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	45D0053108	A. BUILDING _____ B. WING _____	C 01/11/2019

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CHI ST LUKE'S HEALTH BCM MEDICAL CENTER	6720 BERTNER AVENUE HOUSTON, TX 77030

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D 000	INITIAL COMMENTS The laboratory was surveyed in response to complaint TX00303145 for compliance with CMS 42 CFR regulations. Complaint TX00303145 was substaniated and the laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D3000 - 42 C.F.R. § 493.1101 Condition: Facility Administration D5026 - 42 C.F.R. § 493.1217 Condition: Immunohematology; D5200 - 42 C.F.R. § 493.1230 Condition: General laboratory systems; D5300 - 42 C.F.R. § 493.1240 Condition: Preanalytical Systems; D6076 - 42 C.F.R. § 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; D6108 - 42 C.F.R. § 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor; Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.	D 000		
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing	D3000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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D3000	Continued From page 1 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). This CONDITION is not met as evidenced by: Based on surveyor's 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)	D3000		
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 direct observation, review of the Root Cause Analysis, facility/laboratory policy, specimen misidentification forms, transfusion committee minutes, occurrence reports, and in interview with staff, the facility failed to ensure positive identification of a patient's specimen prior to receiving blood products. Findings included: 1. According to the "Root Cause Analysis", Patient [redacted] was discharged from room #25 in Emergency Department (ED) on [redacted] at 0104 hours and her blood tubes were left behind in room #25 (Patient [redacted]	D3023		

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D3023	Continued From page 2	D3023		

-pink tube). On [redacted] at 1142 hours, Patient [redacted] was admitted via Emergency Mobile Services to room #25; initial labs of Patient [redacted] were drawn by RN #1 and labeled by RN #2 and sent to the laboratory (CBC, PT/INR, PTT, BNP, Troponin, Magnesium); at 1234 hours laboratory results prompted an order entry of 1 unit of FFP; at 1659 hours, the type and screen was ordered for Patient [redacted] verbally by RN #1; at 1702 hours, the laboratory label (EPIC label) for Patient [redacted] was printed and placed on a pink top blood collection tube over a white bar code label with Patient [redacted] name (previous patient) and typed as A positive; at 1744 hours.

Patient [redacted] was admitted to ICU; at 2054 hours, the 1 unit of FFP (A positive) was administered with an initial blood pressure of 150/80 mm Hg, and at 2315 hours (end of transfusion) the blood pressure dropped to 110/55 mm Hg (> 20 mm Hg); on [redacted] at 0110 hours, blood in the urine was noted by the nurse and was reported to the resident (no action was taken); on [redacted] at 0111 hours, transfusion of a unit of A positive packed red blood cells began; at 0410 hours blood pressure was 60/35 mm Hg; 0415 hours a transfusion reaction protocol was initiated, arterial line began; at 0424 hours, Patient [redacted] sample was recollected (transfusion reaction protocol) for Type and Screen and it was revealed she typed as B positive and her DAT was positive.

2. During an interview on 01/07/2019 at 10:30 am in the transfusion medicine department, the Transfusion Medicine supervisor was asked whether Emergency Department (ED) sent

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D3023	Continued From page 3 specimens without orders to transfusion medicine, she stated no, those specimens were held in ED until an order was placed. She stated in 2002 an electronic barcode ID was implemented and there was not a second armband for transfusion services. The transfusion department's practice for specimen acceptability was, as long as it had an EPIC label on the blood collection tube. 3. During an interview (conducted by nurse surveyor) on 01/08/2019, The Director of the Emergency Department and Director of Risk Management stated, prior to the death of Patient [redacted], it was a normal practice to draw a "rainbow"- (the practice of drawing extra vials of blood without a physician order) of blood work. The ED nurse would wait for the orders and use the blood that was already drawn to send. A written policy for the above practice was not available. 4. Review of "Specimen Identification, Collection and Transportation Pathology" procedure (effective 07/2017), stated, "Specimen Collection and Labeling Process: ...ii Collect the appropriate specimen(s) and place one label on the primary container in the presence of the patient." The policy also stated, " ...Transfusion Service Specimens. Only two acceptable labels: 1. Epic Specimen Label ...2. Handwritten Label ..." The policy did not indicate specimens were acceptable or rejected with double-labeling,	D3023		

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D3023	Continued From page 4 overlapping of labels, or "patient labels" (white chart labels). 5. During a tour of the transfusion medicine department on 01/07/2019 at 1:45 pm, all specimens collected on the transfusion related fatality patient were observed to be stored in the transfusion medicine department refrigerator. A pink top with a white barcode label had Patient [redacted] name, CSN number, a date of [redacted], date of birth and two other number combinations. Overlaying Patient [redacted] white label was a pink EPIC barcode label with Patient [redacted] name, date of birth, MRN, accession number, location (ER), Type & Screen Auto test, a date of [redacted] at 1702 hours and two other number combinations. (Images of collection tubes are attached to this survey kit) 6. Review of specimen misidentification forms from 10/2017 revealed the following: Patient [redacted] Patient's location: Liver Transplant Clinic Date/Time on Specimen: [redacted] 0955 hours Error discovered: [redacted] 2015 hours "Type and screen specimen and Group specimen w/ABORh discrepancy; Work-up as WBIT (wrong blood in tube); notify Main Lab." Initial Reported Description: "Blood specimen received in Transfusion Services and testing completed. Upon completion of testing a blood type discrepancy was discovered. Patient identity uncertain; specimen was rejected and a redraw was requested. 17B-283T0124 Group typed as O+	D3023		

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D3023	Continued From page 5 17B-283T0041 Type and Screen typed as A+" Special Reviewer Comments/Actions "Assumption: Epic specimen collection process not followed leading to the mis-identification/labeling of collected blood specimens. The process in the Liver Clinic should be audited to ensure compliance with policy." Patient [redacted] Patient's location: Liver Transplant Clinic Date/Time on Specimen: [redacted] hours Error discovered: [redacted] 1400 hours "Historic blood type mismatch. O+ Anti E, K, Bg historical; Specimen #17B-283T0076 A+ negative screen mismatch; Specimen #17B-283T0077 Work-up as WBIT (wrong blood in tube); notify Main Lab." Initial Reported Description: "Blood specimen received in Transfusion Services and testing completed. Upon completion of testing a blood type discrepancy was discovered. Patient identity uncertain; specimen was rejected and a redraw was requested. (Note: The Type and Screen specimen typed as O positive which match the historical blood type and the Group specimen was typed as A positive." Special Reviewer Comments/Actions "Assumption: Epic specimen collection process not followed leading to the mis-identification/labeling of collected blood specimens. The process in the Liver Clinic should be audited to ensure compliance with policy."	D3023		

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7. Review of Transfusion Committee Minutes from 10/26/2017, stated, "Discussion: Staff Nurse Practice Professional Council is developing an educational plan to improve bar code identification. Recent incident of wrong blood in tube points to the need to improve performance. Mandatory nursing skills fair is planned on quarterly basis."

8. According to Transfusion Committee Minutes from 07/2018, two quality alerts were sent out for, "Improperly labeled samples. Samples are being received in laboratory with labels affixed incorrectly. Units are sending samples to Pathology with labels that are crooked or improperly positioned on the tube. Labels not affixed straight on the tube are unable to be read on laboratory analyzers. Samples must be re-labeled once received in lab, causing a delay in processing/analysis and potential for identification errors ..."

9. According to facility's occurrence reports and investigations, from 09/2018 through 01/09/2019, there were 122 incidents involving mislabeling or other discrepancies with labeling of blood (type and screen) laboratory specimens.

In 01/2019, there were 21 incidents involving mislabeled blood collection tubes and 1 was double-labeled.

