

Technical Data Sheet

MacConkey Contact Agar – RT

Ordering number: 1.46427.0020

MacConkey Contact Agar - RT is designed for the isolation of Enterobacteriaceae on dry surfaces and personnel in controlled environments and for **Room Temperature** storage.

Ten contact plates each with a diameter of 55 mm are single-bagged in transparent, hydrogen peroxide impermeable sleeves (non-irradiated). The sleeves consist of polypropylene with a barrier of PE-EVOH-PE.

The formulation of the basic medium (MacConkey Agar) is prepared according to the recommendations of the current European and United States Pharmacopoeia (EP, 2.6.13. and USP, 62).

Mode of Action

MacConkey Agar is a weakly selective medium for the isolation of Enterobacteriaceae or specifically *E. coli* in pharmaceutical products, food, water, and other materials. Enterobacteriaceae can be clearly identified even in the presence of *Salmonella* and *Shigella*.

The MacConkey Agar inhibits the growth of gram-positive bacteria by the addition of crystal violet and bile salts, whereas the growth of most gram-negative bacteria is supported. Bacteria degrading lactose to acids grow in pink to red colored colonies. Additionally *E. coli* and other acid forming bacteria will show a zone of precipitated bile salt around the colonies. Bacteria not degrading lactose will grow colorless.

The family of Enterobacteriaceae is defined by the growth on MacConkey Agar.

It is not possible to detect low numbers of *Salmonella* while the accompanying microbial flora is abundant.

Typical Composition

| | |
|------------------------------|----------|
| Pancreatic Digest of Gelatin | 17 g/l |
| Peptones (Meat and Casein) | 3 g/l |
| NaCl | 5 g/l |
| Lactose monohydrate | 10 g/l |
| Bile Salts | 1.5 g/l |
| Crystal Violet | 1 mg/l |
| Neutral Red | 30 mg/l |
| Agar | 13.5 g/l |

The appearance of the medium is clear and reddish brown. The pH value is in the range of 6.9-7.3. The medium can be adjusted and/or supplemented according to the performance criteria required.

Application and Interpretation

Each plate is provided with a label including a data matrix code for paperless plate identification. The code consists of a two-dimensional 20-digit serial number, which harbors the following information:

Digits 1-3: here code 866 (corresponds to article 146427); digits 4-9: lot number; digits 10-14: batch specific individual number; digits 15-20: expiration date (YY/MM/DD).

Please check each agar plate before using it on sterility and pay attention to aseptic handling in order to avoid false positive results.

According to ISO 14698 the plates are opened and the agar surface is pressed on the dry surface to be tested for some seconds with a steady pressure. Afterwards the plates are closed and transferred to an incubator. Residues of culture medium should be removed from the surface after sampling.

According to the recommendations of the current EP and USP MacConkey Agar is incubated for 18-72 h at 30-35 °C. Growth of colonies indicates the possible presence of *E. coli*. This is confirmed by suitable identification tests.

Storage and Shelf Life

The product can be used for sampling until the expiry date if stored upright, protected from light and properly sealed at +15 °C to +25 °C.

Condensation can be prevented by avoiding quick temperature shifts and mechanical stress.

The testing procedures as described on the CoA can be started up to the expiry date printed on the label.

Disposal

Please mind the respective regulations for the disposal of used culture medium (e.g. autoclave for 20 min at 121 °C, disinfect, incinerate etc.).

Quality Control

| Control Strains | ATCC # | Inoculum CFU | Incubation | Expected Results |
|-------------------------------|--------|----------------|--|--|
| <i>Escherichia coli</i> | 8739 | 10-100 | 18-24 h at 33-35°C 18-24 h at 43-45°C | 50-200 %; good growth; red colonies with precipitation zone 50-200 %; good growth; red colonies with precipitation zone |
| <i>Proteus mirabilis</i> | 29906 | 10-100 | 18-24 h at 33-35°C | 50-200 %; good growth; cream-colored colonies; no swarming |
| <i>Salmonella</i> Typhimurium | 14028 | 10-100 | 18-24 h at 33-35°C | 50-200 %; good growth; honey-colored colonies |
| <i>Staphylococcus aureus</i> | 6538 | 10,000-100,000 | 18-24 h at 33-35°C | No growth |
| <i>Enterococcus faecalis</i> | 19433 | 10,000-100,000 | 18-24 h at 33-35°C | No growth |

Please refer to the actual batch related Certificate of Analysis.

Literature

European Pharmacopoeia 8.0 (2014): 2.6.13. Microbial examination of non- sterile products: Test for specified microorganisms.

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

ISO 14698-1:2003: Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods.

United States Pharmacopoeia 38 NF 33 (2015): <62> Microbiological examination of non-sterile products: Tests for specified microorganisms.

#Ordering Information

| Product | Cat. No. | Pack size |
|-----------------------------|--------------|-------------------|
| MacConkey Contact Agar - RT | 1.46427.0020 | 20 x 55 mm plates |

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