



Microsart® ATMP Bacteria

Rapid detection of total bacteria in ATMPs prior treatment

User Benefits

- Detecting >95% of all known bacteria in one test
- 3h-result: prior to treatment
- Specific TaqMan® probes reduce false-positives
- Non-infectious validation standards
- Less pipetting: controls already included



Product Information

Contaminated ATMPs pose life-threatening risks for immunocompromised patients. Microbial release test results prior to treatment are critical to patient safety. Microsart® ATMP Bacteria enables the detection of bacterial contamination within 3 hours validated according to EP 5.1.6 and EP 2.6.27.

Introduction and Applications

Microsart® ATMP Bacteria utilizes quantitative real-time PCR (qPCR) as the method of choice for sensitive and reliable detection of bacterial contamination in Advanced Therapy Medicinal Products (ATMPs). The Microsart® ATMP Bacteria kit is validated according to EP 5.1.6 with respect to sensitivity, specificity and robustness for detection of bacteria in cell cultures, cell culture derived biologicals and ATMPs. The kit is not suitable to replace sterility testing according EP 2.6.1 or USP <71> yet. Microsart® ATMP Bacteria should be used as pre-check test to get rapid QC results for ATMPs prior patient treatment.

High Performance

Microsart® ATMP Bacteria detects >95 % of all known bacterial species. During kit validation sensitivity (5 to 99 CFU/ml) was proven for 18 bacterial species including 6 standard USP and EP strains. Comparability to the compendial method was demonstrated.

Fast Result

The Microsart® ATMP Bacteria kit is a fast and easy to use real-time PCR kit. The total procedure from DNA extraction to PCR result takes only about 3 hours.

TaqMan® Probes

The use of TaqMan® probes adds specificity to the PCR detection system with reduced risk of false-positives. No subsequent melting curve analysis is necessary as it is for SYBR-Green-based detection.

Summary

The Microsart® ATMP Bacteria kit is the optimal solution for all labs performing bacterial testing of cell cultures, cell culture derived biologicals and ATMPs. Microsart® ATMP Bacteria is the first validated bacterial detection kit which guarantees QC results prior to patient treatment.

Product Versions

a) Microsart® ATMP Bacteria Patient – contains all reagents for testing 10 patients including DNA extraction

b) Microsart® ATMP Bacteria (Bulk) – contains all reagents for 100 qPCR reactions without DNA extraction

Technical Data

Kit Components and Storage

Each kit contains color-coded tubes with ready-to-use Master Mix, buffer, positive control, internal control and PCR grade water. Microsart® ATMP Bacteria Patient additionally contains lysis buffer, suspension buffer and processing tubes.

The lyophilized kit components are stored at +2°C to +8°C and must be kept at < -18°C after rehydration or opening. The Master Mix should be constantly protected from light.

The lot specific Certificate of Analysis can be downloaded from the manufacturer's website (www.minerva-biolabs.com).

Kit Components

	Microsart® ATMP Bacteria (Bulk)	Microsart® ATMP Bacteria Patient	Cap color
ATMP Bacteria Mix	4 × lyophilized	10 × lyophilized	red
Rehydration Buffer	4 × 0.5 ml	10 × 0.5 ml	blue
Positive Control DNA	1 × lyophilized	10 × lyophilized	green
Internal Control DNA	4 × lyophilized	10 × lyophilized	yellow
PCR grade Water	5 × 1.5 ml	20 × 1.5 ml	white
Lysis Buffer	–	10 × 1.8 ml	transparent
Suspension Buffer	–	10 × 1.5 ml	violet
Processing Tubes	–	10 × 3	–

Ordering Information

Description	Quantity	Order No.
Microsart® ATMP Bacteria (Bulk)	100 reactions	SMB95-1008
Microsart® ATMP Bacteria Patient	Reagents for 10 patients	SMB95-1007

Related Products

DNA Extraction kit		
Microsart® Bacteria Extraction	Reagents for 50 extractions	SMB95-2001

Detection Kits for qPCR		
Microsart® AMP Mycoplasma	25 reactions	SMB95-1001
Microsart® ATMP Mycoplasma	25 reactions	SMB95-1003
Microsart® RESEARCH Mycoplasma	25 reactions	SMB95-1005
Microsart® RESEARCH Bacteria	25 reactions	SMB95-1009

