Technical Data Sheet

HYCON® Agar Strips LAC-Y

Ordering number: 1441080040

HYCON® Agar Strips LAC-Y are ready-to-use culture media for assessment of airborne microorganisms with HYCON® Microbial Air Samplers, i.e. RCS® High Flow Touch, RCS® High Flow, RCS® Plus, RCS® Plus Ex, RCS® Standard, and RCS® Isolator in controlled clean room environments of production lines for beta-lactam antibiotics, i.e. grade A and B cleanrooms, RABS or isolators.

Each agar strip is individually sealed in the transparent and flexible primary backing film made from PET. The individually sealed film is double bagged in PP/PA/PA bags and gamma-irradiated at a dose of 16-27 kGy within the polystyrene box. The formulation of the basic medium (Soybean-Casein Digest Agar) complies with the recommendations of the current European, Japanese and United States Pharmacopoeia and is supplemented with neutralizers and a mixture of a broad spectrum Cephalosporinase (beta-lactamase II) and Penase (beta-lactamase I).

Mode of Action

Tryptic Soy Agar (TSA, Soybean Casein Digest Agar) is a complex medium for cultivation and isolation of a wide range of bacteria, yeasts and molds. The medium is supplemented with the neutralizers lecithin and polysorbate 80.

The included beta-lactamase mixture of Cephalosporinase and Penase shows inactivating properties towards a wide variety of penicillins, cephalosporins from the 1st to the 5th generation as well as carbapenems and monobactams.

The neutralizing efficiency towards present residues of beta-lactam antibiotics should be validated at the sampling site.

Typical Composition

Pancreatic digest of casein	15 g/l
Soy bean Peptone	5 g/l
NaCl	5 g/l
Cephalosporinase	1 000 I.U./l
Penicillinase	10 000 I.U./l
Agar	15 g/l
Neutralizers: lecithin, polysorbate 80	
Supplements such as buffer	

The appearance of the medium is clear and yellowish. The pH value is in the range of 7.1 to 7.5. The medium can be adjusted and/or supplemented according to the performance criteria required.

Application and Interpretation

The agar strips are introduced into cleanrooms grade A or B by removing one bag in each material lock.

Prior to use the agar strip should be equilibrated to room temperature. Please check each agar strip before use to verify sterility and take care on aseptic handling in order to avoid false positive results. Contaminated or dehydrated agar strips should not be used for sampling.

Open the wrapper approximately at 1/3 by pealing back the plastic seal at the rounded side of the wrapper. Remove the agar strip with the coated side facing downwards. Insert the agar strip into the opening of the rotor, or the impeller drum according to the directions outlined in the user manual of the respective microbial air sampler. Place the instrument into required position, choose the appropriate sample volume and start the air sampling procedure.

When sampling is finished, remove the agar strip and place it back into the original wrapper. Seal the wrapper with the cover slide. Label the wrapper e.g. with a waterproof pen for identification. The closed agar strips are transferred to an incubator.

Several recommendations are given by different guidelines for incubation: according to USP <1116> the agar media used for environmental monitoring should be incubated between 20 and 35 °C for not less than 72 hours. According to the FDA Aseptic Guide the agar strips for determination of the total aerobic bacterial count should be incubated at 30 to 35 °C for 48 to 72 hours, while the agar strips for determination of the total yeast and mold count should be incubated at 20 to 25 °C for 5 to 7 days. Individual incubation conditions can be chosen and should be validated at the application site.

Finally, the number of CFU per slide is examined.

Grown colonies may be identified using suitable methods related to root cause analysis programs or to support sanitizing management.

Important Notes

• Practice aseptic technique when handling agar strips.

• The coated surface of the agar strips should face down during incubation in order to avoid the formation of satellites by condensing water.

Storage and Shelf Life

The product can be used until the expiry date if stored in the original box, protected from light and properly sealed at the temperature range indicated on the box label. The total shelf from the date of production is 6 months.

Condensation can be prevented by avoiding quick temperature shifts and mechanical stress. Upon storage agar strips should not be placed near heat sources such as refrigerators with heat-emitting condensers. Boxes should be stored with the coated side of the agar strip facing downwards.

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	Incubation	Recovery
Staphylococcus aureus	6538	10-100 CFU	24-48h at 30-35°C	50-200%
Escherichia coli	8739	10-100 CFU	24-48h at 30-35°C	50-200%
Pseudomonas aeruginosa	9027	10-100 CFU	24-48h at 30-35°C	50-200%

Bacillus subtilis	6633	10-100 CFU	24-48h at 30-35°C	50-200%
Candida albicans	10231	10-100 CFU	≤ 72h at 20-25°C	50-200%
Aspergillus brasiliensis	16404	10-100 CFU	≤ 72h at 20-25°C	50-200%
Staphylococcus aureus	6538	Activity test: No growth inhibition with the following antibiotic test discs: Penicillin 10 i.E., Mezlocillin 75 µg; Cefazolin 30 µg; Cefuroxim 30 µg; Cefotaxim 30 µg; Cefepim 30 µg; Meropenem 10 µg		

Please refer to the actual batch related Certificate of Analysis.

Quality

This product is manufactured in a Millipore SAS facility whose quality management system is approved by an accredited registration body to ISO 9001 quality standard.

This product is manufactured in a Millipore SAS facility whose environmental management is approved by an accredited registration body to the appropriate ISO 14001 systems standard.

Literature

EUROPEAN COMMISSION (2008) Volume 4 EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use Annex 1 Manufacture of Sterile Medicinal Products (corrected version)

European Pharmacopoeia 8th Edition (2016): 2.6.12. Microbiological examination of non-sterile products: microbial enumeration tests

FDA (2004) Guidance for industry: 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

Japanese Ministry of Health, Labour and Welfare. (2011): The Japanese Pharmacopoeia. 16th Ed. Chapter 4.05 Microbial Limit Test I. Microbiological Examination of Non-sterile Products: Total viable aerobic count. Japanese Ministry of Health, Labour and Welfare. Tokyo, Japan.

United States Pharmacopoeia 39 NF 34 (2016): <1116> Microbiological Control and Monitoring of Aseptic Processing Environments and <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests