Adventist HealthCare

TRAINING UPDATE

Lab Location:	All sites	**Date Distributed:**	7/11/24
Department:	Core Lab	**Due Date:**	8/12/24
		Implementation:	**Immediately**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
AHC.QA12 Temperature and Humidity Quality Control
Description of change(s):
Section 3: Added Admin on call **Section 5:** Added temp and humidity "out-of-range" requirements to include discontinue testing. **Added Appendix B:** Room temperature Sensitive Equipment Operation RequirementsSection **4:** Added critical issue definition

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

AHC.QA12 Temperature and Humidity Quality Control

Copy of version 11.0 (ready for lab director approval)

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Organization Adventist HealthCare

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	QA Leader approval	7/9/2024	11.0	Cynthia Bowman-Gholston MT(ASCP) (104987)	
Approval	Lab Director	11/24/2023	10.0	 Nicolas Cacciabeve	
Approval	QA Leader approval	11/24/2023	10.0	Cynthia Bowman-Gholston MT(ASCP) (104987)	
Approval	Lab Director	7/7/2022	9.0	Nicolas Cacciabeve	
Approval	QA Leader approval	7/6/2022	9.0	Cynthia Bowman-Gholston (104987)	
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Approval	QA Leader approval	6/24/2020	8.0	Cynthia Bowman-Gholston	
Approval	QA review	6/19/2020	8.0	Leslie Barrett	
Approval	Lab Director	10/12/2019	7.0	Nicolas Cacciabeve	
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Approval Captured outside MediaLab	Lab Director	6/26/2018	6.0	Nicolas Cacciabeve	Recorded on 5/16/2019 by Leslie Barrett (104977) when document added to MediaLab
Periodic review Captured outside MediaLab	Designated Reviewer	6/26/2018	6.0	Nicolas Cacciabeve	Recorded on 5/16/2019 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
10.0	Approved and Current	Major revision	11/20/2023	11/24/2023	Indefinite
9.0	Retired	Major revision	6/21/2022	7/7/2022	11/24/2023
8.0	Retired	Major revision	6/19/2020	6/26/2020	7/7/2022
7.0	Retired	Major revision	10/7/2019	10/12/2019	6/26/2020

6.0	Retired	First version in Document Control	5/16/2019	8/1/2018	10/12/2019

Linked Documents

- AG.F172 Room Temperature Log (Non-Technical)
- AG.F180 Min/Max Room Temperature Log
- AG.F181 Min/Max Humidity Log
- AG.F364 Manual Temperature Log

Non-Technical SOP

Title	**Temperature and Humidity Quality Control**	
Prepared by	Leslie Barrett	Date: 3/19/2009
Owner	Cynthia Bowman-Gholston	Date: 3/19/2009

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

This procedure defines the process for manual monitoring of temperature and humidity dependent equipment or spaces.

2. SCOPE

- This procedure applies to thermometers used by the laboratory.
- The procedure applies to all temperature dependent equipment (refrigerators, freezers, incubators, water baths, ovens and heating blocks) used in the testing process or for the storage of specimens or test reagents.
- This procedure does not apply to Blood Bank thermometers or equipment; refer to the blood bank specific procedures.
- Applies to any device or environment where humidity control is required.
- This also applies to room temperature where critical to the testing process,
- This SOP is not applicable to test equipment with self-monitoring temperature controlled reaction areas (e.g., automated analyzers). These are verified by on-board systems with function checks that are addressed per manufacturer's protocol.

3. RESPONSIBILITY

- All Laboratory staff performing quality control checks must comply with this procedure.
- Group Leads perform and document weekly review.
- Section supervisor, manager or designee performs and documents monthly review.
- The senior QA specialist is responsible for content and review of this procedure.
- Leaders performing the Administrator On-Call Role.

4. DEFINITIONS

Alarm – System that emits an audible signal or alert when temperature exceeds defined limits.

Calibrated Thermometer – A NIST (National Institute of Standards and Technology) traceable thermometer or a thermometer that has been calibrated against a NIST thermometer prior to being used.

High/Low recording device – Records the highest and lowest temperature reached during the period monitored. Also referred to as Min/Max thermometer.

Hygrometer – Records the humidity over time.

Laboratory Incubator – Device designed to maintain a constant temperature at or near 37C.

Laboratory Freezer – Freezer capable of reducing and holding temperature at a range that is suitable for the reagents stored within.

Laboratory Refrigerator – Refrigerator capable of reducing and holding temperature at a level that is above the freezing point of water. Used to store reagents, micobiological material, and biological specimens.

Recording thermometer – Records the temperature versus time.

Laboratory Heating Block Incubator – Device that consists of a solid metal block with holes suitable for holding various size test tubes, designed to maintain a constant temperature at or near 37C.

Laboratory Water Baths – Designed to hold water at a constant temperature and used to heat specimens or test samples placed within, as required for certain serological or biochemical reactions.

5. PROCEDURE

A. General Requirements and Information

1. All temperature dependent equipment must have operational temperature monitored and recorded.
2. Temperature must be read and recorded in degrees centigrade.

3. All thermometers must be either NIST traceable or verified against a NIST traceable thermometer. See procedure Thermometer Selection and Accuracy Verification for details.
4. All equipment must have an acceptable temperature & humidity range defined, based on the intended use. Reagents, slides, quality controls material, patient specimens and other supplies must be stored at the temperature recommended by the manufacturer.
5. The thermometer should be situated where it is easily accessible and most likely to demonstrate an adverse temperature.
6. Humidity levels are monitored because some instruments and assays may be affected by humidity fluctuations. The hygrometer must be NIST-certified. Humidity must be read and recorded as percent humidity.
7. Refer to the Blood Bank manual for more specific procedures for monitoring blood and blood product storage equipment.

B. Requirements and Acceptance Criteria for Specific Applications

1. Laboratory Refrigerators
   a. The thermometer should be immersed in water or glycerin for stable temperature measurements. The immersion line on the thermometer must be at or below the surface of the liquid used.
   b. The temperature range for most laboratory refrigerators is 2°C to 8°C. If an item with a tighter storage requirement is stored in the refrigerator, the refrigerator must be controlled to the tighter requirement.

2. Laboratory Freezer
   a. For best results, the bulb should be immersed in antifreeze solution. Do not use expansion fluid thermometers below –35°C.
   b. Review items stored in freezer to determine appropriate range (use the most stringent requirement for items stored). For freezers that maintain temperatures to -65°C, a tolerance limit of ± 2°C is acceptable.

3. Laboratory Heat block/Incubator
   a. In addition to regular or daily monitoring, rotate the thermometer's position/location to ensure that the temperature in each position is monitored twice a year in order to identify "hot spots".
   b. Acceptable temperature range as defined by technical SOP or target temperature ± 1°C.
   c. If a reading exceeds the acceptable performance range, the location must be taken out of service by placing tape over the hole or otherwise blocking it.

4. Laboratory Water bath
   a. Acceptable temperature range as defined by technical SOP or target temperature ± 1°C.

5. Room temperature in the Laboratory or Supply Storage Areas
   a. Record the room temperature of the Core laboratory area.
   b. Record the room temperature of the areas where temperature-dependent equipment & supplies are stored.

c. Review items stored in each area to determine appropriate range (use the most appropriately stringent requirement for items stored). There will be an exception list for testing with a tighter range, these tests will have temperatures recorded with each result reported such as ESRSTAT 6.
d. A min/max thermometer is required in areas that are not staffed every day of the week to assure the temperature did not exceed the range since the last recording.

6. Relative Humidity in the core laboratory
   a. Record the relative humidity of the Core laboratory area.
   b. The relative humidity fluctuates in response to the room temperature; humidity limits are specified on the QC form.
   c. The temperature must be taken and recorded concurrent with the humidity.

C. Documentation Requirements

1. The temperature / humidity record must be kept at or near the equipment.

2. The temperature / humidity record must include:
   - identity of the equipment or area being monitored
   - identity of the thermometer / hygrometer used for monitoring (the identifier must be traceable; tracked on inventory logs)
   - acceptable performance range
   - date
   - temperature / humidity reading (both Min and Max required for Min/Max devices)
   - when Reset occurred for Min/Max devices
   - tech's initials or other identifier
   - corrective action taken when readings exceeds the acceptable limits, impact (e.g. contents of refrigerator) and the acceptable temperature after corrective action was taken
   - monthly review by supervisor or designee

3. All employees responsible for taking the temperature / humidity reading must be trained in the proper reading of the type of thermometer / hygrometer used.

4. Total / Partial Immersion Thermometer temperatures must be recorded daily. If the temperature cannot be recorded daily, then Min/Max thermometers are required to record out of range temperatures when the department is not staffed.

5. Min/Max Thermometer or Hygrometer:
   - Record both the min/max reading daily unless the department is not staffed.
   - The min/max must be reset daily unless the department is not staffed. If the department is not staffed, the device must be reset the last day worked.
   - When staff returns:
     - Min/max readings are taken and documented on the first working day.
     - There must be documentation indicating that readings did not adversely change from the last time recorded.

- There must be a means to document that staff were not present when no readings were recorded.

6. Record Review
   - If unacceptable readings are observed during the month, ensure acceptable corrective actions were taken and recorded. Sign and date record as reviewed.
   - If unacceptable readings are observed and no corrective actions were taken, determine if any adverse effects have occurred for the items tested on or stored in the equipment and document findings. Sign and date record as reviewed.
   - If gaps occur in the record, the reviewer must determine the cause by interviewing the person responsible for overlooking the monitoring. Documentation must include the cause of the unacceptable readings and the corrective action taken. **Notes:**
     - If the missed temperature is monitored by a min/max thermometer, review the records to assess if the temperature exceeded the acceptable range.
     - The laboratory is transitioning to an electronic temperature monitoring system. Where monitors are in place, those records may be utilized to evaluate and document acceptable temperatures during gaps in manual recordings.

D. Corrective Action

1. If the thermometer liquid has separated causing a break in the column, take the thermometer out of service immediately.

2. Initiate and document appropriate corrective action when the reading exceeds the acceptable performance range. Documentation must include the date/time and description of the corrective action and the reading after corrective action has been performed.

   - When **room temperature** impacts patient testing immediate action MUST include notifying the nursing and lab Administrators On-Call. The Administrator on-call will notify and work with the Medical Director to escalate the appropriate response and involve the appropriate team members. See the Attachments to identify specific equipment and kit operational temperature.

3. Examples of appropriate corrective action are listed below.
   a. If the temperature is out of range while recording daily temperatures or is discovered during normal use, check for any obvious reasons (door ajar, door open too long, thermostat set incorrectly or unit unplugged) and correct the problem.
      1) Make a note on the reverse side of the temperature/humidity log noting the circumstances and what has been done to resolve the out-of-range temperature (notify biomedical engineering, move the contents to another location, monitor the temperature more frequently, etc. Include tech's identification.)

2) Monitor the temperature until it returns to the acceptable range.
3) Record the temperature reading after corrective action has been performed.

b. If the temperature is markedly out of acceptable, **or** the cause of the unacceptable temperature/humidity is not identified, **or** there is a power failure, **or** the circulating fan stops or some other type of malfunction
   1) **Refrigerator or Freezer storage**:
      a) Notify service personnel and the supervisor/designee immediately (if it requires immediate attention)
      b) Transfer the supplies to another refrigerator/freezer. Attach signage to the refrigerator/freezer describing the temporary location of the supplies that have been moved.
      Note: If the temporary device has the same range as the original, daily monitoring is sufficient. If the range is different, more frequent monitoring may be specified by the supervisor.
      c) Make a note on the reverse side of the temperature recording log noting the circumstances and what has been done to resolve the out-of-range situation, include tech's initials.
      d) Take the device out of service and/or use an alternate device.
      e) When the problem is resolved and the temperature returns to the acceptable range, monitor and record temperature every 4 hours for 24 hours. Return the supplies to the original refrigerator/freezer or put the device back in use once acceptable performance is verified. Documentation must include date and time of return to service.

   2) **Room Temperature equipment and storage**:
      a) Notify site service personnel the supervisor/designee immediately
         i. Escalate by notifying nursing supervisor if needed.
         ii. Provide updates to supervisor/designee and nursing supervisor until situation is resolved.
         iii. Notify ED and ICUs if turn-around-time is affected / delayed.
      b) Evaluate which supplies are affected and re-locate those to another area that has a temperature that meets manufacture specifications (refer to appendix).
         i. Take the initial temperature reading using a thermometer with an alarm and document on the Manual Temperature Form along with the location name.
         ii. Monitor the temperature every 2 hours while supplies are stored in this location, if not on a continuous monitoring system.
      c) If temperature exceeds the manufacturer's ranges for operation discontinue testing. Notify the supervisor, administrator on-call, and nurse administrator.
      d) Make a note on the reverse side of the temperature recording log noting the circumstances and what has been done to resolve the out-of-range situation (corrective action), include how long the temperature has been out of range and tech's initials.

e) When the problem is resolved and the temperature returns to the acceptable range, return the supplies to the original location. When equipment is impacted ensure, QC is in range before releasing patient results. Documentation must include date and time of return to service.

f) c. If the humidity reading is outside of the acceptable range, refer to the SOP Humidity Look Back for the corrective action process. If the humidity exceeds the manufacturer's ranges for operation, discontinue testing. Notify the supervisor, administrator on-call, and nurse administrator.

d. Supplies that may be unusable due to improper storage
   1) If the temperature has been out-of-range for an undetermined amount of time and the contents have been stored outside their recommended temperature, then the contents of the refrigerator/freezer/storage area must be quarantined until it can be determined if they have deteriorated by the supervisor or designee.
   2) The supervisor/designee will determine when and if the contents can be used and whether or not a planned deviation will be put into place.
   3) If supplies/products are deemed suitable for use by the supervisor or designee, then documentation must include the basis for that determination.
   4) If supplies/products are unsuitable for use, they must be discarded. Documentation must include products and quantities discarded.

6. RELATED DOCUMENTS

Technical procedure manuals
Temperature and Humidity recording logs (AG.F171, AG.F172, AG.F180, AG.F181)
Thermometer Selection and Accuracy Verification, QA procedure
Humidity Look Back, Chemistry procedure
Humidity Validation for Adventist Laboratories
Manual Temperature Log (AG.F364)

7. REFERENCES

- Policy for Monitoring Temperature Dependent Equipment, Quality Assurance Best Practice, QDNQ704
- College of American Pathologist Lab General Inspection and Department Specific Checklists (most current version)

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SOPs LIS045.001, LIS046.001, L050.000		

Version	Date	Reason for Revision	Revised By	Approved By
000	3/22/2010	Section 5: Item A.3 added reference to Thermometer SOP; Item B.1 lower range for BB refrigerator changed to 2°C Section 6: added Thermometer SOP Section 7: updated references	L. Barrett	C. Bowman
001	4/21/2011	Section 5: Added corrective action for failed humidity (item D.3.c).	C Bowman	C. Bowman
002	2/11/2013	Section 5: Add min/max thermometer (item B.7.d), Edit corrective action for failed humidity (item D.3.c). Section 6: Add Humidity Look Back SOP	L. Barrett	C. Bowman
003	12/17/2013	Section 4: Add hygrometer Section 5: Add humidity and min/max reset to documentation requirements. Add requirement to block hot spots for heat block/incubator Section 6: Add humidity validation Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L. Barrett	C. Bowman
4	11/1/2016	Header: Add other sites Section 5: Add detail for unacceptable room temp storage and performance evaluation Section 6: Add Manual Temp log Section 9: Add supply storage chart	L. Barrett R. SanLuis	C. Bowman
5	6/26/2018	Section 2: Add exclusion for blood bank Section 3, 4, 5: Delete blood bank information Section 5: Update thermometer ID tracking (Item C.2), add escalation process (item D.3.b). Addenda: Update supply list	L Barrett Z Morrow A Chini	C Bowman-Gholston
6	10/3/2019	Header: Change WAH to WOMC Section 9: Remove Iris supplies, add AUWi items	L Barrett	C Bowman-Gholston
7	6/19/20 20	Section 5: Added notes for missed temperatures under item C.6	L Barrett	C Bowman-Gholston
8	7/6/22	Header: Changed site to All Laboratories Footer: Changed prefix to AHC	D Collier	C Bowman-Gholston
9	11/20/23	Appendix: added Atellica reagents, removed Flu kit	D Collier	C Bowman-Gholston
10	7/8/24	Section 3: added Admin on Call Section 5: added temp and humidity out of range requirements to include discontinue testing. Section 9: Added Appendix B Appendix B: Added –Temp and humidity requirements.	R SanLuis D Collier	C Bowman-Gholston

9. ADDENDA AND APPENDICES

Appendix A: Room Temperature Sensitive Supply Storage Requirements
Appendix B. Room Temperature Sensitive Equipment Operation Requirements

Appendix A.

Room Temperature Sensitive Supply Storage Requirements

2 – 30C	2 – 25C	2 – 27C	2 – 35C	1 – 30C	15 – 30C		16 – 26C	15-35C	15-25C
Vista # 1 thru #6	Vista # 7	HIV Kit	Cell Pack DCL	Cell Clean Auto	Occult Blood Reagent	Sysmex Wright-Giemsa Stain	Trigger Solution	Methyl Alcohol Absolute	Atellica Reagent ALB
Ketone Strip	Centaur Acid Base		Cell Pack DFL		Occult Blood QC	Sysmex Phos Buffer Soln			Atellica Reagent CA-2
HCG Qual. Kit	Centaur Wash 1		Fluorocell PLT		Multistix	Clorox bleach			Atellica Reagent CREA-2
Osmo 290	STA Cleaner		Fluorocell RET		Malaria Stain Buffer	Novus 10 Cassette			Atellica Reagent IP
Osmo 50 cal	Phlebotomy tubes		Fluorocell WDF		Verify Now QC	Novus Rinse Additive			Atellica Reagent TP
Osmo 850 cal			Fluorocell WNR		Verify Now Cartridge	Clinitek Atlas Control Strips			Atellica Reagent CA-2
Osmo 2000 cal			Lysercell WDF		FFN Kit	Flammable cabinet			
Para Pak stool			Lysercell WNR		Strep A kit, OSOM				
RSV kit (GEC only)			Na Hydroxide pellets		All micro stain				
Sulfolyser SLS			UFII Search-Bac		Hema stain Buffer				
Atellica #1 thru #12			UFII Search-Sed						
Atellica TBIL reagent			UFII Pack-Bac UFII Pack-Sed UF II Sheath						

Appendix B

Room Temperature Sensitive Equipment Operation Requirements

Instrument/KIT	TEMP	Humidity
Sysmex (Hem)	15C-30C	30-85%
EXL 200 (Chem)	17C-30C	20-80%
Atellica (Chem)	18C-30C	20-80%
Vista (Chem)	18C-25C	20-80%
Stago Satellite (Coag)	15C-32C	20-80%
Stago COMP (Coag)	15C-32C	20-80%
ESR STAT 6 (Hem)	20C-24C	10-80%
QiaSTAT (Molecular)	15C-25C	10-75%
Biofire (Molecular)	15C-30C	20-80%
LIAT (Molecular)	15C-32C	15-80%
Cepheid (Molecular)	15C-30C	20-80%
iSTAT	16C-30C	10-90%
Triage Meter	15C-30C	10-85%
BD FX	18C-30C	25-80%
Clinitek Novus	18C-30C	20-80%
UF1000i	15C-30C	30-80%
MEDTOX Scan	5C-40C	10-90%
Clinitek Status Plus	18C-30C	18-80%
Clinitek Advantus	18C-30C	20-80%