



Microsart® ATMP Bacteria/Fungi/Sterile Release Microsart® RESEARCH Bacteria/Fungi

Rapid detection of total fungi in ATMPs prior treatment

User Benefits

- All critical bacterial and fungal contaminants detected 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

Microsart® ATMP: Contaminated ATMPs pose life-threatening risks for immunocompromised patients. Microbial release test results prior to treatment are critical to patient safety. Microsart® ATMP Bacteria and Fungi or combined Microsart® ATMP Sterile Release that is ready prepared for single samples, enables the detection of bacterial and fungal contamination within 3 hours validated according to EP 5.1.6 and EP 2.6.27. During kit validation sensitivity (5 to 99 CFU/ml) was proven for 18 bacterial and 7 fungal species including 6 standard USP and EP strains. Comparability to the compendial method was demonstrated. The kit is not suitable to replace sterility testing according EP 2.6.1 or USP <71> yet. The Microsart® ATMP kits should be used as pre-check test to get rapid QC results for ATMPs.

Microsart® RESEARCH Bacteria and Fungi are used for fast and reliable direct detection of microbial contamination in cell cultures, cell culture supernatants and cell media components in research and development or whenever there is no need for regulation conform testing (i.e. according to EP/USP/JP).

Kit components and storage

Each kit contains all required reagents for the qPCR reaction. Due to lyophilization they are less temperature sensitive and ensure highest performance stability. Color-coded tubes with master mix, buffers, positive control and negative control, make the handling as simple as possible. For details, see kit components table on page 2.



The expiry date and the storage conditions of the unopened package are noted on the package label. The kit components are stored until use at +2° C to +8° C and must be stored after rehydration or opening at < -18° C. Please note: The master mix, also called Bacteria|Fungi Mix, should be protected from light all the time.

Test Principle

Microsart® ATMP|RESEARCH utilizes real-time PCR. The detection procedure can be performed within 3 hours, including less than 1 hour hands-on time. In contrast to the detection by cell cultivation method, samples do not need to contain vital bacteria.

The assay can be performed with any type of real-time PCR cyclers able to detect the fluorescence dyes FAM™ and ROX™.

Bacteria or fungi are specifically detected by amplifying a highly conserved 16S|18S rRNA coding region in the bacterial|fungal genome. The amplification is detected at 520 nm (FAM™ channel). The kit includes primer and FAM™ labeled TaqMan® probes which allow the specific detection of more than 95% of all known bacterial and fungal species so far described as contaminants of cell cultures and media components. Eukaryotic DNA is not amplified by this primer | probe system.

False negative results due to PCR inhibitors or improper DNA extraction are detected by the internal amplification control which is part of the PCR master mix. The amplification of the internal amplification control is detected at 610 nm (ROX™ channel).

Product versions

- a. Microsart® ATMP Sterile Release—contains all reagents for testing 10 patient samples for bacterial and fungal contamination including DNA extraction
- b. Microsart® ATMP Bacteria—contains all reagents for 100 qPCR reactions to test for bacterial contamination without DNA extraction
- c. Microsart® ATMP Fungi—contains all reagents for 100 qPCR reactions to test for fungal contamination without DNA extraction
- d. Microsart® RESEARCH Bacteria—contains all reagents for 25|100 qPCR reactions to test for bacterial contamination without need of DNA extraction
- e. Microsart® RESEARCH Fungi—contains all reagents for 25|100 qPCR reactions to test for fungal contamination without need of DNA extraction

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

Kit components

Order No.	Cap color	Microsart® ATMP Sterile Release	Microsart® ATMP Bacteria	Microsart® ATMP Fungi	Microsart® RESEARCH Bacteria (25 100)	Microsart® RESEARCH Fungi (25 100)
		SMB95-1007 (10 patient samples)	SMB95-1008 (100 rxn)	SMB95-1012 (100 rxn)	SMB95-1009 (25 rxn) SMB95-1010 (100 rxn)	SMB95-1014 (25 rxn) SMB95-1013 (100 rxn)
ATMP Bacteria Mix	red	10 x lyophilized	4 x lyophilized	-	4 x lyophilized	-
ATMP Fungi Mix	orange	10 x lyophilized	-	4 x lyophilized	-	4 x lyophilized
Rehydration Buffer	blue	10 x 0.5 ml	4 x 0.5 ml	4 x 0.5 ml	4 x 0.5 ml	4 x 0.5 ml
Positive Control DNA	green	10 x lyophilized	1 x lyophilized	1 x lyophilized	1 x lyophilized	1 x lyophilized
Internal Control DNA	yellow	10 x lyophilized	4 x lyophilized	4 x lyophilized	4 x lyophilized	4 x lyophilized
PCR grade Water	white	20 x 1.5 ml	5 x 1.5 ml	5 x 1.5 ml	5 x 1.5 ml	5 x 1.5 ml
Lysis Buffer	transparent	10 x 1.8 ml	-	-	-	-
Suspension Buffer	violet	10 x 1.5 ml	-	-	-	-
Processing Tubes	-	10 x 3	-	-	-	-

