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Kaiser Permanente Medical Center, San Francisco
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Work Instruction

Title: TS-Transfusion Reaction Work-up		**WI Number** SFOWI-0120 **Revision:** 20
Department: Immunohematology **Area:** 2425 Geary Blvd SFO Hospital Lab	***Approved & Released Work Instruction***	**Implementation Date:** 01/11/2018
Type of Document: Work Instruction		**Review Period -** 340 **Days**

PURPOSE

To detect, report and evaluate suspected complications of transfusion, either acute which occurs within 24 hours of blood administration or delayed which occurs days to weeks after transfusion, manifesting hemolysis or cytopenia. **Transfusion reaction work-up is a STAT procedure**. Early recognition is the key to minimizing serious complications. Immediate actions to be taken by the nursing staff include the following:

A. Always stop the transfusion and disconnect the entire infusion set from the needle/catheter.
B. Using a new infusion set, keep the IV line open.
C. Notify the patient's physician so that treatment, if necessary, can begin immediately.
D. Notify Transfusion Service immediately.
E. Send a post-transfusion sample, the implicated blood product including the infusion set and a completed "Transfusion Reaction Investigation" form to the laboratory for immediate work-up.

REAGENT

Daily Blood Bank reagents.

EQUIPMENT

Properly completed "**Transfusion Reaction Investigation**" Form.

SPECIMEN

OBTAIN THE FOLLOWING IMMEDIATELY:

A. One post-transfusion pink or lavender (EDTA) top tube drawn from an extremity away

from the transfusion site, signed, timed and dated.

B. The blood component bag and the transfusion set with the IV solution attached.

C. "**Transfusion Reaction Investigation**" form with the blue section completed by RN or MD.

D. First available urine sample if suspect hemolytic transfusion reaction.

CONTROL

A. The Medical Director or designated pathologist reviews and interprets the transfusion reaction work-up on the next working day.

B. Supervisor reviews the final "**Transfusion Reaction Investigation**" form using the Transfusion Reaction Work-up Checklist.

C. If there is any discrepancy or positive result found in the transfusion reaction work-up, notify the Medical Director or the pathologist on call.

D. Need authorization from a pathologist for subsequent blood product(s) transfusion.

LIMITATIONS

A. **30-day Samples**

1. Due to RBCs degradation during prolong storage, **interpret Hemolysis, DAT and ABORh results with CAUTION on pre-transfusion samples older than 17 days. Other extended testing results e.g. ABSC and phenotype, may also be adversely affected.**

PROCEDURE

A. **Visual Inspection of the Transfusion Set**

1. If there is another bag attached to the Y tubing, make sure it is saline (0.9% NaCl). No other solution or medication can be added or infused through the same line as blood or blood products.

B. **Laboratory evaluation** and documentation on the "**Transfusion Reaction Investigation** " form.

1. Determine specimen acceptability. **Do not delay testing even if the specimen is not properly labeled** (as long as it has the patient's full name and MR#) **or the "Transfusion Reaction Investigation" form is incomplete.**
2. Pull all Transfusion Service Crossmatch / Component Report and attach to the " **Transfusion Reaction Investigation**" form. Quarantine products to prevent release of blood products prior to completion of work up.
3. Perform **clerical check** on all labels and paperwork involved.
   a. Copy the above information from the LIS label attached to the unit bag and record on the line of **BAG TAG**.
   b. Copy the unit number and the unit ABORh from the actual unit and record on the line of **BAG FACE**.
   c. Record the **expiration date of the unit returned** under the Laboratory evaluation.
   d. Record from the **pre-transfusion specimen** the patient's name and medical record number and accession number.

e. Record the patient's name, medical record number, accession number, patient's ABORh, unit number and unit ABORh from the Blood Bank copy of the Transfusion Service Crossmatch / Component Report form on the line of **REPORT FORM**.
f. Compare all the information recorded and the patient information on the upper right hand corner.
g. Interpret the clerical check as no error found if no discrepancy exists, including special need requirements. Record under **Clerical Check**.
h. If clerical errors are found and/or test results indicate acute hemolytic immune transfusion reaction, notify the attending physician immediately.
    i. The supervisor and the Medical Director or designee should also be notified.
    ii. Do further work up as described in Transfusion Reaction Work-up Extended Evaluation section.
    iii. Investigate any clerical error including other patient(s) who may be at risk due to specimen mislabeling.