The facility continued to identify recurring misidentification in labeling patient blood collection tubes and did not ensure procedures were put in place to prevent recurrences. The

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D3023	Continued From page 7 facility failed to establish and follow written policies for ensuring positive identification of patient specimens prior to receiving blood products.	D3023		
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: I. Based on a review of hospital records and confirmed in interview, the hospital failed to ensure end user nursing personnel were adequately trained on the EPIC BPAM (Blood Product Administration Module), BestPractice Advisories (BPA) and the limitations of the software for alerting of possible transfusion reactions to ensure prompt identification of transfusion reactions for all hospital patients receiving blood or blood components. (BPA alerts limited to 2 vital signs - temperature and oxygen saturation) Findings were: 1. A review of the 15 page hospital Policy and Procedure "Transfusion of Blood Products-Patient Care" effective May 2018 revealed the procedure included directions to monitor vital signs, temperature and urine output to monitor for transfusion reaction and a list of 16 possible symptoms of transfusion reaction:	D3025		

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D3025	Continued From page 8 a. Page 5 , 4. Administration Process " p. Monitor vital signs and assess temperature and urine throughout the transfusion process to monitor for adverse reactions to blood products and the effectiveness of treatment." "q. Monitor for signs and symptoms of transfusion reactions. Both acute and delayed hemolytic reactions are potentially life-threatening events (See Transfusion Reaction) b. Page 7. 8. Transfusion reaction "a. Symptoms of a transfusion reaction." "i. Temperature elevation during transfusion 1. greater than 1 degree Celsius (C),or 2. greater than 2 degrees Fahrenheit (F) ii. Chills/rigors iii. Tachycardia or bradycardia iv. Increase or decrease in blood pressure of more than 20 mmHg v. Shock vi. Pain or burning infusion site vii. Chest pain or tightness viii. Back/flank pain ix. Cough (new or increasing) x. Shortness of breath or wheezing Document all abnormal oxygen saturation measurements and treatments given when reporting a suspected reaction to Transfusion Service. xi. Hypoxemia (change in oxygen saturation of greater than 5% or any decrease to less than 90%) xii. Flushed skin xiii. Nausea/vomiting xiv. Hematuria/dark urine xv. Diffuse bleeding xvi. Urticaria/hives (Note: If the only symptom is urticaria or hives, it is necessary to pause a transfusion, call physician for immediate	D3025		

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D3025	Continued From page 9 treatment, and resume transfusion after treatment is initiated)" 2. A review of a sample advisory provided to the surveyor, BPA Hospital Encounter dated [redacted] revealed on [redacted] at 1512 hours nurse 15170 was notified of a BPA due to "Triggers File Doc Flowsheets SpO2: 99%; Sp02: 88%". The BPA message stated: "Suspected transfusion reaction: Stop the transfusion and maintain patency of the IV line. Notify Transfusion Service and patient physician within 15 minutes of reaction. Order a Transfusion Reaction Investigation, complete the Transfusion Reaction form and send blood bag, tubing, and patient sample to the Blood Bank. Transfusion Service may request blood cultures if a significant temperature elevation occurred." 3. A review of patient medical record number [redacted] nursing documentation for transfusion of one unit of fresh frozen plasma on [redacted] and documented as transfused from 2054 to 2215 hours revealed at least two symptoms of transfusion reaction for which a transfusion reaction was not called: a. On [redacted] at 2215 hours documented decrease in blood pressure of greater than 20 mmHg - 158/80 mmHg to 110/55 mmHg. b. On [redacted] at 0110 hours - Hematuria Note: A transfusion reaction was not called until [redacted] at 0410 hours after transfusion of one unit of red blood cells and a documented blood pressure of 60/45 mmHg. 4. An interview on 1/08/2018 in the laboratory conference room with the director of patient care	D3025		

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D3025	Continued From page 10 -CCU and nurse educator revealed nurses that performed blood transfusions did not know which of the indicators or vital sign changes would trigger an BPA alert of suspected transfusion reaction. a. In an interview of the of the director of patient care for CCU on 1/08/2019 at 1033 hours she stated the program [BPAM] would flag us for all four indicators - temperature, blood pressure, O2 Sat [oxygen saturation], pulse. b. In an interview of immunohematology technical supervisor 2 (as listed on the CM-209) on 1/08/2019 at 1038 hours in the conference room he stated that only temperature and O2 Sat is programmed [in the BPAM]. c. In an interview of immunohematology technical supervisor 2 on 1/10/2019 at 1538 hours in the conference room he stated that patient to unit match was the main use - primary objective [of the BPAM software]. Key: CMS- Centers for Medicare & Medicaid Services vital signs- pulse, respirations, blood pressure, and oxygen saturation	D3025		

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D3025	Continued From page 11	D3025		

II. Based on review of the facility's transfusion reaction procedure, EPIC Blood Product Administration Module (BPAM) training, patient transfusion records, and confirmed in interview, the facility failed to ensure transfusion reaction policies promptly identified, investigated and documented transfusion reactions for all blood products.

Findings included:

1. Review of the facility's policy titled "Transfusion of Blood Products-Patient Care" (Effective date May 2018) stated the following:

"3. Assessment Before Transfusion
... ...f. Assess vital signs, including blood pressure, heart rate, respiratory rate, oxygen saturation and temperature. (Initial vital signs must be within the previous 15 minutes).

4. Administrative Process
....p. Monitor vital signs and assess temperature and urine throughout the transfusion process to monitor for adverse reactions to blood products and the effectiveness of treatment. Vitals are done every hour, and when the transfusion is complete.
q. Monitor for signs and symptoms of transfusion reactions. Both acute and delayed hemolytic reactions are potentially life-threatening events. (See Transfusion Reaction).

8. Transfusion Reaction
a. Symptoms of a transfusion reaction.
i. Temperature elevation during transfusion
1. greater than 1 degree Celsius (C), or
2. greater than 2 degrees Fahrenheit (F)
ii. Chills/rigors

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D3025	Continued From page 12 iii. Tachycardia or bradycardia iv. Increase or decrease in blood pressure of more than 20 mmHg v. Shock vi. Pain or burning at infusion site vii. Chest pain or tightness viii. Back/flank pain ix. Cough (new or increasing) x. Shortness of breath or wheezing Document all abnormal oxygen saturation measurements and treatments given when reporting a suspected reaction to Transfusion service. xi. Hypoxemia (change in oxygen saturation [SpO2] of greater than 5% or any decrease to less than 90%) xii. Flushed skin xiii. Nausea/Vomiting xiv. Hematuria/dark urine xv. Diffuse bleeding xvi. Urticaria/hives (Note: If the only symptom is urticarial or hives, it is necessary to pause the transfusion, call physician for immediate treatment, and resume transfusion after treatment initiated.) b. In a suspected transfusion reaction, IMMEDIATELY: i. Stop transfusion and maintain the patency of the IV line. vi. Monitor vital signs vii. Notify Transfusion Service and physician. Notification of Transfusion Service must be within 15 minutes of reaction. viii. Notify house officer was warranted by patient's symptoms ...."	D3025		

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D3025	Continued From page 13	D3025		

2. Review of the nursing training material titled "Documenting Blood Product Administration" (May 2017) for implementation of the EPIC (the facility's laboratory information system) BPAM (Blood Product Administration Module) computer module stated the following:

"Initial Transfusion
Document current vital signs & SpO2 (within the last 60 minutes)"

The facility policy stated, "Initial vital signs must be within the previous 15 minutes." This is not consistent with the training.

"Q. What Do I Document?
A. All vital Signs and Monitoring
Document all vital signs including SpO2
Monitor the patient for the first 15 minutes of the transfusion for signs and symptoms of reaction (then every hour until the transfusion complete and when completed)

Transfusion Reaction Signs & Symptoms
Symptoms of a Transfusion Reaction are listed below.
Epic will display a BPA (Best Practice Advisory) for temperature and SpO2 changes
Do not ignore BPAs
Temperature elevation during transfusion
1. greater than 1 degree Celsius (C), or
2. greater than 2 degrees Fahrenheit (F)
Chills/rigors
Tachycardia or bradycardia
Increase or decrease in blood pressure of more than 20 mmHg
Shock
Pain or burning at infusion site

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D3025	Continued From page 14	D3025		

Chest pain or tightness
Back/flank pain
Cough (new or increasing)
Shortness of breath or wheezing
Document all abnormal oxygen saturation measurements and treatments given when reporting a suspected reaction to Transfusion service.
Hypoxemia (change in oxygen saturation of greater than 5% or any decrease to less than 90%)
Flushed skin
Nausea/Vomiting
Hematuria/dark urine
Diffuse bleeding
Urticaria/hives (Note: If the only symptom is urticarial or hives, it is necessary to pause the transfusion, call physician for immediate treatment, and resume transfusion after treatment
initiated.)
Q. What if I suspect a Transfusion Reaction?
A. Stop the blood, Flush the line, & Call Blood Bank Stat"

This training stated that the BPA (Best Practice Advisory) system will only alert for changes in temperature and SPO2 changes. The system will not alert for any other vital sign changes during a transfusion.

