TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	2/28/2017
Department:	All staff	**Due Date:**	3/21/2017
		Implementation:	**3/21/2017**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Quality Management (QM) Plan SGAH.QA19 v8

Note: this has been converted to a system SOP

Description of change(s):

Section 9: update addenda A

Note:
Reading this SOP is intended to increase staff awareness of the ongoing quality processes for the laboratory and monitors / metrics that are used to measure and evaluate lab services.

This revised SOP will be implemented on March 21, 2017

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

Non-Technical SOP

Title	**Quality Management (QM) Plan**	
Prepared by	Leslie Barrett	Date: 6/25/2009
Owner	Cynthia Bowman-Gholston	Date: 6/25/2009

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

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1. PURPOSE

A. The laboratory Quality Management (QM) plan, in conjunction with the site-specific hospital performance improvement (PI) plan, outlines the systematic processes used to assess, plan, evaluate and implement process changes to improve laboratory performance and achieve patient safety goals.
B. The laboratory QM plan provides direction for all laboratory employees regarding performance improvement activities.
C. The laboratory QM plan provides a system to document complaints, concerns or incidents that may affect the quality of patient care, the subsequent investigation and any corrective and/or preventive action as appropriate.

2. SCOPE

A. Service Levels

1. The laboratory provides clinical laboratory services 24 hours per day, 7 days per week for inpatients, outpatients, emergency department patients and outside clients. Patients range in age from newborns, including premature newborns, to geriatrics.
2. The majority of testing is performed on-site; medical staff approved reference laboratories perform some testing.

B. Critical Success Factors

1. superior outcomes
2. most extraordinary experience
3. best place to work
4. financial success for reinvestment
5. a growing organization vital to the community
6. valued as a faith-based organization

3. RESPONSIBILITY

A. Laboratory Medical Director

1. Responsible for the quality of services provided in the Clinical Laboratory.
2. The Medical Director will provide leadership and guidance for performance improvement activities.

B. Laboratory Performance Improvement Committee (LPIC)

1. A standing committee responsible for developing, monitoring, coordinating, and evaluating laboratory performance improvement activities.
2. Meets at least quarterly.
3. Membership to include Laboratory Medical Director (or Designee), members of laboratory leadership team, and Quality Assurance (QA) personnel.
4. Primary Functions of the LPIC
   a. Establish priorities for improvement activities.
   b. To assess and evaluate laboratory performance improvement (PI) activities based on the following information:
      (1) performance indicators/monitors
      (2) aggregated data from internal Quality Variance (QV) forms
      (3) selected QV incident or follow-up cases brought to the committee for staff education or improvement
      (4) aggregated data from external customers via the hospital's electronic reporting system
      (5) focus reviews
5. Provides training and education for laboratory staff concerning PI concepts and activities.
6. Maintains documentation of all PI activities.
7. Minutes of the LPIC meetings will be posted at both sites. LPIC information is presented to staff in a variety of ways, including posters, meeting minutes or staff presentations.
8. Ad-hoc PI Subcommittees
   a. May be formed at the direction of the LPIC for resolution or study of specific issues.
   b. Membership, mission and term of these subcommittees is to be determined by the LPIC.

C. Laboratory Staff

1. All employees are encouraged to communicate any concerns or complaints with respect to the quality of patient testing and safety through the following ways:
   - Report to your supervisor
   - Report to a QA staff member
   - CHEQline (800) 650 – 9502
   - MyComplianceReport.com (internet access I.D.: QDI)
   - Contact the College of American Pathologists (CAP) via (866) 236 – 7212
2. A QV form should be utilized to document the concern/complaint, the investigation of such and corrective and/or preventive action as appropriate.

4. DEFINITIONS

Quality Measure – a quantifiable quality indicator for a specific activity, monitored on a regular basis; alternatively known as performance indicator, monitor or metric

Critical Success Factors – measures of the laboratories' vision to meet the health care needs of the communities and be recognized as the provider of choice

Threshold – minimally acceptable level of service

Compliance Rate – Also known as percent (%) compliance. Indicates the performance level of the quality measurement: i.e., number of instances in which the threshold was achieved or exceeded vs. the total number of instances. Usually reported as a percentage.

