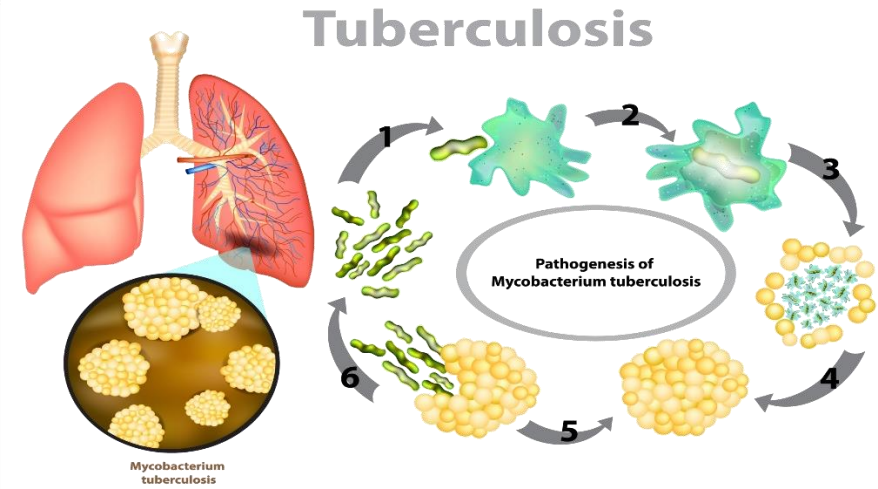
TRUPCR® MTBC One Step Nested Kit

NEED

Worldwide, TB is one of the top 10 causes of death and the leading cause from a single infectious agent. A total of 1.4 million people died from TB in 2019. It is an air-born disease, spread one active TB patient to next through air, by their sneeze, spit and lungs cough. It is caused by Mycobacterium tuberculosis complex (MTC) that mainly affects the all age groups of people in the lungs, producing breathing difficulties. Nontuberculous mycobacteria (NTM) are opportunistic pathogens can cause infections in a wide variety of body sites, most commonly the lungs, Skin, soft tissue & Lymph nodes.

Culture which is the reference method for detection, requires at least 100 viable bacilli to obtain a positive culture with a turn-around time of between 2 and 10 weeks. Therefore, to adequately treat and effectively control MTC, there is a need for effective, rapid and accurate diagnosis.



https://apollohealthlib.blob.core.windows.net/health-library/2021/07/Treat-Tuberculosis-at-Home-scaled.jpg

SOLUTION BY TRUPCR®

TRUPCR® MTBC ONE STEP NESTED KIT accurately differentiates Mycobacterium tuberculosis complex (MTC) from non-tuberculosis Mycobacterium species (NTM) in a qualitative form from various sources of clinical samples using Real time PCR.

This assay that utilizes two sequential polymerase chain reactions (PCR) to detect low load of Mycobacterium DNA in human clinical samples, both pulmonary and extra-pulmonary. The detection is achieved in one step nested PCR, the first amplification is subjected for specific amplification of *M. tuberculosis*. The second amplification is a nested PCR reaction, in order to achieve the maximum sensitivity and specificity of the test.

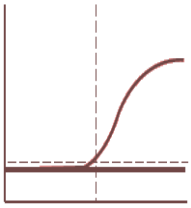
This assay is based on oligonucleotide hydrolysis principle which allows higher specificity and sensitivity. The different targets are detected with the help of three different dyes (FAM/Green, HEX/VIC/Yellow & Texas Red/ROX/Orange).

TARGET PATHOGENS

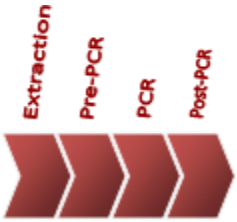
MDR Primer Probe Mix 1

FAM	HEX	TEXAS
NTM	*MTB*	Endogenous IC
HSP	*ISN/MPB*	

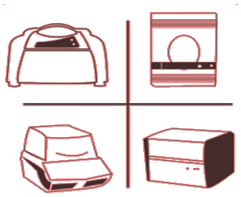
KEY FEATURES



Endogenous 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, Urine, Pus, CSF, Aseptic fluid, Aseptic tissue and Other fluids
- Target Regions – IS-6110, MPB64 and HSP65 gene
- Dual target for Rapid and accurate detection of MTBC infection
- UNG is included in the master mix to avoid carry over contamination
- LOD Data: 10 copies/reaction for MTC and 100 copies/reaction for NTM.
- Internal Control incorporated within the kit to ensure reliable results
- Validated on WHO approved reference materials
- Reaction Volume – 30µl in each tube
- 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, MIC-4 PCR

CLINICAL DATA

			Reference Method			
			Positive		Negative	Total
			MTB	NTM		
TRUPCR Method	Positive	MTB	93	0	2	**95**
		NTM	0	11	0	**11**
	Negative		2	1	163	**166**
	Total		**95**	**12**	**192**	**272**

Parameters	Estimate	
	MTC	NTM
Sensitivity	97.93%	92.3%
Specificity	98.80%	98.80%
Positive Predictive Value	97.93%	100.00%
Negative Predictive Value	98.8%	99.39%

ORDERING INFORMATION

Cat. No.	Description	Size
3B268	TRUPCR® MTBC One Step Nested Kit	48 Reactions
3B269	TRUPCR® MTBC One Step Nested Kit	96 Reactions

PUBLICATIONS

- Dandamudi et al, 2017, Isolation of Mycobacterium monacense from chemoport: A rare case report and review of literature. Indian J Case Reports, Volume 3, Issue 2, Apr - Jun 2017 / Case Report. (https://doi.org/10.32677/IJCR.2017.v03.i02.008)

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