

### TRAINING UPDATE

**Lab Location:** SGAH and WAH      **Date Implemented:** 3.1.2013  
**Department:** Blood Bank      **Due Date:** 3.31.2013

### DESCRIPTION OF PROCEDURE REVISION

<b>Name of procedure:</b>
Transfusion Reaction Investigation, Immediate
<b>Description of change(s):</b>
Added appendix C—instructions for ordering testing on blood products in the LIS system.

Non-Technical SOP

<b>Title</b>	<b>Transfusion Reaction Investigation, Immediate</b>	
<b>Prepared by</b>	Stephanie Codina	Date: 6/9/2012
<b>Owner</b>	Stephanie Codina	Date: 6/9/2012

<b>Laboratory Approval</b>		
<b>Print Name and Title</b>	<b>Signature</b>	<b>Date</b>
<i>Refer to the electronic signature page for approval and approval dates.</i>		
<b>Local Issue Date:</b>		<b>Local Effective Date:</b>

<b>Review:</b>		
<b>Print Name</b>	<b>Signature</b>	<b>Date</b>

**TABLE OF CONTENTS**

1. PURPOSE..... 2  
2. SCOPE..... 2  
3. RESPONSIBILITY..... 2  
4. DEFINITIONS..... 2  
5. SPECIMEN REQUIREMENTS..... 2  
6. PROCEDURE..... 3  
7. RELATED DOCUMENTS ..... 13  
8. REFERENCES ..... 14  
9. REVISION HISTORY..... 14  
10. ADDENDA AND APPENDICES..... 14

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**1. PURPOSE**

Certain risks are associated with the transfusion of blood products and a small percentage of patients experience reactions. Any adverse event associated with transfusion or transfusion error **must** be investigated immediately and thoroughly to provide the clinical staff with timely information necessary for treatment of the patient.

**2. SCOPE**

Applies to any reported suspected adverse reaction associated with a transfusion.

**3. RESPONSIBILITY**

All blood bank staff must demonstrate competency for responding to a reported or suspected transfusion reaction.

**4. DEFINITIONS**

Transfusion Reaction-- any adverse outcome associated with the infusion of blood and blood components. A transfusion reaction can occur during, immediately following, or up to weeks or months following the transfusion of a blood product.

**5. SPECIMEN REQUIREMENTS**

Pre- and post-transfusion red or lavender top tubes. Refer to the SOP 'Sample Specifications for Blood Bank Testing' for labeling requirements.

## 6. PROCEDURE

### 6.1 General Considerations

Step	Action
1	All transfusion reaction evaluations are performed stat; workup must be started within 15 minutes of sample receipt.
2	<p><b>No additional blood products may be issued for the patient until the investigation is completed and a hemolytic reaction is ruled out.</b></p> <p><b>In emergency situations,</b> the Clinical Pathologist on duty will determine whether blood products may be issued. Give O-negative red cell products and AB plasma products until a hemolytic reaction has been ruled out.</p>

### 6.2 Transfusion Reaction Notification

Step	Action
1	<p>The Blood Bank will be notified by the transfusing personnel of <b>all</b> suspected transfusion reactions/incidents/errors. Lack of symptoms does not preclude an investigation if a transfusion error is suspected or known.</p> <p>A. Signs and symptoms suggesting a transfusion reaction include:</p> <ul style="list-style-type: none"> <li>a. Thermal           <ul style="list-style-type: none"> <li>i. Temperature elevation (1°C or 2°F rise in temperature above normal (37°C or 99°F) in a patient who has not been running fevers).</li> <li>ii. Hypothermia</li> </ul> </li> <li>b. Dermatologic           <ul style="list-style-type: none"> <li>i. Rashes</li> <li>ii. Urticaria</li> <li>iii. Flushing</li> <li>iv. Pruritus</li> <li>v. Angioedema</li> <li>vi. Cyanosis</li> <li>vii. Jaundice</li> <li>viii. Pallor</li> </ul> </li> <li>c. Pulmonary           <ul style="list-style-type: none"> <li>i. Dyspnea</li> <li>ii. Tachypnea</li> <li>iii. Orthopnea</li> <li>iv. Stridor</li> <li>v. Increased/Frothy Secretions</li> <li>vi. Wheezing</li> <li>vii. Rales</li> <li>viii. Cough</li> <li>ix. Hoarseness</li> </ul> </li> </ul>

