Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1069736	09/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Kindred Hospital - Dallas Central	8050 Meadow Road, Dallas, 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	The laboratory was surveyed in response to complaint TX00323889 for compliance with CMS 42 CFR regulations. Complaint TX00323889 was substantiated and the laboratory was found out of compliance with the CLIA regulations. The conditions not met were: 493.1100 Facility Administration 493.1240 Pre-Analytical Systems 493.1403 Laboratory Director, (moderate 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.
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 hospital transfusion services, the facility administration failed to meet the requirements specified in 493.1101 through 493.1105. Refer to D3023 and D3025

D3023	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient. This STANDARD is not met as evidenced by: Based on facility documents, facility policy, and staff interview, the facility failed to ensure positive identification of patient's specimen prior to receiving blood products. Findings included: 1. Review of the facility's root cause analysis stated the following: "When did the event occur: 08/31/2019 Day of Week: Saturday Detailed Event Description, Including Timeline: Blood ordered for patient in room 404. Nurse drew blood for type and cross from room 404. Nurse labeled for room 406. Blood administered to room 406 prior to error verified." 2. The facility policy titled "CORE: Blood Specimen Collection" (H-PC 05-001) stated the following: "Procedure: 1. Prior to beginning procedure ... .e. Identity self and identify patient using two patient identifiers .....9. Post Blood Draw ... .b. Label blood samples before leaving the patient's side with: i. Patient's name; ii. Patient ID number; iii. Date and time of specimen collection; iv. Identification of person collecting sample." The facility practice was to use blood armbands for sample labeling and patient identification. This facility policy failed to address the use of blood armbands for sample labeling and patient identification for those patient's receiving blood/blood components. 3. The facility policy titled "CORE: Transfusion Therapy" (H-PC 05-002) stated the following: Policy: 6. Positive patient and blood identification must be performed and documented prior to each transfusion unit by a Registered Nurse and a second licensed caregiver ... .Procedure: 4. Patient Assessment and Education performed by a Registered Nurse: a. Obtain and review physicians or authorized prescriber's order. i. Verify physician's or authorized prescriber's order for blood product infusion and amount, and premedication if indicated .....b. Verify patient's identity using two independent identifiers, not including patient's room number ... ...g. Prior to transfusion, the Registered Nurse and a second licensed caregiver will validate the following at the patient's bedside: i. Patient's name, identification number, and date of birth; ii. Donor number or platelet unit number on the blood bag label; iii. ABO group and Rh type on the blood bag label; iv. Expiration date; v. After bedside verification, the Registered Nurse and second licensed caregiver performing the identification must sign the transfusion record and form." 4. The facility incident report dated 09/01/2019 for Patient HT0000074146 stated the following: "On 08/31/2019 patient received one unit of blood. CCO (Chief Clinical Officer) was notified the morning of 09/01 that the patient had received the wrong blood ... .08/31/2019 nurse received an order to type and cross and transfused another patient but labeled the type and cross with Patient HT0000074146 labels. When the blood arrived to the facility [nurse] identified that there was NOT an order for the blood to be transfused and the patient did NOT have an arm band on. The supervisor told the primary nurse that the nurse who had the patient on the day shift was new and he assumed that she forgot to put the blood band on and put in the order. The blood matched the patient's admission personal armband and the date of birth was correct so they performed the two person verifier and the house supervisor put in the order to transfuse ...." 5. In an interview on 09/05/2019 at 1536 in the facility conference room, the Chief Clinical Officer was asked to describe the events that occurred on 08/31//2019. She stated the patient in room 404 (Patient HT0000072108) had been admitted and discharged from the facility several times. Whenever Patient HT0000072108 had been at the facility in the past, he was always in room 406. For this admission, Patient HT0000072108 was in room 404. She stated

