# Thermo Scientific Triple Wrapped Irradiated Plates

For complete cleanroom and isolator confidence

Triple Wrap Sterile
Pack with VHP
Indicator Sabouraud
Dextrose Agar
with Lecithin,
Polysorbate 80,
Sodium Thiosulphate,
L-Histidine

PO5513D

A general purpose medium for the microbial control of aseptic processes within manufacturing cleanrooms or isolators, particularly in the pharma/biopharma industry.

For professional use only.

Typical Formulation*	Grams per Litre
Meat peptone	5.0
Casein peptone	5.0
Dextrose	40.0
Polysorbate 80	5.0 mL
Lecithin	0.7
Sodium thiosulphate	0.5
L-Histidine	1.0
Agar	15.0

<sup>\*</sup>Adjusted as required to meet performance standards.



### **Form of Product**

Poured plate, contact plate 55mm

#### **Storage**

2-25° C

# **Filling Weight**

 $13 \pm 0.5 g$ 

# **Packaging**

10 plates triple-wrapped in clear film

Primary film with moisture control patch

Secondary film VHP barrier with immobilised desiccant sachet

Tertiary film dust cover

Product label incorporates irradiation and VHP exposure indicators

## **Sterility Assurance Level**

10-5

# рН

 $pH 5.6 \pm 0.2$ 

# **Colour**

Ivory, transparent

#### **Shelf Life**

12 weeks

# **Technique**

Depends on the different methods.



### **Quality Control**

- 1. Control for general characteristics, labelling and printing
- 2. Control for sterility
  - ≥ 5 days at 20-25° C, aerobic
  - $\geq$  5 days at 30–35° C, aerobic
- 3. Biological control

Inoculum size for productivity: 10–100 cfu Inoculum size for specificity (moulds): 1 cfu

#### **Incubation Conditions**

Control Strain	Growth
Up to 5 days at 20–25° C	
Candida albicans ATCC® 10231™	2 mm, cream colonies
Aspergillus brasiliensis ATCC® 16404™	10-30 mm, white mycelium, black spores
Up to 5 days at 30–35° C	
Candida albicans ATCC® 10231™	2 mm, cream colonies
Aspergillus brasiliensis ATCC® 16404™	10-30 mm, white mycelium, black spores

Moderate to heavy growth of the tested organisms. Recovery greater than 50% and less than 150% of the control and is comparable to a previously released batch.

Tested in accordance with BP/EP/JP/USP. Clearly visible growth within 3 days for bacteria and within 5 days for fungi.



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