TRAINING UPDATE

Lab Location:	SGAH and WAH	**Date Implemented:**	09.05.2014
Department:	Blood Bank	**Due Date:**	09.26.2014

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Transfusion Reaction Investigation, Delayed

Description of change(s):

1. Form updated:
    a. Original, repeat, and new sample testing results are more clearly delineated
    b. Antigen typing was moved to Antigen Typing form (simply attach instead of rewriting all units)
    c. Add an area for non-BB reported delayed reactions

2. SOP was updated to reflect changes to the form.

3. Added instructions to document delayed reactions (those reported >48 hours after transfusion) using the form. Previosuly, non-BB reported delayed reactions were put on a PI/variance form.

Electronic Document Control System

Quest Diagnostics

Document No.: WAH.BB128[1]
Title: TRANSFUSION REACTION INVESTIGATION DELAYED
Owner: LESLIE.X.BARRETT LESLIE BARRETT
Status INWORKS
Effective Date: 26-Sep-2014 **Next Review Date:**

Non-Technical SOP

Title	**Transfusion Reaction Investigation, Delayed**	
Prepared by	Stephanie Codina	Date: 6/9/2012
Owner	Stephanie Codina	Date: 6/9/2012

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

Review:		
Print Name	**Signature**	**Date**

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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 potential transfusion reactions that are identified by blood bank staff members or called to blood bank >48 hours post-transfusion.

3. RESPONSIBILITY

All blood bank staff must demonstrate competency for and adhere to this procedure for identifying and working up potential transfusion reactions.

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

This type of transfusion reaction is often identified during subsequent serologic testing. Samples are requested as needed to complete the workup. Labeling will be performed as outlined in procedure, "Sample Specifications for Blood Bank Testing."

6. PROCEDURE

6.1 General Considerations

Step	Action
1	Delayed transfusion reactions occur days to months following transfusion. Potential reactions may be called to the blood bank by the patient or provider. In addition, these types of reactions are often identified by blood bank staff members during subsequent workups. Examples include: A. Reaction in an alloimmunized patient whose antibody titer diminished to undetectable levels. If red cells that express the antigen are subsequently transfused, an anamnestic response may cause the appearance of the antibody that reacts with the transfused cells. B. The new formation of an antibody directed towards donor cells. C. Transfusion-transmitted infection D. Transfusion-associated graft-versus-host disease
2	Blood bank staff members should suspect delayed serologic transfusion reaction when any of the following are seen: A. Positive IgG DAT in a recently transfused patient. B. Antibody present in the eluate. C. Positive antibody screen in a patient who has previously had negative antibody screens. D. Antibody present after transfusion that was not detected before transfusion.
3	Complete a delayed transfusion reaction form when a potential delayed reaction has been called to the blood bank or identified by blood bank staff members. Document the following: A. Patient's name and medical record number. B. Name of the person reporting the potential reaction. Check the box if the reaction was identified by blood bank staff members. If the reaction was reported by a person outside of the blood bank, the following must also be completed: C. Contact information for the person who reported the potential reaction. D. Reason for the workup (patient symptoms, when they occurred, and other pertinent information).
4	Print the patient's transfusion history and attach it to the form. A. Access Sunquest function "Blood Bank Inquiry." B. At the "Lookup by" prompt, select "Patient ID" from the dropdown menu. C. At the "Value" prompt, type the patient's medical record number and click the "Search" button. D. Select the correct patient from the pop-up list and click the "Select" button. E. Click on the "Transfusion History" button. F. Click the "Print" button.

Step	Action
5	Print the patient's laboratory results using Sunquest function, "Laboratory Inquiry." Ensure the range of results pulled includes the date on which the pre-transfusion sample was tested until the time the reaction was suspected. Results that would suggest a hemolytic reaction include: A. Elevated total and indirect bilirubin B. Elevated LDH C. Decreased haptoglobin
6	Summarize blood bank testing on the form. A. Document the results of the original T&S specimen in the first column. B. Document the results of the current T&S specimen in the third column. C. If serologic reaction is suspected AND the original sample is still available, repeat the testing and document results in the second column. Check the box to indicate that the sample is not available, if applicable. D. Document "ND" for not done where applicable. Note: If serologic reaction is suspected, DAT testing should be performed on all available samples and documented on the form.
7	If the patient had an antibody post-transfusion that was not present pre-transfusion: A. Pull stored segments from the units that were transfused to the recipient in the preceding 3 months and perform antigen typing for the antigens that correspond to the new antibody specificity(-ies). B. List all units transfused on the form. Document that the unit segment is no longer available for testing where applicable.
8	A. Submit the completed "Delayed Transfusion Reaction Investigation Form" to the clinical pathologist on-call for review and interpretation. 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. C. The blood bank supervisor will type a written letter to notify the patient's physician of the delayed reaction. The letter should be signed by the pathologist interpreting the suspected reaction or the Blood Bank Medical Director.
9	Additional blood products may be crossmatched and issued per procedure if requested.