3. Review of the nursing training material titled "Blood Transfusion Overview" (2018) for yearly competency of the EPIC BPAM computer module stated the following:

"Blood Product Transfusion
Vital Signs: Entered into EPIC:
Include SpO2 with each set of vital signs

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D3025	Continued From page 15 Before every blood product started (Initial vitals must be within the previous 60 minutes.)" The facility policy stated, "Initial vital signs must be within the previous 15 minutes." "15 minutes after starting transfusion, then Every hour until transfusion is completed, and When the transfusion is completed. Symptoms of an Acute Transfusion Reaction Temperature elevation during transfusion --Greater than 2 degrees Fahrenheit (F) --Note: BPAM will issue a BPA (Best Practice Advisory) if there is a 2 degree increase in the patient's temperature. Chills/rigors Tachycardia or bradycardia Increase or decrease in BP (blood pressure) of more than 20 mmHg Shock Pain or burning at infusion site Chest pain or tightness Back/flank pain Flushed skin Nausea/Vomiting Cough (new or increasing) Shortness of breath or wheezing Hypoxemia Decreased O2 Sat to <90% on room air or PaO2/FiO2 less than or equal to 300 mmHg Hematuria/dark urine Diffuse bleeding Urticaria/hives (Note: If the only symptom is urticarial or hives, it is necessary to pause the	D3025		

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D3025	Continued From page 16 transfusion, call physician for immediate treatment, and resume transfusion after treatment initiated.) Flag for SpO2 Stop Transfusion EPIC BPAM will initiate a BPA if SpO2 changes 5% from baseline, or drops less than or equal to 90% If baseline SpO2 is normal (95%-100%) then STOP transfusion if SpO2 decreases by 5%. If baseline SpO2 is abnormal (<95%) then STOP transfusion if SpO2 falls 5% from baseline or decreases below 90% NOTE: If the SpO2 increases by 5%, no action is needed, continue the transfusion. 'I ALWAYS' Stop the Transfusion 'I Always' stop the transfusion if SpO2 falls 5% from baseline or decreases below 90% 'I Always' immediately notify Transfusion Service and the ordering physician if the transfusion is STOPPED due to a 5% fall in SpO2 and initiate a Blood Transfusion Reaction Investigation report" This training does not address the temperature change of greater than 1 degree Celsius (C) that was specified in the facility policy and the initial nurse training for the BPAM system. 4. Review of Blood Transfusion Records for Patient [redacted] revealed transfusion of one unit of fresh frozen plasma ([redacted]) started [redacted] 2056 hours and stopped [redacted] 2315 hours. The vital signs	D3025		

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D3025	Continued From page 17 during the transfusion were as follows: [redacted] 2054 hours Temp= 97 °F (36.1°C) SpO2=99% BP=158/80 [redacted] 2056 hours Temp= 97°F (36.1°C) SpO2=100% BP=158/80 [redacted] 2100 hours Temp=NO TEMPERATURE DOCUMENTED SpO2=100% BP=NO BLOOD PRESSURE DOCUMENTED [redacted] 2111 hours Temp= 97.5°F (36.4°C) SpO2=99% BP=147/73 [redacted] 2200 hours Temp=NO TEMPERATURE DOCUMENTED SpO2=99% BP=145/66 [redacted]2300 hours Temp=NO TEMPERATURE DOCUMENTED SpO2=97% BP=NO BLOOD PRESSURE DOCUMENTED [redacted]2315 hours Temp= 97.4°F (36.3°C) SpO2=95% BP=110/55 By the end of the transfusion, a >20 mmHg drop in blood pressure and a 5% drop in SpO2 was	D3025		

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revealed from [redacted] 2056 hours. Two of the sixteen criteria for a possible transfusion reaction had occurred.

By the end of the transfusion, facility blood pressure and SpO2 criteria were prompted for transfusion reaction reporting and investigation. The facility did not follow their procedure in promptly identifying and reporting an investigation for a transfusion reaction. The facility did not follow their own written procedures for documenting all vital signs during a transfusion to ensure all transfusion reactions were identified.

The BPAM system did not trigger an alert in response to the 5% change in SpO2 nor was it identified by the facility.

5. Further review of Blood Transfusion Records for Patient [redacted] revealed transfusion of one unit of packed red blood cells ([redacted]) started [redacted] 0118 hours and stopped [redacted] 0405 hours.

Prior to transfusion, a urinalysis collected on [redacted] at 1209 hours was negative for blood and bilirubin.
(No hematuria was noted at this time.)

The vital signs during the transfusion were as follows:

[redacted] 0100 hours
Temp=NO TEMPERATURE DOCUMENTED
SpO2=96%
BP=116/51

According to a written note by the transfusion

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nurse, the following was documented:
"[redacted] 0110 hours
Hematuria Dr notified by telephone. Resident at bedside. No new orders."
This notation was not documented in the EPIC system.

[redacted] 0117 hours
Temp= 96.7°F (35.9°C)
SpO2=98%
BP=105/59

*BPA triggered at 0119 hours
*BPA triggered at 0120 hours
*BPA triggered at 0122 hours; System locked. No more alerts for the next 5 hours.

[redacted] 0132 hours
Temp= 96.6°F (35.9°C)
SpO2=97%
BP=112/55

[redacted] 0200 hours
Temp=NO TEMPERATURE DOCUMENTED
SpO2=93%
BP=112/55

[redacted] 0300 hours
Temp=NO TEMPERATURE DOCUMENTED
SpO2=93%
BP=NO BLOOD PRESSURE DOCUMENTED

[redacted] 0325 hours
Temp=NO TEMPERATURE DOCUMENTED
SpO2=91%
BP=94/46

[redacted]0354 hours
Temp=NO TEMPERATURE DOCUMENTED

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D3025	Continued From page 20 SpO2=96% BP=NO BLOOD PRESSURE DOCUMENTED [redacted]0400 hours Temp=97.5°F (36.4°C) SpO2=97% BP=NO BLOOD PRESSURE DOCUMENTED [redacted] 0405 hours Temp=NO TEMPERATURE DOCUMENTED SpO2=97% BP=NO BLOOD PRESSURE DOCUMENTED [redacted] 0410 hours Temp=NO TEMPERATURE DOCUMENTED SpO2=96% BP=60/35 [redacted]0415 hours Temp= 97.6°F (36.4°C) SpO2=94% BP=61/29 [redacted] 0420 hours Temp=NO TEMPERATURE DOCUMENTED SpO2=97% BP=59/42 Suspected Reaction? =Yes On [redacted] at 0119 hours, 0120 hours and 0122 hours, the BPA system triggered an alert for SpO2. The BPA stated, "Suspected transfusion reaction: Stop the transfusion and maintain the patency of the IV line. Notify Transfusion Service and patient physician within 15 minutes of reaction. Order a Transfusion Reaction Investigation, complete the Transfusion Reaction form, and send blood bag, tubing, and patient sample to the Blood Bank. Transfusion Service	D3025		

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D3025	Continued From page 21 may request blood cultures if a significant temperature elevation occurred." Review of the BPAM report titled "BestPractice Advisories for [redacted] Hospital Encounter" revealed the following: [redacted] 0119 hours User 36743 Actions Taken None Triggers File Doc Flowsheets SpO2 100% SpO2 95% Rule: BPAM Transfusion Reaction CER [178046] [redacted] 0120 hours User 36743 Actions Taken None Triggers File Doc Flowsheets SpO2 100% SpO2 95% Rule: BPAM Transfusion Reaction CER [178046] [redacted] 0122 hours User- 36743 Actions Taken- Acknowledge: See comments [20]-Not a true transfusion reaction. Lockout: 5 hour(s) For; All users, all encounter Triggers - File Doc Flowsheets SpO2 100% SpO2 95% Rule: BPAM Transfusion Reaction CER [178046] The facility did not follow its policy for taking action on the BPA's for vital sign changes and did not report hematuria to the laboratory to prompt a	D3025		

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transfusion reaction investigation.
The transfusion nurse acknowledged the transfusion reaction alert [redacted] at 0122 hours with the comment, "Not a true transfusion reaction", which then locked the system. The system no longer alerted any possible transfusion reactions based on temperature and SpO2 criteria for the next 5 hours.

