



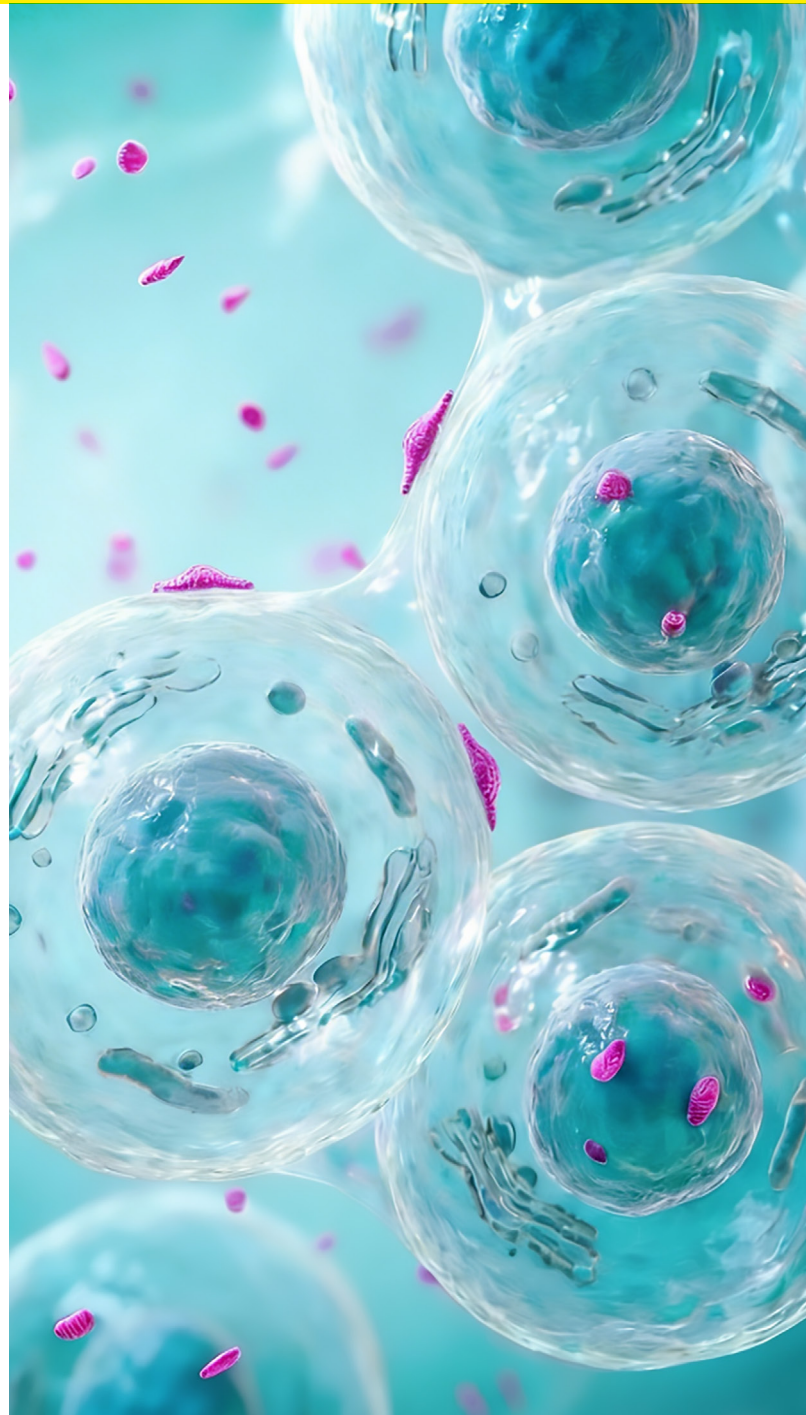
Cyclus[®] Mycoplasma Testing Solutions

Mycoplasma PCR Products: Compliant, Cutting-Edge, Comprehensive

Meet the next generation of rapid mycoplasma detection solutions with the Cyclus[®] Mycoplasma product family. As we pivot from traditional PCR kits, Cyclus[®] offers a comprehensive suite of cutting-edge tools designed to enhance accuracy and efficiency in your mycoplasma testing workflows. Our new range includes Cyclus[®] Bead Extraction for seamless DNA/RNA isolation, Cyclus[®] RT-qPCR Mycoplasma for rapid and sensitive detection, Cyclus[®] 10 CFU and 100 GC standards for robust method validation and routine testing controls.

Designed to meet the evolving needs of biopharmaceutical research and advanced therapy medicinal products, Cyclus[®] Mycoplasma products deliver unparalleled flexibility and performance across various applications. Whether you are conducting high-throughput testing or ensuring compliance with regulatory standards, Cyclus[®] Mycoplasma kits provide reliable and reproducible results that you can trust.

Join us in embracing the future of mycoplasma testing with Cyclus[®] Mycoplasma, where precision meets innovation.





