BioFlux

Bioer Technology

Mycoplasma Nucleic Acid Detection Kit (Fluorescent PCR)

Product Introduction

Mycoplasma contamination is a critical issue in the biopharmaceutical industry, warranting stringent prevention and control measures. Contamination can result in abnormal cell cultures, compromised quality of biopharmaceutical products, and, in severe cases, pose safety risks that jeopardize the success rate and compliance of drug development and manufacturing processes. Detecting and eliminating mycoplasma contamination is essential to maintaining product integrity and ensuring regulatory compliance, ultimately safeguarding the efficiency and safety of pharmaceutical production.

The Bioer Mycoplasma Nucleic Acid Detection Kit (Fluorescent PCR) utilizes polymerase chain reaction (PCR) combined with TaqMan fluorescent probe technology. Primers and probes are designed within the conserved 16S region, validated in accordance with the requirements outlined in Chapter 2.6.7 of the European Pharmacopoeia and other relevant mycoplasma detection standards. This kit enables qualitative detection of nucleic acids from over 200 species of mycoplasma and spiroplasma.

With high sensitivity and broad sample compatibility, the kit incorporates a non-competitive exogenous internal control to monitor the entire extraction and detection process, ensuring accurate and reliable results. As an ideal choice for laboratory mycoplasma contamination testing, it supports quality control in biopharmaceutical research and production, providing robust protection for sample safety.

Product Features

- **Simplified Operation:** Pre-mixed PCR reaction solution in a one-tube format eliminates the need for additional preparation, streamlining the workflow.
- **Robust Quality Control:** Incorporates an exogenous internal control to monitor the entire extraction and amplification process, minimizing the risk of false-negative results.
- **Anti-Contamination System:** Includes dUTP/UDG components to effectively degrade PCR product contamination and prevent false-positive results.
- **Strong Specificity:** No cross-reactivity with over 20 common pathogenic microorganisms, ensuring accurate and reliable results.

Product Specifications

Parameters	Description
Sample Type	Cell cultures, biological products.
Number of Species	>200 species
Method	qPCR
Internal Control	Exogenous internal control, positive control, negative control
Sensitivity	5 CFU/mL
Run Time	50 min
Recommended Purification Kit	BSC86 MagaBio plus Virus DNA/RNA Purification Kit III
Compatible Platform	LineGene 9600, QuantGene 9600, FQD-A1600, and ABI 7500
Storage Condition	-25°C~-15°C

Application Cases

1.Linear Relationship: The experiment used the Mycoplasma Nucleic Acid Detection Kit (Fluorescence PCR) to detect mycoplasma at different concentrations and plotted a standard curve using Ct values. The results are shown in Figures 1 and 2. The correlation coefficient (R) of the standard curve is -1.00, indicating a good linear relationship and high PCR amplification efficiency of the kit.

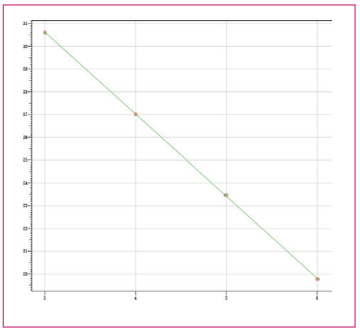

Figure 1: Standard Curve of Mycoplasma Nucleic Acid Detection Kit (Fluorescence PCR)

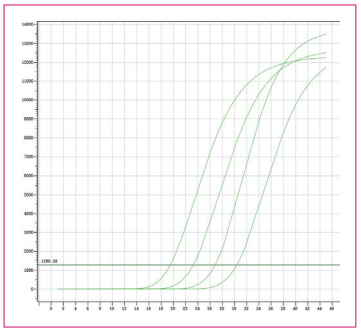

Figure 2: Amplification Curve of Mycoplasma Nucleic Acid Detection Kit (Fluorescence PCR)

2.Limit of Detection: The experiment used the kit to perform 24 tests on 10 common mycoplasma reference strains (5 CFU/mL). The detection rate reached 100%. The results are shown in Table 1.