6. Review of the laboratory policy titled "1.12 Transfusion Reaction Investigation Workup" (Effective date October 2018) stated the following:
"Any unexpected or unfavorable sign or symptom that occurs during or shortly after the transfusion of a unit of blood or blood component should be considered a transfusion reaction. Since it may be impossible to assess the severity of a transfusion based on the presenting symptoms, ALL transfusion reactions should be considered potentially life threatening until clinical observation and/or lab results prove otherwise."

7. The laboratory's "Root Cause Analysis" for the fatal transfusion reaction for Patient [redacted] stated, "FFP went in without incident. The preliminary autopsy report for Patient [redacted] stated, "FFP went in without issue."
The facility failed to recognize that a transfusion reaction occurred as the result of the transfusion of the FFP.

8. The facility was asked to provide documentation of a blood transfusion reaction investigation for the unit of Fresh Frozen Plasma. No documentation was provided.

9. During an interview on 01/09/2019 at 1411 hours the Quality Assurance (QA) Coordinator

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D3025	Continued From page 23 Transfusion Laboratory explained the BPAM modular. She stated that the BPA system triggers alerts only for a 5% change in SpO2 and/or a 2-degree F (1-degree C) temperature increase. She stated the nurses can enter vital signs during a transfusion. The QA Coordinator Transfusion Laboratory stated that the BPA alerts can be bypassed for vital sign changes by nurses with a comment and the system will lockout for 5 hours. If there are changes in the vital signs that are indicative of a transfusion reaction per the BPA criteria, the system will not alert in this 5-hour period of time. She stated when the nurses do not complete the transfusion in the system and a new product transfusion begins, the system is basing changes in vital signs off of the first product's vital signs. When the products are not completed in the system, it will think it is still transfusing that product. In an interview on 01/09/2019 at 1430 hours in the pathology conference room with Technical Supervisor (TS) #1 and Technical Supervisor #2, TS #2 was asked if any transfusion reaction investigation was performed on the FFP. TS #2 stated, "No." TS #1 stated that the statements that the FFP was transfused without issue in the Root Cause Analysis and the patient's preliminary autopsy report were not true. This confirmed the above findings.	D3025		
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.	D5026		

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D5026	Continued From page 24 This CONDITION is not met as evidenced by: Based on surveyor's review of the Immunohematology records, patient records, and interviews the laboratory failed to meet applicable requirements in the speciality of Immunohematology. (refer to D5559)	D5026		
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in §§493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in §493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of records and confirmed in interview, the laboratory failed to meet the requirements of general laboratory systems as evidenced by: 1. The laboratory failed to implement a system in place to identify and document problems that occurred when a breakdown in communication occurred between the provider and the laboratory. (Refer to D5207) 2. The laboratory failed to establish written policies for an ongoing mechanism to monitor,	D5200		

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D5200	Continued From page 25 assess, and correct problems identified in their electronic systems for transfusion medicine. (refer to D5291)	D5200		
D5207 510H 520H 540H 550H	COMMUNICATIONS CFR(s): 493.1234 The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. This STANDARD is not met as evidenced by: Based on review of Root Cause Analysis (RCA) documents, History & Physical (H&P) notes, Blood Product Administration Module (BPAM) Best Practice Advisories (BPA) alerts, patient instrument printouts, patient electronic results, and in interview with staff, the laboratory failed to implement a system in place to identify and document problems that occurred when a breakdown in communication occurred between the provider and the laboratory. Findings included: 1. Review of RCA documents for transfusion related fatality Patient [redacted] included, "Safety Event Transfusion Reaction" timeline document, created by hospital staff. The document stated, "Lab tests showed the INR 1.7 and Hbg [sic] 6.4 so fresh frozen plasma (FFP) and packed red blood cells (PRBC) were administered after type and crossmatch test was performed." The timeline document included, "1144 (hours)	D5207		

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D5207	Continued From page 26 CT brain/stroke protocol initiated ...1234 (hours) Labs resulted INR 1.7, PT 20, HBG 6.8; 1640 (hours) Order for 1-unit plasma but no order for Type & Cross (ICU Fellow)" (Note: Type and Screen [Cross] was ordered at 1659 hours). Intensive Care Unit (ICU) Fellow H&P notes included a documented INR 1.9, but in review of all coagulation test records there was no INR result of 1.9. 2. Review of H&P notes documented by the Intensive Care Unit (ICU) Fellow on [redacted] at 2:32 pm, stated, "SAH: suspected due to recent fall; NSG and neuro ICU rec no intervention; rec to reverse INR 1.3 and repeat CT in AM ...Coagulopathy: INR 1.9 ...vitK and FFP to start to reverse INR quickly to 1.3 per NSG staff recs; confirmed with Dr [name] NSG staff ok to defer Kcentra and opt for vitK and FFP as starters." When the order was placed for FFP by the ICU Fellow in the BPAM system (on [redacted] at 1639 hours), the following BPA alert generated and stated, "Evidence suggests that FFP transfusion is not required in patents with minimally elevated INR (less than 1.8) to prevent bleeding or prior to procedure. Select 'Accept' to remove the transfusion orders - OR - Select the 'Acknowledge Reason' and 'Accept' if the transfusion orders are clinically indicated. Reference 'Effect of fresh-frozen plasma transfusion on prothrombin time and bleeding in patients with mild coagulation abnormalities.' [Authors]: Transfusion. 2006 Aug;46(8):1279-85" and the order included, "User: ICU Fellow name; Actions Taken: Acknowledge: Other Clinical Indication [434] - coagulopathic; Triggers:	D5207		

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D5207	Continued From page 27 ...PREPARE PLASMA; Rule: SL IP PLASMA ADMIN - NO INR IN LAST DAY OR MOST RECENT UNDER 1.8." Review of Patient [redacted] EPIC lab results, PT/INR instrument (STA-R Evolution) printouts, and final test reports revealed the following results: [redacted] 1209 hours - PT 20 sec, INR 1.7 (only INR result prior to FFP order and ICU Fellow notes). Patient [redacted] coagulation results and RCA documentation did not include an INR 1.9 result. The laboratory did not implement a system in place to identify and document problems when their electronic system resulted in a breakdown of communication. 3. During an interview on 01/08/2019 at 3:30 pm, the Quality Assurance coordinator of Transfusion Medicine was asked the frequency of audits for BPAM system (BPA alerts), she stated, as needed and it was a "tedious" report to obtain. There was not an established frequency for quality assessment (QA) of BPAM system. During an interview on 01/08/2019 at 3:45 pm, the Medical Director of Transfusion Service & Coagulation Clinical Pathology explained there were BPA alerts built in the BPAM system for ordering blood products (FFP and PRBC's). When FFP is ordered for a patient with an INR less than 1.8, a BPA alert will generate and providers have the option to bypass by entering a comment (or order of PRBC's for patient with > 7.0 gm/dl). During an interview on 01/09/2019 at 9:05 am,	D5207		

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D5207	Continued From page 28	D5207		

the Medical Director of Transfusion Service & Coagulation Clinical Pathology was asked whether the Transfusion Department staff was involved in creating the BPA alerts for the BPAM system, she said yes, all parties were involved: pathology, transfusion medicine, and the hospital. The BPAM system went live between 07/2017 and 08/2017.

During an interview on 01/10/2019 at 10:25 am, the Hematology Medical Technologist was asked whether verbal laboratory results were ever provided to hospital staff, she stated no, all normal results were auto-verified in the system for review by hospital staff. Abnormal results would be repeated in the analyzer.

