TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	3/27/2017
Department:	All	**Due Date:**	4/30/2017
		Implementation:	**5/1/2017**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Quality Variance Forms SGAH.QA22 v4

Quality Variance Form, Laboratory AG.F14.3

Note: this has been converted to a system SOP

Description of change(s):

SOP -

Section 5: exclude QNS & hemolyzed samples,
add QC and failure to follow SOP,
require photocopy of mislabeled samples,
add detail to notification step

Section 6: add BB SOP, remove flowchart

FORM –

- Add explanations for mislabeled and unlabeled specimens
- Remove variances that aren't used (QNS, clotted, etc.)
- Add requirement to attach photocopy of specimen
- Edit notification prompt and explanation

This revised SOP and FORM will be implemented on May 1, 2017

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

Non-Technical SOP

Title	**Quality Variance Forms**	
Prepared by	Leslie Barrett	Date: 7/21/2009
Owner	Cynthia Bowman-Gholston	Date: 7/21/2009

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**

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1. PURPOSE

To provide procedural guidelines for documentation of laboratory issues/incidents that may affect the quality of patient care. The Quality Variance (QV) form provides a framework for staff reporting, supervisory evaluation and corrective action, and QA tracking and trending of laboratory issues.

2. SCOPE

This procedure applies to all laboratory personnel

3. RESPONSIBILITY

All laboratory staff participates in reporting, recording, and investigating incidents or events as appropriate.
The Senior QA Specialist or designee is responsible for content and review of this procedure.

4. DEFINITIONS

These variances/occurrences must be reported as Quality Variances:

1. Any incident that generates inaccurate or delayed beyond accepted standards test results.

2. Any incident in which the collection of specimens or recollection of unreceived or received specimens is outside accepted standards as defined in the Laboratory policy and section-specific procedure manuals. Samples that are rejected due to hemolysis or insufficient quantity (QNS) are excluded (documentation and tracking is available in LIS).

3. Any patient identification errors, including specimen labeling and Blood Bank or Hospital armband errors.

4. Any delayed or non-notified critical values.

5. Any incident, which requires reporting to hospital Quality Assurance/Risk Management, defined as: "Any occurrence, accident or event that is not consistent with normal patient care or the routine safe operation of the hospital".

6. Any service complaint registered by any staff member from a customer (patient, physician, pathologist, nurse, technician, etc.).

7. Any staff/employee concerns or complaints that reflect concern about quality of patient testing and safety.

8. Any Blood Bank variance that qualifies as an FDA reportable event. Refer to specific procedures in the Blood Bank Quality Plan.

9. Any other incidents designated by the Laboratory Performance Improvement Committee (LPIC).

10. Any variance to normal process/procedure including missed QC and failure to follow procedure (with or without patient impact).

5. PROCEDURE

1. The person responsible for the error or any person aware of the incident will generate a Quality Variance Form.

2. There are two versions of Quality Variance form. (See Related Documents)
   - One is used to document issues relating to all areas of the Laboratory.
   - The other is specific to Blood Bank events and occurrences.

3. Documentation should be legible (preferably printed), contain only factual information and objective comments, and be complete. Do not include opinions or personal judgments in the report. Written entries may be continued on the back of the form.

4. The following information is required:
   a. Site
   b. Occurrence information:
      - occurrence date
      - patient name and medical record number, when the incident involves a patient
      - location
      - accession number
      - test, QC or maintenance documentation

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- select the appropriate variance description from the list, providing additional information in comment space or on reverse side as needed
- assess the incident to determine if it qualifies as an Reportable Quality Issue (RQI), refer to reverse side of form – **if yes, complete the notification section**
- indicate corrective action taken, i.e. corrected report, notified caregiver, etc.
- tech code of person reporting and notification information (name of person notified at the time of the occurrence / event, including date and time)
- Physician name is required if the issue involves a physician complaint or dispute.
- Attach a photocopy of all mislabeled specimens. The copy should show the incorrect labeling as well as the initials/code of the person who collected/labeled the specimen.

5. Supervisory Documentation:

   a. Quality variance forms must include Supervisor Action and Recommendation as appropriate. The Supervisor or designee, QA Specialist, Laboratory Services Director or Medical Director may complete this section.

   b. Any corrective action(s) to be taken must be followed-up and documented ~~by QA Specialist~~ as follows:
      - Log the events into the event database
      - Attach a copy of the follow-up action to the original Quality Variance form if action was documented. Documentation examples are memos, meeting minutes, etc.
      - If future follow-up will occur, enter the internal follow-up date and free text comment into the database.
      - Attach written documentation (if applicable) of the action taken and completion date to the Quality Variance form.
      - When available, attach a copy of the LIS documentation report from LIS function ANIQ by accession number.

