TRAINING UPDATE

Lab Location:	All	**Date Distributed:**	4/18/2013
Department:	QA Team	**Due Date:**	5/1/2013

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
PI (Performance Improvement) Database GEC / SGAH / WAH.QA17 v001
Description of change(s):
All sections: Update PI variance to Quality Variance Section 5: update database entry process and add QV scanning and hyperlink process Section 9: update Incident Description list Changes are shown in color font on the attached SOP

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training all sites (version 001)

Non-Technical SOP

Title	**PI (Performance Improvement) Database**	
Prepared by	Leslie Barrett	Date: 5/18/2009
Owner	Cynthia Bowman-Gholston	Date: 5/18/2009

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 3/31/00

TABLE OF CONTENTS

1. PURPOSE

Describe the use of the Performance Improvement (PI) database to track and trend variances and occurrences involving the laboratory.

2. SCOPE

This procedure applies to QA personnel.

3. RESPONSIBILITY

The Laboratory QA tech inputs summarized information from Quality Variance forms. The QA supervisor is responsible for content and review of this procedure.

4. DEFINITIONS

PI Database - an Excel spreadsheet with input fields and categorized codes to reflect information recorded on Quality Variance (QV) forms. Designed as a tool to track and trend variances involving the laboratory.

QA - Quality Assurance

5. PROCEDURE

1. Quality variance forms are categorized at several levels. These categories are:

   a. Incident type – Pre-analytical
   Analytical
   Post analytical
   Blood Bank

   b. Action taken – Corrected report
   Specimen rejected
   Test credited
   Redrawn

Supervisor to investigate
Discarded unit
Other action

c. Level of Severity: 1 through 7
d. Responsible unit
e. Risk Management occurrence
f. Internal follow-up

2. The QA tech reviews completed QV forms for completeness and clarity. Any QV forms that are incomplete or have inappropriate follow-up will be returned to the Supervisor for completion/follow-up.

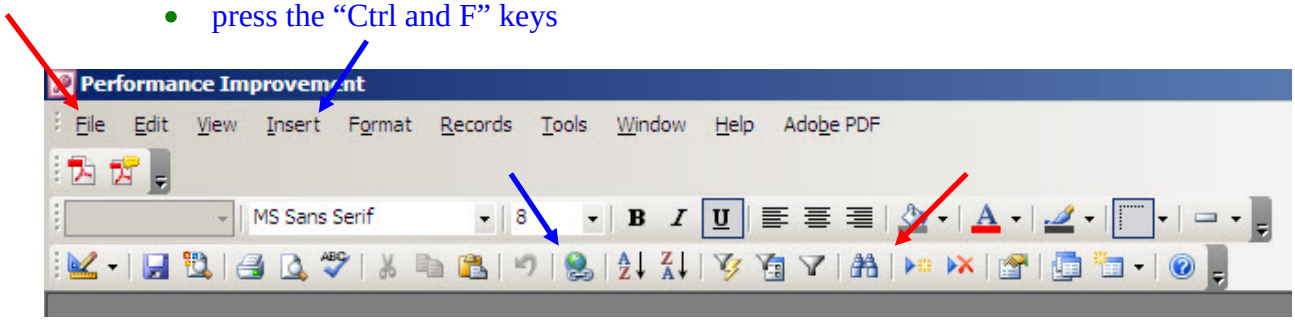
3. Database use:
   a. Open the ~~site-specific spreadsheet~~ database on the G drive.
   b. Select 'Record New Incident'
   c. Enter the **facility** using the drop down
   d. The **occurrence date** in the format mm/dd/yy.
   e. **ID**: Case number will be automatically assigned. Record on the QV form
   f. **Patient Name** field: last name only is sufficient. This field may be left blank if not a specific patient issue.
   g. **MR #**: enter patient's medical record number
   h. **Accession #**: enter the accession number of the test involved in the incident. This field may be left blank.
   i. **Test Code**: enter the involved test code responsible
   j. **Patient location:** enter nursing unit or patient classification (OP)
   k. **Responsible**: enter LIS tech code from drop down or search by last name
   l. **Incident description**: utilize drop down to choose, see listing in Appendix. A detailed description may be added in the appropriate box if necessary
   m. **Action taken**: choose from drop down. A detailed description may be added in the appropriate box if necessary
   n. **Resolution**: enter appropriate information, i.e. submitted Hercules
   o. **Responsible unit**: enter the unit/department responsible.
   p. **Lab section**: enter appropriate information
   q. **Severity level**: enter category chosen by Supervisor, QA makes final determination on severity, amend if needed.
   r. **Wizard #**: if a Hospital incident is involved, enter the number
   s. **RQI #**: enter the number if applicable
   t. **Reported by**: enter employee LIS code
   u. **Resolved by**: enter employee LIS code
   v. Comments may be added to as applicable.

4. QV forms are scanned and saved electronically as follows:
   a. Verify that all pages are the same size. Those with irregularly sized pages must be scanned by hand individually.
   b. Remove all staples while maintaining the order of the pages

Form revised 3/31/00

c. Feed approximately 30 pages through scanner; do not separate packets. Select "2 sided" scanning
d. Re-staple the original files, return to the QA office for filing.
e. Extract PDF pages; file name for each QV is its ID number
f. Save in corresponding folder by hospital, year, and month on the shared drive (file path G:\AHC_Lab\Quality Assurance\PI Data\Quality Variances_PDFs by number)

5. Hyperlink the QV form to the database as follows:
   g. Return to the QA database, select the 'Update Incident' button
   h. A different, tabbed version of the incident form will appear on the screen.
   i. The form will open with the cursor in the PI # field at the top right of the page.
   j. Use one of the following methods to search for the specific incident number:
      - select the binoculars from the toolbar
      - locate the Edit button on the toolbar and choose the Find option from the dropdown
      - press the "Ctrl and F" keys



   k. A search box will open on the screen, with the cursor in the search field
   l. Record the case number that you need to hyperlink and press the button labeled 'Find Next'
   m. When the proper record appears on the screen, select the tab labeled for Update.
   n. Place the cursor in the 'Hyperlink to the original Form' field
   o. Use one of the following methods
      - select the icon on the toolbar that has a globe with chain links
      - locate the Insert button on the toolbar and choose hyperlink option from the dropdown
      - press the "Ctrl and K" keys and select hyperlink from the dropdown list
   p. The hyperlink file will open to the folder containing the file path G:\AHC_Lab\Quality Assurance\PI Data\Quality Variances_PDFs by number)
   q. Locate the PDF file that corresponds to the selected case number. The software will create a hyperlink to that file.
      Note: Do NOT move or change the location of the hyperlinked file or the hyperlink will cease to work.

6. Data may be sorted or graphed by an applicable means.

7. Reports may be printed from the queries for confidential hospital use only.

8. A categorization of variances is utilized to identify and track trends. This information is reported and reviewed by laboratory leadership and the Medical Director at six month intervals.

Note: The database contains confidential information, and as such, is to remain a part of the laboratory internal record. Risk Management and Hospital QA/PI Departments may, at times, require summarized data from the database. At no time will copies of the database be made for any purpose other than updating information for laboratory use.

6. RELATED DOCUMENTS

Quality Variance Forms, QA procedure

7. REFERENCES

N/A

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP QA203.01		
000	4/11/2013	All sections: Update PI variance to Quality Variance Section 5: update database entry process and add QV scanning and hyperlink process Section 9: update Incident Description list	L. Barrett C. Bowman	C. Bowman

9. ADDENDA AND APPENDICES

Incident Descriptions

Quest Diagnostics

Incident Descriptions

Classification	Description
Ordering	Incorrect test ordered by laboratory
	Incorrect test ordered by nursing
	Ordered on wrong FIN visit by laboratory
	Ordered on wrong FIN visit by nursing
	Other preanalytic error
	Test on requisition - not ordered by lab
	Test ordered on wrong patient by lab
	Test ordered on wrong patient by nursing
Maintenance / Temperature / QC	1-3S QC Rule Violation NO LOOKBACK
	Centrifuge maintenance not performed
	Control lot # not in system
	Delta Failure not investigated
	Lot to Lot cross-check not performed
	Maintenance not reviewed or documented
	No SOP available
	QC failure no corrective action
	QC failure no lookback
	QC not documented
	Tech failed to sign documentation
	Temp / Humidity not recorded
	Temp / Humidity out of range
	Unclear SOP
	Wrong kit #/exp date
Before Testing	Cancelled by reference lab still pending in LIS
	Clotted
	Delayed delivery to laboratory
	Delivery problem with pneumatic tube
	FES not performed
	Handled Improperly
	Hemolyzed
	Inappropriate container/specimen
	Incomplete info on requisition
	Incorrect patient - laboratory
	Incorrect patient - nursing
	Incorrect specimen for requested test
	Incorrect test ordered by laboratory
	Incorrect test ordered by nursing
	Information on requisition & specimen do not match
	Leaked or spilled specimen
	Lost specimen
	Mislabeled
	Mislabeled by lab
	Mislabeled by nursing
	No requisition/order received
	Ordered on wrong FIN visit by laboratory
	Ordered on wrong FIN visit by nursing