4. **Visual hemolysis**
    a. Visually inspect for hemolysis on both the pre- and post-transfusion specimen. Record result in the LIS and on the "**Transfusion Reaction Investigation**" form.
    NOTE for Pre-transfusion specimens older than 17 days:
        i. Interpret hemolysis with **caution.**
        ii. Inspect the top portion of the plasma immediately upon retrieval (plasma close to the packed RBC usually demonstrates hemolysis).
        iii. Do not disturb the plasma or centrifuge specimen before inspecting it first.
    b. If the post-transfusion specimen is hemolyzed, request a new specimen to rule out hemolysis caused by a traumatic draw.
    c. If the **second** post-transfusion specimen is **still hemolyzed:**
        i. Perform extended work-up
        ii. Compare the pre and post-transfusion Hemoglobin/Hematocrit values
        iii. Request a urine sample.

5. ABORh Rechk
    a. Perform ABORh on post-transfusion specimen.
    b. Enter result in the LIS and compare it to the pre-transfusion specimen ABORh result.
    c. Also record result on the "**Transfusion Reaction Investigation**" form.
    d. If there is any **discrepancy** between the **pre and post-transfusion** specimens, **retype the pre-transfusion** sample and simultaneously request another specimen for repeat ABORh.
    NOTE: Interpret result with **caution** when typing a pre-transfusion **specimen older than 17 days.**

6. Direct Antiglobulin Test
    a. Perform DAT (first using poly AHG then mono AHG per protocol) on the

post-transfusion specimen and record results in the LIS and on the form.

b. If DAT is negative and the patient has no hemoglobinemia and/or hemoglobinuria, no further work-up is required.

c. If **DAT is negative** and the **patient has hemoglobinemia and/or hemoglobinuria**, perform **elution.**

d. **If DAT is positive,** perform DAT on the pre-transfusion specimen. **NOTE: Interpret result** with **caution** when testing a pre-transfusion **specimen older than 17 days.**

e. If the DAT of the pre- and the post-transfusion specimens has the same strength and no hemoglobinemia and hemoglobinuria, no further work-up is required.

f. Perform **elution** if the **DAT IgG of the pre-transfusion** specimen is **negative** and the **post-transfusion** specimen **DAT IgG is positive or stronger** than the pre-transfusion specimen.

g. Perform **elution** if the **post-transfusion DAT IgG** is **positive** and the **pre-transfusion sample is older than 17 days.**

h. If eluate yields specific alloantibody, type the segment from transfused unit for that antigen and performs Transfusion Reaction Work-up extended Evaluation.

i. Test the eluate against the A1 cell and B cell if the component given contains ABO incompatible plasma.

7. Urine if needed (when hemolysis is suspected)

a. Do dipstick test for hemoglobin on the post transfusion urine.

b. If hemoglobin is positive, centrifuge an aliquot and do a microscopic for RBCs.

c. If supernatant is clear and RBC is present under microscopic examination, it is not hemoglobinuria.

d. Record result under **Urine, if needed** on the form.

8. **Culture / Gram Stain**

a. ***Yes***, if suspect **bacterial contamination** or ordered by MD. See sections C and E for more information. **Gram Stain should be performed STAT.**

b. *No,* if patient has no fever.

9. **No evidence** of hemolytic transfusion reaction when:

a. Clerical check indicates no discrepancy and donor / recipient ABORh are compatible and the component satisfies patient's special need(s).

b. No hemoglobinemia/hemoglobinuria.

c. DAT is negative.

Otherwise, initiate extended investigation. Notify pathologist and the attending physician.

10. **Lab Comments:**

a. Document Gram Stain result when applicable.

b. Document notification of MD and/or pathologist when applicable.