6. The Supervisor, Group Lead, or tech-in-charge will notify the pathologist or on-call pathologist for the following events (24 hours/day, 7 days/week):
   - any event as specified in the hospital policy Significant Event Reporting and Analyzing
   - any other event causing severe harm or death to a patient
   - any immediate hemolytic transfusion reaction, or mistake resulting in a near-miss incident in the Blood Bank
   - any event with significant impact on patient care such that pathologist intervention or follow up with physician is required immediately
   - any severe dispute with a physician

7. Perform an overall assessment to summarize and review errors/incident reports (performed and reported at the quarterly LPIC meetings). This review is utilized to identify trends and initiate corrective and/or preventive actions.

8. The section Supervisor, Lab Services Director, Medical Director or designee may review Quality Variance forms.

9. All variances will be categorized to indicate severity as follows:

   No patient impact
   Minor impact = Redraw / recollection of specimen, treatment delay, rework, patient inconvenience
   Major impact = Therapy required, increased LOS, change in participation in study, potential for serious injury, or more significant outcome

10. Blood Bank Quality Variances that reflect patient-significant variances are sent directly to the Medical Director or designee by the section supervisor. This fast track mechanism ensures timely intervention in areas in which either specimens are irreplaceable, or the incident occurs in an especially high risk section, or both. The pathologist will document any intervention taken. The form is then forwarded to the appropriate reviewers.

11. ~~If follow-up outside the laboratory is required, the event is reported electronically on the Adventist Hospital Intranet~~. File an electronic hospital incident report if additional follow up is required.

    a. Document occurrence date, time and location.
    b. Document event type.
    c. Document patient and/or employee involved or affected.
    d. Provide a brief, concise summary of the problem.
    e. Once submitted, the event is reviewed by Risk Management and referred to the appropriate manager/supervisor for follow-up.
    f. Document the follow-up information, including the tracking number, on the Quality Variance form.

12. When appropriate, Quality Variance forms are discussed with the employee involved to prevent recurrence of the incident/accident. If a laboratory employee error is involved, the section supervisor will document notification of the employee involved on the Quality Variance form, and the employee will date and initial the form to acknowledge receipt of the notification. If employee notification occurs via telephone, the supervisor will document the date and time of the discussion.

13. Completed, signed Quality Variance forms, with corrective measures, notifications and follow-ups attached, are kept in a site-specific area for a period of two (2) years. Blood Bank Quality Variance forms are retained for five (5) years. These files will be under the guidance of QA/Risk Management.

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6. RELATED DOCUMENTS

Blood Bank Quality Variance Forms, BB procedure
Quality Management (QM) Plan, QA procedure

PI (Performance Improvement) Database, QA procedure
Hospital Notification Process for Reportable Quality Issues, QA procedure
Quality Variance Form, Laboratory (AG.F14)
Quality Variance Form, Blood Bank (AG.F15)
~~Laboratory Quality Variance Tool (AG.F322)~~

7. REFERENCES

N/A

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP QA202.01		
000	4/18/2012	Sections 1,4,5,9: Update PI variance to Quality Variance form Section 5: Item 4.b updated to match form Section 6: update titles, add RQI SOP Section 9: revised forms attached	L Barrett C Bowman-Gholston	C Bowman-Gholston
001	5/28/2014	Section 3: change QA supervisor to Senior QA Specialist or designee Section 5: change LPIC reporting to quarterly; specify who must notify pathologist Section 6: add forms Section 9: revise addenda A to match current practice; move forms to section 6 Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	C. Bowman-Gholston	C. Bowman-Gholston
2	3/16/2015	Section 4: remove reference to Nursing Manual Section 5: update severity classifications, insert specific job function for recording on QV form, add requirement to collect tech initials and date upon receipt of QV notification or document phone discussion Section 6: add tool, update RQI SOP title Section 9: remove flowchart	C. Bowman-Gholston	C. Bowman-Gholson
3	3/24/2017	Header: add other sites Section 5: exclude QNS & hemolyzed samples, add QC and failure to follow SOP, require photocopy of mislabeled samples, add detail to notification step Section 6: add BB SOP, remove flowchart	L Barrett S Codina	C. Bowman-Gholson

9. ADDENDA AND APPENDICES

None

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Quest Diagnostics	Quality Variance Form	☐ GEC ☐ SGMC ☐ WAH

Occurrence Date: ___ ___/ ___ ___ /___ ___ ___ ___

Patient name (affix label if available): _____ _____MR#_____
(L Name) *(F Name)*

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

A. Description of Variance: (*Check the appropriate box below and attach* available *ANIQ* documentation)

Ordering
- ☐ CPOE issue
- ☐ Incorrect test ordered by lab
- ☐ Incorrect test ordered by nursing
- ☐ Ordered on wrong visit/FIN by nursing
- ☐ Ordered on wrong visit/FIN by lab
- ☐ Other (explain on reverse)
- ☐ Test ordered on wrong patient by lab
- ☐ Test ordered on wrong patient by nursing
- ☐ Test ordered with wrong priority code
- ☐ Test was on requisition but not ordered by lab

Maintenance/Temperature/QC
- ☐ Lot to Lot crosscheck not performed
- ☐ QC failure, no look back
- ☐ QC not documented
- ☐ Temp/ Humidity not recorded
- ☐ Temp/Humidity out of range, action not documented
- ☐ Maintenance not performed per SOP
- ☐ Maintenance not reviewed or documented
- ☐ Control lot # not in system

Before Testing and Specimen
- ☐ Delivery problem with pneum tube
- ☐ FES not performed
- ☐ Handled Improperly
- ☐ Inappropriate container/specimen
- ☐ Incorrect specimen for requested test
- ☐ Leaked or spilled specimen
- ☐ Lost specimen = RQI if Irreplaceable
- ☐ Mislabeled sample[1] (Lab) = RQI
- ☐ Mislabeled sample[1] (Nursing)
- ☐ Mislabeled during accessioning = RQI
- ☐ Missing date/time/initials on specimen
- ☐ Specimen not received in LIS
- ☐ TAT delay in receipt or collection
- ☐ Unlabeled sample[2] (Lab) = RQI
- ☐ Unlabeled sample[2] (Nursing)
- ☐ Urine >2 hours; Run at physician request
- ☐ Information on requisition and specimen don't match

During Testing
- ☐ Delta failure not investigated
- ☐ Dilution error
- ☐ Failure to follow SOP
- ☐ Instrument error: _____
- ☐ Interpretation error
- ☐ Other (explain on reverse)
- ☐ Results suggest contamination
- ☐ Wrong sample tested

Resulting/Reporting
- ☐ Clerical error
- ☐ Critical value not called
- ☐ Key stroke error
- ☐ Other (explain on reverse)
- ☐ Results entered on wrong patient - lab
- ☐ TAT complaint (after receipt)
- ☐ TAT Reference Lab Results to LIS

Quality Concerns
- ☐ Tech Quality Concern
- ☐ Manufacture Recall
- ☐ Customer Complaint

Comments: (use space back on back of form)

[1] When a specimen from one patient is labeled with another patient's name. Sometimes known as "wrong blood in tube"

[2] Sample has no label OR is missing patient identifier (either name or medical record number)

Assessment and Actions taken: check the appropriate box below and/or describe actions taken

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

☐ Corrected report issued **(Attach a hard copy of the corrected report)**

☐ Specimen rejected, test canceled and called Redrawn? ☐ Y ☐ N ☐ Unknown **(Attach a photo copy of specimen)**

☐ Test credited ☐ Other *(explain on reverse)*

Reported by (**Your Tech Code**) _____ **Notified**: Name* _____ (date/time) _____

Person you spoke to or called

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: _____ Operations Director: _____

CONFIDENTIAL **Case #** _____

Quest Diagnostics	Quality Variance Form	☐ GEC ☐ SGMC ☐ WAH

Laboratory RQI (Reportable Quality Issues)
Any FDA reportable event
Five or more revised reports attributable to a single event, includes product/reagent recalls, local LIS issues and referral laboratory issues.
Any revised report where a test result was changed To a Critical Value OR from a Critical Value
Any revised report that causes a change in patient treatment:
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: ▪ Specimen collection delay (by laboratory staff) ▪ Result reporting delay (excessive TAT) ▪ Critical value notification delay ▪ 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
Irreparable loss* of • specimens from 5 or more patients attributable to a single event • a single (or more) irreplaceable** specimen (or loss of requisitions rendering specimens useless) • any single mislabeled specimen or aliquot submitted for testing that was collected or labeled by laboratory staff • any single unlabeled specimen or aliquot submitted for testing that was collected by laboratory staff
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.

*specimen is damaged, mishandled or lost while in the laboratory's possession or during transport and therefore cannot be tested.
** body fluids, CSF, Stone analysis, Product of Conception (POC) for chromosome analysis, All bone marrow specimens, Lavages, washings and brushings, Cord blood, Meconium for drug testing

For RQI - 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:

_____

_____

_____

_____

_____

CONFIDENTIAL **Case #** _____