

Cell-Based Therapies – Be on the Safe Side

Get QC Results for Advanced Therapy Medicinal Products (ATMPs) Before Treatment

Better to Be on the Safe Side – Fast!

Contaminated ATMPs pose life-threatening risks for immunocompromised patients. Microbial release test results prior to treatment are critical to patient safety.

Shorten Your Time-to-result with Our Rapid Detection Kits for Microbes ...

... from 28 days to 3 hours with our
Microsart® ATMP Mycoplasma kit
... from 14 days to 3 hours with our
new Microsart® ATMP Bacteria
kit – the 1st rapid release of ATMPs
prior treatment test for bacteria

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 available
- Less pipetting: controls already included



Microsart® ATMP Bacteria – Rapid Detection of Total Bacteria in ATMPs Prior Treatment

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.

Applications

Microsart® ATMP Bacteria utilizes Real-time PCR 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, to detect 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 successfully demonstrated.

Product Versions

- Microsart® ATMP Sterile Release – contains all reagents for testing 10 patients including DNA extraction
- Microsart® ATMP Bacteria (Bulk) – contains all reagents for 100 qPCR reactions without DNA extraction

Ordering Information

Order No.	Description	Quantity
SMB95-1008	Microsart® ATMP Bacteria (Bulk)	100 reactions
SMB95-1012	Microsart® ATMP Fungi*	100 reactions
SMB95-1007	Microsart® ATMP Sterile Release	Reagents for 10 patients
SMB95-2001	Microsart® ATMP Extraction (to be used with SMB95-1008 and SMB95-1012)	Reagents for 50 extractions

* See also Microsart® ATMP Fungi for complementation of fungal detection.


Would you like to learn more about our microbial detection kits? Contact: PCR@Sartorius.com for more information.

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