C. **Notify the pathologist and the attending physician immediately** if the following symptoms occur:

1. Suspect **Acute Hemolytic Transfusion Reaction (AHTR) - immune, (intravascular)** rapid red blood cells destruction during, immediately after, or within 24 hours of transfusion with any of the following:
    a. Chills / Rigors
    b. Fever
    c. Back / Flank pain
    d. Hypotension
    e. Hemoglobinuria during or shortly after transfusion
    f. Epistaxis
    g. Oliguria / Anuria
    h. Renal failure
    i. Disseminated intravascular coagulation (DIC)
    j. Pain and / or oozing at IV site.

    See section D. for further work-up instructions.
2. Suspect **Bacterial Contamination (Transfusion Transmitted Infection TTI)** if
    a. Increase temperature (often >1^{o}C or 2^{o}F) and **with at least one** of the following:
        i. Shaking chills or rigor
        ii. Nausea
        iii. Vomiting
        iv. Abdominal cramps
        v. Decrease of more than 20mm Hg in Diastolic or Systolic blood pressure.
        vi. Clinical suspicion of bacterial contamination.

    NOTE: See section E. for further instructions.
3. Suspect **Anaphylactic Reaction (Allergic Reaction)** if the following symptoms are marked:
    a. Shock
    b. Dyspnea
    c. Wheezing
    d. Sudden onset of flushing and hypertension followed by hypotension.
    e. Sometimes nausea and vomiting
    f. Quantitative immunoglobulin level may reveal congenital IgA deficiency and concurrent high-titered IgG antibody to IgA.
4. Suspect **Transfusion-Associated Circulatory Overload (TACO).** Volume infusion that cannot be effectively processed by the recipient either due to high rates and volumes of infusion or underlying cardiac or pulmonary pathology. Characterized by new onset or exacerbation of >3 of the following symptoms within 6 hours of transfusion:
    a. Acute respiratory distress (dyspnea, orthopnea, cough)
    b. Evidence of positive fluid balance
    c. Elevated BNP (Brain Natriuretic Peptide)
    d. Radiographic evidence of pulmonary edema
    e. Evidence of left heart failure
    f. Elevated CVP (central venous pressure).
5. Suspect **Transfusion-Related Acute Lung Injury (TRALI)** if the following

symptoms occur:

a. Acute hypoxemia with PaO_2 / FIO_2 ratio <= 300mm Hg or Oxygen saturation <90% on room air
b. Dyspnea, cyanosis
c. Fever, chills, and possible hypotension
d. X-ray shows bilateral pulmonary non-cardiac edema not more than 6 hours (usually much sooner) of transfusion with no prior history of ALI.
e. Recorded fluid balance not indicative of volume overload.

NOTE: See section F for further instructions.

D. **Extended Work-up**

If suspect **Hemolytic Transfusion Reaction** or instructed by the pathologist, perform the following in addition to the initial work-up. Use the Supplemental Worksheet and the Transfusion Reaction Work-up Extended Evaluation forms for documentation if needed.

1. **Hemolysis Due to Recipient's Antibody to Red Cell Antigen**
   a. Record the DAT on the pre and post-transfusion specimens.
   b. Repeat the ABORh on the unit using the attached segment and the pre-transfusion specimen.
   c. Perform antibody screen on the pre and post-transfusion plasma.
   d. Request a plain red top tube if suspect hemolysis due to antibody that activates complement. Repeat ABSC using poly AHG.
   e. Perform crossmatch on the implicated donor RBC using pre-and post-transfusion plasma.
   f. Perform antibody identification if indicated.
   g. If new antibody is identified, antigen type all units transfused.
   h. Send specimen to Reference Lab at BCP for further studies if unable to identify the antibody.
   i. Repeat antigen typing on the donor unit for all previously identified antibodies.
2. **Hemolysis Due to Problem with Donor Unit**
   a. Perform DAT on the **donor** unit.
   b. Centrifuge a small aliquot of blood from **donor** unit and observe for pink plasma indicating hemolysis.
   c. Notify blood supplier immediately if donor unit is confirmed to be hemolyzed.
3. **Hemolysis Due to Drug**
   a. Check medication history for drugs that can cause hemolysis (Drug Induced Hemolytic Anemia).
   b. If possible, the culpable drug should be substituted with another drug not known to cause hemolysis.
   c. Notified pathologist and patient's physician immediately if suspect DIHA.
4. **Hemolysis Due to Recipient's Polyagglutinable Red Cells**
   a. Intravascular hemolysis that occurs in the absence of RBC transfusion **OR** after transfusion of plasma containing blood products may indicate polyagglutinable autologous RBC.

