The laboratory was surveyed in response to complaint TX00303145 for compliance with CMS 42 CFR regulations.

Complaint TX00303145 was substantiated 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.

D3000 FACILITY ADMINISTRATION CFR(s): 493.1100

Each laboratory that performs nonwaived testing...
## Statement of Deficiencies and Plan of Correction

**Name of Provider or Supplier:** CHI ST LUKE'S HEALTH BCM MEDICAL CENTER  
**Address:** 6720 BERTNER AVENUE, HOUSTON, TX 77030

### Summary Statement of Deficiencies

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<th>Summary Statement of Deficiencies</th>
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<th>Provider's Plan of Correction</th>
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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)

**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])**
### Statement of Deficiencies

**NAME OF PROVIDER OR SUPPLIER**

CHI ST LUKE’S HEALTH BCM MEDICAL CENTER

**STREET ADDRESS, CITY, STATE, ZIP CODE**

6720 BERTNER AVENUE
HOUSTON, TX  77030

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<td>D3023</td>
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- 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; at 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
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

A. BUILDING ________________________

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 45D0053108

(X2) MULTIPLE CONSTRUCTION

A. BUILDING ________________________

B. WING _____________________________

(X3) DATE SURVEY COMPLETED

C 01/11/2019

NAME OF PROVIDER OR SUPPLIER

CHI ST LUKE'S HEALTH BCM MEDICAL CENTER

STREET ADDRESS, CITY, STATE, ZIP CODE

6720 BERTNER AVENUE

HOUSTON, TX 77030

(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

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.
### Statement of Deficiencies and Plan of Correction

**Provider/Supplier/Clinical Laboratory Improvement Amendments (CLIA) Identification Number:**

45D0053108

**Date Survey Completed:**

01/11/2019

---

**Name of Provider or Supplier:**

CHI ST LUKE'S HEALTH BCM MEDICAL CENTER

**Street Address, City, State, Zip Code:**

6720 BERTNER AVENUE
HOUSTON, TX 77030

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<td><strong>Continued From page 4</strong> overlapping of labels, or &quot;patient labels&quot; (white chart labels).**</td>
<td>D3023</td>
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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. Overlying 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: 0955 hours

Error discovered: 2015 hours

"Type and screen specimen and Group specimen w/ABO/Rh 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+"
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:
Patient's location: Liver Transplant Clinic
Date/Time on Specimen: hours
Error discovered: 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."
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<tr>
<td>D3023</td>
<td>Continued From page 6</td>
<td>7. Review of Transfusion Committee Minutes from 10/26/2017, stated, &quot;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.&quot;</td>
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<td>8. According to Transfusion Committee Minutes from 07/2018, two quality alerts were sent out for, &quot;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 ...&quot;</td>
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<td>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</td>
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### Statement of Deficiencies and Plan of Correction

#### Event ID: YDMH11  Facility ID: TX22010121  If continuation sheet Page 8 of 64

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<td>D3023</td>
<td>Continued From page 7</td>
<td>facility failed to establish and follow written policies for ensuring positive identification of patient specimens prior to receiving blood products.</td>
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<td>D3025</td>
<td>REQUIREMENTS FOR TRANSFUSION SERVICES</td>
<td>CFR(s): 493.1103(d)</td>
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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:

1. 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:
### Summary Statement of Deficiencies

**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
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 revealed on at 1512 hours nurse 15170 was notified of a BPA due to "Triggers File Doc Flowsheets SpO2: 99%; SpO2: 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 nursing documentation for transfusion of one unit of fresh frozen plasma 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 at 2215 hours documented decrease in blood pressure of greater than 20 mmHg - 158/80 mmHg to 110/55 mmHg.
   b. On at 0110 hours - Hematuria

Note: A transfusion reaction was not called until 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

