TRAINING UPDATE

Lab Location:	All Labs	**Date Distributed:**	8/17/2022
Department:	Quality Assurance	**Due Date:**	8/31/2022

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
SOP: Process and Equipment Validation Protocol (AHC.QA46)
Description of change(s):
• Added definition of, and the requirement to, assess the Recurring Calendar • Added reference to two new forms: Recurring Calendar (AG.F647) and Master Test Project Plan (AG.F648) • See highlighted test in the attached SOP for changes This revised SOP will be implemented on August 17, 2022

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

AHC.QA46 Process and Equipment Validation Protocol

Copy of version 5.0 (in review)

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Organization Adventist HealthCare

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	3/3/2022	4.0	Nicolas Cacciabeve	
Approval	QA Leader approval	3/1/2022	4.0	Cynthia Bowman-Gholston (104987)	
Approval	Lab Director	3/5/2020	3.0	Nicolas Cacciabeve	
Approval	QA Leader approval	3/5/2020	3.0	Cynthia Bowman-Gholston	
Approval	QA review	2/26/2020	3.0	Leslie Barrett	
Approval Captured outside MediaLab	Lab Director	4/4/2018	2.0	Nicolas Cacciabeve	Recorded on 5/24/2019 by Leslie Barrett (104977) when document added to MediaLab
Periodic review Captured outside MediaLab	Designated Reviewer	4/4/2018	2.0	Nicolas Cacciabeve	Recorded on 5/24/2019 by Leslie Barrett (104977) when document added to MediaLab

Approvals and periodic reviews that occurred before this document was added to the MediaLab Document Control system may not be listed.

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
4.0	Approved and Current	Major revision	2/15/2022	3/3/2022	Indefinite
3.0	Retired	Major revision	2/26/2020	3/11/2020	3/3/2022
2.0	Retired	First version in Document Control	5/24/2019	4/11/2018	3/11/2020

Linked Documents

- AG.F204 Equipment and Process Validation Protocol
- AG.F204A Equipment and Process Validation Protocol (Word version)

Non-Technical SOP

Title	**Process and Equipment Validation Protocol**
Prepared by	Leslie Barrett Date: 7/27/2012
Owner	Cynthia Bowman-Gholston Date: 7/27/2012

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

This procedure describes the process of validation and revalidation of new and revised processes or procedures, and new or repaired equipment.

2. SCOPE

This procedure applies to all non-computer processes or procedures and equipment that require validation.

3. RESPONSIBILITY

- **Testing Personnel** will:
  - Follow the Validation Protocol as designed.
  - Document all steps of the validation protocol.
- The **Lab Services Director, Manager, or Supervisor** (or designee) will:
  - Ensure compliance with this procedure in his/her department.
  - Document all steps of the validation protocol.
  - Ensure that all staff is appropriately trained.

- The **Quality Assurance Department** will:
  - Manage validation documents on the electronic document control system
- The **Medical Director** will:
  - Approve the initial document and any subsequent revisions.
  - Approve all validations prior to implementation.
  - Approve validation protocols.

4. DEFINITIONS

Installation Qualification (IQ): ensures equipment is installed per requirements
- Equipment is installed per manufacturer's specifications
- Equipment operates within the limits required for the process and per manufacturer specifications
- Support utilities (water, electric, air, temperature) must meet manufacturer's specifications

Operational Qualification (OQ): ensures equipment can do what it is supposed to do. Examples: test alarms, check temperatures of empty refrigerator, test RPM/RCF and timers of centrifuge, QC results, etc.

Performance Qualification (PQ): ensures equipment does perform as expected. Test using normal samples under normal and extreme conditions. Must be performed by staff who will utilize the equipment.
Examples: fill the refrigerator and ensure it still maintains temperature in all areas of the refrigerator; ensure filling the refrigerator does not inhibit air flow; fill a centrifuge and make sure it runs appropriately with maximum and/or minimum load, etc.

Validation: "verification, where the specified requirements are adequate for intended use." (Reference: "International vocabulary of metrology, Basic and General concepts and associated terms (VIM) 2008").

