



STANDARD Q TB MPT64 Ag Test

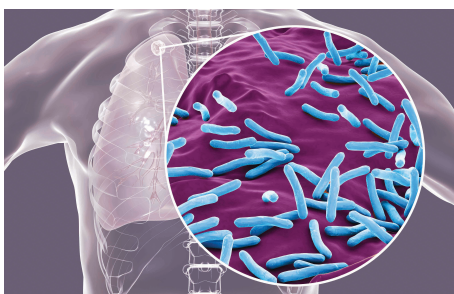
KEY FEATURES

- Accurate identification of the *M. tuberculosis* from other Mycobacterium
- A reliable, rapid and effective method for confirming MTB culture isolates
- Easy handling which does not require specific training
- Fast test result in 10 ~ 15 minutes
- Room temperature storage at 2 ~ 40°C/36 ~ 104°F

CE
MFDS



WHAT IS MPT64 AG AND WHY IS IT IMPORTANT?



Tuberculosis (TB) is caused by *Mycobacterium* (MTB) bacteria¹. Confirmatory Identification of *M. tuberculosis* (MTB) is still being done by conventional biochemical methods. These tests are laborious, time consuming and require elaborate safety precautions².

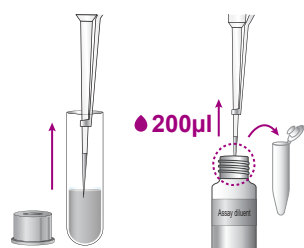
MPT64 is one of the secreted proteins from *Mycobacterium tuberculosis*. **Tests based on the detection of Mycobacterial antigens are of special interest, as they have the potential to provide rapid and direct evidence of active TB disease³.**

PRODUCT SPECIFICATION

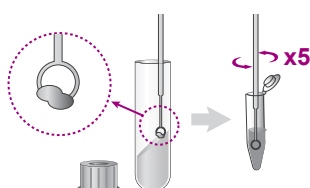
Intended use	Qualitative detection of <i>M. tuberculosis</i> antigen
Specimen type	Liquid culture / Solid culture
Testing time	10 ~ 15 mins
Sensitivity	100% (92/92)
Specificity	100% (67/67)
Storage condition	2 ~ 40°C / 36 ~ 104°F

TEST PROCEDURE

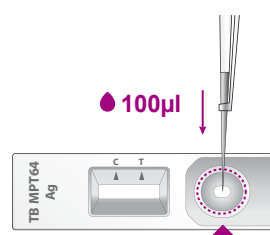
1 Specimen preparation [Liquid culture]



[Solid cultures]



2 Adding of Specimen



3 Reading Time



Read after 10 mins
Do not read after 15 mins

PERFORMANCE CHARACTERISTICS

Clinical evaluation

A single site, single blind, clinical trial for evaluation of the clinical performance of 'STANDARD Q TB MPT64 Ag Test' comparison with RT-PCR in detecting MPT64 Antigen in liquid and solid culture media of human sputum samples

Comparison to the Reference method (RT-PCR)

		RT-PCR	
		Positive	Negative
STANDARD Q TB MPT64 Ag Test	Positive	92	0
	Negative	0	67
Total		92	67
Clinical Sensitivity		100% (92/92)	
Clinical Specificity		100% (67/67)	

ORDERING INFORMATION

Cat. No.	Products	Type	Tests/kit
09MPT10D	STANDARD Q TB MPT64 Ag Test	Device	25T / Kit

REFERENCES

- (1) <https://www.who.int/news-room/fact-sheets/detail/tuberculosis>
- (2) Kumar, Vijay Gs et al. "MPT 64 Antigen detection for Rapid confirmation of M.tuberculosis isolates." BMC research notes vol. 4 79. 24 Mar. 2011, doi:10.1186/1756-0500-4-79
- (3) World Health Organization. High-Priority Target Product Profiles for New Tuberculosis Diagnostics. Report of a Consensus Meeting. 2014. Available online: https://www.who.int/tb/publications/tpp_report/en/ (accessed on 5 February 2020)