	that a type and crossmatch for one unit of packed red blood cells was ordered for Patient HT0000072108 (Room 404). The nurse entered room 404, drew the specimen for the type and crossmatch and labeled the specimen tubes with labels from the patient in room 406 (Patient HT0000074146). She further stated that when the nurse entered room 404 to draw the blood sample, she had the medical chart for the patient in room 406. The Chief Clinical Officer was asked if the facility had a blood sample collection policy for use of blood armbands for patient/sample identification or that required a two-person patient identification collection process. The Chief Clinical Officer stated the facility DID use blood armbands for sample labeling and patient identification for those patient's receiving blood products. She further stated that the facility did NOT have a specific policy for blood component transfusion sample collection and did NOT require a two-person patient identification. The Chief Clinical Officer was asked to describe the blood product recipient identification events that occurred on 08/31//2019. She stated that 1 unit of packed red blood cells labeled for Patient HT0000074146 was received at the facility. The blood component arrived after a shift change of nursing personnel. Patient HT0000074146's primary nurse did check for a provider's order for a blood transfusion but did NOT find the order. She stated that the primary nurse also realized that Patient HT0000074146 did NOT have a blood armband. She further stated that the primary nurse consulted with the House Supervisor. She stated the House Supervisor said he assumed the patient's previous nurse forgot to enter the blood component transfusion order and to put the blood arm band on the patient. The primary nurse and the house supervisor identified the blood recipient based on the patient's admission armband and date of birth. Patient HT0000074146 received the unit of packed red blood cells. The facility policy failed to address the use of blood armbands for sample labeling and patient identification for those patient's receiving blood/blood components. The facility failed to follow its own written policy to verify physician's or authorized prescriber's order for blood product infusion. The facility failed to establish a blood component recipient policy that required a blood component recipient to have a blood armband and that required the blood armband number/blood component verification.
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 and blood product transfusion policies, patient transfusion records, and confirmed in staff interview, the facility failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for all blood products. Findings included: 1. The facility policy titled "CORE: Transfusion Therapy" (H-PC 05-002) stated the following: "8. Transfusion initiation ....b. Continuously monitor and observe patient for signs /symptoms of transfusion reactions during initial 15 minutes of transfusion initiation. Obtain vital signs 15 minutes after transfusion initiation, 30 minutes after transfusion initiation, 1 hour after transfusion initiation, and then hourly until the unit is complete. The last set of vital signs is obtained one-hour post-transfusion. Every occurrence of vital signs includes the observation and documentation of any signs/symptoms of transfusion reactions ... ...d. Signs and Symptoms of reactions include: i. Acute

reactions include allergic, febrile, septic, and hemolytic reactions, air embolism, and circulatory overload. Patients who also multiple blood products within a short time frame may also be at risk for hyperkalemia, hypocalcemia, and hypothermia. ii. Delayed reactions include delayed hemolytic reactions, iron overload (hemosiderosis), GVHD, infectious diseases (e.g. hepatitis B, hepatitis C, CMV, Epstein-Barr virus, malaria, HIV, HTLV). iii. Symptoms of a delayed reaction can vary from mild to severe. Diagnosis may be complicated by the long incubation period between transfusion and reaction and the complexity of diagnostic tests. iv. If patient exhibits signs of transfusion reaction: v. Stop transfusion vi. Follow procedure for transfusion reaction. e. If a transfusion reaction is suspected refer to the Transfusion Reaction section of this policy ... . 11. Transfusion Reactions: a. When a transfusion reaction is suspected, immediately discontinue transfusion .....b. Notify blood bank and Lab of suspected reaction .....c. Notify the ordering physician immediately ....d. Complete the transfusion reaction report." This policy did NOT indicate what vital signs must be monitored and documented for signs of a transfusion reaction. In 2019, the facility had transfused 240 blood components and had never identified and reported a transfusion reaction. GVHD, hepatitis B, hepatitis C, CMV, Epstein-Barr virus, malaria, HIV, HTLV are disease processes that may develop as the result of a blood component transfusion. These afflictions are NOT signs of a transfusion reaction. 2. The facility's Nursing Classroom Orientation training documents in the section titled "Blood Transfusion Reaction" stated, "Transfusion reaction is a problem that can occur after a patient receives blood. The immune system launches a response against the new blood cells or other parts of the transfusion ... ...Symptoms of Transfusion Reaction: Fever-Chills-Rash-Flank pain or back pain---Bloody urine-Fainting or dizziness. Symptoms of transfusion reaction usually appear during or right after the transfusion. Sometimes, they may develop after several days (delayed reaction). Symptoms may stay mild or progress to kidney failure, delayed anemia, or shock. Blood transfusion reaction may also change the results of these tests: RBC count-Hemoglobin, serum-hemoglobin-Hematocrit-Haptoglobin-Fibrin degradation products-Coomb's test indirect-Coomb's test direct-CBC-Bilirubin." This training material did NOT indicate what vital signs must be monitored and documented for signs of a transfusion reaction. The training material did NOT ensure prompt identification of a transfusion reaction. 3. The facility's Annual Nurse Competency documents in the section titled "Blood Administration" stated, "Blood Administration ...Before you start the blood: 2 licensed nurses (1 RN); Check vitals: Before, during and after; When transfusion is finished: Biohazard bag, Complete forms, Chart." This competency material did NOT indicate what vital signs must be monitored and documented for signs of a transfusion reaction. The competency material did NOT ensure prompt identification of a transfusion reaction. 4. Review of patient blood component transfusion records revealed the facility documented patient's vital signs pretransfusion, during transfusion and post-transfusion on the "Blood Transfusion Record" form. Also listed on this form was the following" "Common Symptoms of a Suspected Transfusion Reaction: 1. Temperature increase of 2F or more 2. Blood pressure change: +/- 20 mm Hg from baseline 3. Increase in heart rate 4. Dyspnea 5. Chest tightness 6. Rash/Uticaria 7. Chills 8. Hematuria 9. Flushing." The facility failed to include the Common Symptoms of a Suspected Transfusion Reaction, listed on the "Blood Transfusion Record" form, in the facility policy titled "CORE: Transfusion Therapy" (H-PC 05-002)". 5. Review of Blood Transfusion Records for Patient HT0000074146 revealed transfusion of one unit of packed red blood cells (W035219931531) started 08/31/2019 2100 hours and stopped 09/01/2019 0000 hours. The vital signs during the transfusion were as follows: Pre-transfusion blood pressure 151/58 Blood pressure 15 minutes after start (of transfusion) 139/79 Blood pressure 30 minutes after start (of transfusion) 144/68 Blood pressure 15 minutes after