During a telephone interview on 01/29/2019 at 2:00 pm, the ICU Fellow was asked where the documented INR 1.9 result for Patient [redacted] was obtained, he explained, without seeing the records he could not remember where it was taken from. He explained he must have seen it (INR 1.9) somewhere though or the ER physician might have given Neuro that result and Neuro communicated that result to him. The ICU Fellow was asked if a stroke protocol was initiated for Patient [redacted], he stated no and Neuro did not initiate a stroke protocol either. He explained Neuro was consulted and did not feel the patient should be placed in Neuro-ICU nor that acute intervention was necessary. Neuro's recommendation was to monitor and get a CT scan the following day. He explained the ICU attending was "hesitant" to admit the patient to ICU, but the patient was admitted due to other health conditions. The ICU Fellow explained Neuro's recommendations were to order and administer FFP to the patient. He stated him and

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D5207	Continued From page 29 his attending were "hesitant" to give the patient FFP, but were not going to go against Neuro's recommendations. The laboratory did not implement a system in place to identify and document problems when their electronic system resulted in a breakdown of communication between ordering providers and the laboratory. Problems identified were not documented in the RCA for the transfusion related fatality. The laboratory had not established written policies for an ongoing mechanism to monitor, assess, and correct problems identified in their electronic systems for transfusion medicine. Hbg - hemoglobin PT - prothrombin time PTT - partial thromboplastin time INR - international normalized ratio SAH - subarachnoid hemorrhage NSG - neurosurgery Neuro - neurology Rec - recommend(s)/recommendation(s) CT - computed tomography AM - morning vitK - vitamin K RBC - red blood cells	D5207		
D5291 510H 520H 540H 550H	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the	D5291		

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D5291	Continued From page 30 general laboratory systems requirements specified at §§493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of Root Cause Analysis (RCA) documents, History & Physical (H&P) notes, Blood Product Administration Module (BPAM) Best Practice Advisories (BPA) alerts, patient instrument printouts, patient electronic results, and in interview with staff, the laboratory failed to establish written policies for an ongoing mechanism to monitor, assess, and correct problems identified in their electronic systems used for communication in transfusion medicine. Findings included: 1. Review of RCA documents for transfusion related fatality Patient [redacted] included, "Safety Event Transfusion Reaction" timeline document, created by hospital staff. The document stated, "Lab tests showed the INR 1.7 and Hbg [sic] 6.4 so fresh frozen plasma (FFP) and packed red blood cells (PRBC) were administered after type and crossmatch test was performed." Intensive Care Unit (ICU) Fellow H&P notes included a documented INR 1.9, but in review of all coagulation laboratory test records there was no INR result of 1.9. 2. The electronic system in which providers order blood products was BPAM. BPA alerts/triggers were built in and generated in the system for ordering FFP or PRBC's for a patient not meeting	D5291		

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the laboratory value criteria, as follows:

For FFP - "Evidence suggests that FFP transfusion is not required in patents with minimally elevated INR (less than 1.8) to prevent bleeding or prior to procedure. Select 'Accept' to remove the transfusion orders - OR - Select the 'Acknowledge Reason' and 'Accept' if the transfusion orders are clinically indicated. Reference 'Effect of fresh-frozen plasma transfusion on prothrombin time and bleeding in patients with mild coagulation abnormalities.' [Authors]: Transfusion. 2006 Aug;46(8):1279-85."

For PRBC's - "Evidence suggests that in hemodynamically stable, non-bleeding patients a threshold of 7 gm/dl (or 8 gm/dl in acute coronary syndrome or post surgery) can decrease transfusion requirements and avoid adverse outcomes. Select 'Accept' to remove transfusion orders -OR- Select the 'Acknowledge Reason' and 'Accept' if the transfusion orders are clinically indicated. Reference: 'Clinical Practice Guidelines From the AABB Red Blood Cell Transfusion Thresholds and Storage': [Authors]: JAMA 2016;316(19):2025-2035."

3. FFP for Patient [redacted] was ordered by the ICU Fellow in the BPAM system (on [redacted] at 1639 hours). The trigger for FFP (see above) was generated and bypassed by a comment: "coagulopathic." The patient's last documented INR was 1.7, not 1.9. Patient [redacted] coagulation results and RCA documentation did not include an INR 1.9 result. The laboratory did not implement a system in place to identify and document problems when their electronic system resulted in a breakdown of communication. Refer

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D5291	Continued From page 32 to D5207. The laboratory had not established written policies for an ongoing mechanism to monitor, assess, and correct problems identified in their electronic systems for transfusion medicine. 4. During an interview on 01/08/2019 at 3:30 pm, the Quality Assurance coordinator of Transfusion Medicine was asked the frequency of audits for BPAM system (BPA alerts), she stated, as needed and it was a "tedious" report to obtain. There was not an established frequency for quality assessment (QA) of BPAM system.	D5291		
D5300 510H 520H 540H 550H	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 direct observation, facility/laboratory policy, transfusion committee minutes, occurrence reports, and in interview with staff, 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	D5300		

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D5300	Continued From page 33 ensure positive identification of transfusion medicine patient specimens. Refer to D5311.	D5300		
D5311 510H 520H 540H 550H	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 direct observation, facility/laboratory policy, transfusion committee minutes, occurrence reports, and in interview with staff, the laboratory failed to establish written policies and procedures for specimen labeling, acceptability and rejection to ensure positive identification of transfusion medicine patient specimens. Findings included: 1. Review of "Specimen Identification, Collection and Transportation - Pathology" procedure (effective 07/2017), stated, "Specimen Collection and Labeling Process: ...ii Collect the appropriate specimen(s) and place one label on the primary container in the presence of the patient."	D5311		

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D5311	Continued From page 34 The policy also stated, " ...Transfusion Service Specimens. Only two acceptable labels: 1. Epic Specimen Label ...2. Handwritten Label ..." The policy did not indicate specimens were acceptable or rejected with double-labeling, overlapping of labels, or "patient labels" (white chart labels). 2. During an interview on 01/07/2019 at 10:30 am in the transfusion medicine department, the Transfusion Medicine supervisor was asked whether Emergency Department (ED) sent specimens without orders to transfusion medicine, she stated no, those specimens were held in ED until an order was placed. She stated in 2002 an electronic barcode ID was implemented and there was not a second armband for transfusion services. The transfusion department's practice for specimen acceptability was, as long as it had an EPIC label on the blood collection tube. 3. During a tour of the transfusion medicine department on 01/07/2019 at 1:45 pm, all specimens collected on the transfusion related fatality patient were observed to be stored in the transfusion medicine department refrigerator. A pink top with a white barcode label had Patient [redacted] name, CSN number, a date of [redacted], date of birth and two other number combinations. Overlaying Patient [redacted] white label was a pink EPIC barcode label with Patient [redacted] name, date of birth, MRN, accession number, location (ER), Type & Screen	D5311		

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D5311	Continued From page 35 Auto test, a date of [redacted] at 1702 hours and two other number combinations. (Images of collection tubes are attached to this survey kit) 4. Review of Transfusion Committee Minutes from 10/26/2017, stated, "Discussion: Staff Nurse Practice Professional Council is developing an educational plan to improve bar code identification. Recent incident of wrong blood in tube points to the need to improve performance. Mandatory nursing skills fair is planned on quarterly basis." 5. According to Transfusion Committee Minutes from 07/2018, two quality alerts were sent out for, "Improperly labeled samples. Samples are being received in laboratory with labels affixed incorrectly. Units are sending samples to Pathology with labels that are crooked or improperly positioned on the tube. Labels not affixed straight on the tube are unable to be read on laboratory analyzers. Samples must be re-labeled once received in lab, causing a delay in processing/analysis and potential for identification errors ..." 6. According to facility's occurrence reports and investigations, from 09/2018 through 01/09/2019, there were 122 incidents involving mislabeling or other discrepancies with labeling of blood (type and screen) laboratory specimens. In 01/2019, there were 21 incidents involving mislabeled blood collection tubes and 1 was double-labeled.	D5311		

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D5311	Continued From page 36 The laboratory did not establish written policies and procedures for specimen labeling, acceptability and rejection to ensure positive identification of patient specimens.	D5311		
D5559 510H 520H 550H	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: I. Based on review of laboratory's transfusion reaction procedure, patient transfusion records, laboratory transfusion reaction investigation records and confirmed in interview, the laboratory failed to promptly investigate and document blood bank transfusion reactions for all blood products and make recommendations to medical staff regarding transfusion procedure improvements. Findings included: 1. Review of the laboratory policy titled	D5559		

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"Transfusion of Blood Products-Patient Care" (Effective date May 2018) stated the following: "Any unexpected or unfavorable sign or symptom that occurs during or shortly after the transfusion of a unit of blood or blood component should be considered a transfusion reaction. Since it may be impossible to assess the severity of a transfusion based on the presenting symptoms, ALL transfusion reactions should be considered potentially life threatening until clinical observation and/or lab results prove otherwise."

