The way forward in mycoplasma detection.

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Pharma analytics

Actionable, same-day results to help ensure mycoplasma-free biotherapeutics

In therapeutic development and manufacturing, undetected mycoplasma contamination can negatively impact both product quality and patient safety. Therefore, cGMP manufacturers develop stringent risk mitigation plans for early detection of mycoplasmas to avoid costly manufacturing delays or remediation activities.

Introducing the Applied Biosystems™ MycoSEQ™ Plus Mycoplasma Detection Kit: a quantitative, real-time PCR (qPCR) solution for rapid mycoplasma testing within complex bioproduction samples. Building upon the widely adopted Applied Biosystems™ MycoSEQ™ detection system, the MycoSEQ Plus kit employs gold-standard, probe-based Applied Biosystems™ TaqMan™ chemistry to help deliver a more streamlined workflow and broader species detection, all the while leveraging the high performance for which TaqMan assays are known.

The MycoSEQ Plus Mycoplasma Detection Kit is:

- **Sensitive**—meets or exceeds the recommended regulatory guidance of 10 colony forming units (CFU)/mL or 10 genome copies (GC)/mL for a wide variety of mycoplasma species, including those commonly known to contaminate bioprocessing cultures
- **Specific**—no observed cross-reactivity to closely related non-mycoplasma bacterial species, i.e., *Clostridium* spp., *Lactobacillus* spp., or *Streptococcus* spp.

- **Fast**—qPCR-based workflow delivers actionable results in less than 5 hours, enabling quick confirmation of mycoplasma-free production harvest
- **Accurate**—a discriminatory positive control allows discrimination between true mycoplasma and accidental contamination of test sample
- **Comprehensive**—a multiplex assay enables simultaneous screening of >200 species of *Mycoplasma*, including all key species listed in the US, European, and Japanese Pharmacopeias

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Streamlined qPCR workflow for rapid detection

Per regulatory guidelines, therapies manufactured using cell culture must be proven free of mycoplasma contamination. To be compliant, manufacturers have traditionally outsourced testing to labs that specialize in the 28-day culture-based test method. However, for short shelf-life therapeutics, such as cell therapy or other advanced therapy medicinal products (ATMPs), waiting 28 days for test results just isn't feasible.

The MycoSEQ Plus Mycoplasma Detection Kit offers an integrated, qPCR solution for rapid mycoplasma testing that can deliver actionable results in as little as 5 hours. Comprising functionally confirmed sample-to-answer protocols, commercially available kits for sample preparation and qPCR, and instruments with analytical software to help enable regulatory compliance, the workflow of the MycoSEQ Plus kit provides a flexible and scalable approach to meet a variety of mycoplasma testing applications.

MycoSEQ Plus workflow

Prepare sample → **Set up reaction** → **Run qPCR** → **Analyze**

Applied Biosystems™ Automate *Express*™ Instrument + Applied Biosystems™ PrepSEQ™ Express Nucleic Acid Extraction Kit

MycoSEQ Plus Mycoplasma PCR Detection Kit

Applied Biosystems™ QuantStudio™ 5 or 7500 Fast Real-Time PCR System

Applied Biosystems™ AccuSEQ™ Real-Time PCR Software

~2 hours → ~1.5–2.5 hours

Ordering information

Description	Cat. No.
Mycoplasma detection kits	
MycoSEQ Plus Mycoplasma Detection Kit	18765485
MycoSEQ Plus Mycoplasma Detection Kit with PrepSEQ 1-2-3 Nucleic Acid Extraction Kit	18775505
MycoSEQ Plus Mycoplasma Detection Kit with PrepSEQ Express Nucleic Acid Extraction Kit	18755455
Sample preparation	
PrepSEQ Express Nucleic Acid Extraction Kit	30000678
PrepSEQ Mycoplasma Nucleic Acid Extraction Kit	30000684
AutoMate *Express* Instrument	30055377
Real-time PCR systems	
Pharmaceutical Analytics QuantStudio 5 Real-Time PCR System, 96-well, 0.1 mL, laptop	Speak with a representative
7500 Fast Real-Time PCR System, tower, QST	Speak with a representative
Analysis software	
AccuSEQ Real-Time PCR Software v3.2	18703644
AccuSEQ Real-Time PCR Detection Software v2.2	18753634

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