



**TEMPERATURE MAPPING PROTOCOL  
FOR  
BOD INCUBATOR**

**Protocol No.:**  
**Revision No.:**  
**Effective Date:**  
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**PROTOCOL  
FOR  
TEMPERATURE MAPPING  
OF  
BOD INCUBATOR**

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

**LOCATION: BET/MLT LAB**

|                       |    |
|-----------------------|----|
| <b>Document No.</b>   |    |
| <b>Supersedes</b>     |    |
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**1.0 Protocol Approval:**

This is a specific protocol for Temperature Mapping of BOD 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 BOD 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 protocol is to establish documentary evidence that BOD Incubator (Equipment No.: .....)  
has been qualified to ensure uniformity of temperature at different locations for the incubation of the samples plates.

This protocol is applicable for the temperature mapping of the BOD 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 BOD Incubator (Equipment No.: .....).

**3.2 Scope**

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

**3.3 Topics**

The following topics shall be covered during training:

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



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#### 4.0 Pre – Qualification Requirements

Following instruments shall be required for the temperature mapping of the BOD Incubator (.....).

| S.No. | Instrument Name      | Instrument Code / Sr. 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 shall be attached as **Annexure-02**.



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## 5.0 System / Equipment Description

### 5.1 System / Equipment details

The BOD Incubator shall be used to Incubate the test samples at temperature 22.5<sup>0</sup>C.

### 5.2 System /Equipment Identification

| Component                               | Specifications  |
|---|---|
| Name of equipment                       | BOD incubator   |
| Model                                   |   |
| Serial Number                           |   |
| Tag No.                                 |   |
| Name of the Supplier                    |   |
| Chamber size                            | 900 mm (H) x 600 mm (W) x 600 mm (D)  |
| Temperature range                       | 10 to 60 <sup>0</sup> C   |
| Temperature display                     | Digital with readability of 0.1 <sup>0</sup> C  |
| Trays                                   | 3 Nos. - Perforated   |
| Tray Size                               | 560 x 560 mm  |
| Door                                    | Double wall metal door, magnetic gasket and lock  |
| Chamber Heating                         | By Tubular heater with Stainless Steel fins   |
| Chamber Cooling                         | Using Hermetically sealed compressor coupled with evaporation coil and fan cooled condenser in a removable tray at the bottom of the equipment. |
| Controller                              | Programmable Logic Controller (PLC)   |
| 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 shall be used for temperature mapping of BOD Incubator.

- 6.1 Location of temperature sensors in chambers shall be as shown in the diagram given in **Exhibit – E01**.
- 6.2 16 No. of sensors shall be used for the temperature mapping
- 6.3 One sensor shall be placed at each corner of each shelf and one in the middle.
- 6.4 One sensor shall be placed parallel to the inbuilt sensor.
- 6.5 Set the recording / printing interval as 30 Minutes in data loggers.
- 6.6 Close the door of Incubator.
- 6.7 Now start recording temperature.
- 6.8 Record the temperature profile of the equipment for not less than 24 hours.
- 6.9 Take the print out of the data.
- 6.10 Observations of the temperature mapping shall be recorded as per **Exhibit – E02**.
- 6.11 **Acceptable criteria:** Temperature variation at different locations shall not be more than  $22.5 \pm 2.0^\circ\text{C}$ .
- 6.12 Any deviation observed during Temperature mapping shall be recorded as per **Clause 10.0**.
- 6.13 Observed deviation shall be reported to the Department Head and Quality Head.
- 6.14 If the observed deviation does not have any major impact on the Temperature mapping study the final conclusion shall be provided.
- 6.15 If the observed deviation has major impact on the Temperature mapping, deviation shall be reported to the manufacturer for the corrective action and mapping activity shall be done again.

## 7.0 Acceptance Criteria

Temperature mapping shall 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.





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### **8.0 Qualification Report**

The Temperature mapping report shall consist of a summary document, in narrative form, which shall briefly describe the activity performed along with the observations recorded in relevant exhibits.

This report shall also include the related documents and Attachments/Annexure which were completed at the time of qualification activity.

### **9.0 Approval of Qualification Report**

The report shall be evaluated and proper references / conclusions / recommendations shall be recorded by quality assurance.

The Re-qualification report shall be evaluated and finally approved by 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 |  |
|---------------------------|----------|-----------|--------------------|-----------------------|-----------------------|-------------------------|------------------------------------|--|--|
|                           |          |           |                    |                       |                       |                         |                                    |  |  |
|                           |          |           |                    |                       |                       |                         |                                    |  |  |
|                           |          |           |                    |                       |                       |                         |                                    |  |  |
|                           |          |           |                    |                       |                       |                         |                                    |  |  |
|                           |          |           |                    |                       |                       |                         |                                    |  |  |
| <b>Report Approved By</b> |          |           |                    |                       |                       |                         |                                    |  |  |
|                           |          |           |                    |                       |                       |                         |                                    |  |  |
| <b>Department Head</b>    |          |           |                    |                       |                       | <b>Quality Head</b>     |                                    |  |  |



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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 BOD 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

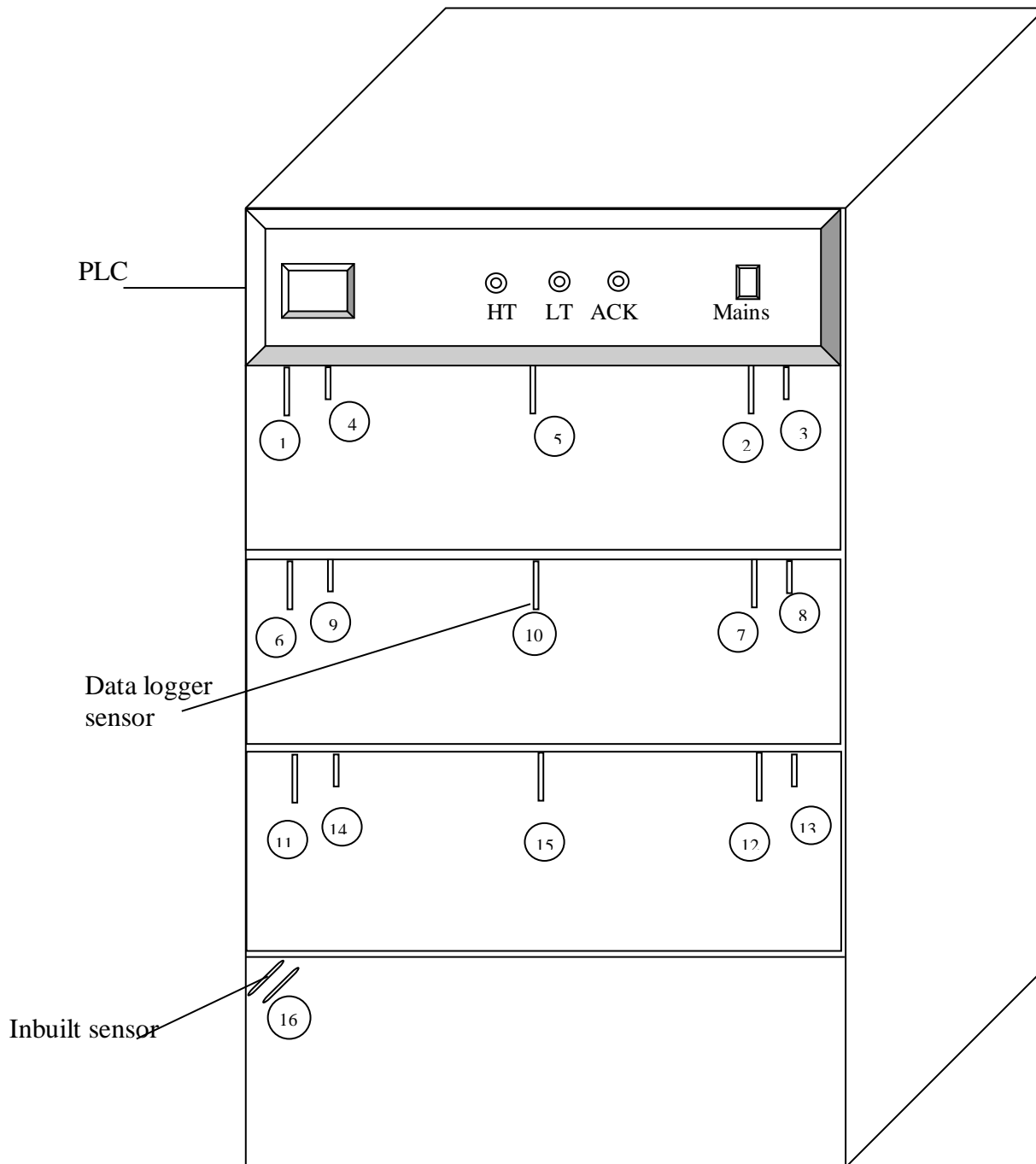


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**Exhibit – E01**

**Diagram Showing Locations of Temperature Probes in BOD 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  $22.5 \pm 2$  °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> | BOD Incubator                  |
| <b>Equipment No.:</b>  | .....                          |
| <b>Location:</b>       | Microbiology Lab (QA/QC Block) |
| <b>No. of Pages:</b>   |                                |



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**Annexure – 02  
Calibration Certificates**

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



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**Annexure – 03**

**Print outs of Data logger**

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