

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

PO5501B

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
Polysorbate 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, 90mm

Storage

2–25° C

Filling Weight

25 ± 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

24 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

2. 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	
<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
Up to 3 days at 20–25° C	
<i>Bacillus subtilis</i> ATCC® 6633™	4–8 mm, cream colonies
Up to 5 days at 30–35° C	
<i>Aspergillus brasiliensis</i> ATCC® 16404™	10–30 mm, white mycelium, black spores
<i>Candida albicans</i> ATCC® 10231™	2 mm, cream colonies
Up to 5 days at 20–25° C	
<i>Aspergillus brasiliensis</i> ATCC® 16404™	10–30 mm, white mycelium, black spores
<i>Candida albicans</i> ATCC® 10231™	2 mm, cream colonies
Up to 2 days at 32° C, anaerobic	
<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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LT2104A Rev1
April 2014

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Part of Thermo Fisher Scientific