TRAINING UPDATE

Lab Location:	All Labs	**Date Distributed:**	8/18/22
Department:	All Departments	**Due Date:**	8/31/22

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Technical SOP: Quality Management (QM) Plan (AHC.QA19)
Description of change(s):
• **Section 5**: Updated the IQCP procedure (see highlighted text in attached SOP) KEY POINT: The test SOP must be revised to include the IQCP plan frequency and approved by the Medical Director **prior** to changing the QC frequency. • **Section 6:** Added reference to IQCP Worksheet (AG.F649) attached to this MTS training document. • **Addendum C**: IQCP Eligibility Flow Chart This revised SOP will be implemented on Aug 18, 2022

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

AHC.QA19 Quality Management (QM) Plan

Copy of version 14.0 (approved and current)

Last Approval or Periodic Review Completed	8/18/2022
Next Periodic Review Needed On or Before	8/18/2024
Effective Date	8/18/2022

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Organization Adventist HealthCare

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	8/18/2022	14.0	Nicolas Cacciabeve	
Approval	QA Leader approval	8/18/2022	14.0	Cynthia Bowman-Gholston (104987)	
Approval	Lab Director	6/7/2022	13.0	Nicolas Cacciabeve	
Approval	QA Leader approval	6/7/2022	13.0	Cynthia Bowman-Gholston (104987)	
Approval	Lab Director	5/18/2021	12.0	Nicolas Cacciabeve	
Approval	QA Leader approval	5/18/2021	12.0	Cynthia Bowman-Gholston	
Approval	QA approval	5/9/2021	12.0	Leslie Barrett	
Approval	Lab Director	3/5/2020	11.0	Nicolas Cacciabeve	
Approval	QA Leader approval	3/5/2020	11.0	Cynthia Bowman-Gholston	
Approval	QA approval	2/28/2020	11.0	Leslie Barrett	
Approval	Lab Director	3/3/2019	10.0	Nicolas Cacciabeve	
Approval	QA Leader approval	3/1/2019	10.0	Cynthia Bowman-Gholston	
Approval	QA approval	2/27/2019	10.0	Leslie Barrett	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
14.0	Approved and Current	Major revision	8/18/2022	8/18/2022	Indefinite
13.0	Retired	Major revision	6/6/2022	6/7/2022	8/18/2022
12.0	Retired	Major revision	5/9/2021	5/18/2021	6/7/2022
11.0	Retired	Major revision	2/28/2020	3/23/2020	5/18/2021
10.0	Retired	Initial version	2/27/2019	3/26/2019	3/23/2020

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:	

TABLE OF CONTENTS

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. Determine if the test is eligible for IQCP.
   b. If eligible for IQCP a risk assessment must be completed and approved by the Medical Director before implementation of the IQCP Plan.
   c. The IQCP Plan must at a minimum meet the manufacturer's instructions. Once implemented, external QC must be performed and acceptable every 31 days and with each new lot, at a minimum.
   d. The test procedure must be revised to the IQCP Plan frequency and approved by the Medical Director prior to changing QC frequency. QC will be performed each day of testing until the revised SOP is effective.
   e. The IQCP go-live will be captured in the SOP by the effective date.
   f. The laboratory has identified all tests using an IQCP and completed the required CAP forms.
   g. 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.
   h. 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
- Individual Quality Control Plan (IQCP) Worksheet (AG.F649)

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
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
8	3/14/2018	Section 3: add posting presentation to B.3 Section 5: specify IQCP re-approval process, change improvement method to DMAIC Section 9: update addenda A	LBarrett CBowman-Gholston	NCacciabeve
9	2/27/2019	Section 9: update addenda A	LBarrett	NCacciabeve
10	2/27/2020	Header: change WAH to WOMC Section 6: update MDR title Section 9: update addenda A	LBarrett	NCacciabeve
11	5/3/21	Section 9: update addenda A	LBarrett	NCacciabeve
12	6/6/2022	Section 9: update addenda A Section 9. Added addenda B – FWMC Header: Changed Site to All Laboratories Footer: Changed SOP prefix to AHC	CBowman	NCacciaveve
13	8/17/22	Section 5: Updated IQCP procedure Section 6: added IQCP Worksheet Addendum C: IQCP Eligibility Flow Chart	R SanLuis	NCacciaveve

9. ADDENDA AND APPENDICES

A. SGMC, WOMC Quality Measures (current year)
B. FWMC Quality Measures (current year)
C. IQCP Eligibility Flow Chart

SGMC, WOMC Quality Measures 2022 - 2023

Metric	Frequency	Monitor Specifications
Pre-Analytical		
Timed Troponin Collection	Monthly	Lab collections within 30 min (target 90% within 30 min; 95% WC)
AM Labs TAT	Monthly	Specimens Resulted by 0800
Blood Culture Volume	Quarterly	> 85% (data set = 1 day/week)
Analytical - TAT for:		
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
Malaria	Monthly	2 hour TAT
Cepheid (C diff and MRSA)	Monthly	< 6 hour TAT (Set target 90%; 95% WC)
COVID (Cepheid & BioFire)	Monthly	< 120 min TAT (target 90%; 95% WC)
COVID (QIAstat)	Monthly	< 4 hour TAT (target 90%; 95% WC)
COVID (LIAT)	Monthly	< 90 min TAT (target 90%; 95% WC) GEC only
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	< 2%
CAP Proficiency DPMO	Monthly	< 7,000 DPMO (target); <3,000 (WC)
Focus Reviews		
Specimen Rejection Rate	Semi-annual	Less than 2% (data set = single month). Nurse collected samples for clotted, mislabeled, or hemolysis by nursing unit. Report at once per year at LPIC

Metric	Frequency	Monitor Specifications
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, K, Tropi & UA w/in 30 min

	Monthly	Box plots for order to collect; collect to receive; order to result (K & Tropi, standardize axis across sites).
Dashboard (Posting for Lab)	Monthly	Stat/timed troponins collected within 30 minutes Count of non-Micro send out specimens cancelled for avoidable reasons: count <10 = target; count <5 = WC Lab collected blood culture contamination rate <2% Troponins resulted within 30 min PT/INR resulted within 30 min CAP DPMO (YTD Cumulative/month)
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 = One Quarter)
WOMC Quality Council	Annual	Stat/timed troponins collected within 30 minutes Count of non-Micro send out specimens cancelled for avoidable reasons Lab collected blood culture contamination rate <2% Troponins resulted within 30 min PT/INR resulted within 30 min CAP DPMO (YTD Cumulative/month); Blood Bank Blood Administration Audits; Blood Wastage
SGMC Performance Improvement Council	Annual	Stat/timed troponins collected within 30 minutes Count of non-Micro send out specimens cancelled for avoidable reasons Lab collected blood culture contamination rate <2% Troponins resulted within 30 min PT/INR resulted within 30 min CAP DPMO (YTD Cumulative/month); Blood Bank Blood Administration Audits; Blood Wastage
Quality Indicators and Audits		
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
Safety Audits	Monthly	Present data Quarterly at LPIC

RQI	Monthly	Present data Annually in PI Summaries
Privacy Review	Annual	Present data at LPIC & PI Summaries
IQCP Review and Re-approval	Annual	Review biennially in ML
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