The procedure also stated:
"8. Transfusion Reaction
a. Symptoms of a transfusion reaction.
i. Temperature elevation during transfusion
1. greater than 1 degree Celsius (C), or
2. greater than 2 degrees Fahrenheit (F)
ii. Chills/rigors
iii. Tachycardia or bradycardia
iv. Increase or decrease in blood pressure of more than 20 mmHg
v. Shock
vi. Pain or burning at infusion site
vii. Chest pain or tightness
viii. Back/flank pain
ix. Cough (new or increasing)
x. Shortness of breath or wheezing
Document all abnormal oxygen saturation measurements and
treatments given when reporting a suspected reaction to Transfusion service.
xi. Hypoxemia (change in oxygen saturation of greater than 5% or any decrease to less than 90%)
xii. Flushed skin
xiii. Nausea/Vomiting
xiv. Hematuria/dark urine
xv. Diffuse bleeding

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D5559	Continued From page 38 xvi. Urticaria/hives (Note: If the only symptom is urticarial or hives, it is necessary to pause the transfusion, call physician for immediate treatment, and resume transfusion after treatment initiated.)" 2. Review of Blood Transfusion Records for Patient [redacted] from [redacted] 2056 hours through [redacted] 0405 hours revealed the patient was transfused with 1 unit of FFP and 1 unit of packed Red Blood Cells, as follows: a. One unit of Fresh Frozen Plasma ([redacted]) transfusion started [redacted] 2056 hours and stopped [redacted] 2315 hours. The following were the patient vitals documented in the EPIC BPAM system: [redacted] 2054 hours Temp= 97° F (36.1 °C) SpO2=99% BP=158/80 [redacted] 2056 hours Temp= 97°F (36.1°C) SpO2=100% BP=158/80 [redacted] 2100 hours Temp=NO TEMPERATURE DOCUMENTED SpO2=100% BP=NO BLOOD PRESSURE DOCUMENTED [redacted] 2111 hours Temp= 97.5°F (36.4°C)	D5559		

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D5559	Continued From page 39 SpO2=99% BP=147/73 [redacted] 2200 hours Temp=NO TEMPERATURE DOCUMENTED SpO2=99% BP=145/66 [redacted] 2300 hours Temp=NO TEMPERATURE DOCUMENTED SpO2=97% BP=NO BLOOD PRESSURE DOCUMENTED [redacted] 2315 hours Temp= 97.4°F (36.3°C) SpO2=95% BP=110/55 By the end of the transfusion, a >20 mmHg drop in blood pressure and a 5% drop in SpO2 were revealed from [redacted] 2056 hours. Two of the sixteen criteria for a possible transfusion reaction had occurred. b. One unit of Packed Red Blood Cells ([redacted]) transfusion started [redacted] 0118 hours and stopped [redacted] 0405 hours. Patient [redacted] vitals: [redacted] 0100 hours Temp=NO TEMPERATURE DOCUMENTED SpO2=96% BP=116/51 [redacted] 0117 hours Temp= 96.7°F (35.9°C) SpO2=98% BP=105/59	D5559		

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[redacted] 0132 hours
Temp= 96.6°F (35.9°C)
SpO2=97%
BP=112/55

[redacted] 0200 hours
Temp=NO TEMPERATURE DOCUMENTED
SpO2=93%
BP=112/55

[redacted] 0300 hours
Temp=NO TEMPERATURE DOCUMENTED
SpO2=93%
BP=NO BLOOD PRESSURE DOCUMENTED

[redacted] 0325 hours
Temp=NO TEMPERATURE DOCUMENTED
SpO2=91%
BP=94/46

[redacted] 0354 hours
Temp=NO TEMPERATURE DOCUMENTED
SpO2=96%
BP=NO BLOOD PRESSURE DOCUMENTED

[redacted] 0400 hours
Temp=97.5°F (36.4°C)
SpO2=97%
BP=NO BLOOD PRESSURE DOCUMENTED

[redacted] 0405 hours
Temp=NO TEMPERATURE DOCUMENTED
SpO2=97%
BP=NO BLOOD PRESSURE DOCUMENTED

[redacted]0410 hours
Temp=NO TEMPERATURE DOCUMENTED
SpO2=96%

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D5559	Continued From page 41 BP=60/35 [redacted] 0415 hours Temp= 97.6°F (36.4°C) SpO2=94% BP=61/29 [redacted] 0420 hours Temp=NO TEMPERATURE DOCUMENTED SpO2=97% BP=59/42 Suspected Reaction? =Yes 4. Review of laboratory transfusion reaction investigation records revealed documentation of a blood transfusion reaction investigation (initiated [redacted] at 0415 hours) for the packed red blood cells. The laboratory was asked to provide documentation of a blood transfusion reaction investigation for the unit of Fresh Frozen Plasma. The laboratory was also asked to provide documentation of review of EPIC BPAM processes and procedures utilized by the facility and corresponding recommendations for transfusion improvements to medical staff. No documentation was provided. 5. During an interview on 01/08/2019 at 1530 hours, QA Coordinator Transfusion Laboratory was asked for BPAM BPA alert audits and how often were they conducted, she stated as needed and the report is very tedious. She stated, they had planned on "QA'ing" (Quality Assurance) the system, but the report is hard to obtain. In an interview on 01/09/2019 at 0904 hours in the pathology conference room with TS #1 and TS #2, TS #2 was asked if any transfusion reaction investigation included the FFP. TS #2	D5559		

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stated, "No."
This confirmed the above findings.

II. Based on review of laboratory policies and records, the laboratory failed to document remedial actions taken to prevent recurrences of transfusion reactions and that all policies were reviewed to ensure adequacy and safety of individuals being transfused.

Findings included:

1. Review of the Blood Product Administration system revealed triggers built into the system that alert when blood products transfusion may be contraindicated or when a patient may be experiencing a transfusion reaction.

The following are the three Best Practice Advisory alerts utilized by this facility:

a. "Evidence suggests that FFP transfusion is not required in patients with minimally elevated INR (less than 1.8) to prevent bleeding or prior to procedure. Select 'Accept' to remove the transfusion orders -OR- Select the 'Acknowledge Reason' and 'Accept' if the transfusion orders are clinically indicated."

b. "Evidence suggests that in hemodynamically stable, non-bleeding patients a threshold of 7 gm/dl (or 8 gm/dl in acute coronary syndrome or post-surgery) can decrease transfusion requirements and avoid adverse outcomes. Select 'Accept' to remove the transfusion orders -OR- Select the 'Acknowledge Reason' and 'Accept' if the transfusion orders are clinically indicated."

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c. "Suspected transfusion reaction: Stop the transfusion and maintain patency of the IV line. Notify Transfusion Service and patient physician within 15 minutes of reaction. Order a Transfusion reaction investigation, complete the Transfusion Reaction form and send blood bag, tubing and patient sample to the Blood Bank. Transfusion Service may request blood cultures if a significant temperature elevation occurred."

The BPA system will only alert for changes in temperature and SpO2 changes during a blood product transfusion.

2. Review of laboratory BPAM transfusion reaction triggers for 10/15/2018, 01/09/2018 and 01/10/2018 revealed the following:

a. From 10/15/2018 0000 through 10/15/2018 2327 hours:
Total Triggers=220
Alert Overridden=14
Cancel BPA=170
Accept BPA/No Action Taken=3

b. From 01/09/2018 2319 hours through 01/10/2018 1200 hours:
Total Triggers=297
Alert Overridden=28
Cancel BPA=241
Accept BPA/No Action Taken=4

3. Review of the Transfusion Committee Minutes from July 25, 2018 in the section titled "EPIC-Blood Order Decision Support (RBC's and FFP)" stated, "EPIC was launched on July 11. Process seems to be working well. An audit of

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overrides is needed."

4. During an interview on 01/09/2019 at 0905 hours, TS#1 and TS #2 were asked when the EPIC BPAM system was implemented, they stated either 07/2017 or 08/2017. They were asked if they or the transfusion medicine department were involved in creating, reviewing and approving the BPA alerts in EPIC BPAM, for vital sign changes and blood product ordering. TS#1 explained, yes, all parties were involved (pathology, transfusion medicine and hospital).

In an interview with facility personnel on 01/08/2019 at 1410 hours in the administration conference room, the QA Coordinator Transfusion Laboratory was asked if the transfusion service conducts audits on BPA triggers that are overridden, cancelled or have no action taken. The transfusion service IT person stated, "The process to go back and print out the list of alerts is very tedious and performed Ad Hoc (as needed)."