b. The patient's cells may have a positive DAT C3 and are non-reactive with **cord** plasma but reactive with all **adult** plasma.
c. Check patient's history for recent bacterial infection.
d. Send to Reference Lab to confirm suspected polyagglutination.
e. Notified pathologist and patient's physician immediately.

NOTE: Plasma products e.g. FFP and cryoprecipitate should not be dispensed. Washed pRBCs and washed platelets should be given.

5. **Additional Testing may Include:**
   a. Bilirubin, hemoglobin and hematocrit 5-7 hours post-transfusion.
   b. Urine hemosiderin.
   c. Serum haptoglobin in both pre- and post-transfusion samples.
   d. DIC panel (fibrinogen, platelet count, PT, PTT, D-dimers).
   e. Potassium level on the patient for possible hyperkalemia.
   f. Creatinine on the patient for possible renal failure.

E. In case of suspected **Bacterial Contamination**,

1. Request **STAT** Gram Stain. Culture of the donor unit must be performed regardless of the gram stain results. **Note:** Gram stain individual units in the pooled cryoprecipitate if available. (See Bact S.O.P. Blood Transfusion Reaction).
   a. **Fill out a manual "Microbiology Laboratory Requisition" with the following information:**
      i) Patient Information: **Patient's last name, first name**
      Patient's MRN
      ii) Ordering Provider: **current CLIA Laboratory Director.**
      Consulting Provider: **current BB Medical Director.**
      iii) Priority: **EX**
      iv) Check the box for **Gram Stain**.
      Source/Specimen type: **See table below**
      v) Check box for OTHER.
      Write **CULTURE (C TRXN)** and **Source:** (see table below)

Blood Product	Source/Specimen type
Cryoprecipitate	**TRXN-Cryo**
Granulocytes	**TRXN-Gran**
Plasma	**TRXN-Plasma**
Platelets	**TRXN-Plt**
Packed RBCs	**TRXN-RBC**
Whole Blood	**TRXN-WB**

   b. Give the requisition and the blood product to the Micro Lab Assistant. **Ask LA for a copy of the requisition (must have RILIS labels with Acc# of Gram Stain and Culture orders) after he/she finishes the DOE.** Attach it to the "**Transfusion Reaction Investigation**" form.

NOTE: LA should DOE Gram Stain and C TRXN.

2. At the same time, notify the physician to order and collect blood culture from the patient immediately.
3. Notify blood supplier immediately by phone and follow up by completing BCP's "**Report of Transfusion Adverse Reaction**" form. Fax the report to BCP. BCP will quarantine any products from the same donor and initiate bacterial testing.
4. Quarantine the other part(s) of the divided unit and other components of the same unit number, if any in our inventory.
5. As soon as possible, inform the pathologist that there is a suspected bacterial contamination.
6. Document the Gram Stain results on the Comments section of the "**Transfusion Reaction Investigation**" form. Attach CIPs or ORV print screen results to the form.
7. Report positive Gram Stain result to the pathologist, attending physician, and blood supplier immediately.
8. Culture follow up:
   a. Transfusion Service will monitor and follow up on the patient and donor culture results.
   b. If the donor or patient culture is positive, Regional Bacteriology will notify Transfusion Service.
      i) Transfusion Service will notify the pathologist, attending physician, and blood supplier.
   c. If the donor culture is negative, notify the blood supplier so that any quarantined units can be released.
   d. Document the culture results on the Comments section of the "**Transfusion Reaction Investigation**" form. Attach CIPs or ORV print screen results to the form.

