

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2113612	(X3) Date Survey Completed 05/11/2021
Name of Provider or Supplier Eminent Medical Center, Llc	Street Address, City, State 1351 West President George Bush Hwy, Richardson, TX	
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	<p>An entrance conference was held with the laboratory representative. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.1100 Facility Administration, 493.1217 Immunohematology 493.1441 Laboratory Director, (high complexity) Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately</p>
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) records and interview with staff, the laboratory failed to test coagulation PT samples in the same manner as it tested patient specimens for 3 of 5 specimens in the 3rd Coagulation PT event of 2020. Findings Included: 1. Review of laboratory policy titled, "Proficiency Testing" (Reviewed by the laboratory director March 2021) stated the following, "Proficiency materials are handled in the same manner as patient specimens to the extent possible. The same rules apply for repeat testing with proficiency testing as for patient samples." 2. Review of the API 2020 Coagulation 3rd Event revealed the following samples were part of the event: COA-11, COA-12, COA-13, CA-14 and COA-15. The laboratory's proficiency testing records included instrument raw data that revealed 3 of the 5 samples had repeated test results. a. COA-12 1st Run 11.12.2020 15:50 APTT- 59.3 PT- 44.5 INR- 4.088 2nd Run 11.12.2020 16.28 APTT- 60.8 PT- 46.4 INR- 4.268 The results reported, for sample COA-12, to the American Proficiency Institute for the 3rd Coagulation PT event of 2020 were: APTT- 59; PT- 44.5; INR-4.1 b. COA-13 1st Run 11.12.2020 15:50 APTT- 51.4 PT- 30.7 INR- 2.789 2nd Run 11.12.2020 16.28 APTT- 52.7 PT- 31.3 INR- 2.846 The results reported, for sample COA-13, to the American Proficiency Institute for the 3rd Coagulation PT event of 2020 were: APTT- 51; PT- 30.7; INR- 2.8 c. COA-14 1st Run 11.12.2020 15:50 APTT- 34.1 PT- 21.2 INR- 1.905 2nd Run 11.12.2020 16.28 APTT- 35.0 PT- 22.3 INR- 2.007 The results reported, for sample COA-14, to the American Proficiency Institute for the 3rd Coagulation PT event of 2020 were: APTT- 34; PT- 21.2; INR- 1.9 3. In an interview on 5/10/2021 at 12:10 PM, in patient room #1, the technical consultant confirmed the PT samples were tested in duplicate. After reviewing the results, the technical consultant could not provide documentation supporting the repeat of PT samples. This confirmed the above findings. The laboratory failed to test PT samples in the same manner as it tested patient specimens for 3 of 5 samples in the 3rd Coagulation PT event of 2020. WORD KEY: INR=International Normalized Ratio

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 records and a review of patient transfusion records (02/2020-04/2021), it was revealed the facility administration failed to meet the requirements specified in 493.1101 through 493.1105, as evidenced by: 1. The facility failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for 5 of 21 patients that received blood products. 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 and laboratory blood/blood product transfusion policies, review of facility blood administration educational material, review of patient transfusion records (02/2020-04/2021), and staff interview, it was revealed the facility failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for 5 of 21 patients that received blood products. Findings included: 1. Review of the laboratory policy titled, "Blood Bank Transfusion Administration" (Reviewed March 2021), stated the following: "C. Transfusion Procedure: 1. Two nurses (1 nurse RN/1 licensed clinical staff member) will review the following information before any transfusion begins ...2. After completion of the clerical check, the nurses or the physician and the nurse will sign the Blood Transfusion Record ...4. Record vital signs (temperature, blood pressure, and pulse) prior to administration on the Blood Transfusion Record ...10. Record patient vital signs of the Blood Transfusion Record after 15 minutes of infusion and again at 30 min. and 1 hour then every hour transfusion is complete, ensure the dates and times are identified with the vital signs. The patient should be monitored at regular intervals throughout the transfusion for signs of a transfusion reaction. 11. Record 30 min post vital signs on the transfusion component tag ...E. Transfusion Reaction ...8.f. Acute Transfusion Reactions: Type: Acute Hemolytic; Signs/Symptoms: Chills and Fever, Chest and Back Pain, Nausea, Hypotension, Flushing, Tachycardia, Hemoglobinuria, Oliguria, Bleeding at surgical site; Type: Febrile Non hemolytic; Signs/Symptoms: Chills and Fever, Headache, Muscle aches, Chest Pain, Nausea, Dyspnea, Flushing, Hypotension (rare); Type: Allergic; Signs/Symptoms: Hives, Itching, Rash, Laryngeal edema; Type: Anaphylactic; Signs/Symptoms: Cough, Bronchospasm, Respiratory distress, nausea, shock, diarrhea, loss of consciousness; Type: Pyrogenic; Signs/Symptoms: Chills and High fever, Shock, Flushing, Abdominal cramps, Diarrhea, Nausea and vomiting, muscle ache; Type: Hypervolemic; Signs/Symptoms: Coughing, Cyanosis, Dyspnea, Hypertension; Type: TRALI Noncardiogenic Pulmonary (rare); Signs/Symptoms: Pulmonary edema, Dyspnea, Chills and vomiting, Cyanosis, Hypotension 2. Review of the facility record titled, "Blood Transfusion Record" (Revised 05/31/2019) revealed areas to be completed for: a. Various clerical checks for physician name, armband number, type of blood component, unit number, unit expiration date, patient type and Rh, Patient antibody screen, confirmation of donor Type and Rh, Visual inspection of unit, Date/Time/Initials for crossmatch completion, Crossmatch results and expiration, Issued by initials, Issued to initials, and Date/Time b. Transfusion Start Date and Time c. Two nurses' signature entry d. Temperature, Pulse, Respiration, and Blood Pressure vital signs at Pretransfusion time, 15 minutes, 30 minutes, 1 hour, 2-hour, 3 hour and 4 hours; Reaction? Yes/No; Transfusionist's initials. e. Transfusion Reaction Criteria: Chills; Chest Tightness; Heat at Infusion site; hemoglobinuria or dark urine; Nausea and Vomiting; Flank of Back Pain; Headache; Fever (Increase of 1C or 2F); Tachycardia (Increase by 20 beats); Wheezing or Coughing; Tachypnea; Urticaria (Hives); Itching; Dyspnea; Hypotension (decrease by 30mm); Hypertension (Increase by 30 mm) f. Suspected Transfusion Reaction: Yes/No g. Date/Time/Initials for Transfusion completion The Blood Transfusion Record failed to include an area to document patient's vital signs 30 minutes post transfusion per laboratory policy. 3.