Step	Action
	<ul style="list-style-type: none"> <li>d. Cardiovascular               <ul style="list-style-type: none"> <li>i. Blood Pressure Changes ↑↓</li> <li>ii. Pulse Changes ↑↓</li> <li>iii. Dysrhythmias</li> <li>iv. Circulatory Shock/Collapse</li> </ul> </li> <li>e. Neurologic               <ul style="list-style-type: none"> <li>i. Pain (IV access site or other locations such as head, chest, lumbar region, abdomen)</li> <li>ii. Central, Peripheral, or Autonomic System Dysfunction</li> <li>iii. Anxiety</li> <li>iv. Tetany</li> </ul> </li> <li>f. Gastrointestinal or Genitourinary               <ul style="list-style-type: none"> <li>i. Nausea</li> <li>ii. Vomiting</li> <li>iii. Diarrhea</li> <li>iv. Urinary Output Changes (Oliguria, Anuria, Hemoglobinuria)</li> </ul> </li> <li>g. Hematologic               <ul style="list-style-type: none"> <li>i. Excess Bleeding</li> <li>ii. Excess Clotting</li> </ul> </li> </ul> <p>B. Signs and symptoms may be masked in a comatose or anesthetized patient. In an anesthetized or comatose patient, the only signs may be generalized bleeding at surgical sites, shock and/or hemoglobinuria.</p>
2	<p>Obtain a “Primary Transfusion Reaction Investigation Form” and complete sections I and II while maintaining phone contact with transfusing personnel.</p> <p>Instruct the transfusionist to follow the instructions for transfusion reaction that are located as reference text in the transfusion band of the electronic medical record or on the “Blood Transfusion Reaction Report” form that is located on the backside of the pink “Blood Bank Product Tag and Administration Record.”</p>
3	<p>Order a transfusion reaction investigation (TRXN) in the LIS per appendix A and dispatch a phlebotomist to collect the post-transfusion reaction specimen. Instruct the phlebotomist to leave the blood bank armband on the patient’s wrist. The blood bank armband should NOT be removed. Refer to Appendix B for instructions to order a transfusion reaction investigation in the LIS.</p>
4	<p>If at any time there is reason to believe an incompatible transfusion has occurred (wrong patient or wrong unit transfused):</p> <ul style="list-style-type: none"> <li>A. <b>Immediately</b> notify the Clinical Pathologist on duty.</li> <li>B. <b>Immediately</b> initiate the transfusion reaction protocol.</li> <li>C. <b>Immediately</b> recall to the Blood Bank any other components that might be involved in a mix-up.</li> </ul>

Step	Action
5	Contact the nursing unit to request the "Transfusion Reaction Evaluation" form if it has not been received within 30 minutes of the initial telephone notification. Document the call.

**6.3 Primary Transfusion Reaction Investigation**

Step	Action
1	Check the "Transfusion Reaction Investigation Form" for completeness. Contact nursing staff taking care of the patient to request any information that is missing.
2	<p>Perform a clerical check. Proceed through the clerical checklist on the evaluation form. <b>NOTE: All units transfused to the recipient in the previous 8 hours must be checked.</b></p> <ul style="list-style-type: none"> <li>A. Record a checkmark in the "OK" column for each item if no errors are detected.</li> <li>B. Record a checkmark in the "Not OK" column if an error or discrepancy is detected.</li> <li>C. Record tech initials.</li> </ul> <p>Verify the following:</p> <ul style="list-style-type: none"> <li>A. Perform a clerical check of the blood product label, the "Blood Bank Component Tag and Administration Record," and the pre- and post-transfusion blood specimen labels. Ensure that the following information is correct and matches EXACTLY where present:             <ul style="list-style-type: none"> <li>a. Recipient's first and last name. Middle name is not required. However, if the middle name is present, it must be correct.</li> <li>b. Recipient's medical record number.</li> <li>c. Blood product unit number or donation identification number.</li> <li>d. Blood group and type.</li> <li>e. Blood product expiration date and time (if applicable).</li> </ul> </li> <li>B. Review the results of the previous type and screen. Verify that the testing is complete and interpretations are correct via function Blood Order Processing.</li> </ul>