F. In case of suspected **TRALI**,
1. Notify pathologist, patient's MD and the blood supplier of the suspected TRALI immediately by phone.
2. Identify the units administered in the last 6 hours.
3. Complete BCP's "**Report of Transfusion Adverse Reaction**" form.
4. If patient's MD is needed to complete the medical information, write the patient's full name and MRN on top of page and fax it to the MD ASAP.
5. Fax the completed form to BCP. BCP will quarantine any products from the same donor.
6. If instructed by BCP to send patient samples for HLA typing, request patient's MD to collect 2 EDTA tubes. **Request that MD add BB Medical Director as Consulting Provider when placing the order in HealthConnect. Otherwise, add the information as Order Comments.**
7. Send samples to BCP Reference Lab for TRALI work up with a copy of the completed form. Attach the original with the "**Transfusion Reaction Investigation**" form.

8. BCP will provide information for the definitive testing:
    a. Anti-neutrophil antibody on serum from all of the implicated female donors and from the pre-transfusion serum of the recipient.
    b HLA Class 1 and 2 antibody on all female donors and from recipient's pre-transfusion sample.
    c. Granulocyte crossmatch between serum from any donor found positive in either of the two tests above and the fresh granulocytes from the recipient.
9. BCP Pathologist will prepare and send a final report when the TRALI work up is completed.

PROCEDURE NOTES

A. DOCUMENTATION and RESULTS

1. Record all results on the "**Transfusion Reaction Investigation**" form.
2. Enter results in LIS.
3. Attach the serological work-up if applicable and other relevant paperwork to the form and fax to Pathology. Keep the original report in Blood Bank for pathologist review and signature the next working day. Save the fax confirmation as BB copy.
4. At the completion of the transfusion reaction work-up, if the patient needs subsequent transfusion, notify pathologist and ask for approval to release additional blood products. Document this in the Blood Bank Communication log book or Blood Bank Comments in LIS.
5. Pathologist or designee will review workup and write their evaluation on the report. Pathologist will consult with patient's physician if necessary or if the adverse event is deemed serious.
6. Pathologist will used NHSN Hemovigilance standardized definitions and criteria to evaluate symptoms and classify the Adverse Reaction.
7. Pathologist's evaluation will be entered into the LIS which transmits to the patient's electronic medical record.
8. File completed report in the Transfusion Reaction binder after supervisory review.

B. SYMPTOMS ASSESSMENT and ADVERSE REACTION CLASSIFICATION

1. Based on NHSN Hemovigilance standardized definitions and criteria:
    a. Transfusion-associated circulatory overload (TACO)
    b. Transfusion-related acute lung injury (TRALI)
    c. Transfusion-associated dyspnea (TAD)
    d. Allergic reaction
    e. Hypotensive transfusion reaction
    f. Febrile non-hemolytic transfusion reaction (FNHTR)
    g. Acute hemolytic transfusion reaction (AHTR)
    h. Delayed hemolytic transfusion reaction (DHTR)
    i. Delayed serologic transfusion reaction (DSTR)
    j. Transfusion-associated graft vs. host disease (TAGVHD)

k. Post transfusion purpura (PTP)
l. Transfusion-transmitted infection (TTI)
m. Other/Unknown

C. EXTERNAL REPORTING

1. Notify FDA of any Biological Product Deviation (See SFOWI-0156 Biological Product Deviation Report).
2. Notify QA department of Severe reactions and Sentinel events (See SFOWI-0155 Unusual Occurrence Management).
3. Notify Blood Supplier of suspected bacterial contamination, TRALI, infectious diseases or an attribute of the donor that may have caused the adverse event.
   a. The collecting facility shall be notified immediately and subsequently in writing, when a suspected transfusion fatality or other unexpected serious complication occurs and is suspected to be due to an attribute of the donor or a unit or blood or component.

