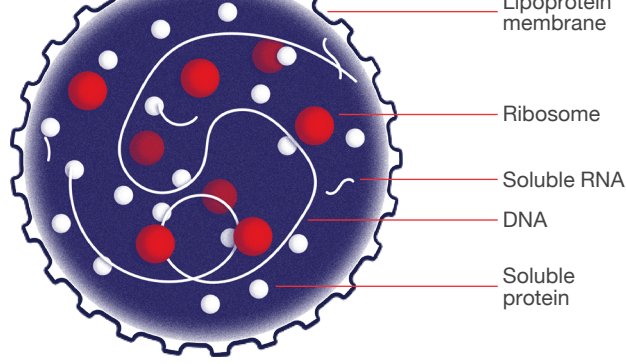


Rapid mycoplasma testing: Meeting regulatory requirements with confidence

This infographic explores the impact of mycoplasma contamination and the most accurate and sensitive way to detect it.

Impact of mycoplasma contamination

An outbreak of mycoplasma can have a high cost for biopharma – halting production for months and requiring extensive decontamination processes. Mycoplasma infections can cause severe problems in the bioprocessing industry. Mycoplasma can alter DNA, RNA, and protein synthesis, diminish amino acid and ATP levels, introduce chromosomal alterations, and modify host cell plasma membrane antigens, thus affecting the products being synthesized.^{1,2}



Loss of time and money



Manufacturing and product quality variability



Invalid scientific data leading to retracted publications



Loss of cell lines, raw materials and batch products



Facility shutdown for decontamination



Reductions in product quality and patient safety

Importance of mycoplasma testing

Regulatory agencies worldwide require that all cell-based therapeutic products be free of mycoplasma. Thus, facilities following current good manufacturing practice (cGMP) guidelines must test their cell cultures to ensure the quality and safety of the final products.



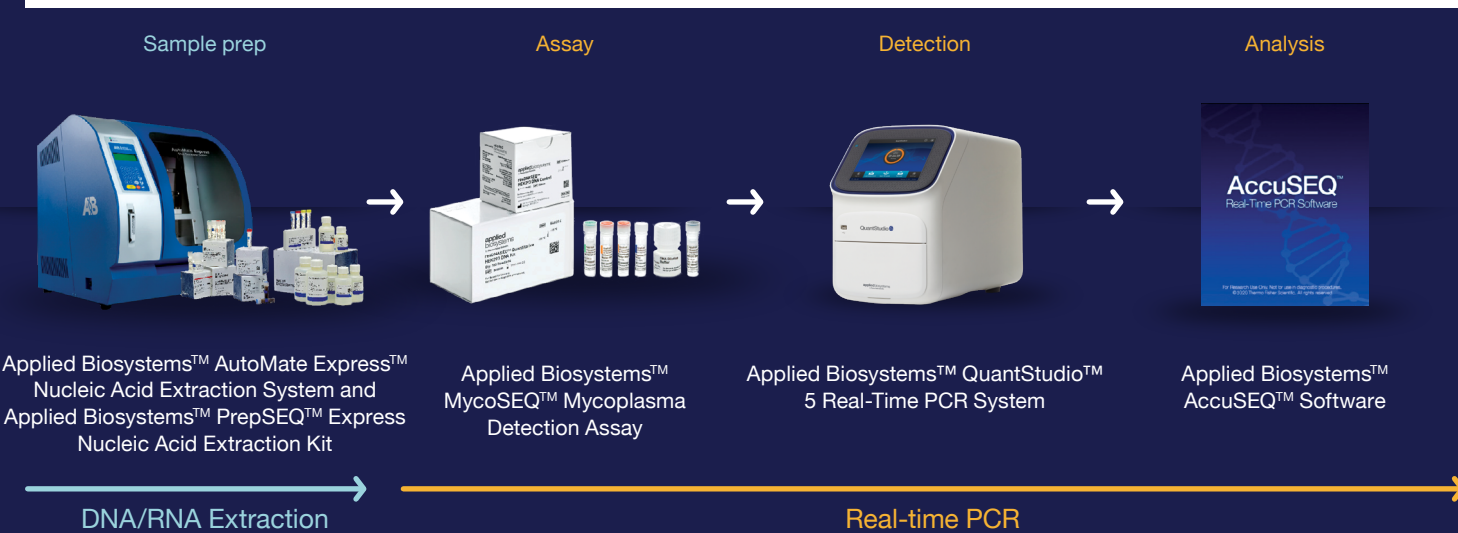
A rapid solution for mycoplasma testing

Traditional culture-based assays for mycoplasma testing are costly, time-consuming (28 days) and require specialized training to interpret the results. Alternatively, real-time qPCR-based assays allow for accurate, sensitive and rapid mycoplasma detection.



