SHENTEK

Mycobacterium 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® Mycobacterium Sensitivity Standards are designed to validate the robustness and sensitivity of nucleic acid amplification techniques (NAT) for the detection of mycobacterium.

Traditional culture methods for mycobacterium test are time-consuming, and will take up to 56 days. Nucleic acid amplification technique, such as qPCR, offers rapid detection for mycobacterium contamination. According to the European Pharmacopoeia (EP), the United States Pharmacopoeia (USP) and the Chinese Pharmacopoeia (ChP), validated NAT methods are recommended to replace culture methods.

The MycoSHENTEK® Mycobacterium Sensitivity Standards (100 CFU or 10 CFU per tube) are non-infectious and not intended for culture. Simply add the specified volume of sample matrix to the Sensitivity Standards to prepare the test solution for further analysis.

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

■ Kit contents and storage

Table 1. Kit components and storage

Product Name	Product No.	Reagent	Part No.	Quantity
Mycobacterium phlei Sensitivity Standard (10 CFU)	1503603	*Mycobacterium phlei* (10 CFU)	NNE002	10 CFU × 3 tubes
		DNA Dilution Buffer (DDB)	NND001	1.5 mL × 3 tubes
Mycobacterium phlei Sensitivity Standard (100 CFU)	1503604	*Mycobacterium phlei* (100 CFU)	NNE001	100 CFU × 3 tubes
		DNA Dilution Buffer (DDB)	NND001	1.5 mL × 3 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 12 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

- Biosafety cabinet
- Benchtop microcentrifuge
- Vortex mixer
- Pipettes: 1000 µL, 100 µL and 10 µL

■ Procedure

1. Thaw the mycobacterium strains at 2-8°C.
2. Based on the volume indicated on the label, add appropriate volume of sample matrix to each tube, to achieve your desired final concentration. For mycobacterium strains at 10 CFU per tube, supplement to a total volume of 400 µL.
3. Vortex for 10 seconds and centrifuge briefly for 3 seconds.
4. Follow the kit instruction for the DNA extraction step.
5. Perform real-time PCR after DNA extraction.

Note

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

2) Use only after equilibration 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.

■ 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.

Effective date: 23 Dec. 2025

Support & Contact

SHENTEK

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