Review of the facility's blood administration educational materials from 2020 and 2021 revealed the facility performed training on March 8, 2020 and conducted a "Blood Transfusion Documentation Skills Fair" from 01/01/2021 through 05/01/2021.

4. Review of the documentation provided for the blood administration training performed on March 8, 2020 included a copy of the Blood Transfusion Record form, a Nursing Blood Bank Competency test, and a Blood Administration handout with the following information: "1. Verify Blood Transfusion Consent is signed 2. Obtain and bring copy of the Doctor's order for transfusion to the lab 3. Check unit out of lab with either lab personnel or additional RN 4. Confirm from the ortho Log Book and Blood Transfusion Record a. Name; b. MR#; c. BB Armband#; d. Pt. Blood type and Rh; e. Unit#; f. Unit Expiration Date; g. Unit visual Check; h. Unit Product type; i. Unit Blood Type; j. Compatibility of the Unit 5. After unit check and no discrepancies noted each person must notate initials, date, and time in the Log Book and on the Blood Transfusion Record. AT THE BEDSIDE 1. One RN and one licensed employee must check the attached patient BB Armband with the Blood Transfusion Record and both personnel must sign in the appropriate boxes prior to the commencement of the transfusion. 2. Record all vital signs prior to administration 3. Blood is administered through a blood filter and hung with normal saline. Only a RN or physician may initiate the transfusion. 4. Record Patient vitals signs on the Blood Transfusion Record after 15 min. of infusion, then 30 min, 1 hour and every hour until transfusion is complete. 4 hours is the maximum time from when the unit left the laboratory. 5. Record vitals 30 mins. post transfusion ..." Further review of the "Nursing Blood Bank Competencies" test revealed only 1 question related to a transfusion reaction. The question was, "16. When a transfusion reaction is suspected what 4 things does nursing send to the laboratory?" The training failed to include signs /symptoms of a transfusion reaction. This training failed to include transfusion reaction criteria (Chills; Chest Tightness; Heat at Infusion site; hemoglobinuria or dark urine; Nausea and Vomiting; Flank of Back Pain; Headache; Fever (Increase of 1C or 2F); Tachycardia (Increase by 20 beats); Wheezing or Coughing; Tachypnea; Urticaria (Hives); Itching; Dyspnea; Hypotension (decrease by 30mm); Hypertension (Increase by 30 mm) specified on the "Blood Transfusion Record". The facility was asked to provide a list of nursing personnel who had completed the training in March 2020. No documentation was provided. 5. Review of the "Blood Transfusion Documentation Skills Fair" conducted from 01/01/2021 through 05/01/2021 revealed the facility used transfusion information prior to February 2020. (The laboratory initiated in-house immunohematology testing in February 2020). The 2021 Skills Fair included the following transfusion reaction information: "Transfusion reactions: Vital signs before transfusion, after 15 min, 30 min, 1 hr, 2 hr, 3hr, 4hr, if completed before the 4th hour no need to document vitals further. Stay with the patient for the first 15 min and observe for adverse reactions: mild reactions: urticaria, rash, pruritus ... Moderately severe reactions: Flushing, urticaria, rigors, fever, restlessness, tachycardia, anxiety, pruritus, palpitations, mild dyspnea, headache ...Life-threatening reactions: Rigor, fever, restlessness, hypotension, tachycardia, hemoglobinuria, DIC, anxiety, chest pain, pain, respiratory distress/shortness of breath, headache ..." The training documents failed to include nausea and vomiting as signs/symptoms of a transfusion reaction per the laboratory policy. The training documents included the following signs/symptoms of a transfusion reaction that were NOT included in the laboratory policy: Restlessness; Anxiety; DIC This training failed to include transfusion reaction criteria (Chills; Chest Tightness; Heat at Infusion site; hemoglobinuria or dark urine; Nausea and Vomiting; Flank of Back Pain; Headache; Fever (Increase of 1C or 2F); Tachycardia (Increase by 20 beats); Wheezing or Coughing; Tachypnea; Urticaria (Hives); Itching; Dyspnea; Hypotension (decrease by 30mm); Hypertension (Increase by 30 mm) specified on the "Blood Transfusion