DPMO –Defects per million opportunities, a measure of process performance

LPIC – Laboratory Performance Improvement Committee, a standing committee whose function is to monitor the quality and performance of the laboratory.

Focus Review - An investigative process, quite often presented as a report from an internal audit, used to assess patient care through data collection and analysis. The Focus Review may be utilized to measure dimensions of care against established thresholds and to evaluate levels of performance, resulting in the creation of recommendations for performance improvement through process change. Monitoring is usually performed on a short term basis.

IQCP – Individualized Quality Control Plan, a 2016 required alternative quality control program that replaced equivalent quality (EQCP) testing to meet the CLIA regulations for non-waived tests based on pre-analytic, analytic and post analytic risk assessment that evaluates the specimen, environment, reagent, test system, and testing personnel.

5. PROCEDURE

Quality Measures

1. The laboratory assesses, plans, implements and evaluates quality using the following: Performance Indicators
   a. Definition – a periodic measure of specific laboratory activities that are deemed critical to the laboratory's mission, have been identified as critical to our customers and clients, are high risk, high volume, or problem prone.
   b. Performance indicators for each laboratory section may be submitted to the LPIC as determined by the supervisor, director, QA staff member, or Laboratory Director.
   c. Ongoing performance indicators include:
      (1) Monthly contracted metrics
      (2) Blood bank internal audits
      (3) Gatekeeper (corrected) report
      (4) Monthly POCT report

(5) Hospital Specific Monitors
(6) Internal metrics, i.e. hospital occurrence reports

d. Documentation of performance indicators
(1) Items to be included in the report are - specific data to be collected, method of data collection, period of data collection, specific parameters to be reported and format, threshold, percent compliance, sample size and frequency of reporting.
(2) Data will be reported via Focus Review form or metrics graph format.
(3) Performance indicators are established yearly by the laboratory leadership and Medical Director (attachment A).

2. Proficiency Testing
a. The laboratory is enrolled in a Proficiency Testing (PT) program administered by the College of American Pathologists (CAP).
b. CAP forwards copies of the proficiency testing results to the State of Maryland and Health Care Financing Administration (HCFA) as required for licensure.
c. The technical supervisor, administrative director, and the Medical Director review the PT results.

3. Competency Assessment
a. All staff performing laboratory testing/procedures have appropriate training and qualifications, as required by the regulatory agencies governing hospital laboratories (AABB, CAP, FDA, and The Joint Commission).
b. Each section supervisor will evaluate the annual competency of their staff.
c. A semiannual overview of competency compliance by section will be reported to the LPIC.
d. Complete details of the laboratory Competency Assessment Program are outlined in the Competency Assessment procedure.

4. Quality Variance Forms
The Quality Variance Forms procedure details the documentation process of QV variances.

5. Individualized Quality Control Plans (IQCP)
a. The laboratory has identified all tests using an IQCP and completed the required CAP forms.
b. Ongoing assessment of IQCPs is performed through monthly review of QC, preventative maintenance and function check records, and evaluation of errors, complaints and corrective actions documented through the QV process. If necessary, the IQCP will be revised.
c. IQCPs are reviewed and re-approved annually in conjunction with the QM plan evaluation and summary (see step 11).

6. Method for Improving Performance
a. When an opportunity for improving performance is identified, the action plan will follow a systematic approach using hospital process of Assess, Plan, Implement, and Evaluate (APIE) method.

b. The LPIC assumes responsibility for assessment of an issue.
c. The supervisor, manager, and other appropriate staff members will coordinate the planning and implementation of the action plan.
d. Assessment and evaluation of the effectiveness of the completed action plan will be accomplished and documented through the LPIC meeting minutes.

7. Safety
Monitor and evaluate occupational injuries or illnesses that require medical treatment via the Quest Diagnostics Safety Officer and reported to the Quest Diagnostics Safety Committee. Monthly hospital safety findings will be submitted to the supervisors, managers, administrative support, and the director for resolution.

