##

Temperature Log Instructions

**Purpose:**

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements for waived testing state that a testing site must follow the current manufacturer’s instructions provided with the test being performed. This includes instructions for reagents, test kits, controls, and patient sample storage.

The manufacturer’s instructions will indicate the acceptable temperature range for storing reagents, test kits, controls, and patient samples. Some products have the option to be stored at multiple temperature conditions. Each testing site should consider environmental factors and equipment availability to determine the best storage condition for reagents, test kits, controls, and patient sample storage.

Refrigerators and freezers are essential for cooling or freezing the test reagents or test kits, controls, and patient samples for preservation. Typically, a refrigerator storing patient samples is kept between 2 and 8 degrees Celsius (36 and 46 Fahrenheit). A freezer used for sample storage is often kept between -25 and -15 degrees Celsius (between -13 and 5 F). The proper temperature range for a freezer or refrigerator should be determined by considering the acceptable temperature range indicated for the reagents or test kits, controls, and patient samples that will be stored in it.

Room temperature is essential for testing conditions and storing some reagents or test kits, controls, and patient samples. Typically, rooms used for testing and storage are kept between 15 and 30 degrees C (59 and 86 F). Refer to the manufacturer’s instructions before storing patient samples and products at room temperature.

To ensure a refrigerator, freezer, or room maintains the proper temperature, check and record the temperature daily and before using the room. This applies whether the refrigerator or freezer has a temperature alarm, a chart recorder thermometer, a digital data logger thermometer, or a continuous temperature monitoring system.

**Contents:**

There are many ways to log the temperature of a refrigerator, freezer, or room. Blank logs are included for your use, along with example logs that demonstrate how to enter site-specific information correctly.

1. Example Refrigerator/Freezer Temperature Log
2. Blank Refrigerator/Freezer Temperature Log
3. Example Room Temperature Log
4. Blank Room Temperature Log
5. Example Minimum/Maximum Temperature Log
6. Blank Minimum/Maximum Temperature Log
7. Example Temperature Log for Multiple Instruments
8. Blank Temperature Log for Multiple Instruments

# **Temperature Log Instructions**

**Instructions for Recording Temperatures:**

1. Post a temperature log in the room or on the refrigerator or freezer door.
2. Read the thermometer(s) in the room, refrigerator, or freezer daily.
3. Optionally, use a digital data logger thermometer with minimum and maximum temperature reading capabilities to monitor temperature on weekends and/or during testing site closures if reagents or test kits will be continuously stored during that time. The display should be reset or cleared after each reading, restarting the clock for the timeframe being monitored.
4. If a continuous temperature monitoring system is in use, the daily temperature should still be reviewed. If applicable, alerts and alarms messages can be used to notify key personnel when temperatures are out of range.
5. Check for separated columns, gas bubbles, and cracks each time the thermometer is read, as applicable.
6. Record the temperature(s) of the room, refrigerator, or freezer.
7. Date and initial/sign the temperature log.
8. If a temperature reading is missed, and there is no available temperature data for that time frame, the entry log should remain blank. Do not make up or guess what the temperature was for that reading.
9. If the temperature falls outside of the recommended range for storage of test reagents or test kits, controls, and patient samples or the testing room for any amount of time, stop testing and contact the person who directs or supervises the testing for guidance and next steps, including if all impacted reagents or test kits should be discarded and when to resume testing. Document all corrective actions.
10. The person who directs or supervises the testing should review and sign when the temperature log is complete for the month

# **Temperature Log – Example**

**Facility:** *Dr. Smith’s Office*

**Location:** *123 Main Street, Atlanta, GA 55555*

## **Refrigerator/Freezer Location:**  ***Lab refrigerator*** **Month/Year:** ***June 2024***

## **Acceptable Temperature Range: *4-8°C***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Date** | **Temperature** | **Checked By** | **Date** | **Temperature** | **Checked By** |
| 1 | *4°C* | *Sara* | 16 | *#* | *#* |
| 2 | *#* | *#* | 17 | *#* | *#* |
| 3 | *#* | *#* | 18 | *4°C* | *Sara* |
| 4 | *4°C* | *Sara* | 19 | *4°C* | *CO* |
| 5 | *4°C* | *Sara* | 20 | *4°C* | *Sara* |
| 6 | *8°C* | *CO* | 21\* | *24°C* | *Sara* |
| 7\* | *15°C* | *Sara* | 22 | *#* | *#* |
| 8 | *4°C* | *Sara* | 23 | *#* | *#* |
| 9 | *#* | *#* | 24 | *4°C* | *Sara* |
| 10 | *#* | *#* | 25 | *4°C* | *Sara* |
| 11 | *4°C* | *Sara* | 26 | *4°C* | *CO* |
| 12 | *4°C* | *Sara* | 27 | *4°C* | *Sara* |
| 13 | *4°C* | *CO* | 28 | *4°C* | *Sara* |
| 14 | *4°C* | *Sara* | 29 | *4°C* | *Sara* |
| 15 | *4°C* | *Sara* | 30 | *#* | *#* |

**\***Enter # for weekends and holidays when temperature is not monitored.

**Corrective Action for Out-of-Range Temperature**

**Date Action taken Initials**

**\*6/7** Refrigerator door was ajar. Closed door, checked in 30 minutes. Temp at 6˚C – OK. Sara

**\*6/21** Refrigerator not staying in range. Called for service. Door seal replaced. QC’d kits
stored in refrigerator. Continue to QC and monitor for problems. Sara

 **Reviewed By: *Janice Smith, office mgr.* Date: *7/2/2024***

**Temperature Log**

**Facility:** *Dr. Smith’s Office*

**Location:** *123 Main Street*

**Refrigerator/Freezer Location: Month/Year:**

**Acceptable Temperature Range:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Date** | **Temperature** | **Checked By** | **Date** | **Temperature** | **Checked By** |
|  |  |  |  |  |  |
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**\***Enter # for weekends and holidays when temperature is not monitored.

**Corrective Action for Out-of-Range Temperature**

**Date Action taken Initials**

 **Reviewed By:** **Date:**

**Room Temperature Log – Example**

**Facility:** *Dr. Smith’s Office*

**Location:** *123 Main Street*

## **Refrigerator/Freezer Location:** ***Lab refrigerator***  **Month/Year:** ***June 2024***

## **Acceptable Temperature Range:**

***4-8° C***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Date** | **Temperature** | **Checked By** | **Date** | **Temperature** | **Checked By** |
| 1 | *20°C* | *Sara* | 16 | *#* | *#* |
| 2 | *#* | *#* | 17 | *#* | *#* |
| 3 | *#* | *#* | 18 | *19°C* | *Sara* |
| 4 | *20°C* | *Sara* | 19 | *18°C* | *CO* |
| 5 | *18°C* | *Sara* | 20 | *19°C* | *Sara* |
| 6 | *20°C* | *CO* | 21 | *20°C* | *Sara* |
| 7 | *20°C* | *Sara* | 22 | *21°C* | *Sara* |
| 8**\*** | *40°C* | *Sara* | 23 | *#* | *#* |
| 9 | *#* | *#* | 24 | *#* | *#* |
| 10 | *#* | *#* | 25 | *18°C* | *Sara* |
| 11 | *18°C* | *Sara* | 26 | *19°C* | *CO* |
| 12 | *19°C* | *Sara* | 27 | *20°C* | *Sara* |
| 13 | *18°C* | *CO* | 28 | *19°C* | *Sara* |
| 14 | *20°C* | *Sara* | 29 | *20°C* | *Sara* |
| 15 | *20°C* | *Sara* | 30 | *#* | *#* |

**\***Enter # for weekends and holidays when temperature is not monitored.

**Corrective Action for Out-of-Range Temperature**

**Date Action taken Initials**

**\*6/8** Power outage. Temp rechecked when power restored. Temp at 20°C – OK. Sara

 **Reviewed By:*****Janice Smith, office mgr.* Date: *7/2/2024***

**Room Temperature Log**

**Facility:**

**Location:**

## **Refrigerator/Freezer Location: Month/Year:**

## **Acceptable Temperature Range:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Date** | **Temperature** | **Checked By** | **Date** | **Temperature** | **Checked By** |
| 1 |  |  | 17 |  |  |
| 2 |  |  | 18 |  |  |
| 3 |  |  | 19 |  |  |
| 4 |  |  | 20 |  |  |
| 5 |  |  | 21 |  |  |
| 6 |  |  | 22 |  |  |
| 7 |  |  | 23 |  |  |
| 8 |  |  | 24 |  |  |
| 9 |  |  | 25 |  |  |
| 10 |  |  | 26 |  |  |
| 11 |  |  | 27 |  |  |
| 12 |  |  | 28 |  |  |
| 13 |  |  | 29 |  |  |
| 14 |  |  | 30 |  |  |
| 15 |  |  | 31 |  |  |
| 16 |  |  |  |  |  |