start (of transfusion) 139/79 Blood pressure 1 hour after start (of transfusion) 130/62 At this time, the patient had blood pressure change of 21 mm Hg A check mark was made on the Blood Transfusion Record form in the section titled "Reaction Status: No Reaction". The facility incident report stated, "No transfusion reaction during the night was noted. The patient's urine color changed from clear to tea color in the morning of 09/01/2019. This is the patient that was type O Positive and received A Positive packed red blood cells. Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Blood pressure change: +/- 20 mm Hg and hematuria. A transfusion reaction was NOT identified or reported by transfusing nurse until the next day (09/01/2019). 6. A random review of patient's blood transfusion records from 01/2019, 06/2019 and 08/2019 revealed the following 6 of 24 transfusion reactions for 01/2019, 2 of 10 transfusion reactions for 06/2019, and 6 of 28 transfusion reactions for 08/2019 that were NOT identified, reported or investigated by the facility. 01/2019 a. Patient HT0000066969; Date/Time of transfusion 01/08/2019 0540 hours Transfusion End Time blood pressure 110/49; Blood pressure 1 hour after completion (of transfusion) 133/74 The patient had blood pressure change of 23 mm Hg A check mark was made in the section titled "Reaction Status: No Reaction". Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Blood pressure change: +/- 20 mm Hg. A transfusion reaction was NOT identified, reported or investigated by the facility. b. Patient HT0000066969; Date/Time of transfusion 01/08/2019 0830 hours Pre-transfusion blood pressure 110/49; Blood pressure 15 minutes after start (of transfusion) 143/62 The patient had blood pressure change of 33 mm Hg A check mark was made in the section titled "Reaction Status: No Reaction". Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Blood pressure change: +/- 20 mm Hg. A transfusion reaction was NOT identified, reported or investigated by the facility. c. Patient HT0000066605; Date/Time of transfusion 01/10/2019 0100hours Pre-transfusion temperature 97.3 F; Temperature 30 minutes after start (of transfusion) 101.3 F The patient had a temperature change of 4 F A check mark was made in the section titled "Reaction Status: No Reaction". Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Temperature increase: 2 F or more. A transfusion reaction was NOT identified, reported or investigated by the facility. d. Patient HT0000067777; Date/Time of transfusion 01/25 /2019 2340 hours Pre-transfusion blood pressure 158/90; Blood pressure 30 minutes after start (of transfusion) 138/81; Blood pressure 1 hour after start (of transfusion) 126 /77. The patient had blood pressure change of 20 mm Hg 30 minutes after transfusion start and 32 mm Hg 1 hour after start. A check mark was made in the section titled "Reaction Status: No Reaction". Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Blood pressure change: +/- 20 mm Hg. A transfusion reaction was NOT identified, reported or investigated by the facility. e. Patient HT0000066928; Date/Time of transfusion 01/27/2019 2045 hours Pre-transfusion blood pressure 118/62; Blood pressure 3 hours after start (of transfusion) 154/75 The patient had blood pressure change of 36 mmHg A check mark was made in the section titled "Reaction Status: No Reaction". Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Blood pressure change: +/- 20 mm Hg. A transfusion reaction was NOT identified, reported or investigated by the facility. f. Patient HT0000066076; Date/Time of transfusion 01/28 /2019 2055 hours Pre-transfusion blood pressure 145/64; Blood pressure 1 hour after start (of transfusion) 122/67 The patient had blood pressure change of 23 mm Hg A check mark was made in the section titled "Reaction Status: No Reaction". Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Blood pressure change: +/- 20 mm Hg. A transfusion reaction was NOT identified, reported or investigated by the facility. 06/2019 g. Patient HT0000071449; Date/Time