Record". The Quality and Infection Control Coordinator provided the names of 20 nursing personnel who completed the 2021 blood transfusion skills fair. 6. Review of the facility's patient transfusion records (02/2020-04/2021) revealed the following 5 of 21 patients in which the facility failed to follow its own policy to ensure transfusion reactions were promptly identified, investigated, and documented for all blood products: a. Patient 3824 Date: 05/02/2020 Unit number #1: WO35220186826 Transfusion Initiated: 05/02/2020; 1042 Pre-Transfusion Vitals; 1042: Temperature 98.8; Pulse 100; Respirations 13; Blood Pressure 127/71 Reaction? No 15 Minute Vitals; 1057: Temperature 98.4; Pulse 101; Respirations 14; Blood Pressure 98/51 Reaction? No 30 Minute Vitals; 1127: Temperature 99.3; Pulse 99; Respirations 14; Blood Pressure 102/60 Reaction? No 1 Hour Vitals; 1227: Temperature 98.4; Pulse 100; Respirations 11; Blood Pressure 97/67 Reaction? No The patient had a Blood Pressure decrease of 30 mm from vitals documented at 1042. Per facility policy, a decrease in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. No documentation of vital signs 30 minutes post transfusion per facility policy. Unit number #2: WO35220202454 Transfusion Initiated: 05/02/2020; 1255 Pre-Transfusion Vitals; 1255: Temperature 98.4; Pulse 99; Respirations 19; Blood Pressure 97/67 Reaction? No 15 Minute Vitals; 13:10: Temperature 98.3; Pulse 101; Respirations 18; Blood Pressure 125/69 Reaction? No 30 Minute Vitals; 1340: Temperature 98.4; Pulse 111; Respirations 20; Blood Pressure 152/89 Reaction? No The patient had a Blood Pressure increase of 55 mm from vitals documented at 1255. Per facility policy, an increase in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. 1 Hour Vitals; 1440: Temperature 98.4; Pulse 116; Respirations 20; Blood Pressure 137/80 Reaction? No 2 Hour Vitals; 1627: Temperature 98.1; Pulse 93; Respirations 16; Blood Pressure 103/53 Reaction? No The patient had a Blood Pressure decrease of 49mm from vitals documented at 1340. Per facility policy, a decrease in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. No documentation of vital signs 30 minutes post transfusion per facility policy. b. Patient 3038 Date: 06/07/2020 Unit number: WO35220167402 Transfusion Initiated: 06/07/2020; 1832 Pre-Transfusion Vitals; 1800: Temperature 98.6; Pulse 103; Respirations 16; Blood Pressure 159/97 Reaction? No 15 Minute Vitals; 1847: Temperature 99; Pulse 110; Respirations 16; Blood Pressure 153/90 Reaction? No 30 Minute Vitals; 1912: Temperature 99.1; Pulse 108; Respirations 18; Blood Pressure 152/80 Reaction? No 1 Hour Vitals; 1935: Temperature 98.4; Pulse 110; Respirations 20; Blood Pressure 148/78 Reaction? No 2 Hour Vitals; 2035: Temperature 98.4; Pulse 106; Respirations 15; Blood Pressure 146/85 Reaction? No 3 Hour Vitals; 2117: Temperature 98.4; Pulse 103; Respirations 19; Blood Pressure 121/97 Reaction? No The patient had a Blood Pressure decrease of 38 mm from vitals documented at 1800. Per facility policy, a decrease in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. No documentation of vital signs 30 minutes post transfusion per facility policy. c. Patient 4006 Date: 06/18/2020 Unit number #1: WO35220244642 Transfusion Initiated: 06/18/2020; 1330 Pre-Transfusion Vitals; 1339: Temperature 98.6; Pulse 96; Respirations 12; Blood Pressure 155/66 Reaction? No 15 Minute Vitals; 1345: Temperature 98.4; Pulse 99; Respirations 15; Blood Pressure 141/70 Reaction? No 30 Minute Vitals; 1415: Temperature 98.9; Pulse 92; Respirations 20; Blood Pressure 119/48 Reaction? No The patient had a Blood Pressure decrease of 36 mm from vitals documented at 1339. Per facility policy, a decrease in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. 1 Hour Vitals; 1515: Temperature 98.8; Pulse 91; Respirations 15; Blood Pressure 142/67 Reaction?