**\***Enter # for weekends and holidays when temperature is not monitored.

**Corrective Action for Out-of-Range Temperature**

**Date Action taken Initials**

 **Reviewed By:** **Date: Min./Max. Temperature Log – Example**

**Facility: *Dr. Smith’s office***

**Location: *123 Main St., Atlanta, GA 55555***

## **Refrigerator/Freezer Location:**  ***Lab refrigerator*** **Month/Year:** ***June 2024***

## **Acceptable Temperature Range:**

***4-8° C***

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Date** | **Min. Temp.** | **Max. Temp.** | **Checked By** | **Date** | **Min.Temp.** | **Max. Temp.** | **Checked By** |
| 1 | *2°C* | *6°C* | *Sara* | 16 | *#* | *#* | *#* |
| 2 | *#* | *#* | *#* | 17 | *#* | *#* | *#* |
| 3 | *#* | *#* | *#* | 18 | *2°C* | *6°C* | *CO* |
| 4**\*** | *2°C* | *9°C* | *Sara* | 19 | *2°C* | *6°C* | *Sara* |
| 5 | *2°C* | *8°C* | *Sara* | 20 | *2°C* | *6°C* | *Sara* |
| 6 | *2°C* | *8°C* | *CO* | 21 | *2°C* | *6°C* | *CO* |
| 7 | *2°C* | *8°C* | *Sara* | 22 | *2°C* | *6°C* | *Sara* |
| 8 | *2°C* | *8°C* | *Sara* | 23 | *#* | *#* | # |
| 9 | *#* |  | *#* | 24 | *2°C* | *6°C* | *CO* |
| 10 | *#* |  | *#* | 25 | *2°C* | *6°C* | *Sara* |
| 11 | *2°C* | *8°C* | *Sara* | 26 | *2°C* | *6°C* | *Sara* |
| 12 | *2°C* | *8°C* | *Sara* | 27 | *2°C* | *6°C* | *Sara* |
| 13 | *2°C* | *8°C* | *CO* | 28 | *3°C* | *8°C* | *CO* |
| 14 | *2°C* | *8°C* | *Sara* | 29 | *2°C* | *8°C* | *Sara* |
| 15 | *2°C* | *8°C* | *Sara* | 30 | *3°C* | *8°C* | *Sara* |

**\***Enter # for weekends and holidays when temperature is not monitored.

**Corrective Action for Out-of-Range Temperature**

**Date Action taken Initials**

**\*6/4** Refrigerator not staying in range. Called for service. Door seal replaced. Sara

QC’d kits stored in refrigerator. Continue QC and monitor for problems.

 **Reviewed By:*****Janice Smith, office mgr.* Date: *7/2/2024***

**Minimum/Maximum Temperature Log**

**Facility:**

**Location:**

## **Refrigerator/Freezer Location:** **Month/Year:**

## **Acceptable Temperature Range:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Date** | **Min. Temp.** | **Max.Temp.** | **CheckedBy** | **Date** | **Min.Temp.** | **Max. Temp.** | **Checked By** |
| 1 |  |  |  | 17 |  |  |  |
| 2 |  |  |  | 18 |  |  |  |
| 3 |  |  |  | 19 |  |  |  |
| 4 |  |  |  | 20 |  |  |  |
| 5 |  |  |  | 21 |  |  |  |
| 6 |  |  |  | 22 |  |  |  |
| 7 |  |  |  | 23 |  |  |  |
| 8 |  |  |  | 24 |  |  |  |
| 9 |  |  |  | 25 |  |  |  |
| 10 |  |  |  | 26 |  |  |  |
| 11 |  |  |  | 27 |  |  |  |
| 12 |  |  |  | 28 |  |  |  |
| 13 |  |  |  | 29 |  |  |  |
| 14 |  |  |  | 30 |  |  |  |
| 15 |  |  |  | 31 |  |  |  |
| 16 |  |  |  |  |  |  |  |

**\***Enter # for weekends and holidays when temperature is not monitored.

**Corrective Action for Out-of-Range Temperature**

**Date Action taken Initials**

**Reviewed By:** **Date:**