In an additional interview on 01/09/2019 at 1411 hours in the Blood Bank, the QA Coordinator Transfusion laboratory stated that alerts could be cancelled, accepted with no action taken, or acknowledged. If the alert of a possible transfusion reaction is acknowledged and a comment entered, the system creates a "lockout" in which no alerts would appear for a 5-hour period of time.

The laboratory was asked to provide an audit of overrides and the corresponding Quality Assessment documentation.
No documentation was provided. This confirmed the above findings.

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III. Based on review of laboratory policies and records, the laboratory failed to have a system in place to review all components documented as part of the transfusion process and to prevent recurrences of incomplete documentation.

1. Review of the facility's policy titled "Transfusion of Blood Products-Patient Care" (Effective date May 2018) stated the following:

"3. Assessment Before Transfusion
... ...f. Assess vital signs, including blood pressure, heart rate, respiratory rate, oxygen saturation and temperature. (Initial vital signs must be within the previous 15 minutes).

4. Administrative Process
....p. Monitor vital signs and assess temperature and urine throughout the transfusion process to monitor for adverse reactions to blood products and the effectiveness of treatment. Vitals are done every hour, and when the transfusion is complete.
q. Monitor for signs and symptoms of transfusion reactions. Both acute and delayed hemolytic reactions are potentially life-threatening events. (See Transfusion Reaction).

9. Documentation
a. Follow guidelines in documenting blood administration using the institution's electronic health record."

2. A random review of patient records from 08/01/2018 through 01/10/2019 revealed 20 of 20 patient records with incomplete documentation of

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D5559	Continued From page 46 vital signs during a transfusion. The following is a random sampling of those patients: a. Patient #56 vitals: [redacted] 1345 hours (Pre-Transfusion) Temp= 97.9°F Pulse=103 Respiration=17 SpO2=100% BP=152/52 [redacted] 1354 hours Temp= 98.2°F Pulse=107 Respiration=16 SpO2=100% BP=145/53 [redacted] 1400 hours Temp= 98.4°F Pulse=105 Respiration=55 SpO2=100% BP=113/46 [redacted] 1415 hours Temp= 95.0°F Pulse=112 Respiration=26 SpO2=100% BP=129/49 [redacted] 1430 hours Temp= 98.4°F Pulse=118 Respiration=31 SpO2=100% BP=126/50	D5559		

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D5559	Continued From page 47 [redacted] 1500 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=106 Respiration=18 SpO2=100% BP=168/60 [redacted] 1515 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=NO PULSE DOCUMENTED Respiration=NO RESPIRATION DOCUMENTED SpO2=NO OXYGEN SATURATION DOCUMENTED BP=159/51 [redacted] 1530 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=NO PULSE DOCUMENTED Respiration=NO RESPIRATION DOCUMENTED SpO2=NO OXYGEN SATURATION DOCUMENTED BP=152/49 [redacted] 1600 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=94 Respiration=16 SpO2=100% BP=149/47 [redacted] 1630 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=NO PULSE DOCUMENTED Respiration=NO RESPIRATION DOCUMENTED SpO2=NO OXYGEN SATURATION DOCUMENTED BP=152/59	D5559		

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D5559	Continued From page 48 b. Patient [redacted] vitals: [redacted] 0100 hours (Pre-Transfusion) Temp=NO TEMPERATURE DOCUMENTED Pulse=55 Respiration=16 SpO2=96% BP=116/51 [redacted] 0117 hours Temp= 96.7°F Pulse=52 Respiration=12 SpO2=98% BP=105/59 [redacted] 0132 hours Temp= 96.6°F Pulse=51 Respiration=10 SpO2=97% BP=112/55 [redacted] 0200 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=56 Respiration=19 SpO2=93% BP=112/55 [redacted] 0300 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=68 Respiration=22 SpO2=93% BP=NO BLOOD PRESSURE DOCUMENTED [redacted] 0325 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=64	D5559		

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D5559	Continued From page 49 Respiration=25 SpO2=91% BP=94/46 [redacted] 0354 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=60 Respiration=21 SpO2=96% BP=NO BLOOD PRESSURE DOCUMENTED [redacted] 0400 hours Temp=97.5°F Pulse=62 Respiration=21 SpO2=97% BP=NO BLOOD PRESSURE DOCUMENTED [redacted] 0405 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=60 Respiration=18 SpO2=97% BP=NO BLOOD PRESSURE DOCUMENTED c. Patient #6 vitals: [redacted] 0111 hours (Pre-Transfusion) Temp=97.6°F Pulse=82 Respiration=16 SpO2=100% BP=110/46 [redacted] 0123 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=NO PULSE DOCUMENTED Respiration=NO RESPIRATION DOCUMENTED SpO2=NO OXYGEN SATURATION DOCUMENTED	D5559		

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D5559	Continued From page 50 BP=106/40 [redacted] 0130 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=79 Respiration=19 SpO2=100% BP=NO BLOOD PRESSURE DOCUMENTED [redacted] 0145 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=79 Respiration=19 SpO2=100% BP=108/45 [redacted] 0200 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=79 Respiration=19 SpO2=100% BP=NO BLOOD PRESSURE DOCUMENTED [redacted] 0203 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=NO PULSE DOCUMENTED Respiration=NO RESPIRATION DOCUMENTED SpO2=NO OXYGEN SATURATION DOCUMENTED BP=89/42 [redacted] 0215 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=90 Respiration=26 SpO2=99% BP=NO BLOOD PRESSURE DOCUMENTED [redacted] 0223 hours	D5559		

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D5559	Continued From page 51 Temp=NO TEMPERATURE DOCUMENTED Pulse=NO PULSE DOCUMENTED Respiration=NO RESPIRATION DOCUMENTED SpO2=NO OXYGEN SATURATION DOCUMENTED BP=89/41 [redacted] 0300 hours Temp=98.9°F Pulse=NO PULSE DOCUMENTED Respiration=NO RESPIRATION DOCUMENTED SpO2=NO OXYGEN SATURATION DOCUMENTED BP=NO BLOOD PRESSURE DOCUMENTED [redacted] 0315 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=84 Respiration=23 SpO2=99% BP=NO BLOOD PRESSURE DOCUMENTED [redacted] 0345 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=83 Respiration=20 SpO2=100% BP=116/40 d. Patient #5 vitals: [redacted] 1615 hours (Pre-Transfusion) Temp=98.6°F Pulse=67 Respiration=24 SpO2=92% BP=116/60 [redacted] 1645 hours No vital signs documented	D5559		

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D5559	Continued From page 52 [redacted] 1700 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=66 Respiration=20 SpO2=98% BP=NO BLOOD PRESSURE DOCUMENTED [redacted] 1718 hours Temp=99.2°F Pulse=67 Respiration=28 SpO2=NO OXYGEN SATURATION DOCUMENTED BP=NO BLOOD PRESSURE DOCUMENTED [redacted] 1800 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=62 Respiration=13 SpO2=NO OXYGEN SATURATION DOCUMENTED BP=NO BLOOD PRESSURE DOCUMENTED [redacted] 1900 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=81 Respiration=32 SpO2=NO OXYGEN SATURATION DOCUMENTED BP=NO BLOOD PRESSURE DOCUMENTED 3. Review of laboratory records revealed no documentation of a system to review completion of all records in the transfusion process to prevent recurrence of transfusion reactions.	D5559		
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)	D5793		

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D5793 510H 520H 540H 550H	Continued From page 53	D5793		

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff.
(c) The laboratory must document all analytic systems assessment activities.
This STANDARD is not met as evidenced by:
Based on review of EPIC Blood Product Administration Module (BPAM) system training, transfusion committee minutes, patient transfusion records, and confirmed in interview, the laboratory failed to have a quality assessment (QA) system in place that included a review of the effectiveness of revision in procedures to prevent recurrence of problems in the EPIC BPAM system.

Findings included:

1. Review of the facility training material titled "Documenting Blood Product Administration" (May 2017) for implementation of the EPIC BPAM system, stated the following:

"Q: How do I complete a Blood Transfusion
A. Follow the directions below:

- Click Add Col to add a column for the current time
- In the rate row for the corresponding blood product, click on the Syringe icon
- Select 'Stopped' Action
- Enter the appropriate volume based on the

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D5793	Continued From page 54	D5793		

blood product transfused
- Enter in the last set of vital signs
- Click Accept & Complete."