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 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
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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<td>iii. Tachycardia or bradycardia</td>
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<td>iv. Increase or decrease in blood pressure of more than 20 mmHg</td>
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<td>v. Shock</td>
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<td>vi. Pain or burning at infusion site</td>
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<td>vii. Chest pain or tightness</td>
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<td>viii. Back/flank pain</td>
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<td>ix. Cough (new or increasing)</td>
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<td>x. Shortness of breath or wheezing</td>
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<td>Document all abnormal oxygen saturation measurements and treatments given when reporting a suspected reaction to Transfusion service.</td>
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<td>xi. Hypoxemia (change in oxygen saturation [SpO2] of greater than 5% or any decrease to less than 90%)</td>
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<td>xii. Flushed skin</td>
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<td>xiii. Nausea/Vomiting</td>
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<td>xiv. Hematuria/dark urine</td>
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<td>xv. Diffuse bleeding</td>
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<td>xvi. Urticaria/hives</td>
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<td>(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.)</td>
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<td>b. In a suspected transfusion reaction, IMMEDIATELY: i. Stop transfusion and maintain the patency of the IV line.</td>
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<td>vi. Monitor vital signs</td>
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<td>vii. Notify Transfusion Service and physician. Notification of Transfusion Service must be within 15 minutes of reaction.</td>
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<td>viii. Notify house officer was warranted by patient's symptoms .... &quot;</td>
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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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| D3025 | Continued From page 14  
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.) | D3025 | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) |

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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<td>Before every blood product started</td>
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<td>(Initial vitals must be within the previous 60 minutes.)&quot;</td>
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<td>The facility policy stated, &quot;Initial vital signs must</td>
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<td>be within the previous 15 minutes.&quot;</td>
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<td>&quot;15 minutes after starting transfusion, then</td>
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<td>Every hour until transfusion is completed, and</td>
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<td>When the transfusion is completed.</td>
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<td>Symptoms of an Acute Transfusion Reaction</td>
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<td>Temperature elevation during transfusion</td>
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<td>--Greater than 2 degrees Fahrenheit (F)</td>
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<td>--Note: BPAM will issue a BPA (Best Practice</td>
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<td>Advisory) if there is a 2 degree increase in the</td>
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<td>Chills/rigors</td>
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<td>Tachycardia or bradycardia</td>
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<td>Increase or decrease in BP (blood pressure)</td>
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<td>of more than 20 mmHg</td>
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<td>Shock</td>
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<td>Pain or burning at infusion site</td>
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<td>Chest pain or tightness</td>
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<td>Back/flank pain</td>
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<td>Flushed skin</td>
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<td>Nausea/Vomiting</td>
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<td>Cough (new or increasing)</td>
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<td>Shortness of breath or wheezing</td>
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<td>Hypoxemia</td>
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<td>Decreased O2 Sat to &lt;90% on room air or</td>
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<td>PaO2/FiO2 less than or equal to 300 mmHg</td>
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<td>Hematuria/dark urine</td>
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<td>Diffuse bleeding</td>
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<td>Urticaria/hives</td>
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<td>(Note: If the only symptom is urticarial or</td>
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<td>hives, it is necessary to pause the</td>
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<td>ID</td>
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<td>TAG</td>
<td>SUMMARY STATEMENT OF DEFICIENCIES</td>
<td>ID</td>
<td>PREFIX</td>
<td>TAG</td>
<td>PROVIDER'S PLAN OF CORRECTION</td>
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<tr>
<td>D3025</td>
<td>Continued From page 16</td>
<td>transfusion, call physician for immediate treatment, and resume transfusion after treatment initiated.</td>
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</tbody>
</table>

