

HYCON® AGAR STRIPS Certificate of Analysis

Catalogue Number : 1.44242.0050
 Medium Abbreviation : AGAR STRIPS YM
 (941196)
 Lot Number : 2589295
 Manufacturing Date : 16-AVR-2015
 Expiration Date : 13-OCT-2015
 Storage Conditions : 2 – 25°C

We certify that the product described herein meets the following criteria:

Product Description

Agar strips are used with RCS® Microbial Air Sampler, Rose Bengal Agar with streptomycin, for determination of yeasts and molds.

For further information, instructions and safety data refer to the package insert and the safety data sheet.

Typical Composition of the Medium

Formula per liter of purified water :

Soytone	6.0 g
D(+)-Dextrose	15.0 g
Maltextract	5.0 g
Yeast Extract	1.0 g
Agar	15.0 g
Selective mix (Rose Bengal, Streptomycin, Chloramphenicol)	
Buffer System	
Supplements	

Good Manufacturing Practices

This product was manufactured in a Millipore SAS facility which adheres to Good Manufacturing Practices.

ISO® 9001 Quality Standard

This product was manufactured in a Millipore SAS facility whose Quality Management System is approved by an accredited registering body to ISO 9001 Quality System Standard.

ISO® 14001 Environmental Management

This product was manufactured in a Millipore SAS facility whose Environmental Management program is approved by an accredited registering body to the appropriate ISO 14001 Systems Standard.

Pharmacopoeia

Complies, where applicable, with European and US Pharmacopoeia recommendations.

Quality Assurance Lot Release Criteria

This manufacturing lot was sampled, tested and released according to the following specifications :

100 % Inspection

Visual control of each agar strip.

Statistical Controls

Packaging integrity.
 Conformity of labelling and packaging.

Biological Tests

Sterility

Representative samples were subjected to a sterility test by direct incubation of the agar strips.

Growth Promotion

Growth Promotion Tests were conducted by direct inoculation of the media. All the samples provided good growth and typical colony morphology.

Batch Record

The lot of agar strips has complete documentation which includes product description, test protocol, test specification and results.

LKI-YMCOQ Rev.A 09/13

Hycon® and RCS® are Registered Trademarks of Merck KGaA

ISO® is a Registered Trademark of the International Organization for Standardization

ATCC® is a Registered Trademark of the American Type Culture Collection

The M Mark is a trademark of Merck KGaA, Darmstadt, Germany.

© 2013 Merck KGaA, Darmstadt, Germany. All rights reserved.



Lot Analysis

This product was designed and manufactured to meet the following specifications:

Criteria	Specifications	Results	Status
pH	7.3 ± 0.2	7.4	Conform
Sterility Assurance Level	Samples were found to be sterile after 7 days at 20-25°C and 30-35°C	No growth	Conform
Growth Promotion Test	Recovery range :		
<i>Staphylococcus aureus</i> ATCC® 6538	≤30% after 24 to 48 hours at 30-35°C	0%	Conform
<i>Bacillus subtilis</i> ATCC® 6633	≤30% after 24 to 48 hours at 30-35°C	0%	Conform
<i>Candida albicans</i> ATCC® 10231	50 - 200% after 72 hours at 20-25°C	93%	Conform
<i>Aspergillus brasiliensis</i> ATCC® 16404	50 - 200% after 72 hours at 20-25°C	64%	Conform

According to the above results, the product complies with Millipore SAS's acceptance criteria and is released.

Christel Noehringer
 BioMonitoring Quality Manager