



**TEMPERATURE MAPPING PROTOCOL  
FOR  
REFRIGERATOR**

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**PROTOCOL  
FOR  
TEMPERATURE MAPPING  
OF  
REFRIGERATOR**

**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 Refrigerator, which is lying in the Incubator room, Microbiology lab.

**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 Refrigerator (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 Refrigerator (Equipment No.: ..... ) has been qualified to ensure uniformity of temperature at different locations for storage of the samples and other material.

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

#### **3.2 Scope**

This Training is applicable to the temperature mapping procedure of the Refrigerator, 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 Refrigerator (.....).

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			

Calibration Certificate shall be attached as **Annexure-02**.



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**5.0 System / Equipment Description**

**5.1 System / Equipment details**

The Refrigerator shall be used for the safe storage of the cultures, BET reagents and media at temperature 2-8° C as well as at temperature below -15° C.

**5.2 System /Equipment Identification**

<b>Component</b>	<b>Specifications</b>
Name of equipment	Refrigerator
Make	LG
Model	.....
Serial Number	.....
Tag No.	.....
Colour	Bright Silver
Chamber size	1832 mm (H) x 640 mm (W) x 705 mm (D)
Capacity	390 Litres
No. of Door	2 Nos.
Equipment Location	Microbiology laboratory (QA/QC Block)



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### 6.0 Temperature Mapping Procedure

The following procedure shall be used for temperature mapping of Refrigerator.

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 Set the recording / printing interval as 30 Minutes in data loggers.

6.4 Close the door of Refrigerator.

6.5 Now start recording temperature.

6.6 Record the temperature profile of the refrigerator for not less than 24 hours.

6.7 Take the print out of the data.

6.8 Observations of the temperature mapping shall be recorded as per **Exhibit – E02**.

#### 6.9 Acceptable criteria:

- De-freezer : NMT -15° C
- Lower Chamber: 2-8°C

6.10 Any deviation observed during Temperature mapping shall be recorded as per **Clause 10.0**.

6.11 Observed deviation shall be reported to the Department Head and Quality Head.

6.12 If the observed deviation does not have any major impact on the Temperature mapping study the final conclusion shall be provided.

6.13 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 Refrigerator is performing as per intended purpose.

### 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.





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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 Refrigerator	
<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

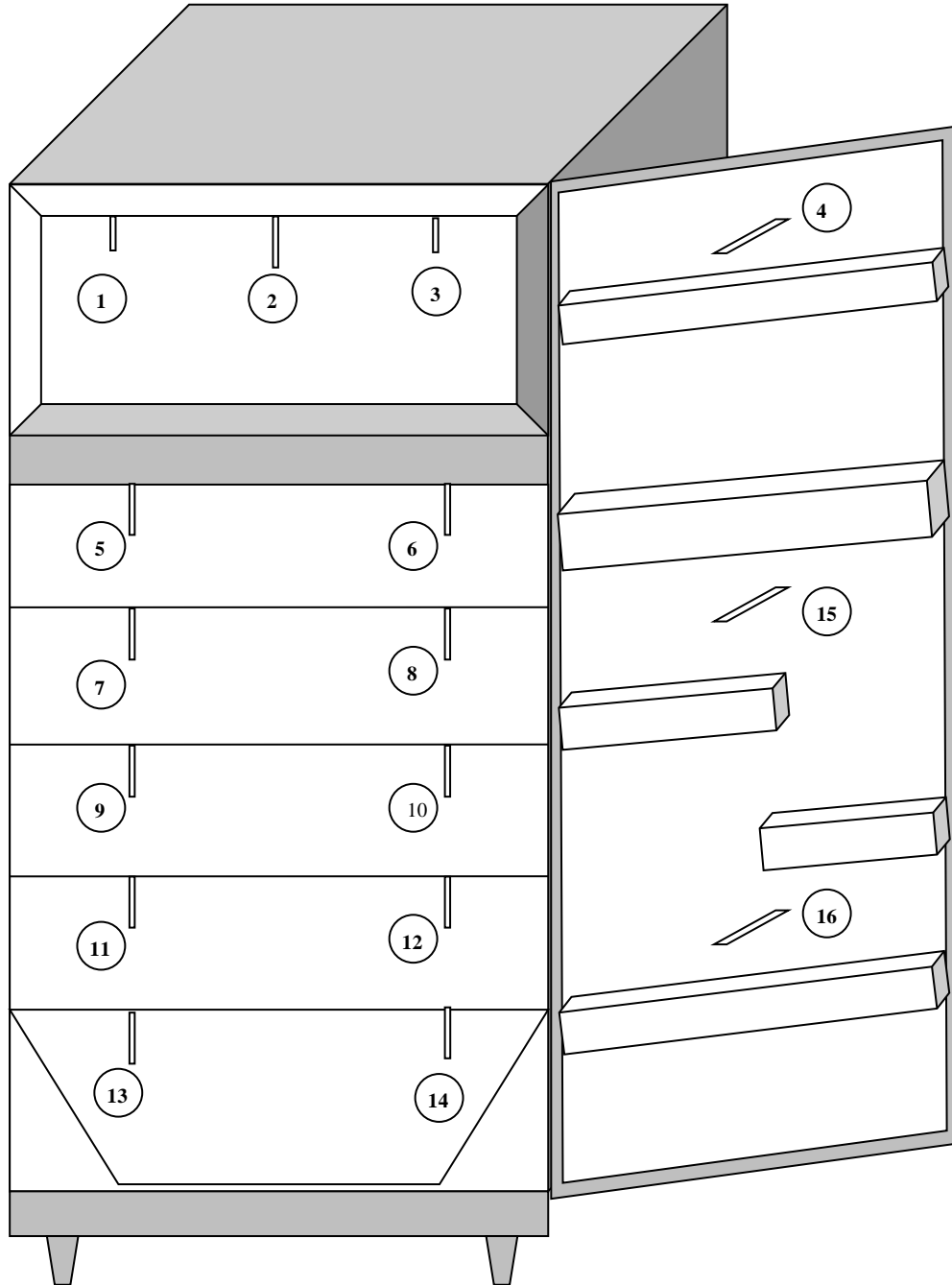


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**Exhibit – E01**

**Diagram Showing Locations of Temperature Probes in Refrigerator**



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>
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 –**

- De-freezer : NMT -15° C
- Lower Chamber: 2-8° 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>	Refrigerator
<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>	Refrigerator
<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>	Refrigerator
<b>Equipment No.:</b>	.....
<b>Location:</b>	Microbiology Lab (QA/QC Block)
<b>No. of Pages:</b>	