TRAINING UPDATE

Lab Location:	SGMC, WAH & GEC	**Date Distributed:**	5/1/2019
Department:	All staff	**Due Date:**	6/4/2019
		Implementation:	**6/4/2019**

DESCRIPTION OF REVISION

Name of procedure:

Quality Variance Form, Laboratory AG.F14.4

Description of change(s):

- Added several new variance items
- Updated logo

This revised FORM will be implemented June 4, 2019

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

Adventist HealthCare	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
- ☐ Issue / error with order
- ☐ 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
- ☐ QC failure, no corrective action documented

Comments: (use space back on back of form)

Before Testing and Specimen
- ☐ Delivery problem with pneumatic 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
- ☐ Complaint of missing specimen
- ☐ Specimen cancelled by Quest
- ☐ Wrong collect date entered by lab
- ☐ Wrong result at order entry by lab
- ☐ Communication failure

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 / patient 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

[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 #** _____

Adventist HealthCare	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 #** _____