

MycotoOL PCR Mycoplasma Detection Kit

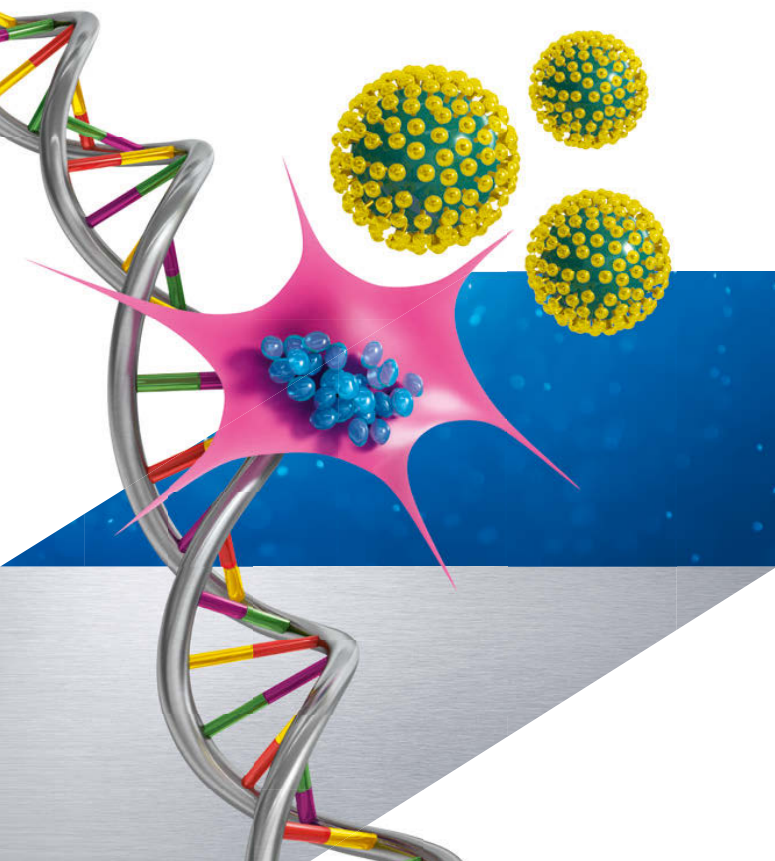
Release your product in hours, not weeks

Mycoplasmas are a common source of contamination in biopharmaceutical production, cultivation of stem cells, and tissue engineering.

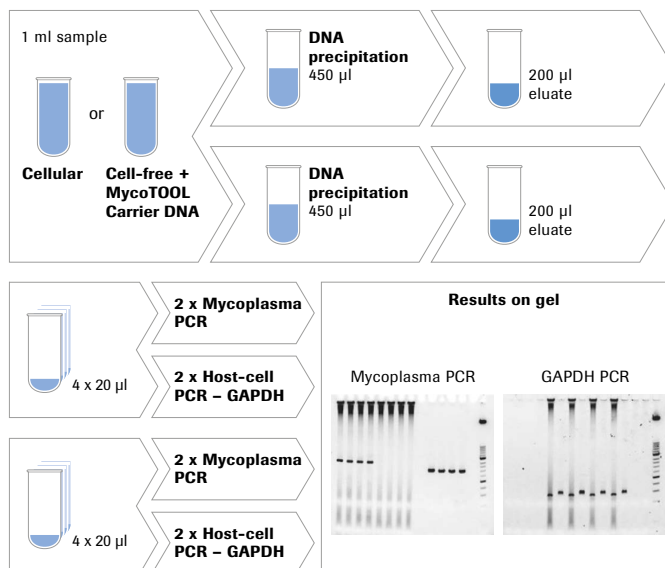
MycotoOL PCR Mycoplasma Detection Kit is accepted for release testing of biopharmaceutical products by FDA, EMA and authorities in several other countries for fast, easy, and reliable Mycoplasma testing.

Detect over 140 Mollicute species including *Spiroplasma* and *Acholeplasma* using universal primer designs

- **Sensitivity you can count on**
<1 CFU/ml for all validated species*
- **Reproducibility you can depend on**
No false positives, due to carryover prevention with dUTP and UNG
- **Time savings you can plan on**
Obtain results in a few hours instead of doing a 28-day culture test



Procedure from sample preparation to result



*Data published by S. M. Deutschmann *et al.*, March 2010.

Validation of a NAT-based Mycoplasma assay according European Pharmacopoeia, Biologicals, Volume 38, Issue 2, Special Section: Mycoplasma, pages 181-248.
For use in quality control/manufacturing process only.

Validation at 1 CFU/ml

Validated: 23 out of 24 replicates to be positive

Species	ATCC	Claimed-sensitivity	Probit analysis of validation data
		1 CFU/ml	CFU/ml
<i>A. laidlawii</i> **	27556	+	<1.0
<i>M. arginini</i>	23838	+	0.15
<i>M. fermentans</i>	19989	+	0.29
<i>M. hominis</i> **	23114	+	<1.0
<i>M. hyorhinis</i>	17981	+	0.51
<i>M. orale</i>	23714	+	0.11
<i>M. pneumoniae</i>	15531	+	0.02
<i>M. salivarium</i>	23064	+	1.41
<i>S. citri</i>	27556	+	0.37
<i>M. gallisepticum</i>	15302	+	not yet validated
<i>M. synoviae</i>	25204	+	not yet validated

**for 1 CFU/ml 24 out of 24 positive; 0.5 CFU/ml and 0.1 CFU/ml not tested

To establish the sensitivity at 1 CFU/ml,

more than 17,000 PCR reactions were generated:

- Nine isolates validated at 1 CFU/ml at a 95% confidence level (23 out of 24 positive).
- Tenfold dilution series of 1000 CFU/ml to 0.01 CFU/ml. Each replicate ran in quadruplicate PCR.
- 96 PCR reactions were performed per concentration.

High Quality

Roche is certified according to ISO 13485. Change notification available upon request

Ordering information

Product	Catalog number	Related products	Catalog number
MycotoOL PCR Mycoplasma Detection Kit (Block PCR analysis via gel)			
QC Sample Preparation Kit	08 146 829 001	MycotoOL Mycoplasma Real-Time PCR Kit (160 PCR reactions)	06 495 605 001
MycotoOL Mycoplasma Detection Prep Kit	05 184 592 001		
MycotoOL Mycoplasma Detection Amplification Kit	05 184 240 001		

Regulatory disclaimer

For use in quality control/manufacturing process only.

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