**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 revealed transfusion of one unit of fresh frozen plasma ( ) started 2056 hours and stopped 2315 hours. The vital signs...
By the end of the transfusion, a >20 mmHg drop in blood pressure and a 5% drop in SpO2 was
<table>
<thead>
<tr>
<th>ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID PREFIX TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>COMPLETION DATE</th>
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</thead>
<tbody>
<tr>
<td>D3025</td>
<td>Continued From page 18 revealed from 2056 hours. Two of the sixteen criteria for a possible transfusion reaction had occurred.</td>
<td>D3025</td>
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<td></td>
<td>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.</td>
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<td>The BPAM system did not trigger an alert in response to the 5% change in SpO2 nor was it identified by the facility.</td>
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<td>5. Further review of Blood Transfusion Records for Patient revealed transfusion of one unit of packed red blood cells (started 0118 hours and stopped 0405 hours.</td>
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<td>Prior to transfusion, a urinalysis collected on at 1209 hours was negative for blood and bilirubin. (No hematuria was noted at this time.)</td>
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<td>The vital signs during the transfusion were as follows:</td>
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<td></td>
<td>Temp=NO TEMPERATURE DOCUMENTED SpO2=96% BP=116/51</td>
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<td>According to a written note by the transfusion</td>
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<td>ID PREFIX TAG</td>
<td>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</td>
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<td>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</td>
<td>COMPLETION DATE</td>
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</table>
| D3025        | Continued From page 19 nurse, the following was documented:  
0110 hours  
Hematuria Dr notified by telephone. Resident at bedside. No new orders."  
This notation was not documented in the EPIC system.  
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.  
0132 hours  
Temp= 96.6°F (35.9°C)  
SpO2=97%  
BP=112/55  
0200 hours  
Temp= NO TEMPERATURE DOCUMENTED  
SpO2=93%  
BP=112/55  
0300 hours  
Temp= NO TEMPERATURE DOCUMENTED  
SpO2=93%  
BP= NO BLOOD PRESSURE DOCUMENTED  
0325 hours  
Temp= NO TEMPERATURE DOCUMENTED  
SpO2=91%  
BP=94/46  
0354 hours  
Temp= NO TEMPERATURE DOCUMENTED | D3025 | | |
<table>
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<tr>
<th>ID</th>
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<th>TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES</th>
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<th>PROVIDER'S PLAN OF CORRECTION</th>
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<tbody>
<tr>
<td>D3025</td>
<td>Continued From page 20 SpO2=96% BP=NO BLOOD PRESSURE DOCUMENTED</td>
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<td>0400 hours</td>
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<tr>
<td>Temp=97.5°F (36.4°C) SpO2=97% BP=NO BLOOD PRESSURE DOCUMENTED</td>
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<td>0405 hours</td>
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<td>Temp=NO TEMPERATURE DOCUMENTED SpO2=97% BP=NO BLOOD PRESSURE DOCUMENTED</td>
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<td>0410 hours</td>
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<td>Temp=NO TEMPERATURE DOCUMENTED SpO2=96% BP=60/35</td>
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<td>0415 hours</td>
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<td>Temp=97.6°F (36.4°C) SpO2=94% BP=61/29</td>
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<td>0420 hours</td>
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<tr>
<td>Temp=NO TEMPERATURE DOCUMENTED SpO2=97% BP=59/42 Suspected Reaction? Yes</td>
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On 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..."
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**NAME OF PROVIDER OR SUPPLIER**

CHI ST LUKE'S HEALTH BCM MEDICAL CENTER

**STREET ADDRESS, CITY, STATE, ZIP CODE**

6720 BERTNER AVENUE
HOUSTON, TX  77030

**SUMMARY STATEMENT OF DEFICIENCIES**

(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)

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<tbody>
<tr>
<td>D3025</td>
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Review of the BPAM report titled "BestPractice Advisories for Hospital Encounter" revealed the following:

**0119 hours**

User 36743
Actions Taken None
Triggers File Doc Flowsheets
SpO2 100%
SpO2 95%
Rule: BPAM Transfusion Reaction CER [178046]

**0120 hours**

User 36743
Actions Taken None
Triggers File Doc Flowsheets
SpO2 100%
SpO2 95%
Rule: BPAM Transfusion Reaction CER [178046]

**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
Continued From page 22
transfusion reaction investigation.
The transfusion nurse acknowledged the
transfusion reaction alert 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 stated, "FFP went in without incident. The
preliminary autopsy report for Patient 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
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.

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.
### SUMMARY STATEMENT OF DEFICIENCIES

**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 specialty of Immunohematology. (Refer to D5559)

**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,
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 \[\text{redacted}\] 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 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 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 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:
### Summary Statement of Deficiencies

#### 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 EPIC lab results, PT/INR instrument (STA-R Evolution) printouts, and final test reports revealed the following results: 1209 hours - PT 20 sec, INR 1.7 (only INR result prior to FFP order and ICU Fellow notes).

Patient 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

Continued From page 28

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...
<table>
<thead>
<tr>
<th>ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID PREFIX TAG</th>
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<tbody>
<tr>
<td>D5207</td>
<td>Continued From page 29 his attending were &quot;hesitant&quot; 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.</td>
<td>D5207</td>
</tr>
<tr>
<td>D5291</td>
<td>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT 510H 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</td>
<td>D5291</td>
</tr>
</tbody>
</table>

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

Event ID: YDMH11 Facility ID: TX22010121
### PROVIDER'S PLAN OF CORRECTION

<table>
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<tr>
<th>ID PREFIX</th>
<th>TAG</th>
<th>D5291</th>
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<tbody>
<tr>
<td>D5291</td>
<td></td>
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<td>general laboratory systems requirements specified at §§493.1231 through 493.1236.</td>
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</tbody>
</table>

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 Continued From page 31
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
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.