Verification: "provision of objective evidence that a given item fulfills specified requirements."

Smartsheet.com: Project management software. New projects are assigned and tracked using the "Master Test Project Plan Template" and the "Recurring Calendar Template".

Recurring Calendar: This Smartsheet Project tracker is used to ensure activities required for regulatory compliance and lab quality are tracked and completed. Examples of activities include Method-Method & Instrument-Instrument comparisons, AMR, Centrifuge, Pipette, or Timer verifications etc.

5. PROCEDURE

1. The Supervisor or designee develops, writes, and submits validation protocol to include laboratory regulations, accreditation standards, and manufacturer's instructions. Refer to addenda B for guidelines.

Notes:

- An Equipment and Process Validation Protocol Form must be used to document the plan. Refer to Related Documents
- For validation of test methods, refer to the procedure Validation Requirements for Quantitative and Semi-Quantitative Methods.

2. The Laboratory Director reviews and approves draft protocol or revises as needed.
3. Installation Qualification and Operational Qualification are performed and documented by the appropriate personnel. This may include Biomedical personnel, manufacturer's representative, in-house or other designated staff.
4. The Supervisor reviews and approves IQ and OQ documentation. Corrective action is documented as necessary.
5. The Supervisor or designee writes draft procedure(s) and training document. Pre-validation training is performed and documented for appropriate staff.
6. Assigned validation staff performs the Performance Qualification and validation. Data is collected and documented on appropriate forms (ie, QC, Maintenance logs)
7. The project management software Smartsheet, is used to document completion of key tasks for processes (example: LIS changes, QC definitions, communication of changes to reference ranges, critical values, and addition of tasks to the recurring calendar, etc).

    - The format allows tasks to be assigned to individuals and prompts for dates for each task. Email reminders are provided to assure projects move to completion.
    - The project champion is responsible for assuring each applicable item is completed, including appropriate documentation (may be uploaded as attachments).
    - Completion of the electronic project manager is required as part of the final validation documentation when changes have the potential to impact analytical tests or test systems.

8. The Technical Supervisor and Medical Director review validation data and approve/disapprove validation via electronic document control system. The procedure(s) is finalized and approved via electronic document control system.
9. The Supervisor or assigned validation staff train remaining staff and document.
10. The process or equipment is implemented.

6. RELATED DOCUMENTS

- Validation Requirements for Quantitative and Semi-Quantitative Methods, QA procedure
- Process / Equipment Validation Protocol, Blood Bank, BB1027
- MediaLab Document Management, QA procedure
- Equipment and Process Validation Protocol Form (AG.F204)
- Recurring Calendar (AG.F647)
- Master Test Project Plan (AG.F648)

7. REFERENCES

Process/Equipment Validation Protocol, Transfusion Service, QDHBB303

8. REVISION HISTORY

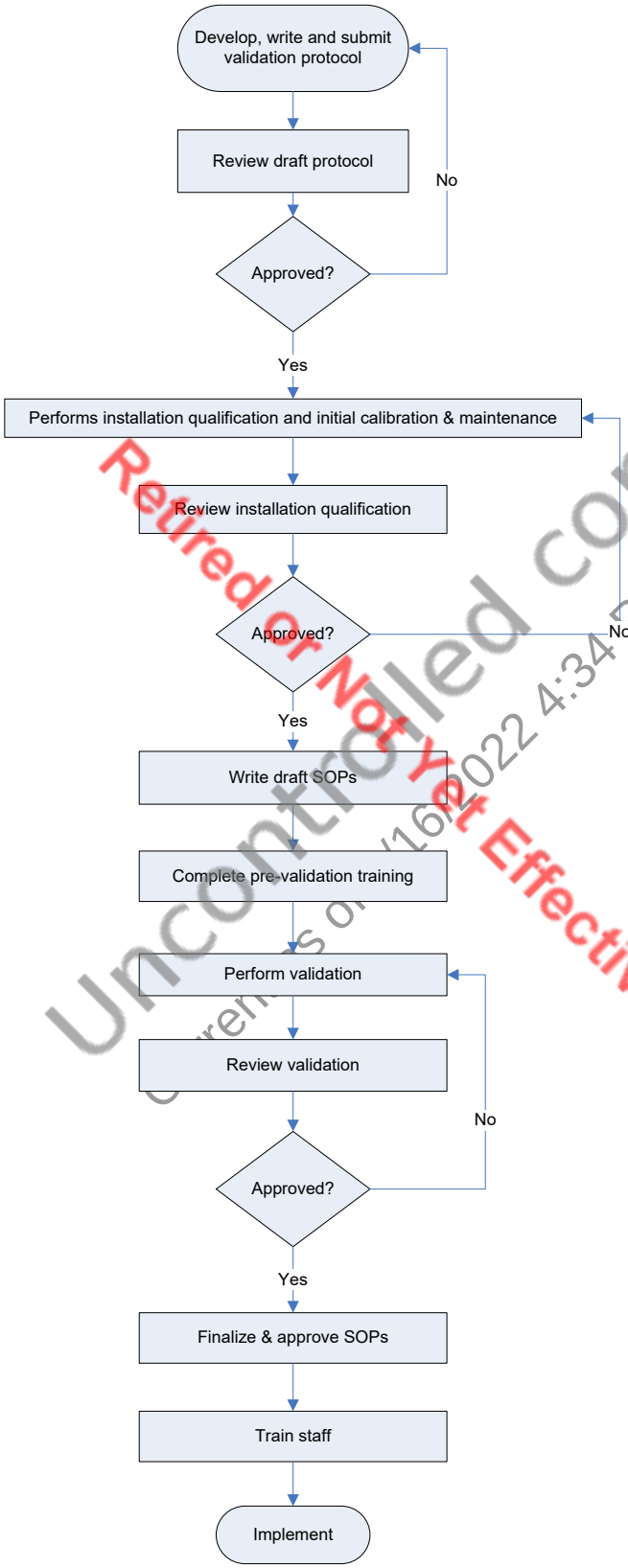
Version	Date	Reason for Revision	Revised By	Approved By
000	3/25/14	Section 5: add process for using Checklist for New/Changed Procedure Section 6: update EDCS title, add Checklist form Section 9: form moved to section 6 Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	C Bowman
1	3/23/18	Header: add other sites Section 5, 6: update number for validation policy	L Barrett	C Bowman-Gholston
2	2/26/20	Header: changed WAH to WQMC Section 4: added Smartsheet.com Section 5: replaced Checklist with software process Section 6: updated SOP titles and numbers, deleted Checklist for New/Changed Procedure	L Barrett	C Bowman-Gholston
3	2/15/22	Header: Changed Site to All Laboratories Footer: Changed SOP prefix to AHC	D Collier	C Bowman-Gholston
4	8/16/22	Section 3 #7 added, addition of tasks to recurring calendar Section 4: updated Smartsheet definition and added Recurring Calendar Section 6 added Master Test Project Plan and Recurring Calendar forms Addendum B part C added to assess Recurring Calendar tasks	R SanLuis	C Bowman-Gholston

9. ADDENDA AND APPENDICES

A. Process Validation Flow Chart
B. Validation Protocol Format

ADDENDUM A

PROCESS VALIDATION FLOW CHART



ADDENDUM B
VALIDATION PROTOCOL FORMAT

The following items are provided as guidelines for a validation protocol.

A. Title and protocol approvals

This section contains the protocol title and a space for a signature approving the protocol.

B. Purpose

1. Identify what equipment or process is being addressed in the validation.
2. Identify the reason the validation or revalidation is required

C. Requirements and Specifications

1. Identify the performance requirements for the equipment or process with the following:
   a. Equipment capabilities and parameters
   b. Regulatory requirements and industry standards associated with the equipment or process
   c. Assess requirement for Recurring Calendar tasks (Method-Method, Instrument-Instrument, Centrifuge, Pipette, or Timer, etc.)
2. References (operator's manual, package insert, etc.)

D. Test Plan

1. Installation Qualifications
   a. Identify all steps required to verify that the equipment was properly installed in environmental conditions that meet the manufacturer's specification.
   b. Provision for sign-off that the installation qualification has been met.

2. Operational Qualifications
   a. Identify all steps required to verify that the equipment or process operates within established limits and specifications supplied by the manufacturer.

3. Performance Qualifications
   a. Identify all steps required to verify that the equipment performs as expected for its intended use in the processes established by the facility and that the output meets the facility's specification.

4. General requirements
   - Each test should compare the expected results from the requirements against the actual results.
   - All steps should provide a space for the person performing the validation to initial and date.
   - The validation plan should specify the number of process runs, when applicable, to provide an accurate measure of variability among successive runs.

Recurring Calendar

Task Name	Responsible Party	Complete	Complete	Complete	Complete
January (Q1)		SGMC Date	GEC Date	WOMC date	FWMC date
Six month competency reminder	QA				
Safety audit due to QA	Safety Team				
Print MTS employee transcripts for review/signature	QA				
Reflex Panel review	LIS Mgr to Med Dr to Med Exec				
Approval of Reference Labs	Medical Director				
GEC Hematology comparison	Technical Specialist	N/A		N/A	
All sites Manual Diff vs. Auto Diff Hematology	Technical Specialist				
Correlation Sysmex XN (SG & WO)	Technical Specialist		N/A		
Stago D-Dimer Linearity	Technical Specialist				
Stago Fibrinogen Linearity	Technical Specialist		N/A		
Pipette Calibration	Technical Specialist				
Comparison STAGO	Technical Specialist				
INR calculation	Technical Specialist				
Platelet Poor Plasma determination	Technical Specialist				
Refrigerator/Freezer PM	Technical Staff / Supvr				
FWMC Replace HemaPRO tubing	Technical Specialist	N/A	N/A	N/A	
February (Q1)		SGMC Date	GEC Date	WOMC Date	FWMC date
Six month competency reminder	QA				
Safety audit due to QA	Safety Team				
Sysmex CSF/Body Fluid vs. manual comparison	Technical Specialist		N/A		
UA Macroscopic Manual to automated comparison	Technical Specialist				
Refractometer Calibration	Technical Specialist				
UA Microscopic Manual to automated comparison	Technical Specialist		N/A		
VerifyNow PRUT instrument Correlation	Technical Specialist	N/A	N/A	N/A	N/A
Specific Gravity on Auwi, Clinitek Status & Dipstick comparison	Technical Specialist				
Ketone (B-Hydroxybutyrate) Linearity	Technical Specialist				
Molecular/PCR Instrument Correlation	Technical Specialist				
Wipe Test Biological Safety Hood	Technical Specialist				
Centrifuge Speed Checks SG & GEC BB	Tech Specialist / Contract Co.				
Annual PI Summary due	QA				
Review CAP Test Activity menu	QA				
QA, CHP, and Safety Effectiveness	QA				

Recurring Calendar

Task Name	Responsible Party	Complete	Complete	Complete	Complete
March (Q1)		SGMC Date	GEC Date	WOMC Date	FWMC date
Six month competency reminder	QA				
EXL Linearity/Comparison FWMC	Technical Specialist	N/A	N/A	N/A	
XN Comparison FWMC	Technical Specialist	N/A	N/A	N/A	
Safety audit due to QA	Safety Team				
Evaluation of Evacuation Routes (all sites)	QA/Safety Team				
Clinical Consultant Assessments (to ML)	QA				
Technical Supervisor & QA assessments by medical director	QA				
General Supervisor Assessments- Core (G drive)	QA				
Technical consultant Assessment POCT (to ML)	QA				
General Supervisor Assessment Blood Bank (to ML)	QA				
Centrifuge Speed Checks WO BB	Tech Specialist / Contract Co.				
Micro/PCR Method Comparisons (Cepheid, BioFire, QIAstat, MDX, LIAT)	Tech Specialist / Technical Supvr				
April (Q2)		SGMC Date	GEC Date	WOMC Date	FWMC date
Six month competency reminder	QA				
Safety audit due to QA	Safety Team				
Mid-cycle CAP inspection	QA				
DI & Sunquest Mini-Validation	Technical Specialist +LIS Team				
Ocular Micrometer Calibration	Technical Specialist				
PFA 100 Control Donor Group	Technical Specialist		N/A		
Refrigerator/Freezer PM	Technical Staff / Supvr				
May (Q2)		SGMC Date	GEC Date	WOMC Date	FWMC date
Six month competency reminder	QA				
Safety audit due to QA	Safety Team				
EXL Linearity/Comparison	Technical Specialist	N/A		N/A	
iSTAT Linearity (GEC)	Technical Specialist	N/A		N/A	
Centaur Linearity/Comparison	Technical Specialist	N/A	N/A		N/A
Centrifuge Speed Checks SG BB and Lab, GEC	Tech Specialist / Contract Co.				
BNP Triage / Centaur and/or Triage/Triage Comparison	Technical Specialist		N/A		
BNP Triage Calibration (F,W)	Technical Specialist	N/A	N/A		

