Customer Information

Transition from Microsart® to Cyclus® Mycoplasma Kits

The European Pharmacopoeia (EP) chapter 2.6.7 is a cornerstone for ensuring reliable detection of mycoplasma contamination in pharmaceutical and biotechnological products. The latest revision of EP 2.6.7 introduces major updates that reflect modern molecular testing capabilities and evolving regulatory expectations.

Sartorius' 10 CFU Microsart® Validation Standards have been fully compliant with the EP 2.6.7 version 01/2008.
Any assay qualification or matrix validation performed using these materials remain valid under the same version.

However, with the revised EP 2.6.7 (12.2.), our Microsart® Validation Standards will no longer meet the updated regulatory requirements. The 10 CFU standards, introduced over a decade ago, were based on a quantification method that has evolved with newer analytical approaches. Cross-validation with the newly introduced digital PCR–based quantification method indicates higher genomic copy (GC) measurements for the Microsart® Validation Standards, consistent with method-specific sensitivity.

According to the revised Ph. Eur. 2.6.7, when a nucleic acid-based method is used in place of a traditional culture or indicator cell culture, the required limit of detection (LOD) is ≤10 CFU/mL or <100 genomic copies (GC)/mL. Because a single microorganism can contain multiple genome copies, the GC unit has been introduced to standardize NAT-based measurements. To ensure meaningful comparison between NAT and culture-based methods, an additional guideline specifies that the GC:CFU ratio should remain below 10.

We hence, introduce a new generation of Sartorius Mycoplasma Detection Solutions:
- Enhanced sensitivity with Cyclus® Bead Extraction & Cyclus® RT-qPCR Mycoplasma
- Enhanced accuracy with dPCR quantified Cyclus® 10 CFU & 100 GC Standards for all relevant Mycoplasma species

Additional guidance for our clients is available via: **PCR@sartorius.com**

Sartorius Mycoplasma Detection Portfolio	Good to know	Compliance
Microsart® Mycoplasma qPCR	Mycoplasma DNA is detected	Validations approved before April 1st, 2026, remain valid under EP 2.6.7 (01/2008) Microsart® products will remain available after the transition to EP 2.6.7 (12.2)
Microsart® Validation Standards (10 CFU)	GC content is determined by qPCR	
Microsart® AMP Extraction	Manual silica spin column-based-protocol	
Cyclus® RT-qPCR Mycoplasma	Mycoplasma DNA and RNA is detected leading to increased sensitivity, to be used only with Cyclus® Standards	Recommended for new matrix validations and requalifications acc. to EP 2.6.7 (12.2)
Cyclus® 10 CFU Standards	GC content is determined by digital PCR (dPCR)	
Cylus® 100 GC Standards	GC content is determined by digital PCR (dPCR)	
Cyclus® Bead Extraction	Increased sensitivity due to use of magnetic beads and option for manual or automated application	

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