Step	Action	
	If...	Then...
	All information is correct and identical	<ol style="list-style-type: none"> <li>1. Document on the "Primary Transfusion Reaction Investigation Form" by checking the "OK" box for each check and proceed to step 3.</li> <li>2. If urticaria (hives) is the only symptom, the workup is complete at this point.</li> </ol>
	A clerical error exists	<ol style="list-style-type: none"> <li>1. Immediately determine whether another patient is involved by searching current record to determine if a misidentification of samples or incorrect issue of components has put another patient at risk.</li> <li>2. Immediately notify the Medical Director or pathologist on call. Document the notification.</li> <li>3. Perform the secondary transfusion reaction investigation.</li> <li>4. Complete a PI/Variance report and hospital incident report promptly when time permits.</li> </ol>
	Another patient is at risk	<ol style="list-style-type: none"> <li>1. Immediately contact the nurse of the second patient and tell him/her to IMMEDIATELY STOP THE TRANSFUSION and initiate a transfusion reaction investigation. Document the notification.</li> <li>2. Quarantine all blood products for both patients until the workup is complete.</li> </ol>
3	Perform a visual inspection of the returned blood product, administration set, and saline IV bag for abnormal appearance. Abnormalities include, but are not limited to, discoloration, visible hemolysis, cloudiness, fluids other than saline attached, or incorrect tubing. Note any problems on the "Transfusion Reaction Evaluation" form.	

Step	Action															
4	<p>Centrifuge the recipient's post-reaction specimen and compare the appearance to the recipient's pre-reaction sample. Look for hemolysis or icterus.</p> <p>A. If the post-reaction specimen is normal or similar to the pre-reaction specimen in appearance, note this on the "Transfusion Reaction Evaluation" sheet and proceed to step 5.</p> <p>B. Request that another specimen be drawn if hemolysis exists in the post-reaction specimen but is not present in the pre-reaction specimen OR if the degree of hemolysis is greater in the post-reaction specimen. The second specimen will help determine if the hemolysis is due to the transfusion reaction or specimen collection. Repeat the visual comparison when the new specimen arrives.</p> <p>C. Immediately notify the Blood Bank Medical Director or pathologist-on-call if the hemolysis or icterus is not due to the collection technique. Record the degree of hemolysis on the "Transfusion Reaction Evaluation" form. Perform secondary transfusion reaction investigation.</p>															
5	<p>Perform a polyspecific DAT on the recipient's post-reaction specimen per procedure, "Direct Antiglobulin Test (DAT)." DAT specimens must be examined both macro- and microscopically when investigating suspected transfusion reactions.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="background-color: #d3d3d3;">If the post-reaction DAT is...</th> <th style="background-color: #d3d3d3;">And the pre-reaction DAT is...</th> <th style="background-color: #d3d3d3;">Then...</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Negative</td> <td style="text-align: center;">Positive, Negative, or Unknown</td> <td>Record the results on the "Transfusion Reaction Evaluation" form and proceed to step 6.</td> </tr> <tr> <td style="text-align: center;">Positive</td> <td style="text-align: center;">Unknown</td> <td>Perform a DAT on the pre-reaction specimen and record results on the "Transfusion Reaction Evaluation" form.</td> </tr> <tr> <td style="text-align: center;">Positive</td> <td style="text-align: center;">Negative</td> <td> <ol style="list-style-type: none"> <li>1. Perform monospecific IgG and C3b,C3d DAT testing and eluate testing if indicated. Refer to procedures "Direct Antiglobulin Test (DAT)" and "Acid Elution."</li> <li>2. Record results on the "Transfusion Reaction Evaluation" form.</li> <li>3. Perform the secondary transfusion reaction investigation.</li> <li>4. Notify the patient care per the Critical Results policy.</li> </ol> </td> </tr> <tr> <td style="text-align: center;">Positive</td> <td style="text-align: center;">Positive</td> <td>Record results on the "Transfusion Reaction Evaluation" form. Notify the Blood Bank Supervisor, Medical Director, or designee if the strength of the post-transfusion reaction DAT is greater than the pre and perform the secondary transfusion reaction investigation.</td> </tr> </tbody> </table>	If the post-reaction DAT is...	And the pre-reaction DAT is...	Then...	Negative	Positive, Negative, or Unknown	Record the results on the "Transfusion Reaction Evaluation" form and proceed to step 6.	Positive	Unknown	Perform a DAT on the pre-reaction specimen and record results on the "Transfusion Reaction Evaluation" form.	Positive	Negative	<ol style="list-style-type: none"> <li>1. Perform monospecific IgG and C3b,C3d DAT testing and eluate testing if indicated. Refer to procedures "Direct Antiglobulin Test (DAT)" and "Acid Elution."</li> <li>2. Record results on the "Transfusion Reaction Evaluation" form.</li> <li>3. Perform the secondary transfusion reaction investigation.</li> <li>4. Notify the patient care per the Critical Results policy.</li> </ol>	Positive	Positive	Record results on the "Transfusion Reaction Evaluation" form. Notify the Blood Bank Supervisor, Medical Director, or designee if the strength of the post-transfusion reaction DAT is greater than the pre and perform the secondary transfusion reaction investigation.
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Form revised 3/31/00



