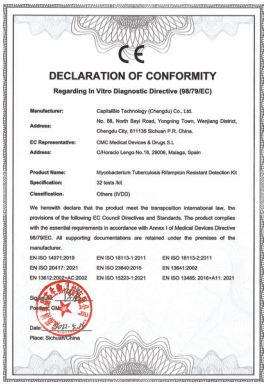
Capital TECHNOLOGY

Rifampicin-resistant Gene Detection Kit for Mycobacterium Tuberculosis (PCR - Melting Curve Method)

A Powerful Tool for Rapid Diagnosis of Rifampicin-Resistant Tuberculosis (RR-TB)

Project Background

Rifampicin is commonly used to treat severe tuberculosis infections, but the epidemiological studies show an increasing risk of rifampicin resistance. The international community is highly concerned about the rifampicin-resistant tuberculosis. China has successively issued the Expert Consensus on Detection of Mycobacterium Tuberculosis Drug Resistance (2019) and the Technical Guidelines for Tuberculosis Prevention and Control in China (2021). The main mechanism of rifampicin resistance in tuberculosis bacteria is mutations in rpoB gene, which is the rifampicin-resistant gene. Traditional methods for detecting drug resistance in tuberculosis are time-consuming with low accuracy and difficulty in culturing, which often leads to overuse of medications, and further worsens the drug resistance. There is an urgent need for a rapid, accurate and sensitive method to detect rifampicin resistance mutations in rpoB gene.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DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Testing Principle

This kit is based on PCR-melting curve technique. During the PCR process, a molecular beacon probe hybridizes with the amplified single-stranded oligonucleotide sequence. In the analysis process of melting curve, the hybridized fragments are monitored simultaneously as the temperature gradually increases. The fluorescence signal at each step produces the characteristic peak (obtaining the melting point, Tm value). When the target sequence of wild-type mycobacterium tuberculosis hybridizes with a probe, an original Tm value will be produced. If there is a point mutation, insertion or deletion in target sequence, the melting point produced from the hybridization between the probe and sequence will differ from the original one, allowing for differentiation between wild-type and mutant-type mycobacterium tuberculosis.

Product Features

This kit enables rapid detection of rpoB gene mutations related to rifampicin resistance in mycobacterium tuberculosis complex, addressing the challenges of long testing cycles, low diagnosis rates, and difficulty in culturing drug-resistant tuberculosis.

01

Rapid

direct detection of sputum samples; the entire test process takes 2.5 hours only

02

Sensitive

with the LOD of 200 bacteria/mL, it is capable of detecting 25% mutated samples

03

Comprehensive

one tube can detect 78 reported mutations

04

Simple

it can be matched with automatic nucleic acid extraction, with the test results automatically interpreted by software

Test Loci

Rifampicin binds to the β-subunit of RNA polymerase (RNAp) encoded by the rpoB gene, thereby inhibiting bacterial mRNA transcription. The rifampicin resistance in mycobacterium tuberculosis typically results from single nucleotide substitutions between 507-533 in rpoB gene, which is primarily within the rifampicin resistance determining region (RRDR), and an 81 bp region. This kit can detect 78 reported mutations in rpoB gene in one tube, providing comprehensive and accurate testing.

Application Scenarios

For suspected tuberculosis patients

it can offer the rapid detection of rifampicin-resistant tuberculosis

&

For confirmed tuberculosis patients (smear / culture / nucleic acid positive)

if can offer the accurate treatment of rifampicin-resistant tuberculosis

Clinical Significance

Early diagnosis

the etiological screening for suspected rifampicin-resistant tuberculosis patients can enable the early identification and reduce the spread of drug-resistant tuberculosis.

Accurate treatment

nsuring precise medication for RR-TB patients or timely adjustments in treatment, effectively preventing the overuse of anti-tuberculosis drugs.

Patient benefits

shortening the treatment duration, reducing the mortality rate, and lowering medical costs for tuberculosis patients.

Epidemiological analysis

analyzing the causes of rifampicin resistance and intervening in the transmission routes of RR-TB.

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