Thermo Scientific Triple Wrapped Irradiated Plates

For complete cleanroom and isolator confidence

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

PO5511D

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
Tween 80	5.0 mL
Lecithin	0.7
Sodium thiosulphate	0.5
L-Histidine	1.0
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^{-5}

pH
7.3 ± 0.2

Colour
Ivory, transparent

Shelf Life
43 weeks

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

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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
Up to 3 days at 30–35° C	
Escherichia coli ATCC® 8739™	2–10 mm, cream colonies
Staphylococcus aureus ATCC® 6538™	1–2 mm, cream shiny colonies
Pseudomonas aeruginosa ATCC® 9027™	3–8 mm, green-yellow colonies
Bacillus subtilis ATCC® 6633™	4–8 mm, cream colonies
Staphylococcus epidermidis ATCC® 12228™	1 mm, cream colonies
Kocuria rhizophila ATCC® 9341™	0.5–0.75 mm, yellow colonies
Up to 3 days at 20–25° C	
Bacillus subtilis ATCC® 6633™	4–8 mm, cream colonies
Up to 5 days at 30–35° C	
Aspergillus brasiliensis ATCC® 16404™	10–30 mm, white mycelium, black spores
Candida albicans ATCC® 10231™	2 mm, cream colonies
Up to 5 days at 20–25° C	
Aspergillus brasiliensis ATCC® 16404™	10–30 mm, white mycelium, black spores
Candida albicans ATCC® 10231™	2 mm, cream colonies
Up to 2 days at 32° C, anaerobic	
Clostridium sporogenes 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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