Features	Cyclus® Bead Extraction SMB95-6000	Cyclus® RT-qPCR Mycoplasma SMB95-6002	Cyclus® 10 CFU SMB95-3011 to 3020	Cyclus® 100 GC SMB95-3001 to 3010
Description	<p>Cyclus® Bead Extraction is intended for the efficient isolation of mycoplasma DNA/RNA from cell culture materials (such as supernatants, cell suspensions, and cryostocks), advanced therapy medicinal products (ATMPs), and biopharmaceutical products. The isolated DNA/RNA should be used directly in combination with Cyclus® RT-qPCR Mycoplasma (SMB95-6002). It can be applied in both manual and automated workflows (using King-Fisher™ Flex), providing a clear advantage for high-throughput applications and ensuring reproducible results.</p>	<p>Cyclus® RT-qPCR Mycoplasma is designed for the rapid and highly sensitive detection of Mycoplasma, Acholeplasma, and Spiroplasma, in cell and gene therapy medicinal products, cell cultures, and other biological matrices. Using reverse transcriptase real time PCR sensitivities of ≤ 10 CFU/mL and < 100 GC/mL are achieved, supporting regulatory compliant testing of diverse sample types with high reproducibility.</p>	<p>Cyclus® 10 CFU are ready-to-use, dPCR quantified and inactivated CFU standards intended for the method validation of nucleic acid amplification technology-based mycoplasma detection methods. They are used for product-specific method validation, including Limit of Detection (LOD) determination, and as low-concentration controls in routine testing when applied as External Positive Control (EPC) described in EP 2.6.7 (12.2) or Extraction Inhibition Control (EIC). The standards are suitable exclusively for molecular NAT methods and are not intended for culture-based mycoplasma assays.</p>	<p>Cyclus® 100 GC are intended for the validation of nucleic acid amplification technology-based mycoplasma detection methods. The standards provide ready-to-use, dPCR quantified, non-infectious nucleic acids for spiking product-specific matrices to determine assay sensitivity (LOD) and robustness as required for pharmacopeial method validation. Cyclus® 100 GC may also be used as low-concentration external positive controls (EPC) in routine NAT-based testing, extraction inhibition control (EIC), or as positive PCR controls (PPC). The standards are suitable exclusively for molecular NAT methods and are not intended for culture-based mycoplasma assays.</p>
Kit components	<p>Lysis Buffer, Binding Buffer, Magnetic Bead Suspension, Wash Buffer 1, Wash Buffer 2, Wash Buffer 3, Elution Buffer, Proteinase K, Rehydration Buffer</p>	<p>Mycoplasma Mix (Lyophilized primers FAM™ and HEX™ labeled probes nucleotides polymerase RT components), Positive Control, Internal Control, PCR grade Water</p>	<p>Inactivated, lyophilized-CFU of either <i>Mycoplasma arginini</i>, <i>M. orale</i>, <i>M. gallisepticum</i>, <i>M. pneumoniae</i>, <i>M. synoviae</i>, <i>M. fermentans</i>, <i>M. hyorhinis</i>, <i>A. laidlawii</i>, <i>S. citri</i>, or <i>M. salivarium</i>, PCR grade Water</p>	<p>100 lyophilized Genome copies of either <i>Mycoplasma arginini</i>, <i>M. orale</i>, <i>M. gallisepticum</i>, <i>M. pneumoniae</i>, <i>M. synoviae</i>, <i>M. fermentans</i>, <i>M. hyorhinis</i>, <i>A. laidlawii</i>, <i>S. citri</i>, or <i>M. salivarium</i>, PCR grade Water</p>

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Validation	Kit is validated in combination with Cyclus® RT-qPCR Mycoplasma according to EP 2.6.7 (12.2), USP<77> (draft), USP <63>, JP18 G3	Kit is validated in combination with Cyclus® Bead Extraction according to EP 2.6.7 (12.2), USP<77> (draft), USP <63>, JP18 G3	In accordance with EP 2.6.7 (12.2), USP<77> (draft), USP <63>, JP18 G3	In accordance with EP 2.6.7 (12.2), USP<77> (draft), USP <63>, JP18 G3
Package size	100 extractions	25 RT-qPCR reactions	3 vials with 10 CFU each	3 vials 100 GC each
Sample/Rehydration volume	250 µl sample volume	10 µl template volume 20 µl total PCR volume	Rehydration volume depends on application (see manual)	Rehydration volume depends on application (see manual)
Shelf life & storage	Store at room temperature. After reconstitution, the Proteinase K should be stored at <-18°C until the labeled shelf life.	Store at +2 °C to +8 °C until use. After rehydration, the Mycoplasma Mix can be stored at <-18 °C for 30 days. After rehydration, the Internal Control and Positive Control can be stored at <- 18 °C until their specified shelf life.	Store at +2 °C to +8 °C. Each vial is intended for single use only. Rehydrated material must not be stored or reused.	Store at +2 °C to +8 °C. Each vial is intended for single use only. Rehydrated material must not be stored or reused. Exception: If the standard is reconstituted in PCR grade Water, the following storage conditions apply: 2-8 °C for up to 7 days, or - 18°C for up to 3 months.

Following our comprehensive offerings with the new Cyclus® Mycoplasma product line, Microsart® RESEARCH Mycoplasma is available to those seeking efficient solutions for rapid mycoplasma detection in research environments. While it is not validated for regulatory compliance, this kit provides a practical approach for quick analyses, perfect for laboratories needing immediate results without extensive validation processes.

Microsart® RESEARCH Mycoplasma

Microsart® RESEARCH Mycoplasma (SMB95-1005) is an ideal solution for rapid mycoplasma analyses in research settings without the need for prior nucleic acid extraction. While not validated for regulatory compliance, this kit offers a straightforward approach to screening cell culture materials. Designed for use with any qPCR cycler compatible with FAM™ and ROX™ dyes, it enables flexibility and ease of integration into existing workflows.

The kit includes lyophilized primers, nucleotides, probes, polymerase, and internal amplification control, aliquoted for 25 reactions. Additionally, it comes with a rehydration buffer, lyophilized positive control, and PCR grade water to facilitate immediate application. With the option to perform tests on sample volumes ranging from 2 µL to 250 µL (when combined with prior DNA extraction), Microsart® RESEARCH is suitable for diverse research applications, delivering a rapid presence/absence result.

This kit is perfect for laboratories seeking a reliable, cost-effective solution for rapid mycoplasma detection without the need for comprehensive validation. Its straightforward protocol and compatibility with standard qPCR equipment make it an excellent choice for ultra rapid analyses.



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