Step	Action
6	<p>Perform ABO/Rh testing on the post-reaction specimen per procedure, "ABO/Rh Testing (Manual Tube)." Record results on the "Transfusion Reaction Evaluation" form.</p> <ul style="list-style-type: none"> <li>A. No further testing is needed if the pre- and post-reaction ABO and Rh types match.</li> <li>B. If the ABO or Rh types differ on the pre- and post-reaction specimens,               <ul style="list-style-type: none"> <li>a. Proceed to secondary transfusion reaction investigation section below.</li> <li>b. Notify the Blood Bank Medical Director or pathologist-on-call immediately. Document the notification.</li> </ul> </li> </ul>
7	<ul style="list-style-type: none"> <li>A. Proceed with the secondary transfusion reaction investigation if indicated.           <ul style="list-style-type: none"> <li>a. If clerical error exists</li> <li>b. If the post-reaction sample is hemolyzed and collection technique has been ruled out</li> <li>c. If the post-reaction DAT is positive when the pre-reaction DAT was negative or if the post-reaction DAT is positive at greater strength than the pre-reaction DAT</li> <li>d. If the ABO or Rh types of the pre-reaction and post-reaction specimens do not agree</li> </ul> </li> <li>B. If the secondary transfusion reaction investigation is not indicated, no further action is required.           <ul style="list-style-type: none"> <li>a. Submit the "Transfusion Reaction Investigation Form" to the Clinical Pathologist On-Call for review and interpretation.</li> <li>b. The pathologist will document actions taken on the Transfusion Reaction Evaluation form within 24 hours of notification of a hemolytic or anaphylactic reaction. All other reactions must be evaluated and signed by the pathologist within 72 hours.</li> <li>c. Retain the blood bag, tubing, and fluids in a blood bank refrigerator for 10 days post-reaction. Place the bag in a zip-lock bag and label with the date of the reaction. Discard by incineration at the end of 10 days.</li> <li>d. Additional blood products may be issued if requested.               <ul style="list-style-type: none"> <li>i. Blood products previously crossmatched on the pre-reaction sample may be issued without further testing as long as                   <ul style="list-style-type: none"> <li>1. There is no evidence of hemolysis.</li> <li>2. The post-reaction DAT is negative (or if DAT is positive with strength <math>\leq</math> pre-reaction DAT results).</li> </ul>                   And                   <ul style="list-style-type: none"> <li>3. The ABO/Rh types on the pre- and post-reactions samples match.</li> </ul> </li> <li>ii. Additional red blood cell products should be crossmatched to the pre-reaction specimen prior to issue.</li> </ul> </li> </ul> </li> </ul>

### 6.4 Secondary Transfusion Reaction Investigation

Step	Action
1	The secondary investigation only needs to be performed if indicated during the primary investigation or at the request of a pathologist. It is unlikely that the secondary investigation will need to be completed for reactions involving non-red cell components. Contact a supervisor or pathologist if questions exist.
2	<p>Request a new sample.</p> <ul style="list-style-type: none"> <li>A. Order a stat Type &amp; Screen specimen with the comment code "TRAN" (post-transfusion specimen) in the LIS via function "Order Entry."</li> <li>B. Retrieve the label and deliver it to a phlebotomist with instructions to draw a properly labeled sample immediately. The previous Blood Bank armband must be removed and a new one applied.</li> <li>C. If a post-transfusion sample cannot be obtained within one hour, notify the pathologist and document on the reaction workup form.</li> </ul>
3	Repeat steps 4 and 5 of the Primary Transfusion Reaction Investigation above. Document the ABO typing in Sunquest.
4	<p>Repeat the ABO and Rh testing on the recipient's pre-transfusion specimen per procedures, "ABO/Rh Testing (Tube Method)." Record results on the "Transfusion Reaction Investigation Form."</p> <p>If the ABO/Rh results of the recipient's pre- and post-reaction samples disagree:</p> <ul style="list-style-type: none"> <li>A. Suspect a sample mix-up or mislabeling incident.</li> <li>B. Have a new specimen collected to confirm the discrepant results are reproducible.</li> <li>C. Search current records to determine if a misidentification of samples or incorrect issue of blood products has put another patient at risk.</li> </ul> <p>If another patient is at risk...</p> <ul style="list-style-type: none"> <li>A. Quarantine all units for both patients involved until the investigation process is complete.</li> <li>B. Contact the nursing unit to stop the other patient's transfusion (if blood products have been issued). Document the notification.</li> <li>C. Notify a supervisor or manager and a pathologist immediately. Document the notification.</li> <li>D. Complete a PI/Variance report and hospital incident report as soon as time permits. Systemic failures will be brought to the attention of the Blood Bank Medical Director via the hospital incident reporting system.</li> </ul>
5	Perform antibody screen testing on recipient's pre- and post-reaction specimens per procedure. If the pre-reaction specimen is negative and the post-reaction specimen is positive, perform antibody identification on the post-reaction specimen.

