TRAINING UPDATE

Lab Location:	SGAH and WAH	**Date Implemented:**	03.06.2015
Department:	Blood Bank	**Due Date:**	03.15.2015

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Quality Variance Form Blood Bank

Description of change(s):

a. Form updated per discussion during March staff meeting.

b. SOP updated to reflect changes to form.

c. SGMC form will be blue while WAH form will be yellow.

Electronic Document Control System

Quest Diagnostics

Document No.: AG.F15[3]
Title: QUALITY VARIANCE FORM BLOOD BANK
Owner: LESLIE.X.BARRETT LESLIE BARRETT
Status INWORKS
Effective Date: 03-Apr-2015 **Next Review Date:**

Non-Technical SOP

Title	**Blood Bank Quality Variance Forms**
Prepared by	Stephanie Codina Date: 11.28.2011
Owner	Stephanie Codina Date: 11.28.2011

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**

Form revised 3/1/00

TABLE OF CONTENTS

1. PURPOSE

This procedure describes the process for detecting, investigating, and responding to events that result in deviations from accepted policies, processes, and procedures or failures to meet requirements defined by regulatory requirements.

2. SCOPE

This procedure applies to any deviation from accepted policy, process, procedure or regulatory requirement.

3. RESPONSIBILITY

All blood bank staff members must understand and adhere to this procedure for reporting non-conformances.

4. DEFINITIONS

N/A

5. PROCEDURE

Initial Reporting

Step	Action
1	All non-conformances will be reported via the Quality Variance Form. These include, but are not limited to, deviations from accepted policy, process, procedure, or regulatory requirement. A. Suspected transfusion reactions will be documented on the Transfusion Reaction Investigation Form per procedure, Transfusion Reaction Investigation. B. Blood product market lookbacks, recalls, and market withdrawals will be documented per procedure, Blood Product Lookbacks, Recalls, and Market Withdrawals.

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Step	Action
2	Obtain a Quality Variance Form and document the following information in the designated spaces: A. Date of occurrence B. Location of occurrence C. Patient's full name, if applicable D. Patient's medical record number, if applicable E. Accession number of test, if applicable F. Test code or name, if applicable G. Patient location
3	Check the box that describes the non-conformance. A. Patient Identification Error a. Incorrect patient drawn by lab (this refers to a situation in which the incorrect patient was drawn and the blood in the tube matches the name on the tube). b. Incorrect patient drawn by nursing (this refers to a situation in which the incorrect patient was drawn and the blood in the tube matches the name on the tube). c. Patient not banded with blood bank armband d. Armband information incomplete or incorrect e. Blood bank armband removed prematurely f. Patient's current ABO/Rh does not match historical ABO/Rh g. Admitting department error in patient identification or merge h. Wrong blood in tube (this refers to a situation in which the label on the tube does not belong to the same person whose blood is in the tube) B. Ordering a. Test or blood products ordered in incorrect patient (computer entry) b. Blood product requested on incorrect patient (transfusion request) c. Incorrect BB number on the request form C. Testing a. Corrected report due to erroneous result b. Clerical/computer data entry error D. Blood Product a. Incorrect label b. Extended expiration date c. Wasted product E. Specimen a. Not labeled with blood bank labeling system b. Unlabeled c. Double labeled (label beneath blood bank label) d. Mispelled name and/or incorrect MRN e. Label missing one or more required pieces of information (name, MRN, collector's initials, time/date of collection) f. Duplicate specimen g. Specimen collected on patient at incorrect time (T&S drawn when

