

Microsart[®] AMP Mycoplasma

Rapid Real-time PCR Mycoplasma Detection Kit



Real-time PCR kit for the specific and sensitive detection of Mycoplasma DNA

Working Principle

A standard DNA extraction followed by a TaqMan[®] probe real-time qPCR is used for the detection of *Mycoplasma* DNA. 200 μ l to 18 ml sample volume can be used as starting material for the DNA preparation. The isolated DNA is amplified in a qPCR cycler and the evaluation can be performed with the standard cycler software.

Introduction

Microsart[®] AMP Mycoplasma enables a reliable and sensitive detection of *Mycoplasma* DNA. The test procedure is successfully validated for sensitivity, specificity and robustness according to EP 2.6.7. The volume range of up to 18 ml ensures highest sensitivity. Carefully selected primer/probe combinations are highly specific for a region within the 16S rRNA gene of more than 70 *Mycoplasma* species. The performance of the kit has been demonstrated in independent laboratories.

Applications

The Microsart[®] AMP Mycoplasma kit is specifically designed for microbiological QC labs in the bio-pharmaceutical industry or contract labs performing *Mycoplasma* contamination in-process controls and | or lot release testing according to EP 2.6.7.

It is used for direct detection of *Mollicutes* (*Mycoplasma*, *Acholeplasma*, *Spiroplasma*) in cell cultures, cell culture media components and derived biologicals.

Sample types:

- Master cell banks
- Working cell banks
- Virus seed lots
- Virus harvests
- Final lots of biologicals produced by cells

High Performance

The Microsart[®] AMP Mycoplasma has been developed for EP compliant *Mycoplasma* testing. A detection limit of less than 10 cfu/ml for all *Mycoplasma* species mentioned in the European Pharmacopoeia fulfills the requirements for the needed sensitivity.

Fast Results

The Microsart[®] AMP Mycoplasma is a fast real-time PCR kit. The total procedure from DNA extraction to PCR result takes only a few hours.



- Maximum reliability performance proved in validation and proficiency tests
- Highest flexibility different protocols for various sample materials
- High stability reagents lyophilized in aliquots

TaqMan[®] Probes

The use of TaqMan[®] probes adds specificity to the PCR detection system. The analysis is performed during the cycling process – no melting curve analysis is needed.

Flexible Sample Volumes

With a volume range from 200 μ l to 18 ml the Microsart[®] AMP Mycoplasma offers highest flexibility for optimal results. A simple concentration step using the Sartorius Vivaspin 6 or 20 spin columns is an option for all users who need highest sensitivity.

Contamination Prevention

The kit contains dUTP instead of dTTP, so the option is available to degrade amplicons from previous analyses by use of uracil-DNA glyco-sylase (UNG). Thus the occurrence of false-positive results can be minimized. UNG is not included in the kit.

Summary

For all QC labs performing European Pharmacopoeia compliant *Mycoplasma* testing for in-process control and lot release Sartorius offers the Microsart[®] AMP Mycoplasma qPCR kit. It ensures highest flexibility in sample volume and preparation and can be used with all common real-time cyclers.

TEL:02-2298-1823 / FAX:02-2298-8100 24889新北市新莊區新北產業園區五工五路21號 www.cmp-micro.com

Typical Sampling Steps For Mycoplasma Testing



Technical specifications

Each kit contains reagents for 25 or 100 reactions. The expiry date of the unopened package is specified on the package label. The kit components are to be stored until use at +2 to +8 °C and must be stored after opening and rehydration below -18 °C. The lot specific Certificate of Analysis can be downloaded from the manufacturer's website (www.minerva-biolabs.com).

Kit Component	25 reactions	100 reactions
Order No.	SMB95-1001	SMB95-1002
Mycoplasma Mix	$1 \times lyophilized$	$4 \times lyophilized$
Rehydration Buffer	1 × 1.3 ml	4 × 1.3 ml
Positive Control	$1 \times lyophilized$	$4 \times lyophilized$
Internal Control	$1 \times lyophilized$	$4 \times lyophilized$
PCR grade Water	1 × 1.4 ml	4 × 1.4 ml

Order Information Mycoplasma Kits

Description	Quantity	Order no.
Microsart [®] AMP Mycoplasma	25 tests	SMB95-1001
Microsart [®] AMP Mycoplasma	100 tests	SMB95-1002
Accessories		
Microsart [®] AMP Extraction	50 extractions	SMB 95-2003
Vivaspin [®] 6, 100,000 MWCO	25 units	VS0641
Vivaspin [®] 20, 100,000 MWCO	12 units	VS2041
Microsart [®] AMP Coating Buffer	$20 \times 2 \text{ ml}$	SMB95-2002
Related Products		
Microsart [®] ATMP Mycoplasma	25 tests	SMB95-1003
Microsart [®] ATMP Mycoplasma	100 tests	SMB95-1004
Microsart [®] RESEARCH Mycoplasma	25 tests	SMB95-1005
Microsart [®] RESEARCH Mycoplasma	100 tests	SMB95-1006

Sartorius Stedim Biotech GmbH August-Spindler-Strasse 11 37079 Goettingen, Germany

Phone +49.551.308.0 Fax +49.551.308.3289 www.sartorius-stedim.com

USA Toll-Free +1.800.368.7178 Argentina +54.11.4721.0505 Brazil +55.11.4451.6226 Mexico +52.5555.62.1102 UK +44.1372.737159 France +33.442.845600 Italy +39.055.63.40.41 Spain +34.913.586.098 Russian Federation +7.812.327.5.327 Japan +81.3.4331.4300 China +86.21.68782300

Specifications subject to change without notice. Copyright Sartorius Stedim Biotech GmbH. Printed in the EU on paper bleached without chlorine. Publication No.: SM-2011-e160905 Order No.: 85032-542-68 Ver. 09 | 2016