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
### PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:

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<tr>
<td>D5300</td>
<td>Continued From page 33</td>
<td>ensure positive identification of transfusion medicine patient specimens. Refer to D5311.</td>
</tr>
<tr>
<td>D5311</td>
<td>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</td>
<td>CFR(s): 493.1242(a)</td>
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<tr>
<td>510H 520H 540H 550H</td>
<td>The laboratory must establish and follow written policies and procedures for each of the following, if applicable:</td>
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<td></td>
<td>(1) Patient preparation.</td>
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<td>(2) Specimen collection.</td>
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<td></td>
<td>(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source.</td>
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<td>(4) Specimen storage and preservation.</td>
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<td>(5) Conditions for specimen transportation.</td>
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<td>(6) Specimen processing.</td>
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<td>(7) Specimen acceptability and rejection.</td>
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<td>(8) Specimen referral.</td>
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<td>This STANDARD is not met as evidenced by:</td>
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<tr>
<td></td>
<td>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.</td>
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</table>

**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."
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<th>PROVIDER'S PLAN OF CORRECTION</th>
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<tr>
<td>D5311</td>
<td>Continued From page 34</td>
<td>D5311</td>
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</table>

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. Overlying Patient [redacted] white label was a pink EPIC barcode label with Patient [redacted] name, date of birth, MRN, accession number, location (ER), Type & Screen
<table>
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<th>TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>COMPLETION DATE</th>
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</table>
| 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.
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**NAME OF PROVIDER OR SUPPLIER**

CHI ST LUKE'S HEALTH BCM MEDICAL CENTER

**STREET ADDRESS, CITY, STATE, ZIP CODE**

6720 BERTNER AVENUE
HOUSTON, TX  77030

**DATE SURVEY COMPLETED**

01/11/2019

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<tbody>
<tr>
<td>D5311</td>
<td>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.</td>
<td>D5311</td>
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<tr>
<td>D5559</td>
<td>IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (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: 1. 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</td>
<td>D5559</td>
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<tr>
<td>510H 520H 550H</td>
<td>(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.</td>
<td>510H 520H 550H</td>
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</table>
"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
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:


   The following were the patient vitals documented in the EPIC BPAM system:

   - **2054 hours**
     - Temp= 97° F (36.1 °C)
     - SpO2=99%
     - BP=158/80

   - **2056 hours**
     - Temp= 97°F (36.1°C)
     - SpO2=100%
     - BP=158/80

   - **2100 hours**
     - Temp= NO TEMPERATURE DOCUMENTED
     - SpO2=100%
     - BP=NO BLOOD PRESSURE DOCUMENTED

   - **2111 hours**
     - Temp= 97.5°F (36.4°C)
### D5559 Continued From page 39

**SpO2=99%
BP=147/73**

**Temp=NO TEMPERATURE DOCUMENTED
SpO2=99%
BP=145/66**

**Temp=NO TEMPERATURE DOCUMENTED
SpO2=97%
BP=NO BLOOD PRESSURE DOCUMENTED**

**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 2056 hours. Two of the sixteen criteria for a possible transfusion reaction had occurred.

b. One unit of Packed Red Blood Cells (Packed Cells) transfusion started 0118 hours and stopped 0405 hours.

**Patient vitals:**

**Temp=NO TEMPERATURE DOCUMENTED
SpO2=96%
BP=116/51**

**Temp= 96.7°F (35.9°C)
SpO2=98%
BP=105/59**
<table>
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<tr>
<th>ID PREFIX</th>
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<td>Continued From page 40</td>
<td>D5559</td>
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</tbody>
</table>

