Shared health
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Document History:

Title: **Temperature and Humidity Monitoring**

Site(s): **Shared Health Diagnostic Services**

Document #:	**100-10-22**	**Version #:**	**03**
Section:	**Operations**	**Subsection:**	**General**

Approved by: **Signature:**	Dr. A. Sokoro (signature on file)	**Date:**	11-JUN-2021
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Details of Recent Revision

Entire document re-formatted
Removed Appendix 1 as the list could not be all-inclusive and staff/sites are to refer to manufacturer recommendations for temperature requirements
Removed Specific Requirements for equipment as this detail is included in individual equipment SOP's
Forms to be archived and replaced with new log:
F100-10-22- Daily Temperature Log
F100-10-22B- Daily Temperature Log
F100-10-22C- Generic Daily Temperature Humidity Log
F100-10-42- Refrigerator Freezer Temperature and Maintenance log
F100-10-42A- Refrigerator or Freezer Temperature and Maintenance Log
F100-140-07- Daily Temperature log
F140-120-08- Ambient Temperature and Humidity Monitoring
F150-80-01A- Refrigerator Freezer Temperature Chart
F150-80-06- Ambient Temperature and Humidity Monitoring
F195-40-10- Freezer Temperature Humidity Maintenance Log
F195-50-02A- FISH Lab Ambient Room Temperature Humidity Log

1.0 Purpose

1.1 To provide general guidelines regarding the minimum requirements for temperature and relative humidity monitoring (as appropriate and required) in the laboratory

1.2 To provide guidelines to ensure that environmental conditions do not adversely affect or invalidate sample handling, instrumentation, analytical testing and calibrations

2.0 Scope

2.1 Applies to all Shared Health Diagnostic Service Laboratories

2.2 This document is intended to supplement equipment specific and/or discipline specific requirements

3.0 Definitions

3.1 Temperature Excursion

- 3.1.1 Any noted temperature that is outside the defined acceptable temperature range set for an area or piece of equipment

3.2 Acceptable Temperature Range

- 3.2.1 Temperature range defined for a specific piece of equipment or area that is based on the minimum and maximum acceptable temperature ranges for product being stored within an area or for testing requirements for which the equipment is being used
- 3.2.2 Acceptable temperature ranges for storage equipment or areas should be determined by reviewing product package inserts for product/consumables being stored in the area
- 3.2.3 Specific test procedures should be reviewed to determine acceptable temperature ranges for testing equipment

3.3 Equipment ID

- 3.3.1 An identifier that is used to uniquely identify a specific piece of equipment
- 3.3.2 This identification is typically a serial number (or similar) that is permanently affixed to the equipment

4.0 General Guidelines

4.1 Shared Health laboratories are designed to provide space, engineering controls and proper environmental conditions for optimal sample storage, sample handling, analysis and calibrations in accordance with general laboratory practices, safety and applicable local, provincial and federal regulations

4.2 Temperature and humidity (if required) within the laboratory will be maintained within limits for the proper performance of each test or analysis and maintained according to manufacturer specifications to ensure proper operation of instruments/equipment

4.3 In laboratory areas where temperature and humidity affect the analytical results, temperature and humidity are monitored and recorded

4.4 Reagents must be stored and handled in a manner that will prevent environmentally induced alterations that could affect reagent stability and test performance

- 4.4.1 If the manufacturer defines a required storage temperature range, the temperature of storage areas must be monitored daily

4.5 Temperature-dependent equipment such as refrigerators, freezers and incubators, containing reagents and or patient specimens must be monitored daily, as equipment failures could affect the accuracy of patient test results

4.6 Equipment such as water baths and heat blocks used only for procedures need only be checked on days of patient testing

- 4.6.1 For heat blocks or dry baths, thermocouple probes may be used as an alternative method for checking the temperature

4.7 Where a discipline or laboratory specific temperature monitoring process exists, that process should be followed (ie. Transfusion Medicine)

4.8 All temperature readings will be taken using appropriately calibrated devices

- 4.8.1 Refer to 100-10-16, Thermometer Calibration or 100-10-16A, Thermometer Calibration and Documentation

4.9 All temperature readings will be recorded on an approved log sheet; log sheets will be retained as outlined in applicable retention policy, refer to 100-10-05, Lab Records and Materials Retention Policy and/or 160-APP-07, Appendix 8 Record Retention Policy (Transfusion Medicine).

- 4.9.1 Log sheets will contain, at minimum, the following information:
  - 4.9.1.1 Facility name/site
  - 4.9.1.2 Laboratory name/location/room number, as applicable

4.9.1.3 Equipment ID
4.9.1.4 Thermometer/hygrometer serial #
4.9.1.5 Acceptable Temperature Range
4.9.1.6 Acceptable Humidity Range (if applicable)
4.9.1.7 Date of monitoring
4.9.1.8 Time readings are taken
4.9.1.9 Initials of person documenting reading
4.9.1.10 Comments section on which to document any action taken for noted excursions
4.9.1.11 Supervisory/designate review

4.10 There shall be evidence of corrective action taken if acceptable temperature ranges for temperature-dependent equipment and environmental temperatures are exceeded, including an evaluation for adverse effects
4.10.1 Document all actions taken directly on the applicable log sheet (using the back of the page and/or additional paper as necessary to capture all details). Include documentation of any personnel notified
4.10.2 As appropriate, stored reagents, controls, calibrators, etc must be checked to confirm the accuracy or quality of the material before use, with records retained

4.11 Temperature checks must be performed and documented daily (seven days a week / 52 weeks a year)
4.11.1 For facilities/areas that do not have 24/7 staff coverage to perform these checks daily, alternate arrangements must be made to ensure that these checks are performed as required (ie assigning alternate staff to perform the task)
4.11.2 If assigning alternate staff to perform the task is not an option, a “Min/Max” type thermometer must be used (see Section 5.0 for details)

5.0 Establishing Acceptable Temperature Ranges

5.1 The temperature range limitations are determined by using the most limiting of the manufacturer’s recommendations for the materials store in or in use in a particular environment/equipment
5.1.1 For example, a refrigerator that contains two reagents: one must be stored between 3˚ to 8˚C and the other between 2˚C to 6˚; the acceptable range for this refrigerator should be 3˚C to 6˚C

6.0 Use of Min/Max (High/Low) Recording Device

6.1 If a minimum/maximum thermometer is used to perform continuous monitoring of temperatures between daily temperature readings or following a laboratory downtime (ie lab closure for weekend or holiday), both the low and high temperatures must be recorded

6.2 To ensure correct temperature readings, the minimum/maximum thermometer device must be reset prior to the monitoring period (follow manufacturer directions)

7.0 Use of Chart Recorder Graphs

7.1 Chart recorders, if in use, will be changed weekly as per manufacturer instructions
7.1.1 On the chart recorder graph there should be documentation including:
7.1.1.1 Equipment ID
7.1.1.2 Date/time chart put into place and initials of person performing task
7.1.1.3 Date/time chart removed and initials of person performing task
7.1.2 Completed charts will be reviewed, dated and initialed, to ensure that temperatures have remained within acceptable ranges and any gaps in information or temperature excursions have an explanation provided (documented on the chart itself or on the pertinent temperature log)

8.0 Use of a Central Monitoring (remote) System

8.1 For equipment that is monitored by a central monitoring system
8.1.1 Staff must have ongoing immediate access to the temperature data
8.1.2 System records must demonstrate daily functionality of the system
8.1.3 Any alarms on the system must be fully documented; this includes:
8.1.3.1 Time of alarm
8.1.3.2 ID of equipment involved
8.1.3.3 Corrective actions taken

8.1.4 A hard copy of the system monitoring results for each piece of equipment should be obtained monthly and reviewed for any excursions (if the monitoring system allows for this)

8.1.5 Printouts should be labelled with the equipment ID, the time period for which the document is for and the reviewers initials and date

8.1.6 Printout will be compared to any documented alarms to ensure they correlate

8.1.6.1 Any previously undocumented excursions must be appropriately investigated and documented

9.0 Humidity Monitoring

9.1 Unless specifically required, based on testing being performed or equipment in use in a particular area, humidity monitoring is not generally required

9.1.1 Only implement humidity monitoring if it is required by the manufacturer

9.1.2 If humidity monitoring is not required, simply mark as not applicable (N/A) on the log sheet

9.1.3 If required based on manufacturer recommendations, determine an acceptable range and document on the log sheet and ensure the measuring device in use is capable of recording humidity

10.0 Ambient Room Temperature Monitoring

10.1 Ambient room temperature should be monitored along a quiet inside wall to eliminate the effect of outside temperature and staff traffic

10.2 The thermometer should be place away from wall or overhead air circulation vents as this may skew the temperature readings

10.3 Readings from different areas in the space may be required to identify hot or cold spots

11.0 References

11.1 www.fda.gov; Facilities and Environmental Conditions, document # ORA-LAB.5.3

11.2 College of American Pathologists Laboratory General Checklist, 2020

11.3 College of American Pathologists All Common Checklist, 2020