2. Review of the facility training material titled "Blood Transfusion Overview" (2018) for yearly competency of the EPIC BPAM system stated the following:

"I Always right click and select 'complete' on the Doc Flowsheet row for the appropriate transfused unit in order to complete the transfusion in EPIC.

Important Points to Remember:
Verify Completion: You must complete a blood product transfusion in the BPAM module in EPIC; otherwise it will continue to show as an active transfusion."

3. Review of transfusion records in the EPIC BPAM system for Patient [redacted] revealed Fresh Frozen Plasma (FFP) was transfused on [redacted] 2056 hours and stopped [redacted] 2315 hours. The documented completion was [redacted] at 1011 hours (elapsed time of 2 days, 10 hours, and 56 minutes between end of transfusion and completion).

Patient [redacted] Packed Red Blood Cells (PRBC's) was transfused on [redacted] 0118 hours and stopped [redacted] 0405 hours. The documented completion was [redacted] at 1427 hours. (elapsed time 10 hours and 22 minutes between end of transfusion and completion).

Since the FFP did not have an accurate completion date entered, the system continued in "active transfusion" mode during the PRBC's

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transfusion. Since there no accurate completion date documented, the system generated vital sign change best practice advisories based on the prior transfusion (FFP).

When a completion date is not entered at the end of a transfusion, the system is not accurately capturing the vital sign changes of the actual unit in transfusion.

4. Review of transfusion records for 2 patients from [redacted] and [redacted] revealed completion dates for transfusions were not entered when actually completed, as follows:

[redacted] - Patient #45: Leuko-reduced RBC's transfusion started [redacted] 1723 hours, ended [redacted] 2041 hours and completion was [redacted] 1015 hours (elapsed time of 3 days, 13 hours, and 34 minutes between end of transfusion and completion).

[redacted] - Patient #41: Leuko-reduced RBC's transfusion started [redacted] 0231 hours, ended [redacted] 0502 hours and completion was [redacted] 1148 hours (elapsed time of 2 days and 6 hours between end of transfusion and completion).

Patient #41: Leuko-reduced RBC's transfusion started [redacted] 2226 hours, end was blank as of [redacted] 1156 hours, and completion was [redacted] 1225 hours.

5. Review of transfusion committee minutes for 01/25/2018 in the section titled "BPAM Update," stated, "Turnover in nurses seems to be leading

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D5793	Continued From page 56	D5793		

to ongoing problems with closure of transfusion events in EPIC. Ongoing training will be needed."

Documentation of "ongoing training" after 01/25/2018 could not be provided.

6. During an interview on 01/10/2019 at 1620 hours, the CEO, CNO, and RN #37 (Information Technology) confirmed the CMS nurse surveyor's findings that single blood transfusion records are not consistently ended and/or not completed in the Electronic Medical Record (EMR) by a nurse when the actual transfusion is completed, which results in the transfusion record continuing to monitor as if it is active. The ending date/time, if not entered, may be inaccurate. The ending/date time can be left open for days, over multiple shifts. If the single blood transfusion record is not completed/ended at the time that the actual transfusion is completed/ended, the record can be altered resulting in an inaccurate patient record.

7. During an interview on 01/09/2019 at 1530 hours in the pathology conference room, TS #1 stated that a report of incomplete transfusions was generated by RN #37 (Information Technology). This report is sent to the appropriate nurse manager and the nurse manager communicates to the appropriate transfusion nurse to complete the transfusion. TS #1 stated that the transfusion completion date and time may not reflect the actual completion date and time. This confirmed the above findings.

The laboratory's review of the EPIC BPAM system was not effective of revision in procedures

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D5793	Continued From page 57 to prevent recurrence of problems. The EPIC BPAM system was not used correctly to ensure vital sign changes were captured specific to the actual unit being transfused for promptly identifying transfusion reactions.	D5793		
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 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. This CONDITION is not met as evidenced by: I. 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 D6094, D6096, D6101) II. Based on direct observation, facility/laboratory policy, transfusion committee minutes, occurrence reports, and in interview with staff, the laboratory director failed to provide overall management. The laboratory director failed to ensure transfusion medicine systems provided quality laboratory services for preanalytic phase of testing. Refer to D6082.	D6076		
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) 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. This STANDARD is not met as evidenced by: Based on direct observation, facility/laboratory	D6082		

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D6082	Continued From page 58 policy, transfusion committee minutes, occurrence reports, and in interview with staff, the laboratory director failed to ensure transfusion medicine systems provided quality laboratory services for preanalytic phase of testing. 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.	D6082		
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. 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. The findings: 1. The laboratory director failed to ensure the laboratory's quality assessment plan identified and corrected problems in laboratory general systems (refer to D5291). 2. The laboratory director failed to ensure the laboratory's quality assessment plan included a review of the effectiveness of corrective actions taken in analytic systems (refer to D5793).	D6094		
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7)	D6096		

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D6096	Continued From page 59 The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on review of the transfusion records and staff interview, it was revealed the laboratory director failed to ensure problems were resolved with the ordering of blood products, incomplete transfusion records, and overriding/lockout of transfusion reaction alerts in EPIC BPAM (Blood Product Administration Module) (refer to D3025, D5207, D5291, D5559, D5793).	D6096		
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on a review of facility records and confirmed in interview, the laboratory director failed to employ a sufficient number of laboratory personnel to monitor the EPIC Blood Product Administration Module (BPAM) and Best Practice Advisories (BPA) alerts to identify problems in the ordering and transfusion of blood components. 1. A review of quality assurance records for monitoring ordering of blood products, incomplete transfusion records, and overriding/lockout of transfusion reaction alerts in EPIC BPAM (Blood	D6101		

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D6101	Continued From page 60 Product Administration Module) revealed no documentation of a defined frequency for audits. 2. During an interview on 01/08/2019 at 3:30 pm, the Quality Assurance coordinator of Transfusion Medicine was asked the frequency of audits for BPAM system (BPA alerts), she stated, as needed and it was a "tedious" report to obtain. 3. A review of the laboratory documents and the CMS-209 revealed the Quality Assurance coordinator of Transfusion Medicine performed bench work, monitored the competency of testing persons and performed quality assurance duties. 4. In an interview of immunohematology technical supervisor 1 (as listed on the CM-209) on 1/10/2019 at 1055 hours in the break room she stated that "staffing was based on billable tests" and they "needed help with quality assurance". Key: CMS- Centers for Medicare & Medicaid Services	D6101		
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 direct observations, laboratory records, manufacturer instructions, and confirmed in interview, the technical supervisor failed to	D6108		

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D6108	Continued From page 61 provide technical oversight of the laboratory (refer to D6118 and D6121).	D6108		
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on review of the transfusion records and staff interview, it was revealed the technical supervisor failed to ensure problems were resolved with the ordering of blood products, incomplete transfusion records, and overriding/lockout of transfusion reaction alerts in EPIC BPAM (Blood Product Administration Module) (refer to D3025, D5207, D5291, D5559, D5793).	D6118		
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on a review of form CMS-209, listing of facility personnel form, competency assessment records and confirmed in interview the immunohematology technical supervisor failed to evaluate the competency for 4 of 4 immunohematology testing personnel hired in 2017 and 2018 (testing persons 3, 12, 20, 25). Findings included:	D6121		

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D6121	Continued From page 62 1. Review of form CMS-209 for the transfusion service department and the Listing of Facility Personnel revealed 1 new testing person hired in 2017 (Testing Person 3) and 3 new testing persons hired in 2018 (Testing Person 12, 20, 25) performing high complexity testing immunohematology testing. 2. Review of the laboratory forms titled "Employee Annual Competency Checklist" for 2017 revealed that the laboratory testing personnel (Testing Person 3) was assessed by an individual other than the Technical Supervisor listed on the CMS-209. 3. Review of the laboratory forms titled "Employee Annual Competency Checklist" for 2018 revealed that the laboratory testing personnel (Testing Person 12, and Testing Person 20, Testing Person 25) were assessed by an individual other than the Technical Supervisor listed on the CMS-209. 3. The individuals who assessed the testing personnel held the position of general supervisor or "lead tech" and did not quality as an Immunohematology Technical Supervisor. 4. In an interview of the immunohematology technical supervisor 1 (as listed on the CMS-209) on 1/10/2019 1055 hours in the break room, she confirmed the above findings. Key:	D6121		

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D6121	Continued From page 63 CMS- Centers for Medicare & Medicaid services	D6121		