



**TEMPERATURE MAPPING REPORT  
FOR  
COOLING INCUBATOR**

<b>Protocol No.:</b>
<b>Revision No.:</b>
<b>Effective Date:</b>
<b>Page No.: 1 of 15</b>

**REPORT  
FOR  
TEMPERATURE MAPPING  
OF  
COOLING INCUBATOR**

**AREA: MICROBIOLOGY LAB (QA/QC BLOCK)**

**LOCATION: BET/MLT LAB**

<b>Document No.</b>	
<b>Supersedes</b>	
<b>Ref. Protocol No.</b>	
<b>Date of Final Approval</b>	
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**1.0 Report Approval**

This is a specific report for Temperature Mapping of Cooling Incubator, which is lying in the Incubator room, Microbiology lab (QA/QC Block).

**Initial Approval**

This protocol has been approved by the following

**Prepared By:**

Name	Designation	Department	Signature	Date

**Checked By:**

Name	Designation	Department	Signature	Date

**Final Approval:**

Name	Designation	Department	Signature	Date



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### 2.0 Overview

#### 2.1 Objective

To establish the methodology for temperature mapping of Cooling Incubator (Equipment No.: .....)  
which is kept in the BET/MLT lab in Microbiology lab (QA/QC Block).

#### 2.2 Purpose and Scope

The purpose of this report is to establish documentary evidence that Cooling Incubator (Equipment No.: .....)  
has been qualified to ensure uniformity of temperature at different locations for storage of the samples and other material.

This report is applicable for the temperature mapping of the Cooling Incubator (Equipment No.: .....)  
which is kept in the BET/MLT lab in Microbiology lab (QA/QC Block).

#### 2.3 Responsibility

- **Protocol / Report Preparation:** Executive Microbiology
- **Protocol / Report checking :** Manager QC / Manager Maintenance/ Manager QA
- **Approval of Protocol / Report:** Head QA
- **Execution of Qualification Activity:** Executive Microbiology / Executive Engineering

#### 2.4 Qualification Team

- Microbiologists / Executive Microbiology
- Engineering Executive / Manager
- Quality Assurance Executive / Manager



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### **3.0 Training Record:**

#### **3.1 Purpose**

The purpose of the training is to familiarize the trainees with overall strategy of temperature mapping of Cooling Incubator (Equipment No.: .....).

#### **3.2 Scope**

This Training is applicable to the temperature mapping procedure of the Cooling Incubator Equipment No. - .....

#### **3.3 Topics**

The following topics have been covered during training:

- Overall strategy of temperature mapping procedure.
- General precautions / guidelines to be followed during qualification.
- *Training record has been attached with the report as Annexure – 01.*



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#### 4.0 Pre – Qualification Requirements

Following instruments were required for the temperature mapping of the Cooling Incubator (Equipment No.: .....).

S.No.	Instrument Name	Instrument Code /S.No.	Calibration Certificate No.	Calibration Due On
1.	Data logger			
2.	Temperature Sensors			
3.	Temperature Sensors			
4.	Temperature Sensors			
5.	Temperature Sensors			
6.	Temperature Sensors			
7.	Temperature Sensors			
8.	Temperature Sensors			
9.	Temperature Sensors			
10.	Temperature Sensors			
11.	Temperature Sensors			
12.	Temperature Sensors			
13.	Temperature Sensors			
14.	Temperature Sensors			
15.	Temperature Sensors			
16.	Temperature Sensors			
17.	Temperature Sensors			
18.	RTD Sensor (Inbuilt)			

Calibration Certificate has been attached as **Annexure-02**.



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## 5.0 System / Equipment Description

### 5.1 System / Equipment details

The Cooling Incubator will be used to store the test samples and other material at temperature 2-8° C.

### 5.2 System /Equipment Identification

Component	Specifications
Name of equipment	Cooling incubator
Model	
Serial Number	
Tag No.	
Name of the Supplier	Newtronic Equipment Company Pvt. Ltd.
Chamber size	900 mm (H) x 600 mm (W) x 600 mm (D)
Temperature range	2 to 8 °C
Temperature display	Digital with readability of 0.1 °C
Trays	3 Nos. - Perforated
Tray Size	550 x 550 mm
Door	Double wall metal door, magnetic gasket and lock
Controller	Programmable Logic Controller (PLC), Make-Schneider
PLC Model No.	
Human Machine Interface (HMI) Model No.	
Control Panel	Panel at front top to view and set temp. real time clock
Temperature sensor	PT 100 type, Make: Simplicon
Equipment Location	Microbiology laboratory (QA/QC Block)
<b>Material of Construction</b>	
Internal Chamber	SS 304
External Chamber	SS 304
Trays	SS 304
Insulation	PUF insulation between outer chamber and inner chamber



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### 6.0 Temperature Mapping Procedure

The following procedure has been used for temperature mapping of Cooling Incubator.

