities transfusion records for 2023 revealed 42,496 blood and blood product transfusion and 97 reported transfusion reactions for a reaction rate of 0.23%. Word Key: AABB=Association for the Advancement of Blood & Biotherapies CAP=College of American Pathologists S/S=Signs and Symptoms CTCT=Centers for Transfusion and Cellular Therapy SOP=Standard Operating Procedure Temp=Temperature Resp=Respiration Rate BP=Blood Pressure mmHg=millimeters of Mercury C=Big C red blood cell antigen K=Kell red blood cell antigen Fyb=Duffy b red blood cell antigen Jkb=Kidd b red blood cell antigen
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 review of laboratory policies, laboratory personnel competency records and interview with staff, the laboratory failed to have a competency assessment policy for assessing competency of Clinical Consultant (CC), Technical Supervisor (TS), and General Supervisor (GS). Findings: 1. Review of laboratory policies found no policy for competency assessment for Clinical Consultant, Technical Consultant, and General Supervisor. 2. Review of competency assessment records found no competency assessment records for 3 of 3 Clinical Consultants (CC), 2 of 2 Technical Supervisors (TS) and 8 of 8 General Supervisors (GS) listed on the form CMS 209 signed by the laboratory director on November 5, 2024. 3. During interview on November 6, 2024, at 12:46pm, the Regulatory Supervisor confirmed the CCs, TSs and GSs listed on the form CMS 209 signed by the laboratory director on November 5, 2024 did not have a competency assessment.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification

	requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of the facility's blood product transfusion procedures, facility transfusion training materials, laboratory procedure, patient transfusion records, and staff interview, the technical supervisors (TS-1 and TS-2) failed to provide technical supervision to ensure immunohematology systems provided quality services. Refer to D6112.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on review of the facility's blood product transfusion procedures, facility transfusion training materials, laboratory procedure, patient transfusion records, and staff interview, the technical supervisors failed to provide technical and scientific oversight for immunohematology. Refer to D3025.