6.2 Additional Testing

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>The pathologist reviewing the transfusion reaction may decide to order additional testing to complete the investigation. Potential test orders include:
<table>
<tr><th>If the symptoms suggest…</th><th>Then the pathologist may request the following additional testing….</th></tr>
<tr><td>A hemolytic transfusion reaction</td><td>• Hemoglobin levels
• Lactate dehydrogenase (LDH)
• International normalized ratio (INR)
• Bilirubin levels
• Blood urea nitrogen (BUN)
• Haptoglobin levels
• Potassium levels</td></tr>
<tr><td>Post-Transfusion Purpura (PTP)</td><td>• Platelet count
• Platelet antibody detection and identification
• Crossmatched platelets</td></tr>
</table></td></tr>
<tr><td>2</td><td>Document any additional tests requested by the pathologist on the “Transfusion Reaction Evaluation” form.</td></tr>
<tr><td>3</td><td>Ensure that the tests are ordered and the appropriate pre- or post- transfusion specimen is obtained for testing.</td></tr>
<tr><td>4</td><td>Print the results of the testing and provide them to the pathologist for interpretation.</td></tr>
<tr><td>5</td><td>Following pathologist review, enter the interpretation of the reaction into the patient’s blood bank administrative data file.</td></tr>
</table>

6.3 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	The FDA requires that we notify our blood supplier if the blood product caused (or is suspected of causing) the transfusion reaction. This includes: 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. 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: a. Transfusion-related acute lung injury (TRALI) b. Serious allergic reactions c. Some hemolytic reactions (e.g. hemolysis in a group A recipient of group O platelets with a high-titer anti-A) 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.
3	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, septic reactions, 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.
4	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."

7. RELATED DOCUMENTS

Form: Delayed Transfusion Reaction Investigation Form (AG.F198)
Form: Antigen Typing
SOP: Antigen Typing
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, 29th edition, 2014.
2. AABB Technical Manual, 18th edition, 2014.
3. Code of Federal Regulations, 21 CFR 606.170, current edition.

9. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes WAH.BB52.000,SGAH.BB54.000		
000	8.27.14	Section 6.1: Updated form and updated procedure to coincide with changes to the form. Added requirement to document potential delayed reactions called to the BB on the new form. Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	SCodina	NCacciabeve

10. ADDENDA AND APPENDICES

N/A

Electronic Document Control System

Quest Diagnostics

Document No.: AG.F198[1]
Title: TRANSFUSION REACTION INVESTIGATION FORM DELAYED
Owner: LESLIE.X.BARRETT LESLIE BARRETT
Status INWORKS
Effective Date: 26-Sep-2014 **Next Review Date:**

Shady Grove Adventist Hospital ▪ Washington Adventist Hospital ▪ Germantown Emergency Center

Delayed Transfusion Reaction Form

Recipient's Name:_____ Recipient's MRN:_____

Reaction Reported By: _____ ◯ Blood Bank Identified (√)

Contact Number for Person Reporting: _____

Date and Time reported: _____

Reason for Workup:

Print the following and attach to this form:

◯ Recipient's transfusion history

◯ Recipient's laboratory results from the time of original testing until time of potential reaction (use Lab Inq)

Original Testing			Repeat Testing of Original Sample ◯ (√) if sample not available			Testing of New Sample		
Accession:			Accession:			Accession:		
Date Collected:			Date Collected:			Date Collected:		
Date Tested:			Date Tested:			Date Tested:		
ABO/Rh:			ABO/Rh:			ABO/Rh:		
Ab Screen:	Pos	Neg	Ab Screen:	Pos	Neg	Ab Screen:	Pos	Neg
AbID:			AbID:			AbID:		
DAT Poly:	Pos	Neg	DAT Poly:	Pos	Neg	DAT Poly:	Pos	Neg
DAT IgG:	Pos	Neg	DAT IgG:	Pos	Neg	DAT IgG:	Pos	Neg
DAT C3:	Pos	Neg	DAT C3:	Pos	Neg	DAT C3:	Pos	Neg
Eluate:			Eluate:			Eluate:		
Recording Tech:			Tech:			Tech:		

Antigen Typing of Transfused Units

If a delayed serologic reaction is suspected, perform antigen typing of all units transfused in the preceding 3 months. Attach a copy of the antigen typing form to this sheet. Indicate on form if units are no longer available for typing.

Pathologist Review and Interpretation

◯ New Antibody Sensitization (DSRX)
◯ Delayed Serologic (DSRX)
◯ Delayed Hemolytic (DHRX)
◯ Other:
◯ Transfusion-Associated Graft-Versus-Host (TAGVHD)
◯ TRALI (TRALI)
◯ Transfusion-Transmitted Infection (TTI)

Pathologist Signature: Date: