I Am Too Hot!

What To Do When Your Temperatures are Out of Range

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Objectives

1. Understand why temperature documentation is critical
2. Know how to correctly read a digital thermometer and document temperatures
3. Know the steps to take when the temperature is out of range: Corrective Action
4. Review the supervisor responsibilities
5. Train ourselves to become critical document auditors

Why take temperatures? Why do we care – Specimen?

- Vendors have determined what temperature ranges will not affect their products use (blood collection tubes, blood culture bottles)
  - Anticoagulant deterioration: will not allow proper clotting of blood
  - Vacuum: will not allow proper filling and blood to anticoagulant ratio will be affected
  - Blood culture broth deterioration: will affect bacterial growth in the bottle
- Assay validation studies have determined at what temperatures the samples need to be transported and stored at before testing
  - Analytes have an optimal temperature range where they are most stable.
  - Analyte recovery can decrease if temperatures are out of range
- **Bottom Line – When the temperature is out of range there is no confidence that a patient's reported result from that collection tube and that sample is accurate!**

Temperature Limits on Labels

Why take temperatures? Why do we care? Testing Products

- Vendors have determined what temperature ranges will not affect their products use (Reagents, Calibrators, Controls,)
  - Reagent storage requirements are provided in the product inserts
  - Reagent storage requirements are also listed on the external packaging
- Assay validation studies have determined at what temperatures the products need to be transported and stored at before testing
  - Testing products have an optimal temperature range where they are most stable.
  - Products may not deliver the intended reactivity if temperatures are out of range
- **Bottom Line – When the temperature is out of range there is no confidence that those products are stabile and provide intended test results!**

Equipment Temperature , Humidity Conditions

Ensure that:

- The temperature of the installation room is between 18 ºC (64.4ºF) a
- The temperature does not fluctuate more than ± 2 ºC.
- The humidity is between 40% and 80% Relative Humidity (RH), and
- The site is well ventilated. Use ventilation equipment if necessary.
- The system is not exposed to direct airflow from air conditioners.

The heat the system outputs during operation is approximately 8,820 KJ p
specified room temperature and humidity ranges fluctuate, the system dat
temperature in the room fluctuates excessively make sure adequate air co

CAUTION

The installation site must be well ventilated. To insure proper loca
refer to section "2.2.3 Installation Space Requirements" in this ch

Temperature and Humidity Conditions When Not in Use

Ensure that:

- The temperature is between 5 ºC (41º F) and 40 ºC (104º F).
- The humidity is between 15% and 90%.

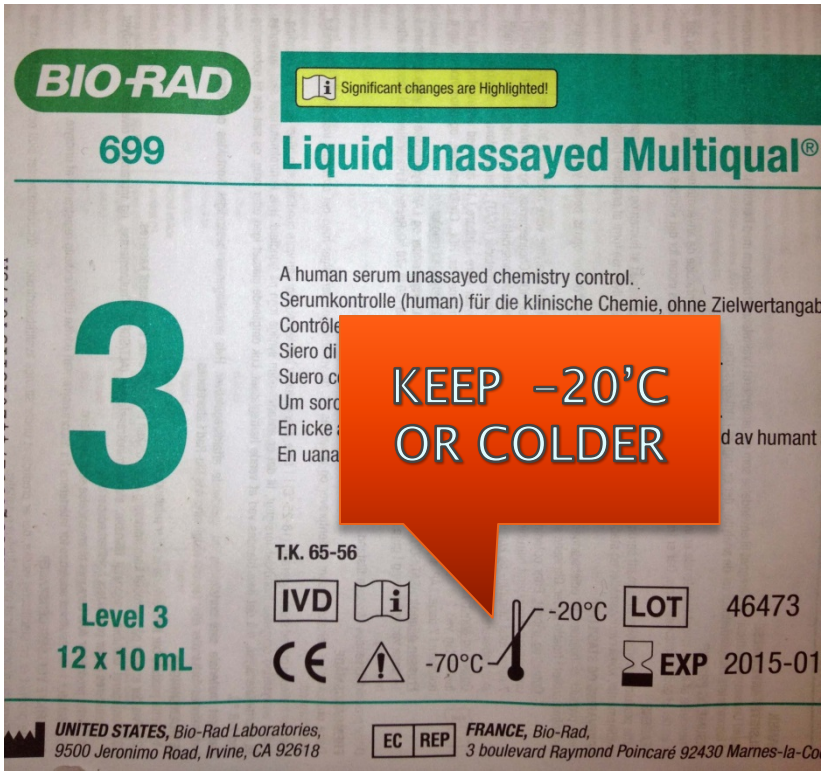
Water Supply

The water supply and liquid waste facilities must be installed before.

This system uses deionized water. For installation of a deionizer and pipin
facility to the deionizer, consult an experienced vendor. Note, deionizer pe
the quality of the water supply to the facility.

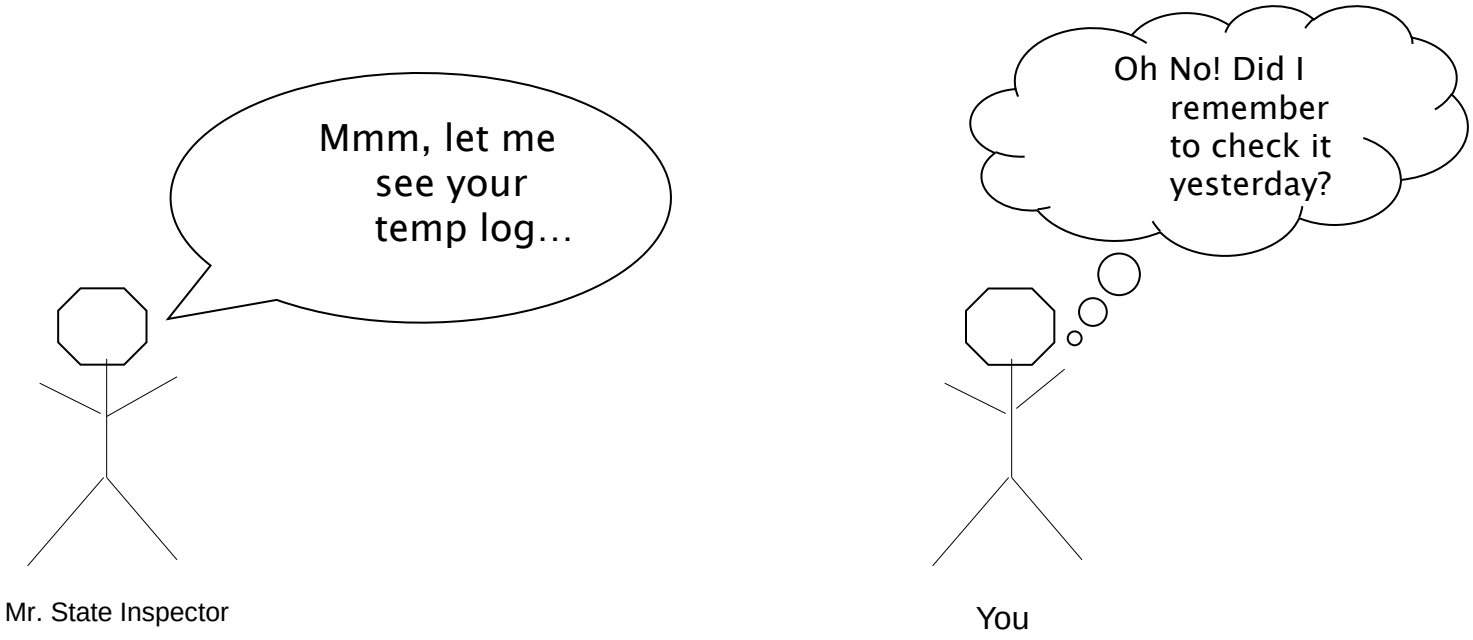
Ensure that:

Frozen Temperature Requirements Vary – Check Labels



Another reason why we care?

Because Regulatory Agencies tell us we have to!



How to Read the Digital Thermometer

- How to read and record the temperatures
  - Read and record the temperature that is displayed on the LCD.
  - Press the Memory Clear button on the front of the thermometer
    - This will clear and reset the min/max readings in the LCS
- Good laboratory practice – take note of the min/max temperature reading when recording the temperature to see if the temperatures were ever out of range
- For freezers and refrigerators – if the door is left open too long and causes the temperature to go out of range then once the door is closed and temperature stabilizes, then the Memory Clear button should be pressed to reset the temperature

- Example Min-Max Digital Thermometer

Temp & Min & Max

Record & Reset

Min/Max Temperature Recording

READ-RECORD-RESET

MIN / MAX TEMPERATURE CHART

Location/Department: _____ Equipment Description/ID: _____ Serial Number: _____

Thermometer ID (Common Tag): _____ Temperature Range (°C): From: _____ To: _____

Time Interval (If applicable): _____ YEAR: _____

Instructions: Temperatures are Read daily as applicable and Recorded as a numerical value below. Reset after reading. Individual recording temperatures must initial.

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Supv Review
JAN	Min																																
	Max																																
	INIT																																
WK REVIEW																																	
FEB	Min																																
	Max																																
	INIT																																
WK REVIEW																																	
MAR	Min																																
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WK REVIEW																																	
MAY	Min																																
	Max																																
	INIT																																
WK REVIEW																																	
JUN	Min																																
	Max																																
	INIT																																
WK REVIEW																																	

NU = Not in Use / or **NR** = Not Recorded

***Corrective Action for Out of Limits Readings and other observations to be documented above or on reverse side**

Corrective Action Log

Equipment Monitored

CORRECTIVE ACTION LOG

DATE	RACK OR UNIT ID *	PATIENT EFFECT YES	PATIENT EFFECT NO	1. DESCRIBE FINDINGS 2. DESCRIBE IMMEDIATE CORRECTIVE ACTION 3. WHAT WAS PATIENT EFFECT, HOW WAS IT ADDRESSED OR WHY IS IT NOT AN ISSUE.	INITIAL
				1. 2. 3.	
				1. 2. 3.	
				1. 2. 3.	
				1. 2. 3.	
				1. 2. 3.	
				1. 2. 3.	

Code 1 = Routine activity causing rise in temperature. Monitor unit and keep door closed until unit recovers.
Code 2 = Unit undergoing routine maintenance
Code 3 = Large # of specimens placed into/removed from freezer tables, causing rise in temperature.
Code 4 = Wires accidentally disconnected. Reconnected wires. Samples not compromised (Explain)
Code 5 = Reason could not be determined
Code 6 = Power failure
Code 7 = Other (Explain)
Code 8 = Temperature was still rising. Monitor unit and keep door closed until unit recovers.
Code 9 = Person notified that service is needed or electronic work order submitted (Describe who was notified and when)
Code 10 = Specimens not compromised (Explain)

* Where applicable

Review _____ Date _____

Corrective Action: What to do when a Temperature is Out of Range

- Check/replace batteries
- Check placement of the sensor
- Check to make sure the door is closed and secured
- Retake the temperature reading 1 – 2 hours later
- If still out then adjust the refrigerator/freezer if model allows
  - Make sure you read the temp after allowing temperature to stabilize to make sure you did not over or under adjust

Corrective Action: What to do when a Temperature is Out of Range

- All corrective action taken needs to be documented on the log or…

IT DIDN'T HAPPEN!

Corrective Action: What to do when a Temperature is Out of Range (Cont.)

