SHENTEK

Mycoplasma Sensitivity Standards

User Guide

Version: A/0
For Research Use Only

Huzhou Shenke Biotechnology Co., Ltd.

(IMPORTANT: Please read this document carefully before experiment.)

■ Product description

The MycoSHENTEK® Mycoplasma Sensitivity Standards are designed to validate the robustness and sensitivity of nucleic acid amplification techniques (NAT) for the detection of mycoplasma.

Traditional culture methods for mycoplasma testing are time-consuming, especially for cell therapy products, because the testing cycle may exceed the product's shelf life. Nucleic acid amplification technique, such as qPCR, offers rapid detection of mycoplasma contamination. According to the European Pharmacopoeia (EP), the United States Pharmacopoeia (USP) and the Japanese Pharmacopoeia (JP), validated NAT methods are recommended to replace culture methods. According to EP 2.6.7, method sensitivity must reach 10 Colony Forming Units per mL of sample volume (CFU/mL) to replace culture methods and 100 CFU/mL to replace indicator cell culture methods.

The MycoSHENTEK® Mycoplasma Sensitivity Standards are non-infectious and are not intended for culture. Simply add the specified volume of sample matrix to the Sensitivity Standards to prepare the test solution for further use.

We also provide the MycoSHENTEK® Mycoplasma DNA Detection Kit and the MycoSHENTEK® Mycoplasma DNA Extraction Kit for Mycoplasma DNA extraction and qPCR detection assays.

■ Kit contents and storage

Table 1. Kit components and storage

Product Name	Product No.	Reagent	Part No.	Quantity
Acholeplasma laidlawii Sensitivity Standard (10 CFU)	1509841-St06	*Acholeplasma laidlawii* (10 CFU)	NNE049	10 CFU × 5 tubes
		DNA Dilution Buffer (DDB)	NND001	1.5 mL × 5 tubes
Mycoplasma fermentans Sensitivity Standard (10 CFU)	1509841-St07	*Mycoplasma fermentans* (10 CFU)	NNE050	10 CFU × 5 tubes
		DNA Dilution Buffer (DDB)	NND001	1.5 mL × 5 tubes
Mycoplasma salivarium Sensitivity Standard (10 CFU)	1509841-St12	*Mycoplasma salivarium* (10 CFU)	NNE045	10 CFU × 5 tubes
		DNA Dilution Buffer (DDB)	NND001	1.5 mL × 5 tubes
Mycoplasma hominis Sensitivity Standard (10 CFU)	1509841-St13	*Mycoplasma hominis* (10 CFU)	NNE048	10 CFU × 5 tubes
		DNA Dilution Buffer (DDB)	NND001	1.5 mL × 5 tubes

The strains should be stored at -65°C and the DDB should be stored at -20°C. The kit has a shelf life of 6 months. Please check the expiration date on the labels.

■ Required materials not included in the kit

- Low retention, RNase/DNase-free, sterile microcentrifuge tubes, 1.5 mL
- Low retention, RNase/DNase-free, sterile filter tips: 1000 μL, 100 μL and 10 μL

■ Related equipment

- Pipettes: 1000 μL, 100 μL and 10 μL
- High-speed refrigerated centrifuge

■ Procedure

1. Thaw the Mycoplasma strains at 2-8℃.
2. Based on the volume indicated on the label, add appropriate volume of sample matrix to each tube to reach 1 mL, to achieve a final concentration of 10 CFU/mL.
3. Vortex for 10 seconds and centrifuge for 30 minutes at 16,000× g, at 2-8℃.
4. Handle the Mycoplasma strain tube carefully to avoid resuspension, slowly remove 500 μL of the supernatant (try not to disturb the pellets), leave the remaining 500 μL and mix well for the DNA extraction step.
5. Performe real-time PCR after DNA extraction.

Note

*1) Each strain **must not be diluted**, and dilution will cause uneven distribution of mycoplasma and create an undetected contamination risk.*

2) Use only after equilibrating to room temperature and avoid repeated freeze-thaw cycles. Appropriate sample DNA extraction is strongly recommended before PCR to reduce the risk of inhibition and to maximize assay sensitivity.

3) Caution: Use microcentrifuge tubes certified for high-speed centrifugation to ensure safe operation.

■ Precaution

1. Do not mix reagents from different batches.
2. Do not use reagents beyond their expiration date.
3. Any operational deviations from the user guide may affect the results.
4. Inhibition of PCR may be caused by the sample matrix, therefore, a negative control sample using the sample matrix should be included.
5. At least one negative control should be included for each test sample.
6. This product is intended for research use only and should not be used for clinical diagnosis or treatment. Use with appropriate caution.
7. For your safety and health, please wear lab clothes and disposable gloves.

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Support & Contact

Huzhou Shenke Biotechnology Co., Ltd.
www.shentekbio.com
Address: 8th Floor, 6B Building, No.1366 Hongfeng Road, Huzhou 313000, Zhejiang Province, China
E-mail: info@shentekbio.com
Phone: +1 (908) 822-3199 / (+86) 400-878-2189