**[lab name]**

**STANDARD OPERATING PROCEDURE**

 **Bacterial Incubator Temperature Distribution and Recovery Study**

**[SOP ID]**

**Based on V1M5 1.7.3.7.(b).(v).(a)**

**VERSION #1.0 Effective date: January 1, 2024**

**APPROVED BY**

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**New version**

**Revision History**

|  |  |
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| Version number and effective date | Revisions made |
| V 1.0 January 1, 2024 | Conforms to 2016 TNI quality system requirements. |
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# INTRODUCTION AND SCOPE

Laboratories are required to perform temperature distribution studies for all microbiology incubation units including circulating water baths. An exception is provided for water baths used solely for the tempering of agar medium or the warming of samples when using Colilert-18. A temperature distribution study allows the laboratory to determine if the incubator is properly maintaining temperatures in all areas of that incubator. The laboratory is responsible for developing and documenting the procedure for the study, evaluating the data, and evaluating the impact on previous data should the study fail to meet the requirements of the method.

# SUMMARY OF METHOD

The laboratory must develop a procedure to determine the temperature distribution and fluctuations within each incubator that is used within the laboratory as required by TNI V1M5 1.7.3.7.(b).(v).(a).

# EQUIPMENT, APPARATUS, INSTRUMENTATION, GLASSWARE/PLASTICWARE AND OTHER MATERIALS

## Equipment/Apparatus/Instrumentation

Thermometers: Calibrated traceable to the International Standard (NIST) and capable of providing readings within the expected and allowed ranges for the incubator. A data logger system can be used if it is traceable to the International Standard.

## Glassware/Plasticware/Other Materials

Sufficient bottles similar in height and width to the standard bacterial bottle. If used, QuantiTrays. Actual bacterial bottles may be used and do not need to be sterilized.

# PROCEDURE

These tests are to be performed when first using an incubator and after any repair or maintenance. If no test results exist when TNI standards are adopted, then these tests are to be performed.

Records are to include the incubator or water bath identification, identification of all thermometers used, the analyst’s initials, and the date the test started.

## Temperature Distribution.

For each shelf in a convection incubator, place a thermometer at the front of the shelf and at the back of the shelf. If there are more shelves than thermometers, then each shelf is to be checked sequentially starting with the bottom shelf. Place the thermometers and allow the incubator to equilibrate. Record the temperature of each thermometer and the shelf location. Repeat for any additional shelves. Continue the recording of time and temperatures for at least 24 hours.

For water baths, place a thermometer in the side nearest the controller and one at the opposite end for the long dimension of the water bath. Allow the water bath to equilibrate. Record the temperature of each thermometer and its location. Continue the recording of time and temperature for at least 24 hours.

## Recovery from Full Load

Determine what would constitute a full load of samples. If all samples are in 100mL bacterial bottles, then determine the highest number of samples, then add 10% more and round up to the nearest bottle. For example, if the largest number of samples is 50, then 10% more is 5 and the total is 55 bottles. Do the same if all samples are QuanitTrays.

If the load is a mix of bottles and QuantiTrays, then take the highest number of bottles plus the highest number of QuantiTrays, then add 10% more to each count. For example, if the highest number of bottles is 25 and the highest number of QuantiTrays is 30, then 10% of 25 is 2.5, which is rounded to 28 bottles. 10% of 30 is 3 and this is 33 QuantiTrays.

Fill each bottle and/or Quantitray with reagent grade water to the mark on bottles or to fill all wells in each QuantiTray. The water does not have to be sterile, and no media is to be added. Place the determined number of bottles and/or QuantiTrays into the incubator. Distribute them evenly and do not stack QuantiTrays higher than allowed by the method. Record the number of each placed in the incubator. Record the time and temperature of the incubator, then close the door. The temperature should be below the allowed temperature range. Return at regular intervals and record the time and temperature. It is suggested that this be done every 10 minutes. The test ends when the incubator temperature is within the specified range.

# DATA ASSESSMENT AND Reporting

## Temperature Distribution

Examine the records. Note any instance where the thermometer read below or above the allowed temperature requirements. Record the differences between each thermometer. If no temperature is below or above the allowed temperature, then the test is successful. Otherwise, examine the incubator and consider whether to repair or replace it.

If necessary, sections of shelves may be marked as unsuitable for samples. If done, no samples may be places in the indicated shelf area.

## Recovery from Full Load

Note the time it takes to recover. When conducting this test after repairs or maintenance, note whether the time has increased or decreased. If time has increased, consider whether maintenance or repairs were successful.

# REFERENCES

* *Microbiological Incubator Guidance*, Pennsylvania Department of Environmental Protection, Draft procedure.
* *Management and Technical Requirements for Laboratories Performing Environmental Analyses*, The NELAC Institute (TNI), Rev 2.1, September 1, 2016
* Laboratory QSM

# DEFINITIONS AND ACRONYMS

All definitions, unless stated below, are as found in the reference method or in TNI 2016, V1M2 section 3.

Acronyms not explicitly stated in the method or of general understanding are listed below.

## Definition

## Acronym