8. Sentinel / Significant Events
   a. If a laboratory instrument, reagent or other device has or may have caused or contributed to a patient death or serious injury, the event must be reported to the FDA. Refer to the Quality Assurance policy for medical device reporting, Process for Complying with FDA Regulations Requiring Device User Facilities to Report MDR Reportable Events.
   b. Refer to site-specific hospital Sentinel Event Policy posted on Adventist Healthcare Intranet.

9. Interaction with Other Hospital Departments
   a. The Laboratory actively participates on various hospital committees and provides relevant information to the proper hospital department/agency.
   b. The director and managers prepare and present Quality Council Reports to inform the hospitals of laboratory performance.

10. Internal and External Customer Satisfaction
    a. An outside contractor collects performance statistics from hospital patients, and filters the performance by department. The laboratory utilizes this data to assess and improve our portion of the hospital's total Patient Customer satisfaction. Issues are addressed as necessary.
    b. Patients, physicians, other hospital departments, and entities receive phone calls or follow-up letters to written or verbal inquires, and in response to incidents
    c. Statistics regarding nursing/laboratory issues are regularly shared with nursing leadership at both sites.
    d. The hospital-wide PI Council disseminates information to various departments, Medical Executive Committee, and to the hospital Board of Trustees.
    e. Discussion of QV incidents allows the laboratory leadership to make process improvements to prevent recurrence(s).

11. Program Evaluation
    a. The Quality Management Plan will be evaluated by the LPIC every year. This assessment will ensure that the effort is comprehensive, cost effective, and results in demonstrable improvements in patient care and services.
    b. An annual summary to assess the QM Plan will be prepared by February 1 each year. This information will be utilized by the LPIC to evaluate the effectiveness of

the program, identify trends and suggest future studies and performance indicators as appropriate.

c. The effectiveness of the program will be documented in the LPIC meeting minutes.

12. Confidentiality
All activities set forth in this Quality Management Plan including minutes, reports and work sheets, are a part of the QA process and, therefore, are confidential. Such materials are to be held in strictest confidence and carefully safeguarded against unauthorized disclosure.

6. RELATED DOCUMENTS

Sentinel Event Policy (Adventist Healthcare Intranet)
Quality Assurance procedures:

- Focus Review
- Proficiency Test Results Evaluation
- Quality Variance Forms
- Process for Complying with FDA Regulations Requiring Device User Facilities to Report MDR Reportable Events

7. REFERENCES

Laboratory General and All Common Checklists, College of American Pathologists, Laboratory Accreditation Program, Northfield, IL 60093, www.cap.org

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOP QA201.002		
000	8/13/2010	Update addenda A	CBowman	NCacciabeve
001	9/27/2011	Update addenda A	CBowman	NCacciabeve
002	4/24/2013	Section 2: clarify Service Levels Section 3&5: revise PI variance to Quality Variance Section 5.1: update performance indicators Section 5.8: add committee participation & reports Section 5.9: add data collection method Section 5.10: add due date for summary & effectiveness documentation Section 6: update SOP titles Section 9: update addenda A	CBowman	NCacciabeve
003	3/10/2014	Section 9: update addenda A Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	LBarrett CBowman	NCacciabeve
4	5/26/2015	Section 9: update addenda A	LBarrett	NCacciabeve
5	2/16/2016	Section 4: remove Quest Blueprint Section 9: update addenda A	LBarrett	NCacciabeve

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Version	Date	Reason for Revision	Revised By	Approved By
6	6/15/2016	Sections 4, 5 & 9: add IQCP Section 7: add All Common checklist	LBarrett	NCacciabeve
7	2/23/2017	Header: add other sites Section 9: update addenda A	LBarrett	NCacciabeve

