

# Thermo Scientific Triple Wrapped Irradiated Plates

For complete cleanroom and isolator confidence

## Triple Wrap Sterile Pack with VHP Indicator Tryptone Soya Agar

PO5510D

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
Tryptone	15.0
Soya peptone	5.0
Sodium chloride	5.0
Agar	18.0

\*Adjusted as required to meet performance standards.

### Form of Product

Poured plate, contact plate 55mm

### Storage

2–25° C

### Filling Weight

13 ± 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<sup>-5</sup>

### pH

7.3 ± 0.2

### Colour

Ivory, transparent

### Shelf Life

43 weeks

### Technique

Depends on the different methods. For information see Oxoid CM0131 specifications.

## Quality Control

- 1. Control for general characteristics, labelling and printing**
- 2. Control for sterility**
  - ≥ 5 days at 20–25° C, aerobic
  - ≥ 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
<b>Up to 3 days at 30–35° C</b>	
<i>Escherichia coli</i> ATCC® 8739™	2–10 mm, cream colonies
<i>Staphylococcus aureus</i> ATCC® 6538™	1–2 mm, cream shiny colonies
<i>Pseudomonas aeruginosa</i> ATCC® 9027™	3–8 mm, green-yellow colonies
<i>Bacillus subtilis</i> ATCC® 6633™	4–8 mm, cream colonies
<i>Staphylococcus epidermidis</i> ATCC® 12228™	1 mm, cream colonies
<i>Kocuria rhizophila</i> ATCC® 9341™	0.5–0.75 mm, yellow colonies
<b>Up to 3 days at 20–25° C</b>	
<i>Bacillus subtilis</i> ATCC® 6633™	4–8 mm, cream colonies
<b>Up to 5 days at 30–35° C</b>	
<i>Aspergillus brasiliensis</i> ATCC® 16404™	10–30 mm, white mycelium, black spores
<i>Candida albicans</i> ATCC® 10231™	2 mm, cream colonies
<b>Up to 5 days at 20–25° C</b>	
<i>Aspergillus brasiliensis</i> ATCC® 16404™	10–30 mm, white mycelium, black spores
<i>Candida albicans</i> ATCC® 10231™	2 mm, cream colonies
<b>Up to 2 days at 32° C, anaerobic</b>	
<i>Clostridium sporogenes</i> ATCC® 19404™	1–2 mm, cream colonies

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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