

## TRAINING UPDATE

**Lab Location:** GEC, SGMC & WOMC  
**Department:** All staff

**Date Distributed:** 3/6/2020  
**Due Date:** 3/31/2020  
**Implementation:** 3/23/2020

### DESCRIPTION OF REVISION

|   |
|---|
| <b>Name of procedure:</b>   |
| <b>Quality Management (QM) Plan      SGAH.QA19 v11</b>  |
| <b>Description of change(s):</b>  |
| <p><i>Most changes to metrics have been discussed at general staff meetings</i></p> <p>Header: changed WAH to WOMC</p> <p>Section 6: update MDR title</p> <p>Section 9: updated addenda A</p> <p><b>This revised SOP will be implemented March 23, 2020</b></p> |

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

Non-Technical SOP

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

| <b>Laboratory Approval</b>   |           |                       |
|--|-----------|-----------------------|
| Print Name and Title   | Signature | Date                  |
| <i>Refer to the electronic signature page for approval and approval dates.</i> |           |                       |
| Local Issue Date:  |           | Local Effective Date: |

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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 and/or the presentation from 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
  - 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 via the electronic document control system.
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 Define, Measure, Analyze, Improve and Control (DMAIC) 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
- Medical Device Reporting (MDR) Reportable Events

### 7. REFERENCES

Laboratory General and All Common Checklists, College of American Pathologists, Laboratory Accreditation Program, Northfield, IL 60093, [www.cap.org](http://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<br>Section 3&5: revise PI variance to Quality Variance<br>Section 5.1: update performance indicators<br>Section 5.8: add committee participation & reports<br>Section 5.9: add data collection method<br>Section 5.10: add due date for summary & effectiveness documentation<br>Section 6: update SOP titles<br>Section 9: update addenda A | CBowman                          | NCacciabeve |
| 003     | 3/10/2014 | Section 9: update addenda A<br>Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.  | LBarrett<br>CBowman              | NCacciabeve |
| 4       | 5/26/2015 | Section 9: update addenda A  | LBarrett                         | NCacciabeve |
| 5       | 2/16/2016 | Section 4: remove Quest Blueprint<br>Section 9: update addenda A   | LBarrett                         | NCacciabeve |
| 6       | 6/15/2016 | Sections 4, 5 & 9: add IQCP<br>Section 7: add All Common checklist   | LBarrett                         | NCacciabeve |
| 7       | 2/23/2017 | Header: add other sites<br>Section 9: update addenda A   | LBarrett                         | NCacciabeve |
| 8       | 3/14/2018 | Section 3: add posting presentation to B.3<br>Section 5: specify IQCP re-approval process, change improvement method to DMAIC<br>Section 9: update addenda A   | LBarrett<br>CBowman-<br>Gholston | NCacciabeve |
| 9       | 2/27/2019 | Section 9: update addenda A  | LBarrett                         | NCacciabeve |
| 10      | 2/27/2020 | Header: change WAH to WOMC<br>Section 6: update MDR title<br>Section 9: update addenda A   | LBarrett                         | NCacciabeve |

## 9. ADDENDA AND APPENDICES

### A. Quality Measures (current year)



**Quality Measures 2020 - 2021**

| Metric                                 | Frequency   | Monitor Specifications   |
|--|-------------|--|
| <b>Pre-Analytical</b>                  |             |  |
| Timed Troponin Collection              | Monthly     | Lab collections within 30 min (target 90% within 30 min; 95% WC)   |
| AM Labs TAT                            | Monthly     | Specimens Received by 0700; Resulted by 0800   |
| Blood Culture Volume                   | Quarterly   | > 85% (data set = 1 day/week)  |
| <b>Analytical - TAT for:</b>           |             |  |
| HGB                                    | Monthly     | [STAT & ASAP] 30 min (target 90% within 30 min; 95% WC)  |
| K                                      | Monthly     | [STAT & ASAP] 30 min (target 90% within 30 min; 95% WC)  |
| PT                                     | Monthly     | [STAT & ASAP] 30 min (target 90% within 30 min; 95% WC)  |
| TROPI                                  | Monthly     | [STAT & ASAP] 30 min (target 90% within 30 min; 95% WC)  |
| Gram Stain                             | Monthly     | 2 hour TAT use all GRAM data   |
| BC received to BACTEC (Positives only) | Monthly     | Received to load 60 min (target 90% within 60 min; 95% WC)   |
| BC Positive to Remove                  | Monthly     | 60 min (target 90% within 60 min; 95% WC)  |
| Malaria                                | Monthly     | 2 hour TAT   |
| Cepheid (C diff and MRSA)              | Monthly     | < 8 hour TAT (Set target 90%; 95% WC)  |
| <b>Post-Analytical</b>                 |             |  |
| 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 Set target at 97%; 99% WC   |
| <b>Quest Hospital Labs</b>             |             |  |
| QHL Metrics                            | Monthly     | Blood Culture Contamination; Blood Product Wastage; Critical Result Notification; Stat Testing TAT                                 |
| <b>Focus Reviews</b>                   |             |  |
| % of Tests ordered STAT                | Monthly     | Unpublished, track by nursing unit. Move to Focus Review @ 6 months and report at LPIC.  |
| Specimen Rejection Rate                | Semi-annual | Less than 2% (data set = 1 monthly). Nurse collected samples for clotted, mislabeled, or hemolysis by nursing unit. Report at LPIC |

| Metric  | Frequency | Monitor Specifications   |
|---|-----------|--|
| <b>Hospital Monitors</b>  |           |  |
| ED metrics for:<br>Hgb, K, Tropi & Ketones                              | Monthly   | Order to collect for BMP (30 min) & UA (90 min) only.<br>Receive to result Hgb, K & Tropi w/in 30 min  |
|   | Monthly   | Box plots for order to collect; collect to receive; order to result (K & Tropi, standardize axis across sites). Present at ED meetings   |
| Dashboard (Posting for Lab)   | Monthly   | AM rec'd by 0700; Resulted by 0800; BC loading in FX w/in 60 min; BC pos to pulled w/in 60 min; Timed Tropi Collections w/in 30 min; Tropi resulted w/in 30 min  |
| 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   |
| Behavioral Health 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)  |
| WOMC Quality Council  | Annual    | AM rec'd by 0700; Resulted by 0800; BC loading in FX w/in 60 min; BC pos to pulled w/in 60 min; Timed Tropi Collections w/in 30 min; Tropi resulted w/in 30 min; Blood Bank Blood Administration Audits; Blood Wastage |
| SGMC Performance Improvement Council                                    | Annual    | AM rec'd by 0700; Resulted by 0800; BC loading in FX w/in 60 min; BC pos to pulled w/in 60 min; Timed Tropi Collections w/in 30 min; Tropi resulted w/in 30 min; Blood Bank Blood Administration Audits                |
| <b>Quality Indicators and Audits</b>                                    |           |  |
| Blood Bank Audits   | Quarterly | Blood Administration, Other BB processes   |
| POCT Reports  | Monthly   | % 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 in PI Summaries  |
| Privacy Review  | Annual    | Present data at LPIC   |
| IQCP Review and Re-approval   | Annual    | Present data Annually in PI Summaries  |
| Customer Satisfaction   | Annual    | Physicians and Nursing, Present data Annually in PI Summaries  |
| Reference Lab Assessment  | Annual    | Micro and AFB TAT, epidemiology reports and antibiograms. Include in PI Summaries  |