9. ADDENDA AND APPENDICES

A. Quality Measures (current year)

Quality Measures 2017 - 2018

Metric	Frequency	Monitor Specifications
Pre-Analytical		
STAT Specimen Collections @ 15 min	Monthly	95% within 15 minutes
% of Tests ordered STAT	Monthly	
AM Labs TAT	Monthly	Specimens Received by 0630; Resulted by 0730
Specimen Rejection Rate	Semi-annual	Less than 2% (data set = 1 month)
Blood Culture Volume	Quarterly	> 85% (data set = 1 day/week)
Analytical - TAT for:		
Antibody Screen	Annual	[STAT Only] 90 min with World Class (WC) at 60 min (data set = 1 month)
BHCG Qualitative	Semi-annual	[STAT & ASAP] 60 min Contract target, WAH & GEC only; 45 min WC (data set = 1 month)
HGB	Monthly	[STAT] 45 min Contract target; 30 min WC [STAT Only]
K	Monthly	[STAT] 60 min Contract target; 45 min WC [STAT Only]
PT	Monthly	[STAT] 60 min Contract target; 45 min WC [STAT Only]
TROPI	Monthly	[STAT & ASAP] 60 min Contract target; 45 min WC
Gram Stain	Monthly	2 hour TAT
Malaria	Monthly	2 hour TAT
Post-Analytical		
Critical Out Patient Notification	Monthly	100% called within 2 hours
AFB	Monthly	24 hour TAT from receipt in Chantilly
Blood Culture Contamination Rate	Monthly	< 3%
CAP Proficiency Percent & DPMO	Monthly	< 7,000 DPMO
Internal Metric Sheet		
Health Stream (Customer satisfaction)	Monthly	> 50th percentile
Corrected Reports - Gatekeeper	Monthly	< 2 / month
RL Solutions (Customer complaints)	Monthly	Present data Quarterly at LPIC
Quest Hospital Labs		
QHL Metrics	Monthly	Blood Culture Contamination; Blood Product Wastage; Critical Result Notification; Specimen Rejection; Stat Testing TAT

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Metric	Frequency	Monitor Specifications
Focus Reviews		
Hemolysis rate (ED)	Annual	< 4%
Hospital Monitors		
ED metrics for: Hgb, K, Tropi & Ketones	Monthly	Order to collect for BMP (30 min) & UA (90 min) only. Receive to result Hgb w/in 30 min, K & Tropi w/in 45 min
	Quarterly	Box plots for order to collect; collect to receive; order to result (K, Tropi, Hgb, UA). Present at ED meetings
Dashboard (Posting for Lab)	Monthly	AM results; Health Stream; Core Lab Stat / ASAP TAT (PT/Tropi w/in 45 min); Stat/Timed Collections; Specimens w/out Orders; Mislabeled Samples
Physical Health & Rehabilitation (ARH) Metrics, Rockville & Takoma Park	Quarterly	STAT K, HGB, PT combined TAT 90 min; UA (all priorities) TAT 90 min; Urine Culture, TAT 3 days (data set = 1 month); Present at ARH quarterly meetings
ABH Metrics, Rockville & Takoma Park	Quarterly	STAT K & HGB combined TAT 90 min; UA (all priorities) TAT 90 min; Urine Culture, TAT 3 days (data set = 3 months); Present at ABH meetings
WAH Quality Council	Annual	AM results; Health Stream; Core Lab Stat / ASAP TAT (PT/Tropi w/in 45 min); Stat/Timed Collections; Specimens w/out Orders; Mislabeled Samples Blood Bank Blood Administration Audits
SGMC Performance Improvement Council	Semi-annual	AM results; Health Stream; Core Lab Stat / ASAP TAT (PT/Tropi w/in 45 min); Stat/Timed Collections; Specimens w/out Orders; Mislabeled Samples Blood Bank Blood Administration Audits
Quality Indicators and Audits		
Blood Bank Audits	Quarterly	Blood Administration, Other BB processes
POCT Reports	Monthly	% Patient ID compliance (target 100%), % QC Testing compliance (target 95%)
Quality Variances with trend analysis	Quarterly	BB, pre-analytic, analytic, post-analytic, QC / PM
Competency Assessment	Quarterly	% completed annual
Training Verification Grids	Quarterly	Review documentation
Safety Audits	Monthly	Present data Quarterly at LPIC
RQI	Monthly	Present data Annually at LPIC
Privacy Review	Annual	Present data at LPIC
IQCP Review and Re-approval	Annual	Present data at LPIC