**0132 hours**
- Temp: 96.6°F (35.9°C)
- SpO2: 97%
- BP: 112/55

**0200 hours**
- Temp: NO TEMPERATURE DOCUMENTED
- SpO2: 93%
- BP: 112/55

**0300 hours**
- Temp: NO TEMPERATURE DOCUMENTED
- SpO2: 93%
- BP: NO BLOOD PRESSURE DOCUMENTED

**0325 hours**
- Temp: NO TEMPERATURE DOCUMENTED
- SpO2: 91%
- BP: 94/46

**0354 hours**
- Temp: NO TEMPERATURE DOCUMENTED
- SpO2: 96%
- BP: NO BLOOD PRESSURE DOCUMENTED

**0400 hours**
- Temp: 97.5°F (36.4°C)
- SpO2: 97%
- BP: NO BLOOD PRESSURE DOCUMENTED

**0405 hours**
- Temp: NO TEMPERATURE DOCUMENTED
- SpO2: 97%
- BP: NO BLOOD PRESSURE DOCUMENTED

**0410 hours**
- Temp: NO TEMPERATURE DOCUMENTED
- SpO2: 96%
### D5559 Continued From page 41

BP=60/35

<table>
<thead>
<tr>
<th>Temp</th>
<th>SpO2</th>
<th>BP</th>
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<tbody>
<tr>
<td>97.6°F (36.4°C)</td>
<td>94%</td>
<td>61/29</td>
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</tbody>
</table>

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 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
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."
**SUMMARY STATEMENT OF DEFICIENCIES**

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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**
### Statement of Deficiencies and Plan of Correction

**A. Building**

**B. Wing**

<table>
<thead>
<tr>
<th>ID</th>
<th>Prefix Tag</th>
<th>Summary Statement of Deficiencies (Each Deficiency Must Be Preceded by Full Regulatory or LSC Identifying Information)</th>
<th>ID</th>
<th>Prefix Tag</th>
<th>Provider's Plan of Correction (Each Corrective Action Should Be Cross-Referenced to the Appropriate Deficiency)</th>
<th>Completion Date</th>
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</thead>
<tbody>
<tr>
<td>D5559</td>
<td>Continued From page 44 overrides is needed.&quot;</td>
<td>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).</td>
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<td>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, &quot;The process to go back and print out the list of alerts is very tedious and performed Ad Hoc (as needed).&quot;</td>
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<td>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 &quot;lockout&quot; in which no alerts would appear for a 5-hour period of time.</td>
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<td>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.</td>
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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).

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..."
### Statement of Deficiencies and Plan of Correction

**Provider/Supplier/CLIA Identification Number:** 45D0053108

**Multiple Construction Building:** A. BUILDING

**Multiple Construction Wing:** B. WING

**Date Survey Completed:** 01/11/2019

**Statement of Deficiencies**

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<th>TAG</th>
<th>Summary Statement of Deficiencies</th>
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</table>
| D5559 | Continued From page 46 | D5559 | Vital signs during a transfusion. The following is a random sampling of those patients:  

a. Patient #56 vitals:  

- **1345 hours (Pre-Transfusion)**  
  - Temp = 97.9°F  
  - Pulse = 103  
  - Respiration = 17  
  - SpO2 = 100%  
  - BP = 152/52

- **1354 hours**  
  - Temp = 98.2°F  
  - Pulse = 107  
  - Respiration = 16  
  - SpO2 = 100%  
  - BP = 148/53

- **1400 hours**  
  - Temp = 98.4°F  
  - Pulse = 105  
  - Respiration = 55  
  - SpO2 = 100%  
  - BP = 113/46

- **1415 hours**  
  - Temp = 95.0°F  
  - Pulse = 112  
  - Respiration = 26  
  - SpO2 = 100%  
  - BP = 129/49