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Step	Action
	current T&S in BB, fetal cell screen collected prior to delivery) h. Collected in incorrect tube type i. Missing specimen F. Maintenance and Quality Control a. Temperature out of range; no corrective action b. Temperature not recorded c. QC not documented d. QC failure, no corrective action G. Issuing a. Issued unit did not meet patient's transfusion requirements b. Incorrect product issued c. Autologous or directed products not issued when available d. Product returned outside of acceptable temperature range e. ABO confirmation not completed prior to blood product issue H. Procedural error a. Failure to follow SOP b. Unclear SOP c. No procedure available d. Tech misunderstood SOP I. Supplier error a. Manufacturer recall (excludes blood product recalls) b. Incorrect or unfilled order J. Tech concern (document details on back of form) K. Customer complaint (document details on back of form)
4	Describe the event, applicable details, and immediate corrective actions taken in the free-text box on the back of the form if the details are not obvious from the description of the variance. A. For specimen labeling variances, attach a photocopy of the specimen label to the variance form. B. For wastage due to nursing errors, attach a photocopy of the "request for transfusion form" to the variance form.
5	Determine if the non-conformance is: A. An RQI per procedure, Hospital Notification Process for Reportable Quality Issues. B. An FDA-reportable event per procedure, Biological Product Deviation Reporting—FDA Reportable Event. Notify a supervisor IMMEDIATELY if the non-conformance is an FDA-reportable event or RQI. Document the notification on the front of the form.

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Step	Action
6	Immediately investigate the incident and take appropriate corrective action. A. If the non-conformance involves a blood product that has been issued: a. Attempt to retrieve the blood product prior to transfusion. b. If transfusion has begun, notify the transfusionist to stop the transfusion immediately if the potential for patient harm exists. c. Notify the on-call pathologist. B. Quarantine all blood products with potential non-conformances prior to issue. Refer to procedure, Quarantine of Blood Products.
7	If notification was made, document the name of the person notified, the date and time of notification, and your tech code in the notification area of the variance form.
8	Give the Quality Variance Form to a supervisor or place in the designated location.

Supervisor's Investigation

Step	Action
1	The supervisor will A. Determine the effect, if any, on the quality of products or services. B. Evaluate the effect on interrelated activities. C. Analyze the event to understand root cause (for blood bank errors). D. Report errors via the hospital incident reporting system when other hospital departments are involved and aid in root cause analysis, if performed. E. Implement corrective action and discipline, as appropriate. F. Report to external agencies, when required. G. Confer with the Blood Bank Medical Director and Quality Assurance department, when applicable.
2	Documentation of the investigation and corrective action (if implemented) will be documented on the back of the form.
3	Determine the level of severity. A. No patient impact B. Minor impact = redraw/recollection of specimen, treatment delay, rework, patient inconvenience C. Major impact = Therapy required, increased LOS, change in participation in study, potential for serious injury, or more significant outcome
4	Completed forms will be forwarded to the Blood Bank Medical Director when the error involves a blood product or blood bank process. The Medical Director will review the non-conformance and approve corrective action by signing the form.

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Step	Action
5	All completed forms will be forwarded to the Quality Assurance department for tracking and trending.

6. RELATED DOCUMENTS

Form: Quality Variance Form (AG.F15)
SOP: Transfusion Reaction Investigation
SOP: Blood Product Lookbacks, Recalls, and Market Withdrawals
SOP: Biological Product Deviation Reporting—FDA Reportable Event.
SOP: Hospital Notification Process for Reportable Quality Issues
SOP: Quarantine of Blood Products

7. REFERENCES

a. Fung, M.K., Grossman, B.J., Hillyer, C.D., and Westhoff, C.M. 2014. Technical Manual of the AABB, 18th ed. AABB Publishing, Bethesda, Maryland.

b. Standards for Blood Banks and Transfusion Services, 29th ed. AABB Publishing, Bethesda, Maryland.

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes WAH-SGAH B835a.01		
000	3.4.15	Section 5: Updated procedure to reflect changes to form; removed requirement to document whether sample redrawn or corrected report issued; updated levels of severity Section 6: Updated list Footer: Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	SCodina	NCacciabeve

9. ADDENDA AND APPENDICES

None

Quest Diagnostics

BB Variance Form

☐ GEC
☐ SGMC
☐ WAH

Occurrence Date: __ __/__ __/__ __ __ __ Occurrence Location: _____

Patient name: _____ _____ MR#_____
(*L Name*) (*F Name*)