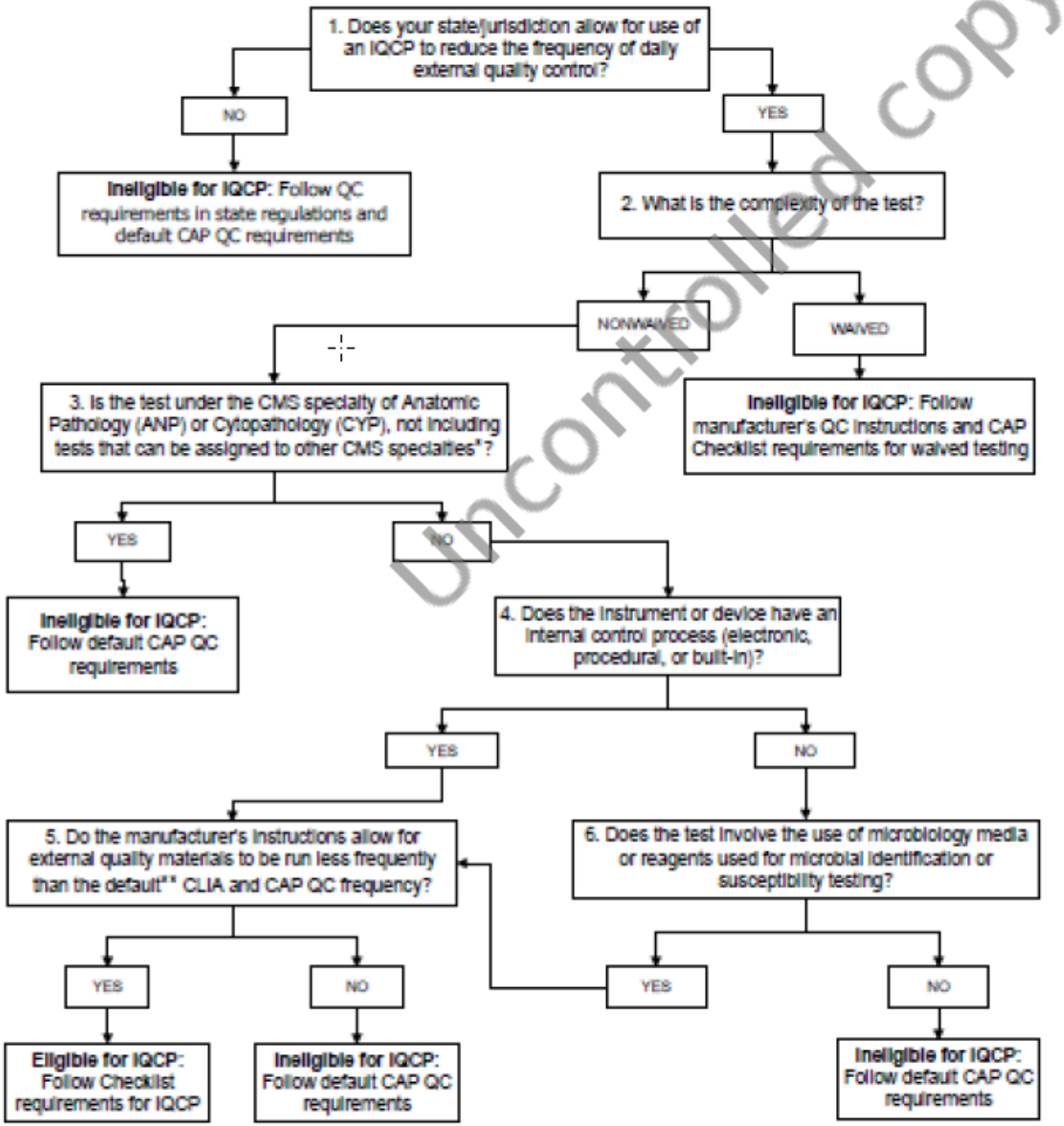
FWMC Quality Measures 2022 - 2023

Metric	Frequency	Monitor Specifications
Pre-Analytical		
Timed Troponin Collection	Monthly	Lab collections within 30 min (target 90% within 30 min; 95% WC)
AM Labs TAT	Monthly	Specimens Resulted by 0800
Analytical - TAT for:		
HGB	Monthly	[STAT & ASAP] 45 min (target 90% within 45 min; 95% WC)
K	Monthly	[STAT & ASAP] 45 min (target 90% within 45 min; 95% WC)
PT	Monthly	[STAT & ASAP] 45 min (target 90% within 45 min; 95% WC)
TROPI	Monthly	[STAT & ASAP] 45 min (target 90% within 45 min; 95% WC)
COVID (QIAstat)	Monthly	< 4 hour TAT (target 90%; 95% WC)
COVID (LIAT)	Monthly	< 90 min TAT (target 90%; 95% WC)
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	< 2%
CAP Proficiency DPMO	Monthly	< 7,000 DPMO (target); <3,000 (WC)

Metric	Frequency	Monitor Specifications
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, K, Tropi & UA w/in 45 min
	Monthly	Box plots for order to collect; collect to receive; order to result (K & Tropi, standardize axis across sites).
Dashboard (Posting for Lab)	Monthly	Stat/timed troponins collected within 30 minutes Count of non-Micro send out specimens cancelled for avoidable reasons: count <10 = target; count <5 = WC Lab collected blood culture contamination rate <2% Troponins resulted within 45 min PT/INR resulted within 45 min CAP DPMO (YTD Cumulative/month)