- **1430 hours**  
  - Temp = 98.4°F  
  - Pulse = 118  
  - Respiration = 31  
  - SpO2 = 100%  
  - BP = 126/50
<table>
<thead>
<tr>
<th>ID</th>
<th>Prefix</th>
<th>Tag</th>
<th>Summary Statement of Deficiencies</th>
<th>ID</th>
<th>Prefix</th>
<th>Tag</th>
<th>Provider's Plan of Correction</th>
</tr>
</thead>
<tbody>
<tr>
<td>D5559</td>
<td>Continued From page 47</td>
<td>D5559</td>
<td>Temp=NO TEMPERATURE DOCUMENTED Pulse=106 Respiration=18 SpO2=100% BP=168/60</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1500 hours</td>
<td></td>
<td>Temp=NO TEMPERATURE DOCUMENTED Pulse=NO PULSE DOCUMENTED Respiration=NO RESPIRATION DOCUMENTED SpO2=NO OXYGEN SATURATION DOCUMENTED BP=159/51</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1515 hours</td>
<td></td>
<td>Temp=NO TEMPERATURE DOCUMENTED Pulse=NO PULSE DOCUMENTED Respiration=NO RESPIRATION DOCUMENTED SpO2=NO OXYGEN SATURATION DOCUMENTED BP=152/49</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1530 hours</td>
<td></td>
<td>Temp=NO TEMPERATURE DOCUMENTED Pulse=NO PULSE DOCUMENTED Respiration=NO RESPIRATION DOCUMENTED SpO2=NO OXYGEN SATURATION DOCUMENTED BP=152/59</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1545 hours</td>
<td></td>
<td>Temp=NO TEMPERATURE DOCUMENTED Pulse=94 Respiration=16 SpO2=100% BP=149/47</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1600 hours</td>
<td></td>
<td>Temp=NO TEMPERATURE DOCUMENTED Pulse=NO PULSE DOCUMENTED Respiration=NO RESPIRATION DOCUMENTED SpO2=NO OXYGEN SATURATION DOCUMENTED BP=152/59</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1630 hours</td>
<td></td>
<td>Temp=NO TEMPERATURE DOCUMENTED Pulse=NO PULSE DOCUMENTED Respiration=NO RESPIRATION DOCUMENTED SpO2=NO OXYGEN SATURATION DOCUMENTED BP=152/59</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
### CHI ST LUKE'S HEALTH BCM MEDICAL CENTER

**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

**45D0053108**

**A. BUILDING**

**B. WING**

**DATE SURVEY COMPLETED**

01/11/2019

---

<table>
<thead>
<tr>
<th>ID PREFIX TAG</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
<th>ID PREFIX TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</th>
<th>COMPLETION DATE</th>
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</thead>
<tbody>
<tr>
<td>D5559</td>
<td>Continued From page 48 b. Patient vitals: Temp=NO TEMPERATURE DOCUMENTED Pulse=55 Respiration=16 SpO2=96% BP=116/51</td>
<td>D5559</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0117 hours Temp= 96.7°F Pulse=52 Respiration=12 SpO2=98% BP=105/59</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0132 hours Temp= 96.6°F Pulse=51 Respiration=10 SpO2=97% BP=112/55</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0200 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=56 Respiration=19 SpO2=93% BP=112/55</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0300 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=68 Respiration=22 SpO2=93% BP=NO BLOOD PRESSURE DOCUMENTED</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0325 hours Temp=NO TEMPERATURE DOCUMENTED Pulse=64</td>
<td></td>
<td></td>
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</tr>
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</table>

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Event ID: YDMH11
Facility ID: TX22010121

If continuation sheet Page 49 of 64
**SUMMARY STATEMENT OF DEFICIENCIES**

<table>
<thead>
<tr>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
<th>COMPLETION DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>D5559</td>
<td>Continued From page 49</td>
<td>SpO2=91% BP=94/46</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0354 hours</td>
<td>Temp=NO TEMPERATURE DOCUMENTED Pulse=60 Respiration=21 SpO2=96% BP=NO BLOOD PRESSURE DOCUMENTED</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0400 hours</td>
<td>Temp=97.5°F Pulse=62 Respiration=21 SpO2=97% BP=NO BLOOD PRESSURE DOCUMENTED</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0405 hours</td>
<td>Temp=NO TEMPERATURE DOCUMENTED Pulse=60 Respiration=18 SpO2=97% BP=NO BLOOD PRESSURE DOCUMENTED</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**c. Patient #6 vitals:**

<table>
<thead>
<tr>
<th>ID</th>
<th>PREFIX</th>
<th>TAG</th>
<th>PROVIDER'S PLAN OF CORRECTION</th>
<th>COMPLETION DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0111 hours (Pre-Transfusion)</td>
<td>Temp=97.6°F Pulse=82 Respiration=16 SpO2=100% BP=110/46</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0123 hours</td>
<td>Temp=NO TEMPERATURE DOCUMENTED Pulse=NO PULSE DOCUMENTED Respiration=NO RESPIRATION DOCUMENTED SpO2=NO OXYGEN SATURATION DOCUMENTED</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
D5559 Continued From page 50
BP=106/40

0130 hours
Temp=NO TEMPERATURE DOCUMENTED
Pulse=79
Respiration=19
SpO2=100%
BP=NO BLOOD PRESSURE DOCUMENTED