   Note: Also refer to SFOWI-0155 Unusual Occurrence Management, SFOWI-0050 Transfusion Transmitted Disease, SFOWI-0051 LookBack Notification.
4. **Notify FDA**'s Center for Biologics Evaluation and Research (CBER) in case of a **Fatal Reaction**.
   a. **As soon as possible after confirming a complication of transfusion to be fatal** by:
      i. phone call: 800-835-4709 or 240-402-8010 **during regular business hours**

      OR

      ii. Voice-mail: 240-402-9160 **after regular business hours**

      OR

      iii. E-mail: fatalities2@fda.hhs.gov

      OR

      iv. Fax number: 301-595-1304 or 301-827-0333, Attn: CBER Fatality Program Manager

   b. **In writing, within 7 days after the fatality** to the address below:
      U.S. Food and Drug Administration
      Center for Biologics Evaluation and Research
      Document Control Center
      10903 New Hampshire Avenue
      WO71, G112
      Silver Spring, MD 20993-0002
      NOTE: Verify that the address is current by going to the FDA CBER website prior to mailing.

   c. Instructions for reporting are available on the FDA CBER website.

REFERENCES

A. AABB, Standards for Blood Banks and Transfusion Services, current edition, Bethesda,

MD.
B. AABB Technical Manual, current edition, Bethesda, MD.
C. FDA CBER website.

Associated Documents:

External Documents:

BCP's forms printed from website

bv-hv-protocol-current_12-4-17.pdf

Associated Documents:

SFOWI-0121 -- TS-Delayed Transfusion Reaction
SFOWI-0155 -- TQ-Unusual Occurrence Management
SFOWI-0050 -- TC Transfusion-Transmitted Disease
SFOWI-0051 -- TC Lookback Notification
SFOWI-0156 -- TQ-Biological Product Deviation Reporting

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Documents Generated:

Document Revision History:

Revision: 20	**Date Created:** 09/22/2005 **Date of Last Revision:** 01/11/2018	**Last Approval Date:** 01/11/2018

Document Author: Cara H Lim	**Document Manager:** Richard Chui

Reason for Change:

Revision:	Sec/Para Changed	Change Made:	Date
1	N/A	Initial Issue of Document	12/22/05
2	Documentation and result Approver	Notify pathologist and get approval for release of product. New Lab Director	9/30/06 1/14/07
3	Procedure	Change Lifeline procedure to RILIS procedure	5/13/07
4	Procedure Approver	Modify RILIS TRXN PATH resulting. New Lab Director	6/1/07
5	Procedure A-5-b	Changed Lifeline to computer	11/30/07
6	Procedure	Notification of positive culture from Regional lab should be called to the pathologist to notify attending physician immediately. STAT blood culture on the patient should be ordered,.	4/5/08
6	Sections B-3 & D (Revised by Wanda Lau on 6/6/08)	Revised (B-3) Symptoms Assessment for Bacterial Contamination and Section D for suspected bacterial contamination	6/6/08
7	Procedure F. Procedure B.4. Procedue A.10. Procedure A.	CDC Adverse Reaction Definitions and Case Definition Criteria Added TACO. Added Lab Comments. Deleted Computer check.	10/15/10
8	Procedure G. SPECIMEN	Deleted RILIS procedure. Added obtained "Transfusion Reaction Investigation" form immediately. Added 'and DOCUMENT'.	6/1/11