No 2 Hour Vitals; 1615: Temperature 98.7; Pulse 87; Respirations 13: Blood Pressure 175/76 Reaction? No The patient had a Blood Pressure increase of 57 mm from vitals documented at 1415. Per facility policy, an increase in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. No documentation of vital signs 30 minutes post transfusion per facility policy. Unit number #2: WO35220141504 Transfusion Initiated: NO DOCUMENTATION OF START DATE AND TIME Pre-Transfusion Vitals; 1725: Temperature 98.2; Pulse 84; Respirations 12: Blood Pressure 188/89 Reaction? No 15 Minute Vitals; 1749: Temperature 98.2; Pulse 90; Respirations 16: Blood Pressure 195/88 Reaction? No 30 Minute Vitals; 1815: Temperature 98.4; Pulse 82; Respirations 14: Blood Pressure 166/78 Reaction? No 1 Hour Vitals; 1915: Temperature 98.2; Pulse 91; Respirations 14: Blood Pressure 165/81 Reaction? No 2 Hour Vitals; 2015: Temperature 97.2; Pulse 97; Respirations 15: Blood Pressure 157/84 Reaction? No The patient had a Blood Pressure decrease of 38 mm from vitals documented at 1749. Per facility policy, a decrease in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. No documentation of vital signs 30 minutes post transfusion per facility policy. d. Patient 4302 Date: 08/13/2020 Unit number: WO35220277117 Transfusion Initiated: 08/13/2020; 0959 Pre-Transfusion Vitals; 0959: Temperature 35.0; Pulse 80; Respirations 10: Blood Pressure 76/42 Reaction? No 15 Minute Vitals; 1014: Temperature 35.1; Pulse 75; Respirations 10: Blood Pressure 97/56 Reaction? No 30 Minute Vitals; 1029: Temperature 35.1; Pulse 75; Respirations 10: Blood Pressure 106/68 Reaction? No The patient had a Blood Pressure increase of 30 mm from vitals documented at 0959. Per facility policy, an increase in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. No documentation of vital signs 30 minutes post transfusion per facility policy e. Patient 4235 Date: 10/13/2020 Unit number: WO35220319333 Transfusion Initiated: 10/13/2020; 1220 Pre-Transfusion Vitals; 1210: Temperature 98.6; Pulse 101; Respirations 15: Blood Pressure 123/73 Reaction? No 15 Minute Vitals; 1235: Temperature 98.9; Pulse 105; Respirations 16: Blood Pressure 121/74 Reaction? No 30 Minute Vitals; 1300: Temperature 99.3; Pulse 103; Respirations 14: Blood Pressure 139/67 Reaction? No 1 Hour Vitals; 1400: No temperature documented; Pulse 102; Respirations 14: Blood Pressure 105/59 Reaction? No The patient had a Blood Pressure decrease of 34 mm from vitals documented at 1300. Per facility policy, a decrease in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. 2 Hour Vitals; 1500: No temperature documented; Pulse 101; Respirations 14: Blood Pressure 116/62 Reaction? No 3 Hour Vitals; 1600: No temperature documented; Pulse 100; Respirations 14: Blood Pressure 105/60 Reaction? No 4 Hour Vitals; 1700: No temperature documented; Pulse 102; Respirations 14: Blood Pressure 108/60 Reaction? No No documentation of vital signs 30 minutes post transfusion per facility policy The facility failed to follow its own policy to ensure transfusion reactions were promptly identified, investigated, and documented for all blood products. 7. A random review of the Blood Transfusion records revealed the following: a. Patient 359 Date 02/26/2020; 1727 Unit number: WO35220121794 Vitals were documented at Pretransfusion, 15 minutes, and 4 hours. The facility failed to document patient vital signs at 30 minutes, 1 hour, 2-hour, 3 hour and 30 minutes post transfusion. b. Patient 3634 Date 03/25/2020; 0930 Unit number #1: WO35220159208 The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. Date 03/25/2020; 1215 Unit number #2: WO35220096409 The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. c. Patient 3923 Date 05/22/2020; 0740 Unit number #1: W35220168671 The facility failed to

document patient vital signs at 30 minutes post transfusion per laboratory policy. Date 05/22/2020; 1020 Unit number#2: WO35220159409 The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. d. Patient 3038 Date 06/05/2020; 1052 Unit number: W35220206640 The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. e. Patient 4068 Date 06/27/2020; No start time documented Unit number #1: W35220208845 The facility failed to document temperature at 30 minutes, 1 hour, and 2 hours. The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. No start date and time documented Unit number #2: W35220243289 The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. f. Patient 3537 Date 07/08/2020; 1955 Unit number #1: W35220221554 The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. Date 07/08/2020; 2323 Unit number #2: W35220217874 The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. g. Patient 5410 Date 04/27/2021; 1521 Unit number: WO35221178486 The signature entry Blood Transfusion Record was signed by one person not listed as having participated in the Blood Transfusion Documentation Skills Fair in 2021. The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. 8. During an interview on 05/11/2021 at 10:15am in the breakroom, the facility Quality and Infection Control coordinator was asked if the facility has its own Blood Administration policy. She stated that she was not aware of a policy. The Quality and Infection Control coordinator was shown the blood transfusion record signed by nursing personnel not listed on the 2021 Blood Transfusion Skills Fair completion list. She stated that the nurse was an agency (contract) nurse and agency nurses did not receive the blood administration training. The Quality and Infection Control coordinator reviewed the patients listed in #6 above and confirmed the facility did not follow its own blood transfusion reaction policy to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions. This confirmed the above findings. WORD KEY: Min-minutes Hr-hour RN=Registered Nurse MR#=Medical record number BB armband#=Blood Bank Armband number Pt=patient Unit#= Blood product unit number DIC=Disseminated Intravascular Coagulation TRALI=Transfusion Related Acute Lung Injury

D5026

IMMUNOHEMATOLOGY
CFR(s): 493.1217

If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1271, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:
Based on surveyor's review of the immunohematology records, patient records, and staff interviews the laboratory failed to meet applicable requirements in the specialty of Immunohematology. Refer to D5559.

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 the laboratory's policies, submitted Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and staff interview, it was revealed the laboratory failed to have documentation of a policy to assess competency, based on the position responsibilities, for 1 of 1 General Supervisors (GS-1). Findings included: 1. A review of the laboratory's policies revealed the laboratory failed to have documentation of a policy of when and how a competency assessment was to be performed on the general supervisor. 2. Review of the submitted Centers for Medicare and Medicaid Services (CMS) 209 form listed one General Supervisor (GS-1). 3. Review of personnel records for GS-1 revealed a hire date of 04 /11/2019. Further review of personnel records for GS-1 revealed there was no documented annual competency assessment for the duties performed as a general supervisor. 4. During an interview on 05/11/2021 at 1:15pm in the breakroom, the Technical Consultant confirmed the above findings.

