

SARTORIUS



Rapid Sterility Solutions

Microsart® ATMP Sterile Release

A cutting-edge solution for reliable and time-efficient release testing of advanced therapy medicinal products (ATMPs)

- Microsart® ATMP Sterile Release for single sample final release testing
- Microsart® ATMP Bacteria & Microsart® ATMP Fungi for high-throughput testing
- Microsart® ATMP Extraction for efficient extraction of fungi and bacteria

Rapid Sterility Solutions

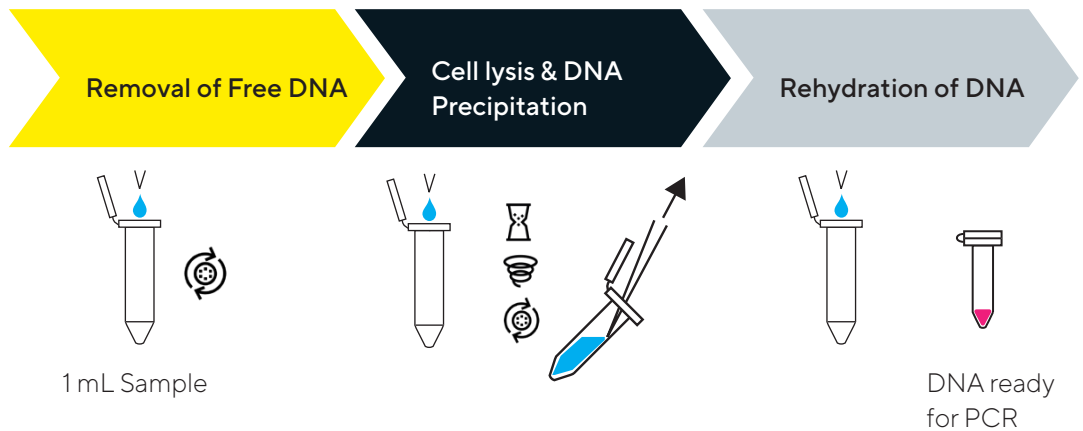
One of the key challenges in the development and testing of ATMPs is the need for sterile conditions throughout the manufacturing process. Any contamination can lead to serious health risks for patients, it is hence critical to have reliable methods for testing the sterility of these products, ideally prior to administration. The Microsart® ATMP Sterile Release Kit is specifically designed to meet this need, offering a fast and accurate way to test the sterility of ATMPs and other short shelf-life products.

The technology is based on a multiplex real time polymerase chain reaction (PCR), widely used in molecular biology applications to amplify DNA sequences. Microsart® ATMP Sterile Release therefore allows for a sensitive presence/absence detection of any contaminating bacteria and fungi in ATMP samples-with detection limits between 99 CFU/mL and 2.5 CFU/mL for all USP/EP relevant species. Its broad range of detection, including slow growing microbes or dormant cell stages, its specificity and fast time-to-result hence make it an ideal solution for the sterility testing of low volume, short shelf-life products. The kit includes stable, lyophilized & ready to use components for sample preparation and PCR testing.

Highly specific TaqMan® probes and an integrated amplification control rule out false positive- and negative results. Different product versions offer full flexibility for single patient sample-, high-throughput-, in-process- or research testing. Its ease of use, reliability, and accuracy make Microsart® ATMP Sterile Release an valuable addition to any quality control program, contributing to patient safety and process efficiency of these novel and important medical products.

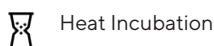
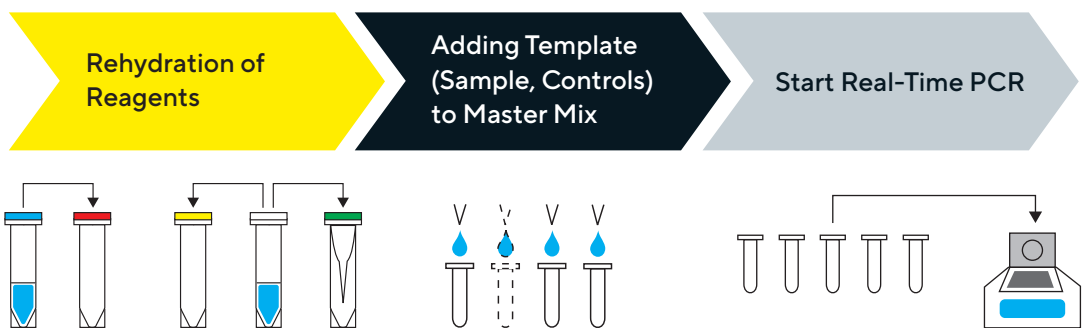
DNA Extraction

An efficient DNA extraction with a few handling steps to reduce cross contamination risks



PCR Setup

Uniform in all Microsart® ATMP kits



Microsart® real-time PCR Kits and PCR related products

Bacteria & Fungi Detection

Order No.	Description	Quantity
SMB95-1007	Microsart® ATMP Sterile Release	10 patient sample releases
SMB95-1008	Microsart® ATMP Bacteria	100 reactions
SMB95-1012	Microsart® ATMP Fungi	100 reactions
SMB95-1009	Microsart® Research Bacteria	25 reactions
SMB95-1014	Microsart® Research Fungi	25 reactions

DNA Extraction Kit

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	Microsart® Research Mycoplasma	25 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 and fungi

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	<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>
SMB95-2020	<i>Mycoplasma salivarium</i>

Order No.	Description
SMB95-2037	<i>Candida albicans</i>
SMB95-2038	<i>Aspergillus brasiliensis</i>
SMB95-2039	<i>Aspergillus fumigatus</i>
SMB95-2040	<i>Penicillium chrysogenum</i>
SMB95-2041	<i>Candida glabrata</i>
SMB95-2042	<i>Candida krusei</i>
SMB95-2043	<i>Candida tropicalis</i>

Microsart® Calibration Reagent

1 vial, 10⁸ genomes/vial for all bacteria and 10⁶ genomes/vial for all fungi


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>
SMB95-2044	<i>Candida albicans</i>
SMB95-2045	<i>Aspergillus brasiliensis</i>
SMB95-2046	<i>Aspergillus fumigatus</i>
SMB95-2047	<i>Penicillium chrysogenum</i>
SMB95-2048	<i>Candida glabrata</i>
SMB95-2049	<i>Candida krusei</i>
SMB95-2050	<i>Candida tropicalis</i>

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