Form revised 3/3/100

Step	Action
6	<p>Perform an extended crossmatch per procedure, "Crossmatch."</p> <ul style="list-style-type: none"> <li>A. Test the recipient's pre-reaction specimen against all implicated red cell components.</li> <li>B. Test the recipient's post-transfusion specimen against all implicated red cell components.</li> </ul> <p>If the pre-reaction specimen is compatible and the post-reaction specimen is incompatible....</p> <ul style="list-style-type: none"> <li>a. Repeat the crossmatch on the pre-reaction specimen to confirm results.</li> <li>b. Perform a polyspecific DAT on the red cell unit in question per procedure, "Direct Antiglobulin Test (DAT)."</li> <li>c. Repeat any applicable phenotyping on the red cell unit per procedure, "Antigen Typing."</li> <li>d. Consult with a supervisor, manager, or pathologist.</li> </ul>
7	<p>Record all results on the "Transfusion Reaction Investigation Form."</p>
8	<p>Confirm the ABO and Rh type of the blood product issued per procedure "Reprocessing Blood From Outside Sources." If the ABO or Rh of the blood product does not agree with the ABO or Rh on the label:</p> <ul style="list-style-type: none"> <li>A. Contact the blood supplier. Document the notification.</li> <li>B. Complete a PI/Variance form and hospital incident report when time permits.</li> <li>C. Notify a supervisor, manager, or pathologist as soon as possible. Document the call.</li> </ul>
9	<p>If no abnormalities or discrepancies are noted from the testing and clerical checks, no further action is required. Submit the form to the clinical-pathologist on-call for review and interpretation.</p> <ul style="list-style-type: none"> <li>A. The pathologist will document actions taken on the "Transfusion Reaction Investigation Form" within 24 hours of notification of a hemolytic or anaphylactic reaction.</li> <li>B. All other reactions must be evaluated and signed by the pathologist within 72 hours.</li> </ul>
10	<p>Retain the blood bag, tubing, and fluids in a blood bank refrigerator for 10 days post-reaction. Place the bag in a zip-lock bag and label with the date of the reaction. Discard by incineration at the end of 10 days.</p>