- 6.1 Location of temperature sensors in chambers was as shown in the diagram given in **Exhibit – E01**.
- 6.2 16 No. of sensors were used for the temperature mapping
- 6.3 One sensor was placed at each corner of each shelf and one in the middle.
- 6.4 One sensor was placed parallel to the inbuilt sensor.
- 6.5 The recording / printing interval was set as 30 Minutes in data loggers.
- 6.6 Closed the door of Incubator and started the temperature recording.
- 6.7 Recorded the temperature profile of the equipment for 24 hours.
- 6.8 The print out of the data was taken and has been attached along with the report as **Annexure-03**.
- 6.9 Observations of the temperature mapping have been recorded as per **Exhibit – E02**.
- 6.10 **Acceptable criteria:** Temperature variation at different locations shall not be more than  $5.0 \pm 2.0^{\circ}\text{C}$ .
- 6.11 No deviation was observed during Temperature mapping study.

### 7.0 Acceptance Criteria

Temperature mapping will be considered acceptable when requirements listed in section 6.0 of this protocol has been fulfilled and Cooling Incubator is performing as per intended purpose.

### 8.0 Results and Conclusion

Based on temperature mapping data (24 hours) of Cooling Incubator (Equipment No.: ..... ) in BET/MLT lab in Microbiology lab it is evident that the temperature is maintained as per the acceptance criteria. The mapping activity was carried out by putting 16 probes (Refer Section 6.0) which is found consistent.

Hence the temperature mapping activity stands validated and Cooling Incubator can be used for the routine use.

### 9.0 Approval of Qualification Report

The temperature mapping report has been evaluated and finally approved by Head Quality Assurance.





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**10.0 Observed Deviation**

Sr. No.	Page No.	Point No.	Observed Deviation	Deviation Reported By	Deviation Approved By	Corrective Action Taken	Justification of Corrective Action	Corrective action taken and justification given by

**Report Approved By**

**Department Head**

**Quality Head**



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**11.0 List of Exhibits / Annexure**

**11.1 List of Exhibits**

<b>Exhibit No.</b>	<b>Exhibit Title</b>	<b>No. of Pages</b>
<b>E01</b>	Diagram Showing Locations of temperature probes in Cooling Incubator	
<b>E02</b>	Temperature mapping record	
<b>Total No. of Pages</b>		

**11.2 List of Annexure**

<b>Annexure No.</b>	<b>Annexure Title</b>	<b>No. of Pages</b>
<b>01</b>	Training Record	
<b>02</b>	Calibration certificates	
<b>03</b>	Printouts of Data logger	
<b>Total No. of Pages</b>		