of transfusion 06/04/2019 0310 hours Pre-transfusion blood pressure 98/52; Blood pressure 1 hour after completion (of transfusion) 135/62 The patient had blood pressure change of 37 mm Hg A check mark was made in the section titled "Reaction Status: No Reaction". Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Blood pressure change: +/- 20 mm Hg. A transfusion reaction was NOT identified, reported or investigated by the facility. h. Patient HT0000071340; Date/Time of transfusion 06/08/2019 0450 hours Blood pressure 1 hours after start (of transfusion) 146/47; Blood pressure 3 hours after start (of transfusion) 126/48 The patient had blood pressure change of 20 mm Hg A check mark was made in the section titled "Reaction Status: No Reaction". Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Blood pressure change: +/- 20 mm Hg. A transfusion reaction was NOT identified, reported or investigated by the facility. 08/2019 i. Patient HT0000073189; Date/Time of transfusion 08/05/2019 0215 hours Pre-transfusion blood pressure 141/82; Blood pressure 1 hour after completion (of transfusion) 117/54 The patient had blood pressure change of 24 mm Hg A check mark was made in the section titled "Reaction Status: No Reaction". Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Blood pressure change: +/- 20 mm Hg. A transfusion reaction was NOT identified, reported or investigated by the facility. j. Patient HT0000073213; Date/Time of transfusion 08/06/2019 2130 hours Pre-transfusion blood pressure 161/74; Blood pressure a transfusion end time 141/69 The patient had blood pressure change of 20 mm Hg A check mark was made in the section titled "Reaction Status: No Reaction". Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Blood pressure change: +/- 20 mm Hg. A transfusion reaction was NOT identified, reported or investigated by the facility. k. Patient HT0000072934; Date/Time of transfusion 08/09/2019 1945 hours Pre-transfusion blood pressure 169/89; Blood pressure 1 hour after start (of transfusion) 92 /50 The patient had blood pressure change of 77 mm Hg A check mark was made in the section titled "Reaction Status: No Reaction". Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Blood pressure change: +/- 20 mm Hg A transfusion reaction was NOT identified, reported or investigated by the facility. l. Patient HT0000073460; Date/Time of transfusion 08/12 /2019 2300 hours Pre-transfusion blood pressure 115/47; Blood pressure a transfusion end time 137/72 The patient had blood pressure change of 22 mm Hg A check mark was made in the section titled "Reaction Status: No Reaction". Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Blood pressure change: +/- 20 mm Hg. A transfusion reaction was NOT identified, reported or investigated by the facility. m. Patient HT0000070359; Date/Time of transfusion 08 /17/2019 0500 hours Pre-transfusion blood pressure 171/50; Blood pressure a transfusion end time 131/40 The patient had blood pressure change of 40 mm Hg A check mark was made in the section titled "Reaction Status: No Reaction". Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Blood pressure change: +/- 20 mm Hg. A transfusion reaction was NOT identified, reported or investigated by the facility. n. Patient HT0000073189; Date/Time of transfusion 08/18/2019 1720 hours Pre-transfusion blood pressure 103/56; Blood pressure 2 hours after start (of transfusion) 125/69 The patient had blood pressure change of 22 mm Hg A check mark was made in the section titled "Reaction Status: No Reaction". Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Blood pressure change: +/- 20 mm Hg. A transfusion reaction was NOT identified, reported or investigated by the facility. o. Patient HT0000073874; Date/Time of transfusion 08/31/2019 1645 hours Pre-transfusion pulse 77; Pulse 15 minutes after start (of transfusion) 103 The patient had an increase of heart rate of 26. A check mark was made in the section titled "Reaction Status: No