Strains	Positive/ Total	Strains	Positive/ Total
Acholeplasma laidlawii	24/24	Mycoplasma hyorhinis	24/24
Mycoplasma arginini	24/24	Mycoplasma orale	24/24
Mycoplasma fermentans	24/24	Mycoplasma salivarium	24/24
Mycoplasma gallisepticum	24/24	Mycoplasma synoviae	24/24
Mycoplasma hominis	24/24	Mycoplasma pneumoniae	24/24

Table 1 Results of mycoplasma Nucleic Acid Detection Kit (Fluorescent PCR)

The amplification curves during the limit of detection validation are shown using Mycoplasma orale and Mycoplasma synoviae as examples (Figures 3 and 4):

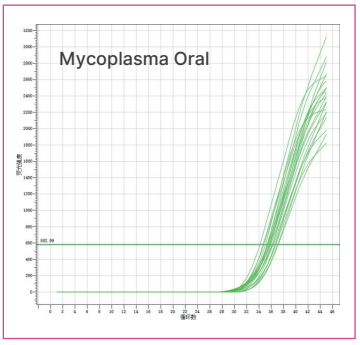

Figure 3: Limit of Detection Amplification Curve of Mycoplasma Oral

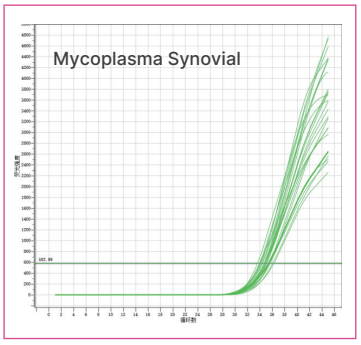

Figure 4: Limit of Detection Amplification Curve of Mycoplasma Synovial

3.Detection Specificity: The experiment used the kit to test 27 pathogens and common cell lines (including: HEK293T, CHO, Vero, hybridoma cells, Escherichia coli, Legionella pneumophila, Neisseria meningitidis, Pseudomonas aeruginosa, Haemophilus influenzae, Streptococcus pneumoniae, Bordetella pertussis, Staphylococcus aureus, Group A Streptococcus, Listeria monocytogenes, Shigella sonnei, Yersinia enterocolitica, Group B Streptococcus, Klebsiella pneumoniae, Campylobacter jejuni, Acinetobacter baumannii, Candida albicans, Campylobacter concisus, Clostridium difficile, Xanthomonad-like bacteria, Bacillus cereus, Salmonella, Human-type Mycoplasma).

Result: The results showed that, except for mycoplasma, no amplification was observed for other pathogens or cell lines, indicating that the kit has good specificity.

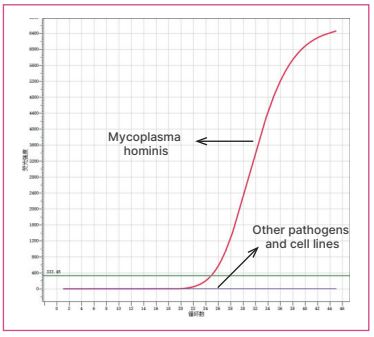

Figure 5: Specificity Verification Amplification Curve of Mycoplasma Nucleic Acid Detection Kit (Fluorescence PCR)

4.Competitor Comparison: The experiment used the Mycoplasma Nucleic Acid Detection Kit and Competitor T to detect 10 common mycoplasma strains. The results showed that when detecting a positive mycoplasma synovial sample, the kit gave a positive result, while Competitor T showed a negative result. For the remaining 9 positive mycoplasma samples, 6 showed no significant difference between the Bioer kit and Competitor T, while for 3 of the samples, the kit detected the result significantly earlier than Competitor T. Overall, the Bioer product demonstrated superior performance compared to Competitor T. The results are shown in Table 2.

Strains	CT Value		Strains	CT Value	
	Bioer	Competitor T		Bioer	Competitor T
Acholeplasma laidlawii	25.27	37.94	Mycoplasma hyorhinis	27.69	27.61
Mycoplasma arginini	25.48	26.47	Mycoplasma orale	26.91	26.83
Mycoplasma fermentans	24.61	24.64	Mycoplasma salivarium	26.10	26.62
Mycoplasma gallisepticum	27.21	27.52	Mycoplasma synoviae	31.52	-
Mycoplasma hominis	28.67	28.52	Mycoplasma pneumoniae	26.38	37.08

Table 2: Summary of Ct Values for Mycoplasma Positive Samples Detected by Bioer and Competitor T

Ordering Information

Product Name	Cat. No.	Package	Storage Condition
Mycoplasma Nucleic Acid Detection Kit (Fluorescent PCR)	BSJ52	50T/100T	-25°C~-15°C
MagaBio plus Virus DNA/RNA Purification Kit III	BSC86	16T/32T/48T/96T	2°C-25°C

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