



**TEMPERATURE MAPPING
REPORT
FOR
LABORATORY INCUBATOR**

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**REPORT
FOR
TEMPERATURE MAPPING
OF
LABORATORY INCUBATOR**

AREA: MICROBIOLOGY LAB (QA/QC BLOCK)

LOCATION: BET/MLT LAB

Document No.	
Supersedes	
Ref. Protocol No.	
Date of Final Approval	
No. of Pages	



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1.0 Report Approval:

This is a specific report for Temperature Mapping of Laboratory 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 Laboratory Incubator this 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 Laboratory Incubator has been qualified to ensure uniformity of temperature at different locations for the incubation of the samples plates.

This report is applicable for the temperature mapping of the Laboratory Incubator 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 Laboratory Incubator.

3.2 Scope

This Training is applicable to the temperature mapping procedure of the Laboratory Incubator.

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 Laboratory 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 Laboratory Incubator (Equipment No.:) will be used to Incubate the test samples at temperature 43.0 °C.

5.2 System /Equipment Identification

Component	Specifications
Name of equipment	Laboratory incubator
Model	
Serial Number	
Tag No.	
Name of the Supplier	Newtronic Equipment Company Pvt. Ltd.
Chamber size	450 mm (H) x 450 mm (W) x 450 mm (D)
Temperature range	5°C above ambient to 60 °C
Temperature display	Digital with readability of 0.1 °C
Trays	2 Nos. - Perforated
Temperature sensor	PT 100 type
Equipment Location	Microbiology laboratory (QA/QC Block)
Material of Construction	
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 laboratory 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 laboratory 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 $43.0 \pm 2.0^{\circ}\text{C}$.
- 6.11 No deviation has been 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 BOD Incubator is performing as per intended purpose.

8.0 Summary and Conclusion

Based on temperature mapping data (24 hours) of laboratory 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 laboratory Incubator (Equipment No.) can be used for the routine use for testing.

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:

S.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

Exhibit No.	Exhibit Title	No. of Pages
E01	Diagram Showing Locations of temperature probes in laboratory Incubator	
E02	Temperature mapping record	
Total No. of Pages		

11.2 List of Annexure

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

12.0 Reference Documents (If Any)

NA

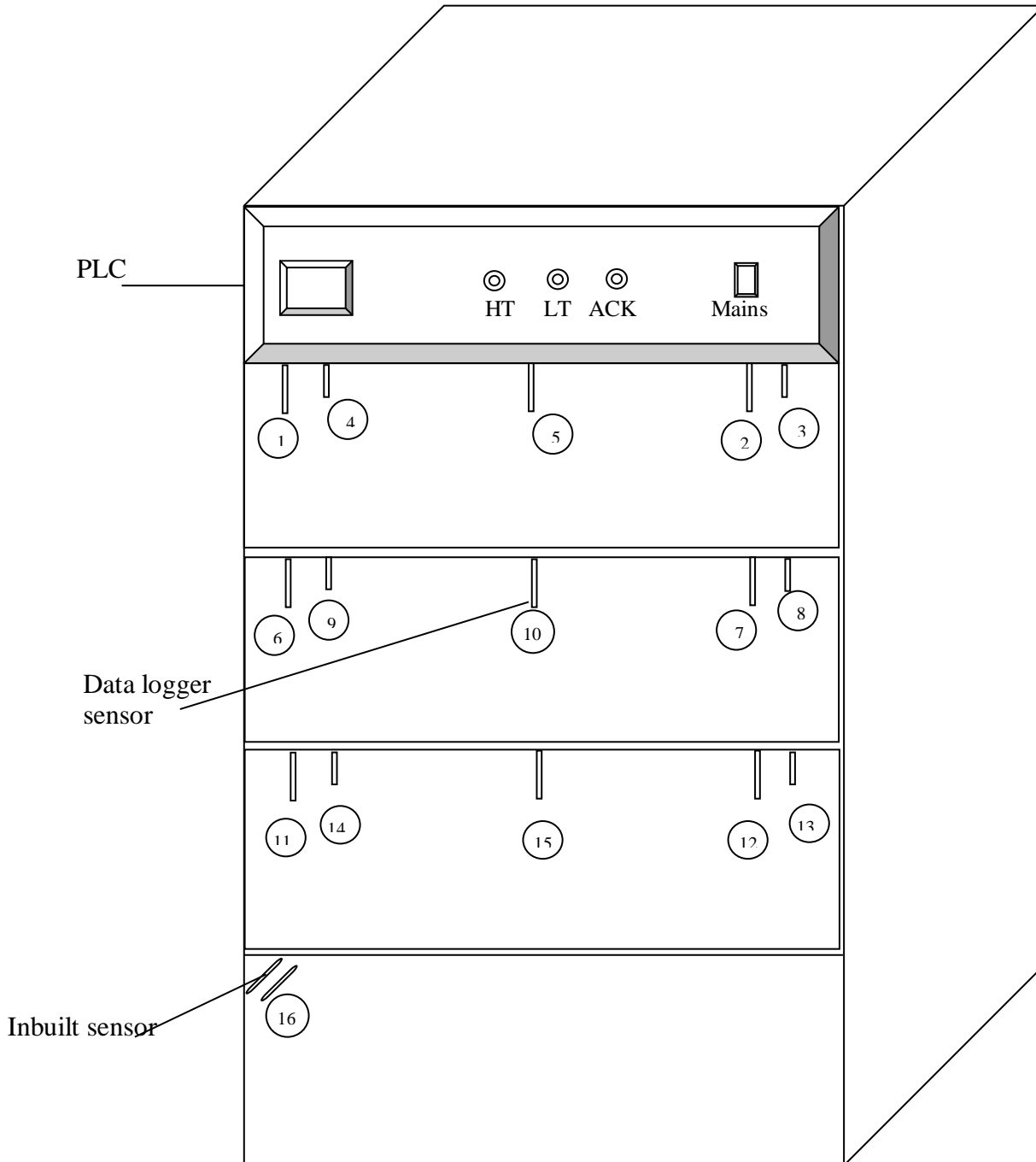


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Exhibit – E01

Diagram Showing Locations of Temperature Probes in Laboratory 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:

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

Acceptance Criteria – Temperature at any location shall not show variation more than 43.0 ± 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**

Equipment Name:	Laboratory Incubator
Equipment No.:	
Location:	Microbiology Lab (QA/QC Block)
No. of Pages:	



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**Annexure – 02
Calibration Certificates**

Equipment Name:	Laboratory Incubator
Equipment No.:	
Location:	Microbiology Lab (QA/QC Block)
No. of Pages:	



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**Annexure – 03
Print outs of Data logger**

Equipment Name:	Laboratory Incubator
Equipment No.:	
Location:	Microbiology Lab (QA/QC Block)
No. of Pages:	