Microsart® Validation Standard according to EP 2.6.7 and USP <63> for Mycoplasma species and EP 2.6.1, EP 2.6.27 and USP <71> for other bacteria

3 vials with 10 CFU/vial for Mycoplasma species and 6 vials with 99 CFU/vial for other bacteria

Order No.	Description
SMB95-2005	<i>Bacillus subtilis</i>
SMB95-2006	<i>Pseudomonas aeruginosa</i>
SMB95-2007	<i>Kocuria rhizophila</i>
SMB95-2008	<i>Clostridium sporogenes</i>
SMB95-2009	<i>Bacteroides vulgatus</i>
SMB95-2010	<i>Staphylococcus aureus</i>
SMB95-2011	<i>Mycoplasma arginini</i>
SMB95-2012	<i>Mycoplasma orale</i>
SMB95-2013	<i>Mycoplasma gallisepticum</i>
SMB95-2014	<i>Mycoplasma pneumoniae</i>
SMB95-2015	<i>Mycoplasma synoviae</i>
SMB95-2016	<i>Mycoplasma fermentans</i>
SMB95-2017	<i>Mycoplasma hyorhinis</i>
SMB95-2018	<i>Acholeplasma laidlawii</i>
SMB95-2019	<i>Spiroplasma citri</i>

Microsart® Calibration Reagent

1 vial, 108 genomes/vial

Order No.	Description
SMB95-2021	<i>Mycoplasma arginini</i>
SMB95-2022	<i>Mycoplasma orale</i>
SMB95-2023	<i>Mycoplasma gallisepticum</i>
SMB95-2024	<i>Mycoplasma pneumoniae</i>
SMB95-2025	<i>Mycoplasma synoviae</i>
SMB95-2026	<i>Mycoplasma fermentans</i>
SMB95-2027	<i>Mycoplasma hyorhinis</i>
SMB95-2028	<i>Acholeplasma laidlawii</i>
SMB95-2029	<i>Spiroplasma citri</i>
SMB95-2030	<i>Bacillus subtilis</i>
SMB95-2031	<i>Pseudomonas aeruginosa</i>
SMB95-2032	<i>Kocuria rhizophila</i>
SMB95-2033	<i>Clostridium sporogenes</i>
SMB95-2034	<i>Bacteroides vulgatus</i>
SMB95-2035	<i>Staphylococcus aureus</i>
SMB95-2036	<i>Mycoplasma salivarium</i>

User-supplied Equipment and Material

Consumables

- Laboratory gloves
- PCR Clean™ (Minerva Biolabs, Prod. No. 15-2025) and PCR Clean™ wipes (Minerva Biolabs, Prod. No. 15-2001)
- DNA-free pipette filter tips that must be free from bacterial DNA (Biosphere® filter tips from Sarstedt are recommended: 0.5-20 µl, Prod. No. 70.1116.210; 2-100 µl, Prod. No. 70.760.212; 20-300 µl, Prod. No. 70.765.210; 100-1000 µl, Prod.No. 70.762.211)
- DNA-free PCR reaction tubes (PCR 8-SoftStrips with attached caps from Biozym are recommended: 0.1 ml Low Profile, Prod. No. 710975 and 0.2 ml High Profile, Prod. No. 710970)

Equipment

- DNA-free PCR reaction tubes (PCR 8-SoftStrips with attached caps from Biozym are recommended: 0.1 ml Low Profile, Prod. No. 710975 and 0.2 ml High Profile, Prod. No. 710970)
- Isolator/glovebox (further information, supplier and prices are available on request, please contact PCR@sartorius.com)
- Heat block
- Microcentrifuge for 1.5 ml reaction tubes (Centrisart A-14, Prod. No. A-14-1EU)
- Vortex Mixer
- qPCR device with filter sets for the detection of the fluorescence dyes FAM™ and ROX™ and suitable for 25 µl PCR reaction volumes
- Minicentrifuge for PCR-tubes
- Pipettes (Sartorius)
 - mechanical:
 - 0.5 – 10 µl Sartorius Prod. No. LH-729020
 - 10 – 100 µl Sartorius Prod. No. LH-729050
 - 100 – 1000 µl Sartorius Prod. No. LH-729070
 - or electrical:
 - 0.2 – 10 µl Sartorius Prod. No. 735021

For PCR support and recommendation please contact PCR@sartorius.com.

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