## 6.5 Additional Testing

Step	Action												
1	<p>The pathologist reviewing the transfusion reaction may decide to order additional testing to complete the investigation. Potential test orders include:</p> <table border="1" data-bbox="402 464 1338 1797"> <thead> <tr> <th data-bbox="402 464 805 537">If the symptoms suggest...</th> <th data-bbox="805 464 1338 537">Then the pathologist may request the following additional testing...</th> </tr> </thead> <tbody> <tr> <td data-bbox="402 537 805 848">A hemolytic transfusion reaction</td> <td data-bbox="805 537 1338 848"> <ul style="list-style-type: none"> <li>• Hemoglobin levels</li> <li>• Lactate dehydrogenase (LDH)</li> <li>• International normalized ratio (INR)</li> <li>• Bilirubin levels</li> <li>• Blood urea nitrogen (BUN)</li> <li>• Haptoglobin levels</li> <li>• Potassium levels</li> </ul> </td> </tr> <tr> <td data-bbox="402 848 805 1121">A septic transfusion reaction</td> <td data-bbox="805 848 1338 1121"> <ul style="list-style-type: none"> <li>• Gram stain on blood product</li> <li>• Blood cultures on blood product</li> <li>• Blood cultures on recipient</li> <li>• Notification to blood supplier</li> <li>• Refer to Appendix C for additional instructions</li> </ul> </td> </tr> <tr> <td data-bbox="402 1121 805 1419">An anaphylactic reaction</td> <td data-bbox="805 1121 1338 1419"> <ul style="list-style-type: none"> <li>• Quantitation of IgA levels and testing for anti-IgA on recipient's pre-transfusion specimen</li> <li>• IgA-deficient blood products to be provided until the results of testing for IgA are available and have been evaluated</li> </ul> </td> </tr> <tr> <td data-bbox="402 1419 805 1608">Post-Transfusion Purpura (PTP)</td> <td data-bbox="805 1419 1338 1608"> <ul style="list-style-type: none"> <li>• Platelet count</li> <li>• Platelet antibody detection and identification</li> <li>• Crossmatched platelets</li> </ul> </td> </tr> <tr> <td data-bbox="402 1608 805 1797">Transfusion-Related Acute Lung Injury (TRALI)</td> <td data-bbox="805 1608 1338 1797"> <ul style="list-style-type: none"> <li>• Testing of donor and/or recipient for HLA antibodies and/or granulocyte antibodies</li> <li>• Notification to blood supplier</li> </ul> </td> </tr> </tbody> </table>	If the symptoms suggest...	Then the pathologist may request the following additional testing...	A hemolytic transfusion reaction	<ul style="list-style-type: none"> <li>• Hemoglobin levels</li> <li>• Lactate dehydrogenase (LDH)</li> <li>• International normalized ratio (INR)</li> <li>• Bilirubin levels</li> <li>• Blood urea nitrogen (BUN)</li> <li>• Haptoglobin levels</li> <li>• Potassium levels</li> </ul>	A septic transfusion reaction	<ul style="list-style-type: none"> <li>• Gram stain on blood product</li> <li>• Blood cultures on blood product</li> <li>• Blood cultures on recipient</li> <li>• Notification to blood supplier</li> <li>• Refer to Appendix C for additional instructions</li> </ul>	An anaphylactic reaction	<ul style="list-style-type: none"> <li>• Quantitation of IgA levels and testing for anti-IgA on recipient's pre-transfusion specimen</li> <li>• IgA-deficient blood products to be provided until the results of testing for IgA are available and have been evaluated</li> </ul>	Post-Transfusion Purpura (PTP)	<ul style="list-style-type: none"> <li>• Platelet count</li> <li>• Platelet antibody detection and identification</li> <li>• Crossmatched platelets</li> </ul>	Transfusion-Related Acute Lung Injury (TRALI)	<ul style="list-style-type: none"> <li>• Testing of donor and/or recipient for HLA antibodies and/or granulocyte antibodies</li> <li>• Notification to blood supplier</li> </ul>
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2	Document any additional tests requested by the pathologist on the "Transfusion Reaction Evaluation" form.												

Step	Action
3	Ensure that the tests are ordered and the appropriate pre- or post- transfusion specimen is obtained for testing.
4	Print the results of the testing and provide them to the pathologist for interpretation.

### 6.6 Blood Product Cultures

Step	Action
1	If a septic reaction is suspected (generally when recipient's temperature increases by >1°C or 2°F), blood product cultures may be ordered.
2	Order the blood product culture using the downtime requisition. <ul style="list-style-type: none"> <li>A. Request a stat gram stain and culture.</li> <li>B. Include the unit number and the recipient's name and medical record number on the form. Complete one form for each unit in question.</li> </ul>
3	Deliver the completed downtime requisition and the blood product(s) to microbiology.
4	The culture and stat gram stain must be performed on blood unit. <ul style="list-style-type: none"> <li>A. If the blood bag was returned with transfusion tubing attached (no exposed ports), culture and gram stain should be done from the blood container itself.</li> <li>B. If the bag was returned with open ports, sample for micro testing should be taken from an attached segment.</li> </ul>

### 6.7 Notification

Step	Action
1	The pathologist will be responsible for notifying the recipient's physician when a hemolytic or septic reaction has occurred or is suspected to ensure the patient receives all necessary care. The pathologist may choose to notify the patient's physician in other situations.

