

Thermo Scientific Triple Wrapped Irradiated Plates

For complete cleanroom and isolator confidence

Triple Wrap Sterile Pack with VHP Indicator Sabouraud Dextrose Agar

PO5512D

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
Agar	15.0

*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

pH 5.6 ± 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
 - ≥ 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	
<i>Candida albicans</i> ATCC® 10231™	2 mm, cream colonies
<i>Aspergillus brasiliensis</i> ATCC® 16404™	10–30 mm, white mycelium, black spores
Up to 5 days at 30–35° C	
<i>Candida albicans</i> ATCC® 10231™	2 mm, cream colonies
<i>Aspergillus brasiliensis</i> 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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Contact Information:

microbiology@thermofisher.com
USA +1 800 255 6730
International +44 (0) 1256 841144

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