Accession #: _____ Test Code: _____ Patient location: _____

A. Description of Variance (specify the incident). Check the appropriate box below.

Patient Identification Error

- ☐ Incorrect patient drawn by lab
- ☐ Incorrect patient drawn by nursing
- ☐ Patient not banded with blood bank armband
- ☐ Armband information incomplete or incorrect
- ☐ Blood bank armband removed
- ☐ Patient's Current ABO/Rh does not match patient's historical ABO/Rh
- ☐ Admitting Department error in patient identification or MRN merge
- ☐ Wrong blood in tube

Ordering

- ☐ Test or blood product ordered on wrong patient (computer entry)
- ☐ Blood product requested on incorrect patient (transfusion request)
- ☐ Incorrect BB number on request form

Testing

- ☐ Corrected report due to erroneous result
- ☐ Clerical (computer data entry error)

Blood Product

- ☐ Incorrect label
- ☐ Extended expiration date
- ☐ Wasted Product

Specimen

- ☐ Not labeled with blood bank label
- ☐ Not labeled
- ☐ Double labeled (label beneath BB label)
- ☐ Misspelled name and/or incorrect MRN
- ☐ Label missing one or more required pieces of information (name, MRN, collector's initials, time or date of collection)
- ☐ Duplicate specimen
- ☐ Specimen collected on patient at incorrect time (TS drawn with current TS on file, Fetal Screen collected prior to delivery)
- ☐ Collected in wrong tube type
- ☐ Missing specimen (i.e. cord blood)

Maintenance/Temperature/QC

- ☐ Temp out of range; no corrective documentation
- ☐ Temp not recorded
- ☐ QC not documented
- ☐ QC failure, no corrective action

Issuing

- ☐ Issued unit did not meet transfusion requirement
- ☐ Wrong product issued
- ☐ Autologous or directed products not issued when available
- ☐ Product returned outside of acceptable temperature range
- ☐ ABO confirmation not completed prior to product issue

Procedural Error

- ☐ Failure to follow SOP
- ☐ Unclear SOP
- ☐ No procedure available
- ☐ Tech misunderstood SOP

Supplier Error

- ☐ Mfg recall (excludes blood products)
- ☐ Incorrect or unfilled order

Quality Concern / Complaint

- ☐ Tech Quality Concern (Document on back)
- ☐ Customer Complaint (Document on back)

Comments (use space on back of this form)

If this is an RQI *(See reverse)*, reported to: _____ Date: _____ RQI # _____

If this is FDA reportable *(See procedure)*, reported to: _____ Date: _____ FDA # _____

Notified: _____ (date/time) _____ by: _____ (Tech Code)

B. Supervisor Action and Recommendation: (***document all follow-up actions taken on reverse***) (*Tracking*) Tech code: _____
No lab involvement (√)_____

C. Level of Severity

☐ No patient impact ☐ Minor impact ☐ Major impact

D. Follow-Up: Hospital Incident Report # _____ Date: _____

E. Signatures (Sign/Initial and date)

Supervisor: _____ Medical Director: _____ QA Specialist: _____ Admin. Director: _____

Case # _____

Quest Diagnostics	BB Variance Form	☐ GEC ☐ SGMC ☐ WAH

Laboratory RQI (Reportable Quality Issues)
Any FDA reportable event
Any revised result for Blood Bank testing including but not limited to ABO group, Rh type, atypical antibody screen/identification, DAT, RBC antigen typing
Any Significant Procedural Delay resulting in known or potential impact to patient care (treatment or discharge) including: ▪ Inability to provide timely blood products during an emergent event
Any Significant Specimen Collection issue (by laboratory staff) causing physical or psychological harm to the patient
Any issue or event judged by a Pathologist or the CLIA Laboratory Director to have known or potential impact on current patient care
A variation or deviation from the local Hospital Policy and Procedure that has known or potential impact on current patient care.

For RQI or FDA reportable - Notify a Supervisor immediately and document on the front of the form

Use these lines for additional information or to document Tech Quality Concerns:

Supervisor Action and Recommendation:

Case # _____