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 review of laboratory policy, American Proficiency Institute (API) proficiency testing (PT) records and confirmed in interview, the laboratory failed to review and evaluate the result obtained on proficiency testing for 1 of 5 samples in the 3rd Immunology/Immunochemistry event of 2020. Findings Included: 1. Review of laboratory policy titled, "Proficiency Testing" (Reviewed by the laboratory director March 2021) stated the following, "Unacceptable Results: PT Challenges that were not graded: All reports that contain a not graded code will be reviewed by the Laboratory Director to determine acceptability of the response provided by the laboratory." 2. Review of the API 2020 Immunology/Immunochemistry 3rd Event revealed the following PT results: Sample- SER-11 Performance- Not Graded Further review of the event revealed the API performance review was signed by the technical supervisor. No documentation of result evaluation of Sample SER-11 by the laboratory director was provided. 3. In an interview on 5/10/2021 at 12:10 PM, the technical supervisor confirmed the laboratory director did not document their review of Not Graded PT results. This confirmed the above findings. The laboratory failed to follow its own procedure for review of not graded PT results for 1 of 5 samples in the 3rd Immunology/Immunochemistry event of 2020.

D5555

IMMUNOHEMATOLOGY
 CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 laboratory policy, surveyor observation, and staff interview it was revealed the laboratory failed to ensure the nursing staff who assisted in the monitoring of the blood bank alarm system understood what the alarm was for and what steps to follow when the alarm was sounding. Findings included: 1. The laboratory policy titled, "Blood Bank Refrigerator Temperature Quality Control" (Reviewed March 2021), stated, "Procedure: The alarms systems must be in place and allow continuous monitoring (24 hours/7 days a week) of the storage device. The following criteria must be met: Alarms systems must be in place and allow continuous monitoring (24 /7) of the storage device. A remote alarm system must be used to monitor the local alarm (24/7) ..." 2. In an interview on 05/11/2021 at 11:15am, testing person 1 was asked to explain the how the blood bank refrigerator alarm was monitored when laboratory personnel were not present in the laboratory. She explained the laboratory is normally staffed during the day and that when laboratory personnel were not in the laboratory, the alarm could be heard outside of the laboratory by nurses at the nearby nurses' station. The nurse would then call laboratory personnel. 3. Surveyor observation of alarm checks performed by the Testing Person 2 on 05/11/2021 at 11: 34 am, revealed the blood bank refrigerator alarm sounded in the laboratory. The alarm sounded while there was 1 nurse seated at the nurses' station. The surveyor asked the nurse present what the alarm meant. She stated that she did not hear an alarm and that she was not really paying attention. The surveyor asked the nurse what she would do if she did hear the refrigerator alarm sounding in the laboratory. She stated she would call the laboratory. The surveyor asked the nurse what she would do if there was no one in the laboratory. She stated that there is usually someone in the laboratory. NOTE: The laboratory is NOT staffed 24 hours a day, 7 days a week. 4. The laboratory was asked to provide documentation of training of the nursing personnel to ensure they knew what the alarm indicated and the steps to take when it was sounding. No documentation was provided. 5. An interview with the technical consultant on 05/11/2021 at 12:03pm in the laboratory confirmed the findings.

D5559

IMMUNOHEMATOLOGY
 CFR(s): 493.1271(e)(f)

(e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (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 review of the laboratory blood/blood product transfusion policies, patient transfusion records (02/2020-04/2021), and staff interview, the laboratory failed to ensure transfusion reactions were promptly identified, investigated, documented, and recommendations were made to medical staff regarding transfusion procedure improvements for 5 of 21 patients that received blood products. Findings included: 1. The laboratory policy titled, "Transfusion Reaction Investigation" (Reviewed March

2021), stated the following: 'Principle: A transfusion service must have a system to evaluate and report suspect adverse reactions to transfusions. Detection of a reaction is the responsibility of the transfusionist, nurse, doctor or anyone else that comes in contact with the patient to immediately notify a responsible physician and the Blood Bank. Any adverse reaction of the patient associated with transfusion should initiate a transfusion reaction investigation. No additional units of blood should be issued to a patient with a suspected transfusion reaction until the laboratory testing portion of the evaluation has been completed.' 2. Review of the laboratory policy titled, "Blood Bank Transfusion Administration" (Reviewed March 2021), stated the following: "C. Transfusion Procedure: 1. Two nurses (1 nurse RN/1 licensed clinical staff member) will review the following information before any transfusion begins ...2. After completion of the clerical check, the nurses or the physician and the nurse will sign the Blood Transfusion Record ...4. Record vital signs (temperature, blood pressure, and pulse) prior to administration on the Blood Transfusion Record ...10. Record patient vital signs of the Blood Transfusion Record after 15 minutes of infusion and again at 30 min. and 1 hour then every hour transfusion is complete, ensure the dates and times are identified with the vital signs. The patient should be monitored at regular intervals throughout the transfusion for signs of a transfusion reaction. 11. Record 30 min post vital signs on the transfusion component tag ...E. Transfusion Reaction ...8.f. Acute Transfusion Reactions: Type: Acute Hemolytic; Signs/Symptoms: Chills and Fever, Chest and Back Pain, Nausea, Hypotension, Flushing, Tachycardia, Hemoglobinuria, Oliguria, Bleeding at surgical site; Type: Febrile Non hemolytic; Signs/Symptoms: Chills and Fever, Headache, Muscle aches, Chest Pain, Nausea, Dyspnea, Flushing, Hypotension (rare); Type: Allergic; Signs/Symptoms: Hives, Itching, Rash, Laryngeal edema; Type: Anaphylactic; Signs/Symptoms: Cough, Bronchospasm, Respiratory distress, nausea, shock, diarrhea, loss of consciousness; Type: Pyrogenic; Signs/Symptoms: Chills and High fever, Shock, Flushing, Abdominal cramps, Diarrhea, Nausea and vomiting, muscle ache; Type: Hypervolemic; Signs/Symptoms: Coughing, Cyanosis, Dyspnea, Hypertension; Type: TRALI Noncardiogenic Pulmonary (rare); Signs/Symptoms: Pulmonary edema, Dyspnea, Chills and vomiting, Cyanosis, Hypotension" 3. Review of the facility record titled, "Blood Transfusion Record" (Revised 05/31/2019) revealed areas to be completed for: a. Various clerical checks for physician name, armband number, type of blood component, unit number, unit expiration date, patient type and Rh, Patient antibody screen, confirmation of donor Type and Rh, Visual inspection of unit, Date/Time/Initials for crossmatch completion, Crossmatch results and expiration, Issued by initials, Issued to initials, and Date/Time b. Transfusion Start Date and Time c. Two nurses' signature entry d. Temperature, Pulse, Respiration, and Blood Pressure vital signs at Pretransfusion time, 15 minutes, 30 minutes, 1 hour, 2-hour, 3 hour and 4 hours; Reaction? Yes/No; Transfusionist's initials. e. Transfusion Reaction Criteria: Chills; Chest Tightness; Heat at Infusion site; hemoglobinuria or dark urine; Nausea and Vomiting; Flank of Back Pain; Headache; Fever (Increase of 1C or 2F); Tachycardia (Increase by 20 beats); Wheezing or Coughing; Tachypnea; Urticaria (Hives); Itching; Dyspnea; Hypotension (decrease by 30mm); Hypertension (Increase by 30 mm) f. Suspected Transfusion Reaction: Yes/No g. Date/Time/Initials for Transfusion completion The Blood Transfusion Record failed to include an area to document patient's vital signs 30 minutes post transfusion per laboratory policy. 4. Review of the facility's patient transfusion records (02/2020-04/2021) revealed the following 5 of 21 patients in which the facility failed to follow its own policy to ensure transfusion reactions were promptly identified, investigated, and documented for all blood products: a. PATIENT 3824 Date: 05/02/2020 Unit number #1: WO35220186826 Transfusion Initiated: 05/02/2020; 1042 Pre-Transfusion Vitals; 1042: Temperature 98.8; Pulse 100; Respirations 13: Blood Pressure 127/71

Reaction? No 15 Minute Vitals; 1057: Temperature 98.4; Pulse 101; Respirations 14: Blood Pressure 98/51 Reaction? No 30 Minute Vitals; 1127: Temperature 99.3; Pulse 99; Respirations 14: Blood Pressure 102/60 Reaction? No 1 Hour Vitals; 1227: Temperature 98.4; Pulse 100; Respirations 11: Blood Pressure 97/67 Reaction? No The patient had a Blood Pressure decrease of 30 mm from vitals documented at 1042. Per facility policy, a decrease in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. No documentation of vital signs 30 minutes post transfusion per facility policy. Unit number #2: WO35220202454 Transfusion Initiated: 05/02/2020; 1255 Pre-Transfusion Vitals; 1255: Temperature 98.4; Pulse 99; Respirations 19: Blood Pressure 97/67 Reaction? No 15 Minute Vitals; 13:10: Temperature 98.3; Pulse 101; Respirations 18: Blood Pressure 125/69 Reaction? No 30 Minute Vitals; 1340: Temperature 98.4; Pulse 111; Respirations 20: Blood Pressure 152/89 Reaction? No The patient had a Blood Pressure increase of 55 mm from vitals documented at 1255. Per facility policy, an increase in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. 1 Hour Vitals; 1440: Temperature 98.4; Pulse 116; Respirations 20: Blood Pressure 137/80 Reaction? No 2 Hour Vitals; 1627: Temperature 98.1; Pulse 93; Respirations 16: Blood Pressure 103/53 Reaction? No The patient had a Blood Pressure decrease of 49mm from vitals documented at 1340. Per facility policy, a decrease in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. No documentation of vital signs 30 minutes post transfusion per facility policy. b. PATIENT 3038 Date: 06/07/2020 Unit number: WO35220167402 Transfusion Initiated: 06/07/2020; 1832 Pre-Transfusion Vitals; 1800: Temperature 98.6; Pulse 103; Respirations 16: Blood Pressure 159/97 Reaction? No 15 Minute Vitals; 1847: Temperature 99; Pulse 110; Respirations 16: Blood Pressure 153/90 Reaction? No 30 Minute Vitals; 1912: Temperature 99.1; Pulse 108; Respirations 18: Blood Pressure 152/80 Reaction? No 1 Hour Vitals; 1935: Temperature 98.4; Pulse 110; Respirations 20: Blood Pressure 148/78 Reaction? No 2 Hour Vitals; 2035: Temperature 98.4; Pulse 106; Respirations 15: Blood Pressure 146/85 Reaction? No 3 Hour Vitals; 2117: Temperature 98.4; Pulse 103; Respirations 19: Blood Pressure 121/97 Reaction? No The patient had a Blood Pressure decrease of 38 mm from vitals documented at 1800. Per facility policy, a decrease in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. No documentation of vital signs 30 minutes post transfusion per facility policy. c. PATIENT 4006 Date: 06/18/2020 Unit number #1: WO35220244642 Transfusion Initiated: 06/18/2020; 1330 Pre-Transfusion Vitals; 1339: Temperature 98.6; Pulse 96; Respirations 12: Blood Pressure 155/66 Reaction? No 15 Minute Vitals; 1345: Temperature 98.4; Pulse 99; Respirations 15: Blood Pressure 141/70 Reaction? No 30 Minute Vitals; 1415: Temperature 98.9; Pulse 92; Respirations 20: Blood Pressure 119/48 Reaction? No The patient had a Blood Pressure decrease of 36 mm from vitals documented at 1339. Per facility policy, a decrease in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. 1 Hour Vitals; 1515: Temperature 98.8; Pulse 91; Respirations 15: Blood Pressure 142/67 Reaction? No 2 Hour Vitals; 1615: Temperature 98.7; Pulse 87; Respirations 13: Blood Pressure 175/76 Reaction? No The patient had a Blood Pressure increase of 57 mm from vitals documented at 1415. Per facility policy, an increase in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. No documentation of vital signs 30 minutes post transfusion per facility policy. Unit number #2: WO35220141504 Transfusion Initiated: NO DOCUMENTATION OF START DATE AND TIME Pre-Transfusion Vitals; 1725: Temperature 98.2; Pulse 84; Respirations 12: Blood Pressure 188/89

Reaction? No 15 Minute Vitals; 1749: Temperature 98.2; Pulse 90; Respirations 16: Blood Pressure 195/88 Reaction? No 30 Minute Vitals; 1815: Temperature 98.4; Pulse 82; Respirations 14: Blood Pressure 166/78 Reaction? No 1 Hour Vitals; 1915: Temperature 98.2; Pulse 91; Respirations 14: Blood Pressure 165/81 Reaction? No 2 Hour Vitals; 2015: Temperature 97.2; Pulse 97; Respirations 15: Blood Pressure 157/84 Reaction? No The patient had a Blood Pressure decrease of 38 mm from vitals documented at 1749. Per facility policy, a decrease in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. No documentation of vital signs 30 minutes post transfusion per facility policy. d. PATIENT 4302 Date: 08/13/2020 Unit number: WO35220277117 Transfusion Initiated: 08/13/2020; 0959 Pre-Transfusion Vitals; 0959: Temperature 35.0; Pulse 80; Respirations 10: Blood Pressure 76/42 Reaction? No 15 Minute Vitals; 1014: Temperature 35.1; Pulse 75; Respirations 10: Blood Pressure 97/56 Reaction? No 30 Minute Vitals; 1029: Temperature 35.1; Pulse 75; Respirations 10: Blood Pressure 106/68 Reaction? No The patient had a Blood Pressure increase of 30 mm from vitals documented at 0959. Per facility policy, an increase in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. No documentation of vital signs 30 minutes post transfusion per facility policy e. PATIENT 4235 Date: 10/13/2020 Unit number: WO35220319333 Transfusion Initiated: 10/13/2020; 1220 Pre-Transfusion Vitals; 1210: Temperature 98.6; Pulse 101; Respirations 15: Blood Pressure 123/73 Reaction? No 15 Minute Vitals; 1235: Temperature 98.9; Pulse 105; Respirations 16: Blood Pressure 121/74 Reaction? No 30 Minute Vitals; 1300: Temperature 99.3; Pulse 103; Respirations 14: Blood Pressure 139/67 Reaction? No 1 Hour Vitals; 1400: No temperature documented; Pulse 102; Respirations 14: Blood Pressure 105/59 Reaction? No The patient had a Blood Pressure decrease of 34 mm from vitals documented at 1300. Per facility policy, a decrease in blood pressure by 30 mm indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. 2 Hour Vitals; 1500: No temperature documented; Pulse 101; Respirations 14: Blood Pressure 116/62 Reaction? No 3 Hour Vitals; 1600: No temperature documented; Pulse 100; Respirations 14: Blood Pressure 105/60 Reaction? No 4 Hour Vitals; 1700: No temperature documented; Pulse 102; Respirations 14: Blood Pressure 108/60 Reaction? No No documentation of vital signs 30 minutes post transfusion per facility policy The facility failed to follow its own policy to ensure transfusion reactions were promptly identified, investigated, and documented for all blood products. 5. A random review of the Blood Transfusion records revealed the following: a. PATIENT 359 Date 02/26/2020; 1727 Unit number: WO35220121794 Vitals were documented at Pretransfusion, 15 minutes, and 4 hours. The facility failed to document patient vital signs at 30 minutes, 1 hour, 2-hour, 3 hour and 30 minutes post transfusion per laboratory policy. b. PATIENT 3634 Date 03/25/2020; 0930 Unit number #1: WO35220159208 The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. Date 03/25/2020; 1215 Unit number #2 : WO35220096409 The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. c. PATIENT 3923 Date 05/22/2020; 0740 Unit number: W35220168671 The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. Date 05/22/2020; 1020 Unit number: WO35220159409 The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. d. PATIENT 3038 Date 06/05/2020; 1052 Unit number: W35220206640 The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. e. PATIENT 4068 Date 06/27/2020; No start time documented Unit number #1: W35220208845 The facility failed to document temperature at 30 minutes, 1 hour, and 2 hours. The facility failed to

document patient vital signs at 30 minutes post transfusion per laboratory policy. No start date and time documented Unit number #2: W35220243289 The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. f. PATIENT 3537 Date 07/08/2020; 1955 Unit number #1: W35220221554 The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. Date 07/08/2020; 2323 Unit number #2: W35220217874 The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. g. PATIENT 5410 Date 04/27/2021; 1521 Unit number: WO35221178486 The signature entry Blood Transfusion Record was signed by one person not listed as having participated in the Blood Transfusion Documentation Skills Fair in 2021. The facility failed to document patient vital signs at 30 minutes post transfusion per laboratory policy. 6. In an interview on 05/10/2021 at 2:20pm in the laboratory, Testing Person #2 was asked how many transfusion reactions have been reported since 2020. She stated zero. (Transfusion records documented 43 units of packed Red Blood Cells had been transfused by the facility from 02/2020 through 04/2021.) During an interview with the on 05/11/2021 at 10:15am in the breakroom, the facility Quality and Infection Control coordinator reviewed the patients listed in #4 above and confirmed the facility did not follow its own blood transfusion reaction policy to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions. This confirmed the above findings.

