

TRUPCR® Rif/INH MTB Drug Resistant Detection Kit

NEED

Worldwide, TB is one of the top 10 causes of death and the leading cause from a single infectious agent. It is one of the main causes of morbidity and mortality, due to the emergence of antibiotic resistant *Mycobacterium* strains. In 2018, an estimated 500,000 people worldwide developed MDR-TB where patient does not respond to the two most powerful anti-TB drugs isoniazid and/or rifampicin. Drug Resistant TB accounts for about 1 in 3 deaths from antimicrobial resistance.

Culture which is the reference method for detection, requires at least a turn-around time of between 2 and 10 weeks & then again testing for these anti-TB drugs will take another few weeks. New WHO recommendations aim to speed up detection and improve treatment outcomes for MDR-TB through use of a molecular diagnostic test.

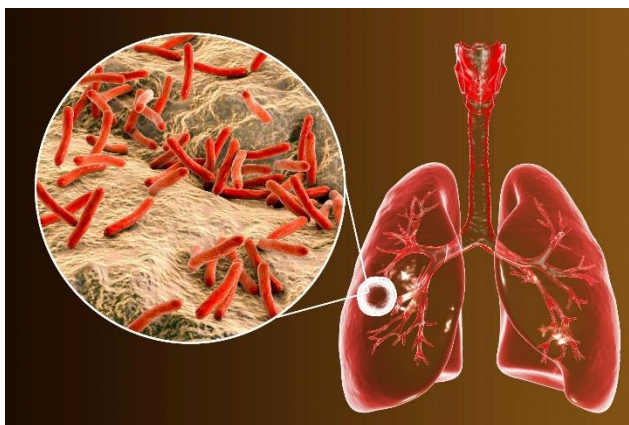


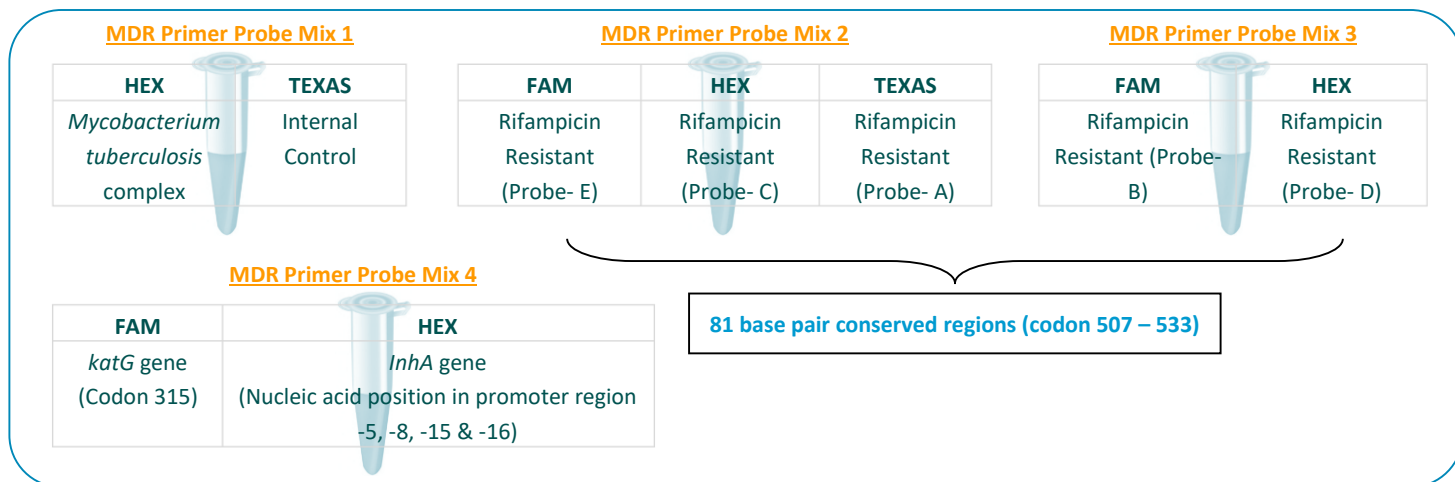
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SOLUTION BY TRUPCR®

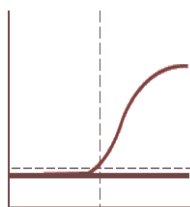
TRUPCR® Rif/INH MTB Drug Resistant Detection Kit is designed for accurate identification of *Mycobacterium tuberculosis* complex (MTC) along with Rifampicin and Isoniazid resistance/susceptible status from various sources of clinical samples using Real time nested PCR.

This assay utilizes four different tubes where one tube specifically detects MTC whereas another three tubes detects MDR. Each test is a multiplex reaction where targets are detected through FAM/Green, Hex/Yellow/VIC and/or Tex Red/Orange/ROX channels.

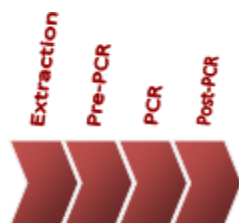
TARGET PATHOGENS / GENES



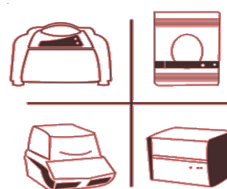
KEY FEATURES



Internal Control incorporated within the kit to ensure reliable results



Complete workflow solution available from Extraction of sample to Post-PCR analysis



Platform agnostic as compatible with various platforms



Rapid and reliable results within 100-120 minutes after PCR Start

TECHNICAL SPECIFICATIONS

- Sample Type – Sputum, BAL, Pus, CSF, Aseptic fluid, Aseptic tissue, Urine and Other fluids samples of human origin
- Clinical Validation – Validated on more than 500 clinical samples
- Target Regions – For MTBC: IS-6110 and MPB64
- For Rifampicin resistance: *rpoB* gene (81 base pair conserved regions)
- For Isoniazid resistance: *katG* and *inhA* gene
- Reaction Volume – 30µl in each tube
- LOD Data: 120 CFU/ml of sputum.
- Compatible Instruments – Applied Biosystems™ 7500 series, Applied Biosystems™ StepOne series, Applied Biosystems™ QuantStudio® series, Rotor-Gene Q, Bio-Rad CFX96, CFX384, AriaMx Real-Time PCR, Roche - LightCycler® 480 –II, Line gene K Real-Time PCR

CLINICAL DATA

		Reference Method		
		Positive	Negative	Total
TRUPCR Method	Positive	85	2	87
	Negative	3	190	193
Total		88	192	280

Parameters	Estimate
Sensitivity	96.70 %
Specificity	98.96 %
Positive Predictive Value	97.77 %
Negative Predictive Value	98.46 %



ORDERING INFORMATION

Cat. No.	Description	Size
3B1280	TRUPCR® Rif/INH MTB Drug Resistant Detection Kit	48 Reactions
3B1275	TRUPCR® Rif/INH MTB Drug Resistant Detection Kit	96 Reactions