



## Microsart® ATMP Mycoplasma

Rapid Real-time PCR Mycoplasma Detection Kit for testing ATMPs



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

- Highest Level of Security
- Designed for ATMP Testing
- Easy Handling

### Working Principle

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

### Introduction

Microsart® ATMP Mycoplasma utilizes quantitative, real-time PCR (qPCR) as the method of choice for sensitive and reliable detection of *Mycoplasma* contamination in autologous cell transplant culture. The Microsart® ATMP Mycoplasma kit was validated according EP 2.6.7 in combination with EP 2.6.21 with respect to detection limit for all listed *Mycoplasma* species, specificity and robustness for autologous cell transplants (e.g. chondrocytes).

### Applications

The Microsart® ATMP Mycoplasma real-time PCR kit is especially designed for all hospitals, institutions and companies which are involved in testing *Mycoplasma* contamination according to EP 2.6.7 in cell-based therapeutics like autologous chondrocyte transplants (ATMPs – advanced therapy medical products).

### High Performance

The Microsart® ATMP Mycoplasma kit has been developed for EP complaint *Mycoplasma* testing in autologous cell transplants. 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 and specificity.

### Fast Result

The Microsart® ATMP Mycoplasma kit is a fast and easy to use real-time PCR kit. The total procedure from DNA extraction to PCR result takes only a few hours.

### 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.

### 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 glycosylase (UNG). Thus the occurrence of false-positive results can be minimized. UNG is not included in the kit.

### Summary

The Microsart® ATMP Mycoplasma kit is the optimal solution for all QC labs which performing *Mycoplasma* testing of cell-based therapeutics like autologous chondrocyte transplants.

Unlike competitive PCR Detection kits, the Microsart® ATMP Mycoplasma kit is dedicated for the specific application in regard to sample volume, sensitivity, robustness and specificity.

### Technical Specifications

Each Kit contains all required reagents for 25 or 100 reactions including polymerase as part of the Mycoplasma Mix. 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](http://www.minerva-biolabs.com)).

Kit Component	25 Reactions	100 Reactions
Order No.	SMB95-1003	SMB95-1004
Mycoplasma Mix	1 × lyophilized	4 × lyophilized
Rehydration Buffer	1 × 1.0 ml	2 × 1.0 ml
Positive Control	1 × lyophilized	1 × lyophilized
Internal Control	1 × lyophilized	4 × lyophilized
PCR grade Water	1 × 1.5 ml	4 × 1.5 ml

### Order Information Mycoplasma Kits

Description	Quantity	Order No.
Microsart® ATMP Mycoplasma	25	SMB95-1003
Microsart® ATMP Mycoplasma	100	SMB95-1004

### Accessories

Microsart® AMP Extraktion	50 extractions	SMB95-2003
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### Related Products

Microsart® AMP Mycoplasma	25	SMB95-1001
Microsart® AMP Mycoplasma	100	SMB95-1002
Microsart® RESEARCH Mycoplasma	25	SMB95-1005
Microsart® RESEARCH Mycoplasma	100	SMB95-1006

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