Step	Action
2	<p>The FDA requires that we notify our blood supplier if the blood product caused (or is suspected of causing) the transfusion reaction. This includes:</p> <ul style="list-style-type: none"> <li>A. Reactions due to compatibility problems when a reference laboratory such as the American Red Cross Immunohematology Laboratory performed any of the testing or provided specially selected (e.g. antigen-negative) blood products.</li> <li>B. All transfusion reactions in which a problem with the manufacturing may have caused the reaction. This includes, but is not limited to, the following possible or confirmed reactions:               <ul style="list-style-type: none"> <li>a. Septic reactions</li> <li>b. Transfusion-related acute lung injury (TRALI)</li> <li>c. Serious allergic reactions</li> <li>d. Some hemolytic reactions (e.g. hemolysis in a group A recipient of group O platelets with a high-titer anti-A)</li> </ul> </li> </ul> <p>If any of these reactions are suspected, the pathologist reviewing the transfusion reaction must complete the “American Red Cross Possible Transfusion Reaction Case Report” form.</p>
3	<p>The FDA requires that we notify our blood supplier if the blood product caused a possible transfusion-transmitted infection in the recipient. All types of possible recipient transfusion-transmitted infections should be reported to ARC including, but not limited to, hepatitis B, hepatitis C, and HIV. If any of these are suspected, the pathologist reviewing the transfusion reaction must complete the “American Red Cross Possible Recipient Transfusion-Transmitted Infection Case Report” form.</p>
4	<p>All suspected transfusion-related fatalities must be reported to the Center for Biologics Evaluation and Research (CBER) via telephone within 1 day and via written report within 7 days of the initial reaction. Refer to procedure, “Biologic Deviation Reporting—FDA Reportable Event.”</p>

**7. RELATED DOCUMENTS**

- Form: Primary Transfusion Reaction Investigation Form
- Form: Secondary Transfusion Reaction Investigation Form
- SOP: Sample Specifications for Blood Bank Testing
- SOP: ABO/Rh Typing (Manual Tube)
- SOP: Direct Antiglobulin Test (DAT)
- SOP: Antibody Screen
- SOP: Crossmatch
- SOP: Antibody Identification
- SOP: Antigen Typing
- SOP: Acid Elution
- SOP: Biologic Deviation Reporting - FDA Reportable Event

**8. REFERENCES**

1. Standards for Blood Banks and Transfusion Services, AABB, 27<sup>th</sup> edition, 2011.
2. AABB Technical Manual, 17<sup>th</sup> edition, 2011.
3. Code of Federal Regulations, 21 CFR 606.170, current edition.

**9. REVISION HISTORY**

<b>Version</b>	<b>Date</b>	<b>Reason for Revision</b>	<b>Revised By</b>	<b>Approved By</b>
		Supersedes WAH.BB52.000,SGAH.BB54.000		
000	2.19.13	Sections 6.5 & 10: Added appendix C	SCodina	NCacciabeve

**10. ADDENDA AND APPENDICES**

- Appendix A: Ordering a Primary Transfusion Reaction Evaluation in the LIS
- Appendix B: Resulting a Primary Transfusion Reaction Evaluation in the LIS
- Appendix C: Ordering Testing on a Blood Product in the LIS System
- Attachment D: American Red Cross Form 11.4.frm059 v-1.0 "Recipient Complication - Transfusion Reaction Report."
- Attachment E: American Red Cross Form 11.4.frm058 v-1.0 "Possible Recipient Complication - Infectious Disease Report."

**Appendix A**  
**Ordering a Primary Transfusion Reaction Evaluation in the LIS**

Step	Action
1	Access Sunquest function, "Order Entry."
2	In the "Lookup by" field, select "Patient ID" from the dropdown menu.
3	At the "Value" prompt, type the patient's medical record number.
4	Select the correct patient from the pop-up list and click the "Select" button.
5	Press the "Tab" button to default the current date in the "Collect date" field. In the "Collect time" field, type "N" for now and press the "Tab" key.
6	At the "Order physician" prompt, type in the number of the physician or click the ellipse button to lookup the physician by name then press the "Tab" key.
7	In the "Order Code" box, type "TRXN" for transfusion reaction evaluation and press the "Tab" key.
8	Click the "Save" button.
9	Notify phlebotomy staff that the order has been placed and the sample should be collected ASAP.