Recurring Calendar

Task Name	Responsible Party	Complete	Complete	Complete	Complete
June (Q2)		SGMC Date	GEC Date	WOMC Date	FWMC date
Six month competency reminder	QA				
Safety audit due to QA	QA				
Test directory (JDOS) review by medical director (biennial)	QA				
Vista Linearity/Comparison (WOMC)	Technical Specialist		N/A		
Osmometer Linearity	Technical Specialist		N/A		
Avox iMeter (Blood Gas) Linearity	Technical Specialist		N/A		
Procalcitonin Linearity	Technical Specialist		N/A		
Centrifuge Speed Checks WO BB and Lab	Tech Specialist / Contract Co.				
Full Data Innovation Validation	Technical Specialist + LIS Team				
July (Q3)		SGMC Date	GEC Date	WOMC Date	FWMC date
Safety audit due to QA	Safety Team				
Print MTS employee transcripts for review/signature	QA				
Correlation Sysmex XN (SG & WO)	Technical Specialist				
All sites Manual Diff vs. Auto Diff Hematology	Technical Specialist				
GEC Hematology comparison	Technical Specialist	n/a		n/a	
Stago D-Dimer Linearity	Technical Specialist				
Stago Fibrinogen Linearity	Technical Specialist				
Comparison STAGO	Technical Specialist				
INR calculation	Technical Specialist				
Platelet Poor Plasma determination	Technical Specialist				
Pipette Calibration	Technical Specialist				
Timer Verification	Technical Specialist				
Thermometer Inventory & Verification	Technical Specialist				
Tachometer Calibration	Technical Specialist				
Hygrometer Inventory	Technical Specialist				
Competency compliance	QA				
NIST Thermometer Calibration	Technical Specialist				
Refrigerator/Freezer PM	Technical Staff / Supvr				
FWMC HemaPRO Tubing Replacement	Technical Specialist	N/A	N/A	N/A	
Six month competency reminder	QA				

Recurring Calendar

Task Name	Responsible Party	Complete	Complete	Complete	Complete
August (Q3)		SGMC Date	GEC Date	WOMC Date	FWMC date
Six month competency reminder	QA				
Safety audit due to QA	Safety Team				
Critical Values	QA via MediaLab				
LIS Calculation Verification	LIS Manager				
Delta Value Verification - DI vs. LIS	LIS Manager				
Sysmex CSF/Body Fluid vs. manual comparison	Technical Specialist				
Refractometer Calibration	Technical Specialist				
UA Microscopic Manual to automated comparison	Technical Specialist		N/A		
VerifyNow PRUT instrument Correlation	Technical Specialist	N/A	N/A	N/A	N/A
Specific Gravity on Auwi, Clinitek Status & Dipstick comparison	Technical Specialist				
Ketone (B-Hydroxybutyrate) Linearity	Technical Specialist				
Wipe Test Biological Safety Hood	Technical Specialist				
Centrifuge Speed Checks SG & GEC BB	Tech Specialist / Contract Co.				
Ultra Centrifuge Yearly Maintenance (Beckman Coulter)	Tech Specialist/Contractor				
HIPAA Privacy Audit	QA				
September (Q3)		SGMC Date	GEC Date	WOMC Date	FWMC date
Six month competency reminder	QA				
Request TB requisitions for staff	Mgmt Team				
Safety audit due to QA	Safety Team				
Centrifuge Speed Checks WO BB	Tech Specialist / Contract Co.				
Update Reference Lab Certification	QA				
Micro/PCR Method Comparisons (Cepheid, BioFire, QIAstat, MDX, LIAT)	Technical Specialist				
October (Q4)		SGMC Date	GEC Date	WOMC Date	FWMC date
Six month competency reminder	QA				
Safety audit due to QA	Safety Team				
CAP Proficiency Testing Order	QA				
PFA 100 Control Donor Group	Technical Specialist				
Biological Safety Hood (BSC) inspection all sites	Contractor (PO thru CHY)				
Chart review by medical director	LIS/IT				