Classification	Description
	Other preanalytic error
	Patient care issue
	QC not documented
	QNS
	Specimen not drawn
	Specimen not received in LIS
	TAT before receipt-collection
	Test on requisition - not ordered by lab
	Test ordered on wrong patient by lab
	Test ordered on wrong patient by nursing
	Unlabeled
	Urine >2 hours, run at physician request
	Wrong patient tested/specimen mix-up
During Testing	Delta Failure not investigated
	Dilution
	Failure to follow SOP
	Instrument technical error
	Interpretation error
	No SOP available
	Other analytical Error
	Questionable results
	Results suggest contamination
	Tech Misunderstood SOP
	Tech technical error
	Unclear SOP
	Wrong patient tested
	Wrong sample tested
Resulting / Reporting	Clerical error
	Critical value not called
	Key stroke error
	Other - supply details
	Results wrong patient - Lab
	Results wrong patient - Nursing
	TAT after receipt
Blood Bank	ABO/Rh typing error
	ABO/Rh, Antibody, DAT, Eluate interpretation error
	Admitting error in PID or MRN merge
	Armband removed (current specimen)
	Auto or DD blood not crossmatched and/or issued first
	Blood product requested on incorrect patient (transfusion request)
	Blood product requested on wrong patient
	Clerical
	Component issue error
	Crossmatching error
	Customer Complaint
	Data entry-clerical error

Classification	Description
	Duplicate sample collected
	Erroneous Report correction
	Failure to follow SOP
	Hospital policy not followed
	Incorrect component ordered
	Incorrect identification number
	Incorrect or incomplete BB armband
	Incorrect or unfilled order from blood supplier
	Incorrect tests ordered
	Incorrect tube type
	Informational - Patient
	Informational - Supplier
	Label missing one or more required information
	Labeling beneath Hollister
	Labeling error (wrong patient label on specimen)
	Manufacturer reagent recall used on patient
	Mispelled Name
	Missed antibody
	Missed RhIG
	Missing BB specimen
	No ABO confirmation prior to product issue
	No phlebotomist-collector ID
	Other blood bank error
	Patient not banded with BB armband
	Patient specimen collected too soon
	Patient's Current ABO/Rh doesn't match historical
	Pre-printed label
	Specimen not labeled
	Special antigen typings not done
	Specimen collected at incorrect time
	Specimen not labeled with BB labeling System
	Tech Quality Concern
	Test or product ordered on incorrect patient (LIS order)
	Test performed with expired reagents/cells
	Tests/Components ordered on incorrect patient
	Unit returned temp greater than 10 degrees C
	Wasted Component
	Wrong blood in tube
	Wrong patient drawn
	FDA Product labeled with incorrect ABO, Rh, Ag, Ab, product type, or unit number
	FDA Unsuitable unit issued due to improper ABO and/or Rh
	FDA SOPs for quality control and distribution not followed. Component specifications unacceptable or not documented
	FDA Unit information missing: ABO
	FDA Unit information missing: Rh
	FDA Unit information missing: product type
	FDA Unit information missing: exp date
	FDA Unit information missing: unit number

Classification	Description
	FDA Unit information missing: volume
	FDA Unit labeled with an extended expiration date
	FDA Additional information on Autologous unit missing or incorrect
	FDA SOPs for labeling not followed
	FDA Unit labeled with incorrect information on leukoreduction, irradiation
	FDA Unit not labeled with biohazard or irradiated label when indicated
	FDA Unsuitable unit issued : clotted
	FDA Unsuitable unit issued: hemolyzed
	FDA Unsuitable unit issued: outdated
	FDA Unsuitable unit issued: shipped/stored at incorrect temperature
	FDA Transfusion order request for special processing or testing not met for: CMV neg
	FDA Transfusion order request for special processing or testing not met for: leukoreduced or irradiated components
	FDA Wrong unit issued for patient because of labeling or processing error
	Wrong product issued