

Sabouraud Dextrose Agar: 55 mm Contact Plates

Reference Number 25144e, 850, 2511e

Intended Use

Sabouraud Dextrose Agar (SDA) is a universal complex medium for cultivation and isolation of yeasts and moulds. The formulation of the basic medium is prepared according to the recommendations of the current United States Pharmacopoeia (USP) and the European Pharmacopoeia (EP).

SDA in contact plates is used for total viable count of yeasts and moulds on surfaces. The medium can be supplemented with antibiotics in order to inhibit the accompanying bacterial flora. Contact plates are often supplemented with neutralizers for inactivation of disinfectants residue.

The following SDA contact plates are available:

- **SDA Contact w. LTHTh selective - ICR**
reference number 25144e
(SDA medium including the neutralizers lecithin, Tween 80, histidine and sodium thiosulfate as well as irradiation-resistant antibiotics; the medium is coloured in order to avoid mix up with TSA contact plates)

Features of **ICR** contact plates for **I**solators and **C**lean **R**ooms: triple wrapped media; irradiated within the final packaging; storage at room temperature; long shelf life

- **SDA Contact + LTHTh - ICR+**
reference number 850
(SDA medium including the neutralizers lecithin, Tween 80, histidine and sodium thiosulfate)

Features of **ICR_{plus}** contact plates for **I**solators and **C**lean **R**ooms: triple wrapped media; irradiated within the final packaging; storage at room temperature; long shelf life; data matrix code for identification of each single plate; double lock system for safe transport and incubation under different incubation conditions

- **SDA Contact w. Chloramphenicol - RT**
reference number 2511e
(SDA medium including chloramphenicol)

Features of **RT** contact plates: single wrapped, storage at room temperature, long shelf life

Typical Composition per litre

Meat Peptone	5 g
Casein Peptone	5 g
Dextrose	40 g
Agar	15 g

if applicable:

Chloramphenicol	50 mg
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Irradiation resistant antibiotics

Neutralizers

Final pH 5.6 ± 0.2

The medium is clear and yellowish. Selective, irradiated plates are red coloured.

Description

The nutrient content of SDA, especially the combination of the two peptones, promotes the growth of fastidious bacteria as well as moulds and yeasts. The high concentration of Dextrose in addition with the low pH promotes the growth, the formation of spores (conidia and sporangia) as well as the formation of pigments of yeasts and moulds. The supplementation with chloramphenicol or other irradiation-resistant antibiotics in the case of irradiated plates inhibits the accompanying bacterial flora.

The combination of neutralizers in the SDA w. LTHTh (lecithin, Tween 80, histidine and sodium thiosulfate) inactivates a variety of disinfectants. According to Wallhäusser lecithin and Tween 80 are effective against a broad spectrum of disinfectants such as phenols, phb esters, quaternary ammonium compounds, chlorohexidines and dequadin. Histidine is effective against formaldehydes and thio derivatives against iodophoric compounds.

In house investigations on the neutralizer combination LTHTh in Tryptic Soy Agars did show a good inactivation for example of the following disinfectants:

- Sterillium (active ingredients: alcohols, quaternary ammonium compounds)
- Dismozon® pur (active ingredients: peroxide compounds)
- Chloroclen® (active ingredients: hypochloride compounds)

Nevertheless it should be taken into consideration to use contact plates on dry surfaces only.

Culture Conditions

The medium can be used for hygiene monitoring of surfaces and personnel. Contact plates used for determination of the total viable count of yeasts and mould should be incubated for 5-7 days at 20 to 25°C according to the FDA-Guidance for Industry. The plates should be evaluated at different times during this period.

Quality Control

A typical growth promotion test performed for SDA contact plates is shown in the table below.

Test strain	Culture conditions	Growth characteristics
<i>Candida albicans</i> ATCC 10231	3d 22.5 ± 2.5°C	small white dry colonies, recovery rate ≥ 50 %
<i>Aspergillus niger</i> ATCC 16404	3d 22.5 ± 2.5°C	colonies with light mycelium, recovery rate ≥ 50 %
<i>Sacharomyces cerevisiae</i> ATCC 9763	3d 22.5 ± 2.5°C	medium sized white colonies; recovery rate ≥ 50 %
* <i>Staphylococcus aureus</i> ATCC 6538	3d 22.5 ± 2.5°C	no growth
** <i>Echerichia coli</i> ATCC 8739	3d 22.5 ± 2.5°C	no growth

10 – 100 CFU inoculated; *tested on reference 25144e only; **tested on reference 2511e only

Further Identification

In case of growth it is recommended to identify the colonies. The action and alert limits for total viable counts including yeasts and moulds are described in different guidelines:

USP30 >1116>

Class 100: ≤ 3 cfu per plate (including floor) in the facility; ≤ 3 cfu per plate for gloves; ≤ 5 cfu per plate for personnel clothing & Garb

Class 10. 000: ≤ 5 cfu per plate and ≤ 10 cfu per plate (floor) in the facility; ≤ 10 cfu per plate for gloves; ≤ 20 cfu per plate for personnel clothing & garb

EU Guide to GMP:

Class A: ≤ 1 cfu per plate; ≤ 1 cfu per plate for glove print five fingers

Class B: ≤ 5 cfu per plate; ≤ 5 cfu per plate for glove print five fingers

References

EC Guide to Good Manufacturing Practice for Medicinal Products (2003): Annex 1.

European Pharmacopoeia 6.0 (2007): 2.6.13. Microbiological examination of non-sterile products.

Gerten, B. and Lauer, B. (2007): Testing of the disinfectant-neutralizing effect of Tryptic Soy Agar with the neutralizers LTHTh in a surface independent method. Poster presented at the annual meeting of DGHM (Deutsche Gesellschaft für Hygiene und Mikrobiologie)

Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice. (September 2004): Pharmaceutical CGMPs.

United States Pharmacopoeia (2007): 30 NF 25 - <61>. Microbiological examination of non-sterile products: Microbial Enumeration tests - <1116> Microbial Evaluation of Clean Rooms

Wallhäuser, K.H. (1995): Praxis der Sterilisation-Desinfektion-Konservierung. Georg Thieme Verlag Stuttgart-New York. 5th Edition, p.40-44.