**Appendix B**  
**Resulting a Primary Transfusion Reaction Evaluation in the LIS**

**Entry Prior to Pathologist Interpretation**

Step	Action
1	Access Sunquest function "Blood Order Processing."
2	At the "Lookup By" prompt, click on the dropdown menu to select "Patient ID."
3	In the "Value" prompt, type in the patient's medical record number and click "Search."
4	Select the correct patient from the pop-up menu, if applicable.
5	Select the "TRXN" specimen from the list and click on the "Select" button.
6	<p>Enter the ABO/Rh results per procedure, "ABO/Rh Typing (Manual Tube)." Enter the DAT results per procedure, "Direct Antiglobulin Test (DAT)."</p> <p>If urticaria was the only symptom, type ";HIDE" in the data entry fields that do not apply to the reaction. You must also credit any ABO, Rh, or DAT tests that were not performed. In the Add Spec Test field, type the mnemonic that corresponds to the credit test to be ordered:</p> <ul style="list-style-type: none"> <li>A. Type ";CABO" to credit the ABO test.</li> <li>B. Type ";CRH" to credit the Rh test.</li> <li>C. Type ";CDAT" to credit the DAT test.</li> </ul>
7	<p>In the Clerical Check field,</p> <ul style="list-style-type: none"> <li>A. Type "T" for acceptable if the clerical check revealed no errors.</li> <li>B. Type "Q" for not acceptable if the clerical check revealed errors.</li> </ul>
8	<p>In the Post Hemolysis Check field,</p> <ul style="list-style-type: none"> <li>A. Type "T" for acceptable if no hemolysis or icterus was noted in the post-reaction specimen.</li> <li>B. Type "T" for acceptable if hemolysis or icterus was noted in the post-reaction specimen, but was less than that in the pre-reaction specimen.</li> <li>C. Type "Q" for not acceptable if hemolysis or icterus was noted in the post-reaction specimen and it was either not seen in the pre-reaction specimen or was seen in smaller amounts in the pre-reaction specimen.</li> </ul>
9	<p>In the Visual Inspection field,</p> <ul style="list-style-type: none"> <li>A. Type "T" for acceptable if the blood product passed visual inspection and only normal saline or Plasmalyte were attached.</li> <li>B. Type "Q" for unacceptable if the blood product failed visual inspection or if a fluid/medication other than saline or Plasmalyte was infused with the blood product.</li> </ul>

Step	Action
10	The Pathologist Interpretation field will remain blank until the investigation has been reviewed and interpreted by a pathologist.
11	Click the "Save" button.

**Entry Following Pathologist Interpretation**

Step	Action
1	Access Sunquest function "Blood Order Processing."
2	At the "Lookup By" prompt, click on the dropdown menu to select "Patient ID."
3	In the "Value" prompt, type in the patient's medical record number and click "Search."
4	Select the correct patient from the pop-up menu, if applicable.
5	Select the "TRXN" specimen from the list and click on the "Select" button.
6	Enter the pathologist interpretation when available: A. ALRE = Allergic transfusion reaction B. HEMR1 = Acute hemolytic transfusion reaction (immune) C. HEMR2 = Acute hemolytic transfusion reaction (non-immune) D. DHRH = Delayed hemolytic transfusion reaction E. DSRX = Delayed serologic transfusion reaction F. HPOR = Hypotensive transfusion reaction G. FEBR = Febrile, non-hemolytic transfusion reaction H. PTP = Post-transfusion purpura I. TACO = Transfusion-associated circulatory overload J. TAD = Transfusion-associated dyspnea K. TTI = Transfusion-transmitted infection L. TRALI = Transfusion-related acute lung injury M. TAGVHD = Transfusion-associated graft-versus-host disease
7	Click the "Save" button.
8	Enter a comment into the patient's historical blood bank file indicating the type and date of reaction. For example, "Allergic reaction to plasma unit 53X12345 on 3.29.2011."
9	The evaluation worksheet is retained in the Blood Bank file, after LIS documentation is completed.

**Appendix C**  
**Ordering Testing on a Blood Product in the LIS System**

<b>Step</b>	<b>Action</b>
1	Access Sunquest function "Order Entry."
2	When the lookup screen appear, click the "New Patient" box in the lower, right-hand corner of the screen.
3	In the "Patient ID" field, type "BB-" then click the "Create" button.
4	A new screen will open. Complete the following fields. Press the "Tab" button after each entry. A. Patient name: Enter "Unit" followed by a comma ",", then the unit number. B. Date of birth/age: Enter the date of the transfusion reaction. C. Sex: Select "Unknown."
5	When all data has been entered, click the "Save" button on the lower, right-hand corner of the screen.
6	A new MRN will be generated and Sunquest will automatically default to the order entry screen.
7	Order testing that has been requested on the unit. A. GS is ordered for gram stain. B. XBLC is ordered for blood culture.
8	Record the MRN and accession number of the testing on the transfusion reaction investigation form.