

MYCOPLASMA DETECTION KIT FOR ATMPs AND BIOPHARMACEUTICALS



- Designed and optimised for mycoplasma detection in biopharmaceutical products
- Fast and simple
- Compliant with European, US and Japanese pharmacopeias (EP 2.6.7, USP 63 and JP 17)
- High sensitivity and specific

MycoFinder Real-Time PCR kit offers a sensitive, reliable, rapid and cost-effective solution for quality control of Advances Therapy Medicinal Products (ATMPs) and biopharmaceuticals. Its simple and innovative format considerably eases sample preparation and significantly reduces turnaround time. MycoFinder is fully compliant to European, US and Japanese Pharmacopeias (EP 2.6.7, USP 63 and JP17).

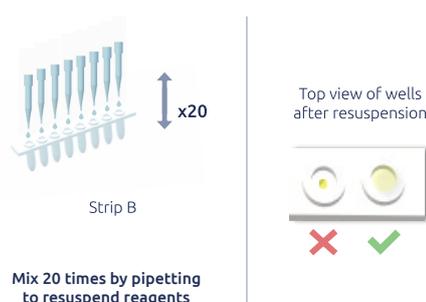
Description	Compliant
<p>MycoFinder has been designed to accurately and specifically detect mycoplasma DNA in complex matrices associated with biopharmaceutical products.</p>	<ul style="list-style-type: none"> ▶ Extensively and rigorously tested during product development. ▶ Fully compliant with European, US and Japanese Pharmacopeias (EP 2.6.7, USP 63 and JP 17).
Easy to use	Rapid
<ul style="list-style-type: none"> ▶ Master Mix components are pre-aliquoted and lyophilised into PCR strips. ▶ Reduces reagents handling and pipetting variability. ▶ Rapid protocol; PCR sample preparation in minutes using 4 simple steps. 	<ul style="list-style-type: none"> ▶ Optimised Master Mix results in a highly specific and efficient PCR. ▶ Real-Time PCR cycling time under 60 minutes. ▶ End-to-end sample to result in 120 minutes.
Highly performant	Flexible & Cost Effective
<ul style="list-style-type: none"> ▶ Limit of detection (LOD) below 10 CFU/mL. ▶ Highly specific - detects up to 142 different mycoplasma strains (<i>in-silico</i>). ▶ No cross-reactivity with other bacteria, fungi or mammalian cells. 	<ul style="list-style-type: none"> ▶ PCRstrip format—use only the number strips/tubes required per run. ▶ Remaining strips are stored at +2°- 8°C for up to 12 months. ▶ Kit contains 2 types of plastic strips (clear and white) compatible with most thermocyclers for optimal fluorescence detection.

4-STEP PROTOCOL

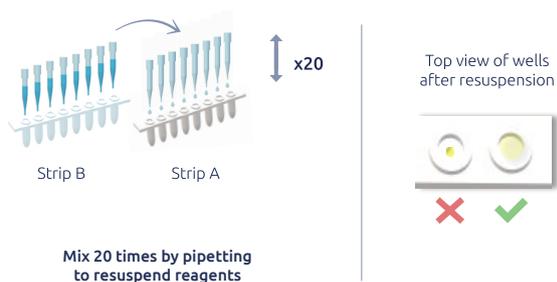
1 - Sample preparation



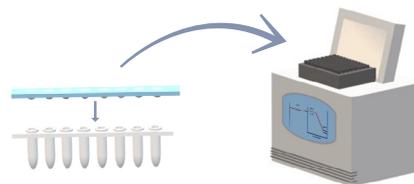
2 - Transfer 25 μL of sample into strip B



3 - Transfer all liquid from strip B into strip A



4 - Seal strips with caps and start real-time PCR



**The end-user selects the appropriate real-time PCR strip (white or transparent) with respect to optical properties of the thermocycler to be used.
If the thermocycler runs with transparent tubes (Strip B). First resuspend the sample in master mix Strip A, then transfer resuspended mix to Strip B for final resuspension prior to PCR.
If the thermocycler runs with white tubes (Strip A). First resuspend sample in master mix Strip B then transfer all to Strip A, for final resuspension prior to PCR.*

Kit Components

Test strips with pre-aliquoted lyophilised Master Mix
6x Test strip A (white) *
6x Test strip B (transparent) *
Positive control (2 x 10³ copies / μL)
Negative control (DNase Free Water)

Product Number

P/N 69202, 48 reactions/kit

Shelf life (see expiration date)

12 Months

Storage

Store at +2°- 8°C