The MycoSEQ™ Mycoplasma detection assay is an integrated system that includes automation systems for sample preparation, real-time PCR reagents and instrument, and a fully integrated software

End-to-end workflow solution



DNA/RNA Extraction <2 hours

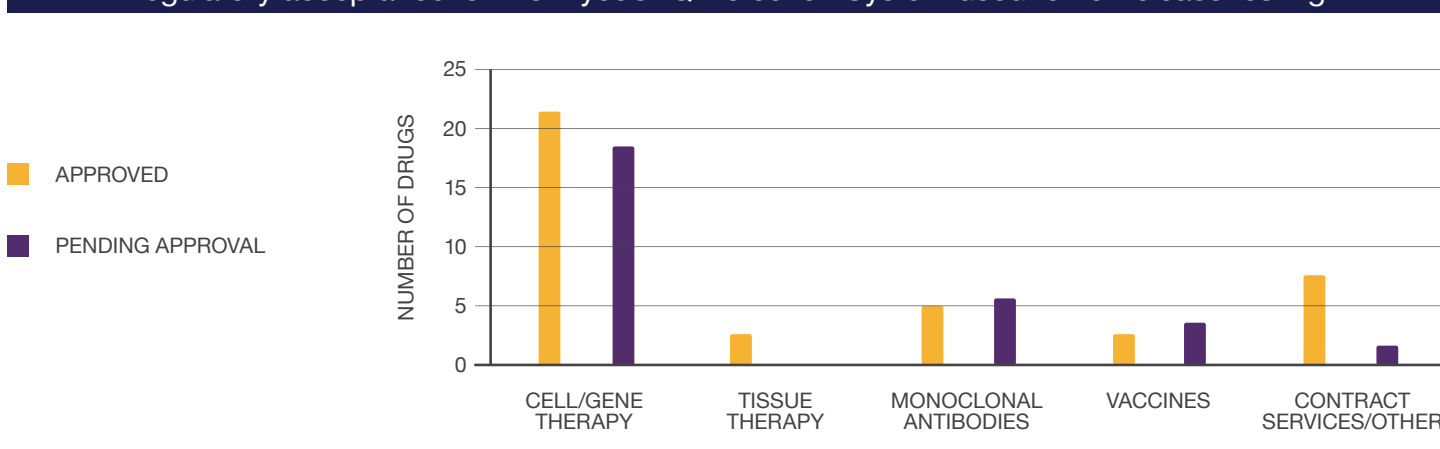
Real-time PCR ~1.5-2.5 hours

The assay provides quantitative detection of more than **90 mycoplasma species** in under **5 hours** with consistent and comprehensive detection under **10 genome copies**

Meet regulatory compliance with confidence

The MycoSEQ system was developed to achieve the sensitivity required by regulators. The system also includes software to help meet 21CFR Part 11 compliance. Several drugs have already received regulatory acceptance to use this system for lot release testing applications across multiple therapeutic modalities.

Regulatory acceptance for the MycoSEQ Detection System used for lot release testing*



Benefits of the MycoSEQ Mycoplasma Detection Kit



Widely accepted by regulatory agencies in a cGMP environment: over 40 regulatory approvals worldwide



Proven sensitivity and specificity to less than 10 copies/reaction: no known cross-reactivity



Saves time: same-day actionable results for production packages and raw materials



Live mycoplasma is NOT required for testing



Total workflow solution from sample prep to analysis



Regulatory and technical guidance throughout the validation process

Detect mycoplasma with confidence
thermofisher.com/mycoplasma-detection

References

- Young L, Sung J, Stacey G, Masters JR. Detection of mycoplasma in cell cultures. *Nat Protoc.* 2010;5(5):929-934. doi: 10.1038/nprot.2010.43
- Rottem S, Naot Y. Subversion and exploitation of host cells by mycoplasmas. *Trends Microbiol.* 1998;6(11):436-440. doi: 10.1016/s0966-842x(98)01358-4

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