

# ExAmplar MTB v2.0 72T

Qualitative identification of Mycobacterium tuberculosis

Target: MTB Complex Specific (IS Element)

Fully Lyophilized, Ready-To-Use,

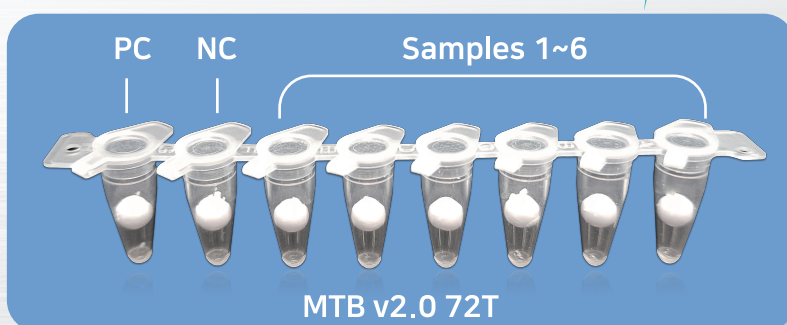
- Exclusive for ExAmplar
- Controls Included
- Sensitivity: 1.8 copies/rxn (MTB Whole Genome)
- 2 controls + 6 samples/run
- Total time 33 minutes



## Test Procedure

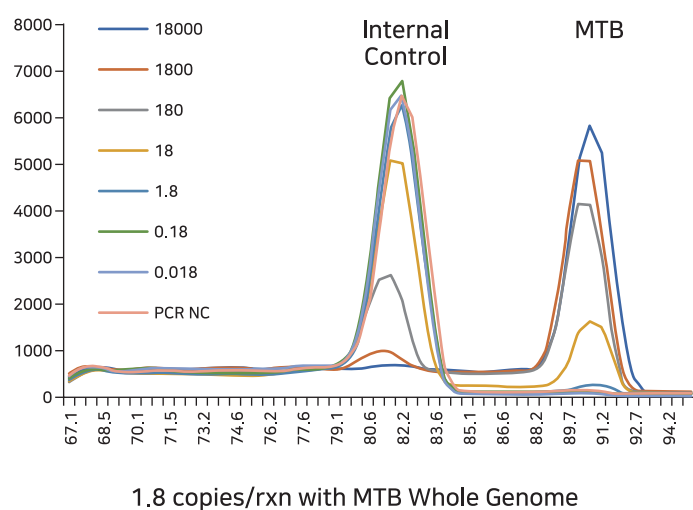
- 1 Add 17.5  $\mu$ L Resuspension Buffer to all reaction tubes.
- 2 Add 2.5  $\mu$ L PC, NC and samples of extracted DNA using NuActor System with Sputum DNA extraction Cartridge.
- 3 Mix well and centrifuge lightly.
- 4 Using 'ExAmplar' : Select '+/- test' → 'MTB'
- 5 Assign PC, NC and Sample name
- 6 Run.

## ExAmplar



## Performance Data

### 1. Analytical Sensitivity



UGC MTB NU-EX Kit	Reference MTB Kit		Total
	Positive	Negative	
Positive	73	5	78
Negative	2	111	113
Total	75	116	191

#### Clinical Samples

Kappa Value = 0.924 SE of kappa = 0.028

95% confidence interval: From 0.868 to 0.979

### 2. Analytical Specificity

No cross reactivity with known sputum pathogens as well as with Non Tuberculoïd Mycobacterium (NTM).

### 3. Stability

Shipping : ambient temp (under 45°C )

Storage : 12 months at 2-8°C

### 4. Kit components

Components	Quantity
ExAmplar MTB reaction tube (lyophilized): 8 tube strip	12 Strips
Resuspension Buffer	2 vials
MTB Positive control	1 vial
Negative control	1 vial
Internal Control	1 vial