Related products

DNA Extraction kits

Order No.	Description	Quantity
SMB95-2001	Microsart® ATMP Extraction	Reagents for 50 extractions
SMB95-2003	Microsart® AMP Extraction (only for Mycoplasma qPCR)	Reagents for 50 extractions

Mycoplasma Detection Kits for qPCR

Order No.	Description	Quantity
SMB95-1001 1002	Microsart® AMP Mycoplasma	25 100 reactions
SMB95-1003 1004	Microsart® ATMP Mycoplasma	25 100 reactions
SMB95-1005 1006	Microsart® RESEARCH Mycoplasma	25 100 reactions

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 and all fungi

Order No.	Description
SMB95-2005	Bacillus subtilis
SMB95-2006	Pseudomonas aeruginosa
SMB95-2007	Kocuria rhizophila
SMB95-2008	Clostridium sporogenes
SMB95-2009	Bacteroides vulgatus
SMB95-2010	Staphylococcus aureus
SMB95-2011	Mycoplasma arginini
SMB95-2012	Mycoplasma orale
SMB95-2013	Mycoplasma gallisepticum
SMB95-2014	Mycoplasma pneumoniae
SMB95-2015	Mycoplasma synoviae
SMB95-2016	Mycoplasma fermentans
SMB95-2017	Mycoplasma hyorhinis
SMB95-2018	Acholeplasma laidlawii
SMB95-2019	Spiroplasma citri
SMB95-2020	Mycoplasma salivarium
SMB95-2037	Candida albicans
SMB95-2038	Aspergillus brasiliensis
SMB95-2039	Aspergillus fumigatus
SMB95-2040	Penicillium chrysogenum
SMB95-2041	Candida glabrata
SMB95-2042	Candida krusei
SMB95-2043	Candida tropicalis

Microsart® Calibration Reagent, 1 vial, 108 genomes/vial for all bacteria and 106 genomes/vial for all fungi

Order No.	Description
SMB95-2021	Mycoplasma arginini
SMB95-2022	Mycoplasma orale
SMB95-2023	Mycoplasma gallisepticum
SMB95-2024	Mycoplasma pneumoniae
SMB95-2025	Mycoplasma synoviae
SMB95-2026	Mycoplasma fermentans
SMB95-2027	Mycoplasma hyorhinis
SMB95-2028	Acholeplasma laidlawii
SMB95-2029	Spiroplasma citri
SMB95-2030	Bacillus subtilis
SMB95-2031	Pseudomonas aeruginosa
SMB95-2032	Kocuria rhizophila
SMB95-2033	Clostridium sporogenes
SMB95-2034	Bacteroides vulgatus
SMB95-2035	Staphylococcus aureus
SMB95-2036	Mycoplasma salivarium
SMB95-2044	Candida albicans
SMB95-2045	Aspergillus brasiliensis
SMB95-2046	Aspergillus fumigatus
SMB95-2047	Penicillium chrysogenum
SMB95-2048	Candida glabrata
SMB95-2049	Candida krusei
SMB95-2050	Candida tropicalis

User-supplied equipment and material

- For DNA extraction we recommend the DNA-free Microsart® ATMP Bacteria kit, Order No. SMB95-2001
- DNA-free PCR reaction tubes for the specific qPCR device
- Microcentrifuge for 1.5 ml reaction tubes, i.e. Centrisart A-14, Order No. A-14-1EU
- Pipettes with DNA-free filter tips (10, 100 and 1000 µl)
- qPCR device with filter sets for the detection of the fluorescence dyes FAM™ and ROX™ and suitable for 25 µl reaction volume

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

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