**12.0 Reference Documents (If Any)**

NA

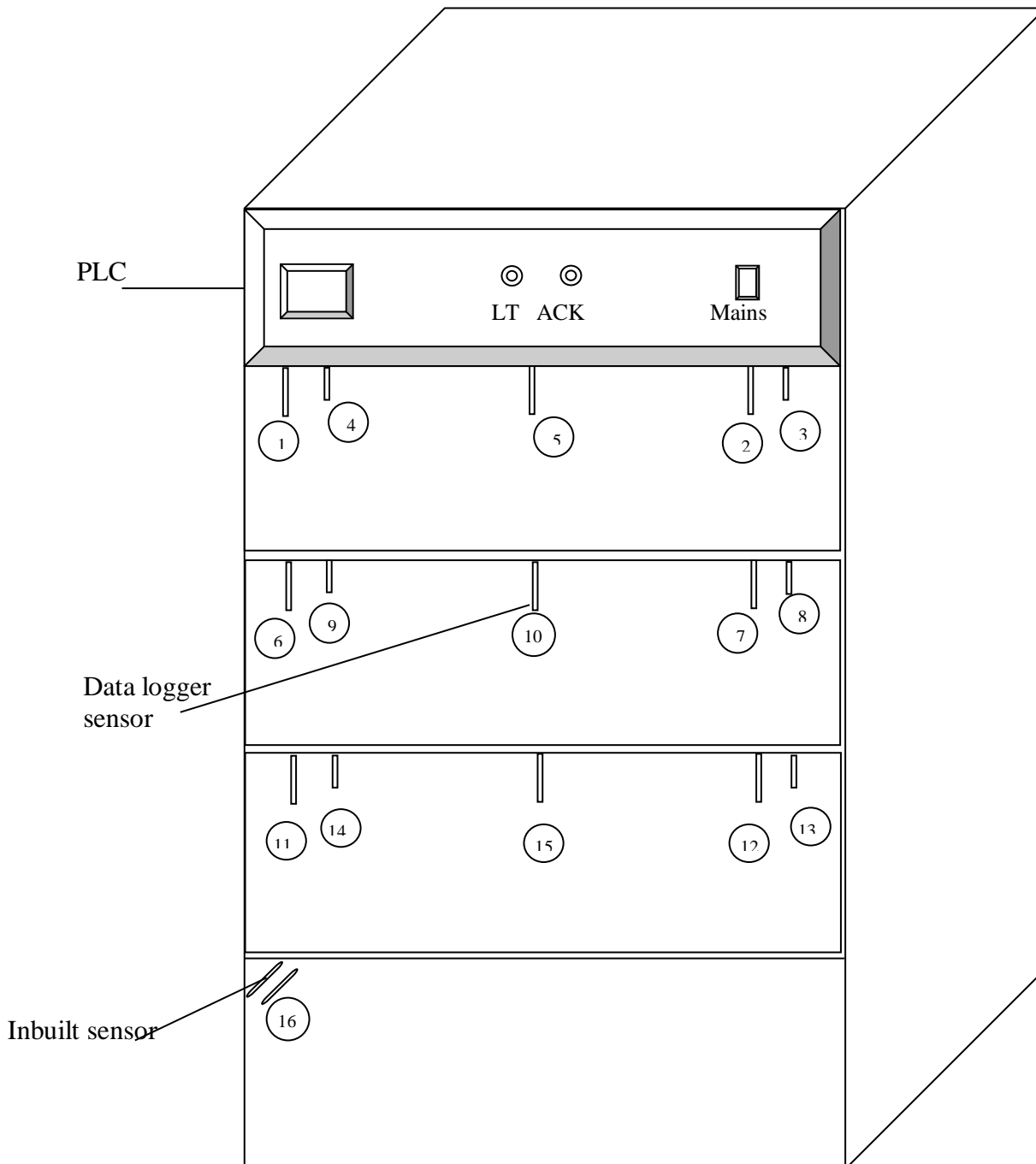


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**Exhibit – E01**

**Diagram Showing Locations of Temperature Probes in Cooling Incubator**



1 to 16 No. is sensors of External data logger.

**Checked By:** \_\_\_\_\_  
(QC) (Name) (Sign) (Date)

**Verified By:** \_\_\_\_\_  
(QA) (Name) (Sign) (Date)



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**Exhibit – E02**

**Temperature Mapping Record**

Mapping started on :

Set Temperature (°C):

Holding time started at/date:

Holding time ended at/date:

<b>Probe Description</b>	<b>Minimum Temperature (°C)</b>	<b>Maximum Temperature (°C)</b>	<b>Average Temperature (°C)</b>	<b>Remarks</b>
<b>Probe 1</b>				
<b>Probe 2</b>				
<b>Probe 3</b>				
<b>Probe 4</b>				
<b>Probe 5</b>				
<b>Probe 6</b>				
<b>Probe 7</b>				
<b>Probe 8</b>				
<b>Probe 9</b>				
<b>Probe 10</b>				
<b>Probe 11</b>				
<b>Probe 12</b>				
<b>Probe 13</b>				
<b>Probe 14</b>				
<b>Probe 15</b>				
<b>Probe 16</b>				

**Acceptance Criteria** – Temperature at any location shall not show variation more than  $5.0 \pm 2$  °C.

**Remarks:** Temperature at all the locations **is within/is not within** acceptance criteria.

**Checked By:** \_\_\_\_\_  
 (QC) (Name) (Sign) (Date)

**Verified By:** \_\_\_\_\_  
 (QA) (Name) (Sign) (Date)



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**Annexure – 01  
Training Record**

<b>Equipment Name:</b>	Cooling Incubator
<b>Equipment No.:</b>	
<b>Location:</b>	Microbiology Lab (QA/QC Block)
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**Annexure – 02  
Calibration Certificates**

<b>Equipment Name:</b>	Cooling Incubator
<b>Equipment No.:</b>	
<b>Location:</b>	Microbiology Lab (QA/QC Block)
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**Annexure – 03  
Print outs of Data logger**

<b>Equipment Name:</b>	Cooling Incubator
<b>Equipment No.:</b>	
<b>Location:</b>	Microbiology Lab (QA/QC Block)
<b>No. of Pages:</b>	