TAKE HOME MESSAGE

- An Out-of-Range reading is NOT to be ignored and needs to be addressed same day
- Temperatures should not be out for more than 1 day and should be brought to the attention of the supervisor, manager, and/or consultant if there is no resolution

Supervisor's Responsibilities

- Every month the Temperature Logs need to be reviewed and signed by supervisor in a timely manner
  - Ideally supervisors/consultants should be doing this weekly, or when performing the monthly QC audit.
  - Timely review means during the first 7-10 days of the month you should reviewing last month's log
- What are you reviewing?
  - temperature readings
  - employee's initials
  - corrective action taken when the temperature exceeds the acceptable limits and the acceptable temperature after corrective action is taken.
  - Document completeness

Critical Document Review

- If unacceptable temperatures are observed during the month, the supervisor must ensure acceptable corrective action was taken and recorded. Sign and date the record as reviewed.

- If unacceptable temperatures are observed and no corrective actions were taken, determine if any adverse effects have occurred for the items stored in the equipment and document findings. Sign and date record as reviewed.

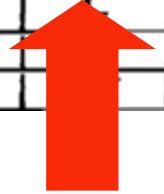
- If gaps occur in the record, the reviewer must determine the cause by interviewing the person responsible for overseeing the temperature monitoring. Documentation must include the cause of the unacceptable temperatures and the corrective action taken.

A Dummy's Guide to Reviewing Temperature Logs

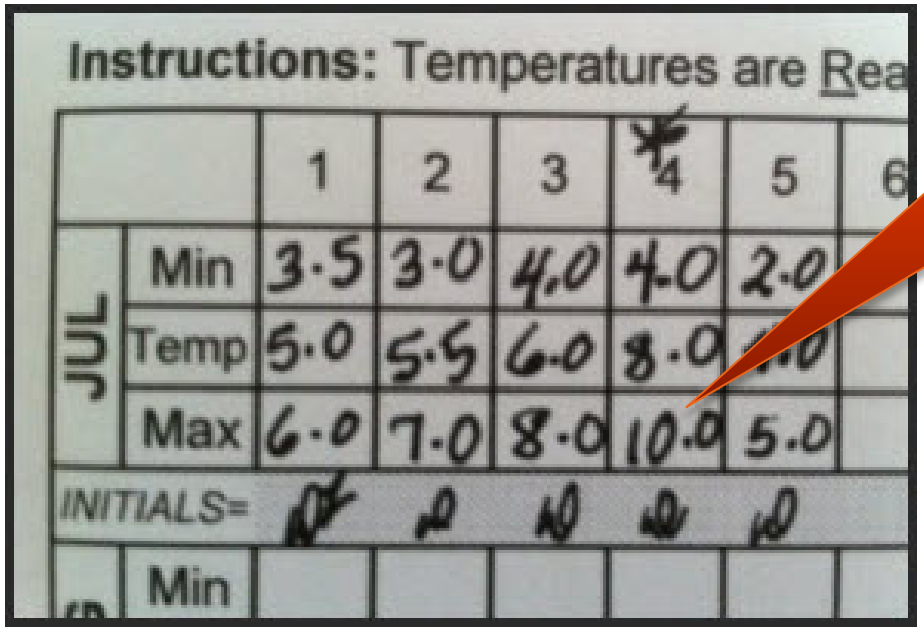
- Check that all logs have the identifying information (month, year, location)
- Check for initials and dates
- Make sure all fields are filled out – scan rows and columns
  - As you scan down each column compare the temp recorded against the acceptable temperature range
  - When a temp is recorded that is out of range immediately flip to the Out of Control log to review what Corrective Action was taken, if any
- When reviewing Out of Control logs check for dates, initials, and that the corrective action was appropriate for the situation
- If anything is missing from the log then it is the reviewer's responsibility to document on the Out of Control Log what was missing and the corrective action. Don't forget to date and initial all comments and actions.
- Don't forget trends! Just because something is not out-of-range doesn't mean that there isn't a problem or potential problem.