	Approver	Changed Medical Director.	
9	Specimen and Document	Changed 'needed' to 'suspect hemolytic transfusion reaction'.	10/21/11
10	Procedure Notes.B.3. Procedure C. Procedure D. Procedure D.1. Associated Documents	Changed instructions to keep the completed original TRXN form in BB. Use of the Transfusion Reaction Work-up Extended Evaluation form is changed to optional. Added Supplemental Worksheet. Changed the sequence of instructions. Added STAT for gram stain priority. Added 2 documents.	9/20/12
11	Approver Procedure D.1.a.&b. Procedure D.6. Procedure D.8. Procedure E.	New Lab Director. Added instructions for ordering Gram Stain & Culture per new Regional Lab's protocol. Added instructions to document Gram Stain results on form. Added instructions to document culture results on form. Revised section and changed the chronology of the tasks. Added instructions to include Dr.Cherny as Consulting Provider on the HLA Typing order.	3/4/13
12	Procedure Procedure A.	Reformatted numbering. New.	5/16/13
13	Approver Whole document	New BB Medical Director. Changed Dr.Fang to current CLIA Laboratory Director and Dr.Serrano to current BB Medical Director.	8/6/13
14	Procedure C. Procedure C.3.	Updated FDA contact information. Added Note to refer to associated SOPs.	10/4/13
15	Procedure E.1.a.i)	Revised. Changed from ordering transfusion reaction culture on QA MRN to actual patient MRN effective 7/17/14 per standardized KP NCAL BB Peer Group practice.	7/2/14
16	Procedure C.2.v. Procedure Notes C.4.	Defined drop in blood pressure as >20mm Hg for diastolic or systolic in suspected bacterial infection (per information from Dr.Pandey at BCP). Updated FDA CBER's contact information.	9/12/14
17	Limitations Purpose D. Purpose E. Procedure B.4.a. Procedure B.4.c.ii.&iii. Procedure B.5.d. Procedure B.6.d. Procedure B.6.g.	New section for 30-day. Added to interpret with caution DAT, ABORh, hemolysis and other extended tests results e.g. ABSC & phenotype on pre-tx sample > 17 days old. Added to notify Transfusion Service immediately of the TRXN. Revised instructions to send TRXN sample STAT to lab. Added NOTE instructions to interpret Hemolysis with **caution** and not to disturb plasma prior to visual inspection on sample >17 days old. Added to check pre & post-tx Hgb/Hct and request for urine. Added instructions to retype pre-tx sample if there is an ABORh discrepancy between the pre and the post-tx sample. Added to interpret ABORh results with **caution** on pre-tx sample >17 days old. Added to interpret with caution DAT results on samples >17 days old. Added to perform elution on post-tx DAT positive sample when pre-tx sample is >17 days old.	7/23/15
17	Implementation date Purpose E. Whole document	Changed from 9/1/15 to 10/5/15 due to postponement of the 30 Day Pre-Op Specimen implementation. Added to send the implicated blood product with infusion set for TRXN work-up. Updated BCP's form for reporting TRXN.	8/31/15 9/28/15
18	Procedure F. Procedure F.3 Procedure E. Procedure Notes	Changed instructions from automatically request patient samples for HLA typing to only if requested by BCP. Deleted instructions to complete the first page of the form. Deleted instructions to add template TRXN CULT DETAILS as Order Comments. Modified sections per revised AABB Std. 7.3 requiring the use of standardized definitions to classify adverse events.	6/22/16

	Procedure D. Procedure D.1.d Procedure D.3 Procedure D.4	BV-HV-protocol-current_Jan 2016_6-13-16.pdf Reformatted into subsections. Added instructions to request for plain red top tube if suspect antibody that activates complement and repeat ABSC with poly AHG. New. Added instructions to check medication history for Drug Induced Hemolytic Anemia. New. Added instructions for suspected TRXN due to polyagglutination in the absence of RBC transfusion or after plasma transfusion.	8/9/16
19	Procedure D.2.c. Procedure D.3.c. and 4.e. Procedure Notes A.5. Procedure Notes C.4. Procedure Notes A.7.	Notify blood supplier immediately if donor unit is confirmed to be hemolyzed. Added to notify patient's physician immediately if suspect DIHA and polyagglutinable red cells. Added that pathologist will consult patient's doctor if necessary or serious adverse event. Updated FDA contact information. Added that pathologist's evaluation will be entered into the LIS which transmits to the patient's electronic medical record.	10/20/16
20	External Documents	Updated to the latest version of NHSN Hemovigilance Module Surveillance Protocol v2.4.	12/4/17

Notification List:

Approvals:

First Approver's Signature

Name: Maria F Serrano/CA/KAIPERM — Jan 11, 2018 09:07:45 AM PST - Approved by: Maria F Serrano/CA/KAIPERM
Title: Transfusion Service Medical Director

Second Approver's Signature

Name: Eric Suba/CA/KAIPERM — Jan 2, 2018 02:46:16 PM PST - Approved by: Eric Suba/CA/KAIPERM
Title: Chief of Pathology; CLIA Director

Document History Section