0145 hours
Temp=NO TEMPERATURE DOCUMENTED
Pulse=79
Respiration=19
SpO2=100%
BP=108/45

0200 hours
Temp=NO TEMPERATURE DOCUMENTED
Pulse=79
Respiration=19
SpO2=100%
BP=NO BLOOD PRESSURE DOCUMENTED

0203 hours
Temp=NO TEMPERATURE DOCUMENTED
Pulse=NO PULSE DOCUMENTED
Respiration=NO RESPIRATION DOCUMENTED
SpO2=NO OXYGEN SATURATION DOCUMENTED
BP=89/42

0215 hours
Temp=NO TEMPERATURE DOCUMENTED
Pulse=90
Respiration=26
SpO2=99%
BP=NO BLOOD PRESSURE DOCUMENTED

0223 hours
### Patient #5 vitals:

**0300 hours**
- Temp: 98.9°F
- Pulse: 84
- Respiration: 23
- SpO2: 99%
- BP: 116/40

**0315 hours**
- Temp: 98.9°F
- Pulse: 83
- Respiration: 20
- SpO2: 100%
- BP: 116/40

**0345 hours**
- Temp: 98.6°F
- Pulse: 67
- Respiration: 24
- SpO2: 92%
- BP: 116/60

**1615 hours (Pre-Transfusion)**
- Temp: 98.6°F
- Pulse: 67
- Respiration: 24
- SpO2: 92%
- BP: 116/60

**1645 hours**
- No vital signs documented
### Statement of Deficiencies and Plan of Correction

**Provider/Supplier/CLIA Identification Number:**

45D0053108

**Date Survey Completed:**

01/11/2019

**Name of Provider or Supplier:**

CHI ST LUKE'S HEALTH BCM MEDICAL CENTER

**Street Address, City, State, Zip Code:**

6720 BERTNER AVENUE
HOUSTON, TX  77030

**Summary Statement of Deficiencies**

<table>
<thead>
<tr>
<th>ID</th>
<th>Prefix</th>
<th>Tag</th>
<th>Date</th>
<th>事件描述</th>
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</thead>
<tbody>
<tr>
<td>D5559</td>
<td></td>
<td></td>
<td>1700 hours</td>
<td>Temp=NO TEMPERATURE DOCUMENTED, Pulse=66, Respiration=20, SpO2=98%, BP=NO BLOOD PRESSURE DOCUMENTED</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1718 hours</td>
<td>Temp=99.2°F, Pulse=67, Respiration=28, SpO2=NO OXYGEN SATURATION DOCUMENTED, BP=NO BLOOD PRESSURE DOCUMENTED</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1800 hours</td>
<td>Temp=NO TEMPERATURE DOCUMENTED, Pulse=62, Respiration=13, SpO2=NO OXYGEN SATURATION DOCUMENTED, BP=NO BLOOD PRESSURE DOCUMENTED</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1900 hours</td>
<td>Temp=NO TEMPERATURE DOCUMENTED, Pulse=81, Respiration=32, SpO2=NO OXYGEN SATURATION DOCUMENTED, BP=NO BLOOD PRESSURE DOCUMENTED</td>
</tr>
</tbody>
</table>

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.

**Analytic Systems Quality Assessment**

CFR(s): 493.1289(b)(c)
(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
### Statement of Deficiencies and Plan of Correction

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<th>COMPLETION DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>D5793</td>
<td></td>
<td></td>
<td>Continued From page 54 blood product transfused - Enter in the last set of vital signs - Click Accept &amp; Complete.”</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 revealed Fresh Frozen Plasma (FFP) was transfused on 2056 hours and stopped 2315 hours. The documented completion was at 1011 hours (elapsed time of 2 days, 10 hours, and 56 minutes between end of transfusion and completion).

Patient Packed Red Blood Cells (PRBC's) was transfused on 0118 hours and stopped 0405 hours. The documented completion was 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
<table>
<thead>
<tr>
<th>ID</th>
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</tr>
</thead>
<tbody>
<tr>
<td>D5793</td>
<td>Continued From page 55 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.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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

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

Patient #41: Leuko-reduced RBC's transfusion started 2226 hours, end was blank as of 1156 hours, and completion was 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..."
### Statement of Deficiencies and Plan of Correction

**A. Building**

**State of Texas**

**Provider/Supplier/CLIA Identification Number:**

45D0053108

**Date Survey Completed:**

C
01/11/2019

**Name of Provider or Supplier:**

CHI St. Luke's Health BCM Medical Center

**Street Address, City, State, Zip Code:**

6720 Bertner Avenue
HOUSTON, TX 77030

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**Summary Statement of Deficiencies**

<table>
<thead>
<tr>
<th>ID</th>
<th>Prefix</th>
<th>Tag</th>
<th>ID</th>
<th>Prefix</th>
<th>Tag</th>
<th>Provider's Plan of Correction</th>
</tr>
</thead>
<tbody>
<tr>
<td>D5793</td>
<td>Continued From page 56</td>
<td>to ongoing problems with closure of transfusion events in EPIC. Ongoing training will be needed. &quot;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.
### Summary Statement of Deficiencies

<table>
<thead>
<tr>
<th>ID</th>
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<th>TAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>D5793</td>
<td>Continued From page 57</td>
<td>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.</td>
</tr>
<tr>
<td>D6076</td>
<td>LABORATORY DIRECTOR</td>
<td>CFR(s): 493.1441</td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>This CONDITION is not met as evidenced by:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>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)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>D6082</td>
<td>LABORATORY DIRECTOR RESPONSIBILITIES</td>
<td>CFR(s): 493.1445(e)(1)</td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>This STANDARD is not met as evidenced by:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Based on direct observation, facility/laboratory</td>
<td></td>
</tr>
<tr>
<td>ID PREFIX TAG</td>
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<td>ID PREFIX TAG</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>D6082</td>
<td>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.</td>
<td>D6082</td>
</tr>
<tr>
<td>D6094</td>
<td>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).</td>
<td>D6094</td>
</tr>
<tr>
<td>D6096</td>
<td>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7)</td>
<td>D6096</td>
</tr>
<tr>
<td>ID</td>
<td>PREFIX</td>
<td>TAG</td>
</tr>
<tr>
<td>----</td>
<td>--------</td>
<td>-----</td>
</tr>
<tr>
<td>D6096</td>
<td>Continued From page 59</td>
<td>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).</td>
</tr>
<tr>
<td>D6101</td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

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
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
LABORATORY TECHNICAL SUPERVISOR

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
**STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION**

<table>
<thead>
<tr>
<th>(X4) ID</th>
<th>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</th>
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<th>(X5) COMPLETION DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>D6108</td>
<td>Continued From page 61 provide technical oversight of the laboratory (refer to D6118 and D6121).</td>
<td>D6108</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D6118</td>
<td>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5)</td>
<td>D6118</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>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).</td>
<td></td>
<td></td>
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<tr>
<td>D6121</td>
<td>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i)</td>
<td>D6121</td>
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<td>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:</td>
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<tr>
<td>ID PREFIX TAG</td>
<td>SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)</td>
<td>ID PREFIX TAG</td>
<td>PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)</td>
<td>COMPLETION DATE</td>
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<td>D6121</td>
<td>Continued From page 62</td>
<td>D6121</td>
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</table>

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 qualify 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:
## Statement of Deficiencies and Plan of Correction

### A. Building

<table>
<thead>
<tr>
<th>ID</th>
<th>Prefix</th>
<th>Tag</th>
<th>Summary Statement of Deficiencies (Each Deficiency Must Be Preceded By Full Regulatory Or LSC Identifying Information)</th>
<th>ID</th>
<th>Prefix</th>
<th>Tag</th>
<th>Provider's Plan of Correction (Each Corrective Action Should Be Cross-Referenced To The Appropriate Deficiency)</th>
<th>Completion Date</th>
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<tr>
<td>D6121</td>
<td>Continued From page 63</td>
<td>CMS- Centers for Medicare &amp; Medicaid services</td>
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</table>

### B. Wing

**Name of Provider or Supplier:**

**CHI St Luke’s Health BCM Medical Center**

**Street Address, City, State, Zip Code:**

6720 Bertner Avenue

Houston, TX 77030

**Provider's Plan of Correction**

**Event ID:** YDMH11

**Facility ID:** TX22010121

**If continuation sheet Page:** 64 of 64

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**Note:** This document is an extract from the CMS-2567(02-99) form, which is used by the Centers for Medicare & Medicaid Services to report deficiencies and plans of correction for healthcare providers and suppliers.