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 = One Quarter)
FWMC Quality Council	Annual	Stat/timed troponins collected within 30 minutes Count of non-Micro send out specimens cancelled for avoidable reasons Lab collected blood culture contamination rate <2% Troponins resulted within 45 min PT/INR resulted within 45 min CAP DPMO (YTD Cumulative/month); Blood Bank Blood Administration Audits; Blood Wastage
Quality Indicators and Audits		
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
Safety Audits	Monthly	Present data Quarterly at LPIC
RQI	Monthly	Present data Annually in PI Summaries
Privacy Review	Annual	Present data at PI Summaries
IQCP Review and Re-approval	Annual	Review biennially in ML
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

Eligibility Determination for Individualized Quality Control Plan (IQCP) Option



WOMC, SGMC, FWMC, or GEC

	Enter test or Method Name Here	IQCP Local Data Review / Risk Assessment
Current QC Process		

Important Note: Until the IQCP Plan is approved and the SOP is revised and approved QC must be run each day of patient testing and with each new lot and shipment.

	Date Range of Records Reviewed	Num. tests	Num. failed	Failure Rate	Itemize and group incidents by root cause	Did process controls fail?	If no, describe effective process control. If yes, issue should be addressed in QC plan.
Validation/ Verification *(Add row for each instrument verified)*							
Historical External QC							
Historical Electronic QC							
Method Comparison							

	Date Range of Records Reviewed	Significant Deviations (Itemize)	Root Cause	Corrective Action / Effect on Test Results	Did process controls fail?	If no, describe effective process control. If yes, address in QC plan.
Temperature and Humidity Records						
Routine Instrument Maintenance and Function Records						
Vendor performed Preventative Maintenance						
Method Failures						

Proficiency Testing Records (CAP survey or other)						
Competency Assessment Records						

	Date	Issue	Root Cause	Laboratory Investigation	Resolution
Vendor Recalls or Issues					
Complaints					
QA Activities					

	Instructions consistent with manufacturer?	Instructions available to collection staff?	Processes to monitor deviations	Deviations observed / Actions Needed
Specimen Collection Instructions				

	Date/# Reissued	Type - Amended or Revised	Description	Action(s) taken
Reissued Reports				

Local Laboratory Data Review Summary:

Other Comments:

Reviewed By: _____ Date: _____

Approved By: _____ Date: _____

SUMMARY OF VALIDATION RESULTS FOR:

Assay or Method Name:

The validation of the _____ Assay has shown that the assay performed well for the detection of _____ A summary of the validation results is shown below:

Complete the following:

Specimen Type	
Stability:	
Accuracy:	
Recovery Study	
Accuracy:	
Method Comparison	
Intra assay precision	
Inter assay precision	
Analytical Sensitivity:	
Limit of Detection	
Analytical Specificity:	
Cross reactivity	
Analytical Specificity: Interference	
Linearity	
Reference Range	
Analytical Sensitivity: Limit of Quantitation	
Analytical Measurement Range (AMR)	
Clinical Reportable Range (CRR)	

Data Collected & Reviewed

Training Plan and Records Reviewed
Patient results
External Quality Control Records
Temperature Records
Maintenance Records

Implementation Plan/Change Control

IQCP Review Results (Findings)

No issues detected on maintenance records other than replacement of 1 I-CORE module.
Training Documents reviewed.
Patient result review acceptable.
External and Internal QC acceptable.
Temperature acceptable.
Medical Staff complaints – None
Patient Testing Issues – None

The _____ Assay uses the same collection procedure, transport media, instrument, and testing procedure as the _____ Assay. Therefore, in addition to the risk assessments performed specifically for this assay, the risk assessments performed for the _____ Assay are also applicable for the _____ Assay.

Conclusions

The _____- Assay has been in use and approved for patient testing by the Adventist Healthcare laboratories since _____. The manufacturer's QC instruction is to run the External QC each time a new lot or a new shipment of the same lot is received. In addition, the CAP also requires QC to be performed every 31 days of use. The purpose of IQCP requirements is to perform a risk assessment to determine the appropriate QC plan to ensure the accuracy and reliability of patient results being reported as a number of factors as listed with the document above and the risk assessment could potentially impact the performance of the test system.

Our internal risk assessment demonstrates that testing as outlined within our procedure adequately ensures safe and reliable patient results.

The following is the approved IQCP for _____ utilizing the _____ Assay.

Controls Used

Name	Supplier and Catalog Number

QC Frequency and Procedure	

Tolerance Limits and Criteria for Acceptable QC

Control Type	Instrument-Reported Assay Result

Validation reviewed by: *Refer to the electronic signature manifest* **Date: _____**

Approved by: *Refer to the electronic signature manifest* Date: _____