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 review of the laboratory's submitted Centers for Medicare and Medicaid (CMS -209) form, laboratory policy, laboratory personnel records, and in interview with staff, the technical consultant failed to perform testing personnel competency assessments at least twice the first year of patient testing for 2 of 24 testing persons listed on Form CMS-209. Findings included: 1. Review of the CMS 209 form (signed by the laboratory director on 04/07/2021) revealed 24 Testing Persons (TP -1 - TP-24) performing moderate complexity testing on the moderate complexity Abbott iSTAT chemistry analyzer. 2. Review of the laboratory policy titled, "Lab Specific Orientation /Training Programs, Competency, and Continuing Education" stated the following: "Initial Evaluation Period. Competency and performance level of testing personnel is evaluated during the first six months of employment. The employee must be able to maintain initial competencies and demonstrate progress of competency at the annual evaluation. Failure to demonstrate initial competencies will require time limited work improvement plan. Failure to meet minimum competencies by the end of the prescribed work improvement plan will result in reassignment to more appropriate tasks or termination." 3. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of personnel competency assessments at least twice the first year of patient testing for the following 2 of 24 testing personnel (as listed on Form CMS-209) who performed moderate complexity testing on the Abbott iSTAT chemistry analyzer. a. Testing person 6 Initial training on the Abbott iSTAT chemistry analyzer 11/13/2018 The next competency assessment was performed 06/16/2019 The next competency assessment was performed 02/22/2020 The technical consultant failed to perform two competency assessments for Testing

	<p>Person -6 in the first year of patient testing for moderate complexity testing on the Abbott iSTAT chemistry analyzer. b. Testing person 15 Initial training on the Abbott iSTAT chemistry analyzer 10/24/2018 The next competency assessment was performed 10/17/2019 The next competency assessment was performed 01/28/2020 The technical consultant failed to perform two competency assessments for Testing Person -15 in the first year of patient testing for moderate complexity testing on the Abbott iSTAT chemistry analyzer. 4. During an interview on 05/10/2021 at 12:10 pm in the Patient Room #1, the Testing Person-1 confirmed the above findings.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the facility and laboratory blood/blood product transfusion policies, review of facility blood administration educational material, review of patient transfusion records (02/2020-04/2021), the laboratory director failed to provide overall management and direction in accordance with 493.1445 of this subpart. The laboratory director failed to ensure testing systems provide quality laboratory services for immunohematology. Refer to D6082.</p>
<p>D6082</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)</p> <p>The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory blood/blood product transfusion policies, review of facility blood administration educational material, review of patient transfusion records (02/2020-04/2021), the laboratory director failed to ensure testing systems provide quality laboratory services for immunohematology, as evidenced by: 1. The facility failed to promptly identify, investigate and report blood transfusion reactions to the laboratory for 5 of 21 patients transfused blood products in 2020 and 2021 (02/2021-04/2021). Refer to D3025. 2. The laboratory failed to promptly identify, investigate, and document blood transfusion reactions for 5 of 21 patients transfused blood products in 2020 and 2021 (02/2021-04/2021). Refer to D5559.</p>
<p>D6127</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p>

This STANDARD is not met as evidenced by:

Based on review of the CMS209, laboratory policy, laboratory personnel records for 2020 and confirmed in interview, the technical supervisor failed to perform two competency assessments in the first year of patient testing for 4 of 4 testing persons (TP) for high complexity Ortho ID-Micro Testing System immunohematology testing. Findings included: 1. Review of the CMS209 signed by the laboratory director on 05/07/2021 revealed 4 testing persons (TP-1, TP-2, TP-3 and TP-4) who performed high complexity immunohematology testing (ABO and Rh grouping, Antibody detection, and Compatibility testing). 2. Review of the personnel records from 2020 revealed the following training and competency documentation for high complexity Ortho ID-Micro Testing System immunohematology testing: a. Testing Person-1; Initial Training 02/03/2020 The next competency assessment was performed 02/17/2020 by Testing Person-2 The next competency assessment was performed 08/07/2020. The "Reviewed by" entry was signed by Testing Person-1. The technical supervisor for Immunohematology failed to perform two competency assessments for Testing Person-1 in the first year of patient testing for high complexity Ortho ID-Micro Testing System immunohematology testing. b. Testing Person-2; Initial Training 11/21/2019 The next competency assessment was performed 02/24/2020 by Testing Person-1 The next competency assessment was performed 08/05/2020 by Testing Person-1 The technical supervisor for Immunohematology failed to perform two competency assessments for Testing Person -2 in the first year of patient testing for high complexity Ortho ID-Micro Testing System immunohematology testing. c. Testing Person-3; Initial Training 05/21/2020 The next competency assessment was performed 08/15/2020 by Testing Person-1 The next competency assessment was performed 04/10/2021 by Testing Person-1 The technical supervisor for Immunohematology failed to perform two competency assessments for Testing Person -3 in the first year of patient testing for high complexity Ortho ID-Micro Testing System immunohematology testing. d. Testing Person-4; Initial Training 12/31/2020 The next competency assessment was performed 04/02/2021 by Testing Person-1 The technical supervisor for Immunohematology failed to perform the first semiannual competency assessment for Testing Person -4 in the first year of patient testing for high complexity Ortho ID-Micro Testing System immunohematology testing. 3. During an interview on 05/10/2021 at 12:10 pm in the Patient Room #1, the Testing Person-1, after review of the records, confirmed the above findings.