Let's Review Some Logs!

Month June	Year 2012							Location: ABC	
			CHECK DAILY					CHECK WEEKLY & MONTHLY	
	Refrigerator (2-8°C)	Freezer Temp (<0°C)	Room Temp (15-30°C)	Supply Area Temp (20-25°C)	Supplies	Counter Disinfected	Initials		
1	6	-21.2	22	23	✓	✓	✓	**WEEKLY** (Record dates) **Eye Wash** Eye wash cups loosely seated & pop off readily. Run water for 1 minute-check for consistent flow and pressure. Check that water arches meet. Check that water is clear-no rust. Clean out sink area-clean off water globes. Eye Wash sign is in place. Area around eye wash is clear.	Date & Initials
2	/	/	/	/	/	/	/		
3	/	/	/	/	/	/	/		
4	4	-20.0	23	23	✓	✓	✓		
5	5	-22.1	22	22	✓	✓	✓		
6	5	-21.5	21	22	✓	✓	✓		
7	6	-22.0	21	22	✓	✓	✓		
8	3	-23.0	21	22	✓	✓	✓		
9	/	/	/	/	/	/	/		
10	/	/	/	/	/	/	/		
11	3	-22.1	23	23	✓	✓	✓	**Decontamination** Clean all waste receptacles Clean face shield.	
12	4	-23.1	23	22	✓	✓	✓		
13	4	-20.2	22	22	✓	✓	✓		
14	21	-20.9	23	22	✓	✓	✓	**MONTHLY** (Record dates) **Fire Extinguisher** Dial is in the green (4) Date on tag (It is valid 1	
15	[illegible]	-19.1	21	23	✓	✓	✓		
16		/	/	/	/	/	/		
17		/	/	/	/	/	/		



What to do when limits exceeded



Instructions: Temperatures are Rea

		1	2	3	4	5	6
JUL	Min	3.5	3.0	4.0	4.0	2.0	
	Temp	5.0	5.5	6.0	8.0	[illegible]	
	Max	6.0	7.0	8.0	10.0	5.0	
INITIALS=		[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	
	Min						

Loaded Supplies Earlier, Door was left open extended time, Mention this on the Action Log

What Are You Expecting To See?

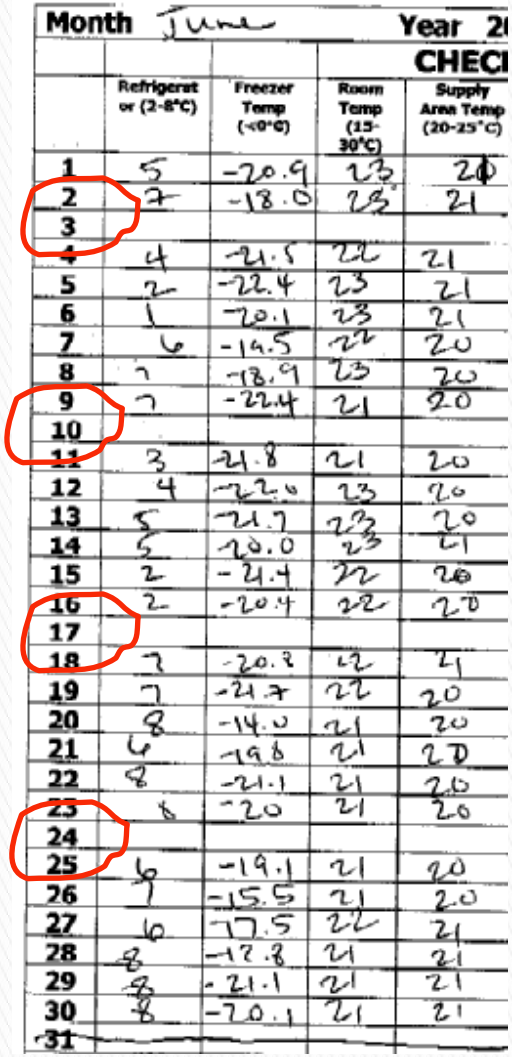
The corrective action log should have the following:

- The current date
- What was out or “out of control” and when
- The action or actions that were taken to correct the out of control temp
- An assessment of whether this affected patient specimens (why or why not)
- The initials of the person who took action

What Are You Expecting to See?

DATE	OUT OF CONTROL SITUATION	CORRECTIVE ACTION	INITIALS
6/14/12	Refrg temp at 21°C	Noted that refrig door was not closed all the way. closed door & retook temp 2 hours later. Temp now reading 4°C. No specimens affected because refrigerator was empty during this time.	LtR

Let's review this log…



Month June Year 2

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	Refrigerator (2-8°C)	Freezer Temp (<0°C)	Room Temp (15-30°C)	Supply Area Temp (20-25°C)
1	5	-20.9	23	20
2	7	-18.0	23	21
3				
4	4	-21.5	22	21
5	2	-22.4	23	21
6	1	-20.1	23	21
7	6	-19.5	22	20
8	7	-18.9	23	20
9	7	-22.4	21	20
10				
11	3	-21.8	21	20
12	4	-22.0	23	20
13	5	-21.7	23	20
14	5	-20.0	23	21
15	2	-21.4	22	20
16	2	-20.4	22	20
17				
18	7	-20.3	22	21
19	7	-21.7	22	20
20	8	-14.0	21	20
21	6	-19.8	21	20
22	8	-21.1	21	20
23	8	-20	21	20
24				
25	6	-19.1	21	20
26	7	-15.5	21	20
27	6	-17.5	22	21
28	8	-17.8	21	21
29	8	-21.1	21	21
30	8	-20.1	21	21
31				

- There is nothing marked for days 3,10, 17, and 24
- When doing a review we cannot make assumptions
- Most likely those days are days when the Lab is not open or staffed (these days were Sundays)
- Employee should have used "/" to mark those boxes to indicate that the Lab was not staffed those days

Supervisor Review of Log

DATE	OUT OF CONTROL SITUATION	CORRECTIVE ACTION	INITIALS
7/5/12	no notation marked	PSC closed on these	HHK
	on 6/3, 6/10, 6/17	days. Demanded	
	6/24.	staff to use the	
		key to mark days	
		PSC is not stated.	
		(/)	

Let's review one last log!

	Refrigerator (2-8°C)
1	5
2	5
3	
4	4
5	6
6	7
7	7
8	7
9	
10	
11	7
12	8
13	7
14	8
15	9
16	
17	
18	7
19	7
20	8
21	8
22	8
23	
24	
25	9
26	8
27	8
28	8
29	8
30	8

DATE	OUT OF CONTROL SITUATION	CORRECTIVE ACTION	INITIALS
6/15/12	Refrig temp 9°	Adjusted Refrig control. Temp stabalized at 7°	LTH
6/25/12	Refrig temp 9°	Adjusted refrig control. Temp stabalized at 8°.	LTH

Analysis

- Temperature has been running on the high end of the acceptable range over 2 weeks
- Employee has adjusted the control knob twice and temperature goes back into range
- Take Action!
  - Check the control knob to see if it is at its maximum adjustment
  - Proactively replace the unit

In Conclusion

- Take back to your staff that recording temperatures is an important component to ensuring quality at the pre-analytical phase
- Documentation and corrective action is mandated by our regulatory agencies
- Supervisors have a responsibility to review and ensure that their sites are maintaining complete temperature log documentation to meet compliance
- Challenge your staff to become trouble-shooters when assessing a problem rather than documenters
- Challenge yourself to become critical document auditors when reviewing logs