	Reaction". Common sign of suspected transfusion reaction indicated on the Blood Transfusion Record: Increase in heart rate. A transfusion reaction was NOT identified, reported or investigated by the facility. 4. In an interview on 09/05/2019 at 1130 hours in the facility conference room, the Area Director of Laboratory was asked to provide documentation of a transfusion reaction investigation for Patient HT0000074146. He provided an email from Carter Blood Care, dated 09/03/2019. The email stated the following: "On September 1, 2019, at 1000, Carter Blood Care was notified of a transfusion reaction on Patient HT0000074146. The patient's reaction was identified as hemolytic. The patient was transfused one unit of LRBC's on August 31, 2019. The patient's pre-transfusion sample ABO/Rh tested A positive; however, the post transfusion sample tested as O positive. At this time, we will require an investigation by your facility regarding this occurrence. Proper patient identification and labeling are in question. The investigation should include root cause analysis and the corrective action taken to prevent future occurrence. Please provide the investigation resolution and documentation by September 20, 2019," The facility's root cause analysis stated the following: "When did the event occur: 08/31/2019 Day of Week: Saturday Detailed Event Description, Including Timeline: Blood ordered for patient in room 404. Nurse drew blood for type and cross from room 404. Nurse labeled for room 406. Blood administered to room 406 prior to error verified." 7. In an interview on 09/05/2019 at 1519 hours in the facility conference room, a transfusion nurse was asked to describe signs and symptoms of a transfusion reaction. She stated, "Kidney pain and a change in temperature." The nurse was asked what the signs and symptoms of a transfusion reaction were as listed on the facility's "Blood Transfusion Record". The nurse stated that she did not realize there were any symptoms listed on this form. The nurse was asked how much of a blood pressure change indicated a transfusion reaction. She stated that she did not know what the specific blood pressure change was. The facility failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for all blood products. Word Key: GVHD=Graft versus Host Disease CMV=Cytomegalovirus HIV=Human Immunodeficiency Virus HTLV=Human T cell Lymphotropic Virus TACO=Transfusion Associated Circulatory Overload TRALI-Transfusion Related Acute Lung Injury CBC=Complete Blood Count RN=Registered Nurse mm Hg=millimeter Mercury
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on facility policy, facility root cause analysis report for Patient HT0000074146, and staff interview, the laboratory failed to meet the requirements of preanalytical systems. The laboratory failed to establish written policies and procedures for specimen labeling, acceptability and rejection to ensure positive identification of transfusion medicine patient specimens. Refer to D5311.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

	CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of facility policy, facility root cause analysis report for Patient HT0000074146, and staff interview, the laboratory failed to establish and follow written policies for sample preparation, collection, and labeling for recipients of blood and/or blood components. Findings included: 1. The facility policy titled "CORE: Blood Specimen Collection" (H-PC 05-001) stated the following: "Procedure: 1. Prior to beginning procedure ... .e. Identity self and identify patient using two patient identifiers .....9. Post Blood Draw ... .b. Label blood samples before leaving the patient's side with: i. Patient's name; ii. Patient ID number; iii. Date and time of specimen collection; iv. Identification of person collecting sample." The facility practice was to use blood armbands for sample labeling and patient identification. This facility policy failed to address the use of blood armbands for sample labeling and patient identification for those patient's receiving blood/blood components. 2. Review of facility incident report revealed the following: a. Review of the facility's root cause analysis stated the following: "When did the event occur: 08/31/2019 Day of Week: Saturday Detailed Event Description, Including Timeline: Blood ordered for patient in room 404. Nurse drew blood for type and cross from room 404. Nurse labeled for room 406. Blood administered to room 406 prior to error verified." 3. In an interview on 09/05/2019 at 1536 in the facility conference room, the Chief Clinical Officer was asked to provide a blood sample collection policy for use of blood armbands for patient/sample identification and a policy that required a two-person patient identification collection process. The Chief Clinical Officer stated the facility DID use blood armbands for sample labeling and patient identification for those patient's receiving blood products. She further stated that the facility did NOT have a specific policy for blood component transfusion sample collection and did NOT require a two-person patient identification.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient transfusion records, and staff interview, the laboratory's quality assessment (QA) program did not include a review of effectiveness of corrective actions taken to resolve problems and review of procedures to prevent recurrence of problems in preanalytic systems, as evidenced by: 1. The laboratory failed to establish and follow written policies for sample preparation,

	collection, and labeling for recipients of blood and/or blood components. Refer to D5311
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the facility records and staff interview, it was revealed the laboratory director failed to provide overall management for the laboratory. Refer to D6007 and D6021
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) 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; This STANDARD is not met as evidenced by: Based on review of laboratory's policy and patient transfusion records, the laboratory director failed to ensure that blood component transfusion practices provided quality laboratory services, as evidenced by: 1. The facility failed to ensure positive identification of patient's specimen prior to receiving blood products. Refer to D3023. 2. The facility failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for all blood products. Refer to D3025. 3. The laboratory failed to establish and follow written policies for sample preparation, collection, and labeling for recipients of blood and/or blood components. Refer to 5311.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the facility records and staff interview, it was revealed the

	laboratory director failed to ensure a quality assessment plan identified and corrected problems. Refer to D5393