Recurring Calendar

Task Name	Responsible Party	Complete	Complete	Complete	Complete
IQCP annual assessment	QA/Core leaders				
Refrigerator/Freezer PM	Technical Staff / Supvr				
November (Q4)		SGMC Date	GEC Date	WOMC Date	FWMC date
Six month competency reminder	QA				
Safety audit due to QA	Safety Team				
FDA registration renewal for SG	BB manager				
EXL Linearity/Comparison (GEC)	Technical Specialist				
iSTAT Linearity	Technical Specialist				
Centaur Linearity/Comparison	Technical Specialist				
Renew Bio-Rad Unity Web QC	Technical Specialist				
Centrifuge Speed Checks SG BB and Lab, GEC	Tech Specialist / Contract Co.				
BNP Triage / Centaur and/or Triage/Triage Comparison	Technical Specialist	N/A	N/A		
BNP Triage Calibration (S,W)	Technical Specialist				
December (Q4)		SGMC Date	GEC Date	WOMC Date	FWMC date
Six month competency reminder	QA				
Make next years Recurring Calenar	QA				
Make the ADMIN on-call calendar	QA				
Safety audit due to QA	Safety Team				
Normal range reviews	QA via MediaLab				
Competency compliance	QA				
Disaster Preparedness - Mock Drill for BB	BB Manager				
Vista Linearity/Comparison	Technical Specialist				
Avox iMeter (Blood Gas) Linearity	Technical Specialist		N/A	N/A	N/A
Procalcitonin Linearity	Technical Specialist				
Osmometer Linearity	Technical Specialist				
Centrifuge Speed Checks WO BB and Lab	Tech Specialist / Contract Co.				

Master Test Project Plan

Task Name	Assigned To	Due Date	Complete Date
Test Validation Plan			
Create Validation Plan			
Validation Plan Approved			
Test setup complete (Vendor)			
Maintenance & Function Checks (Vendor)			
Validation Complete			
Validation Approved			
Approved SOP			
Create or Revise SOP			
Create or Revise Forms (i.e. Maintenance, Calibration, QC)			
Procedure approved and under document control			
Forms approved and under document control			
Establish QC frequency and update related forms and schedules			
Inventory Control			
Identify all Required supplies, QC, calibrators, consumables			
Identify Inventory Stability & Storage Requirements			
Supplies in inventory with Min/Max Est.			
Inventory added to count sheets			
Quality			
Add test to CAP Activity menu			
Add CAP PT Survey			
Update Training & Competency Documents			
Add to Recurring Calendar			
IT Validation			
LIS change request submitted,must include the following:			
CDM,CPT,LOINC			
Send CDM to Cerner BI Team for Quest Billing			
Send CDM to PLS Pricing			
Report Format			
AHC Cerner changes			
VerifyREF Ranges are identical in procedure,instrument			
Validate instrument interface(s) SQ/DI/RALS			
Validate Computer Interfaces-LIS,HIS,POCT			
Training and competency assessment			
Training checklist and competency created			
Training update created MTS			
Training Completed - Documented			
Competency Completed - Documented			
Go live plan in place			
Select live date			
JDOS (Joint Directory of Service)			
Internally / externally via electronic Lab Alert			

Master Test Project Plan

Task Name	Assigned To	Due Date	Complete Date
Test dictionary (JDOS) updated - AHC Intranet			