ENGLISH

MTB/NTM Screening & Drug-Resistant TB Detection

using Real-time PCR

CE-IVD Marked

Anyplex™ MTB/NTM Real-time Detection

- Simultaneous detection of MTB and NTM

Anyplex™ II MTB/MDR/XDR Detection

- Simultaneous screening for MTB infection, 25 MDR mutations and 13 XDR mutations

Anyplex™ II MTB/MDR Detection

- Simultaneous detection of MTB and 25 mutations associated with MDR-TB
- Rifampicin-resistance (18 mutations)
- Isoniazid-resistance (7 mutations)

Anyplex™ II MTB/XDR Detection

- Simultaneous detection of MTB and 13 mutations associated with XDR-TB
- Fluoroquinolone-resistance (7 mutations)
- Injectable drug-resistance (6 mutations)

Superior

HIGH SENSITIVITY & SPECIFICITY

Multiplex real-time PCR with high sensitivity and specificity by utilization of DPO™ and TOCE™ technologies

Seegene

Cost-effective assays for MTB, NTM and drug-resistant TB

Anyplex™ MTB/NTM Real-time Detection is an efficient method to screen TB quickly in the first instance.
Anyplex™ II MTB/MDR, Anyplex™ II MTB/XDR and **Anyplex™ II MTB/MDR/XDR Detection** are able to identify TB and drug-resistant TB simultaneously and rapidly, which allows cost-saving test. An ideal testing algorithm is to screen patient samples with Anyplex™ MTB/NTM Real-time Detection followed by three assays. It allows reductions in cost, time, and labor for addiotional sample collection and nucleic acid extraction.

Complete Solution for TB Screening and Drug-Resistant TB Detection

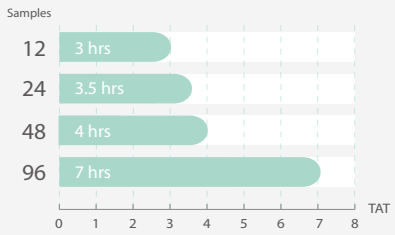
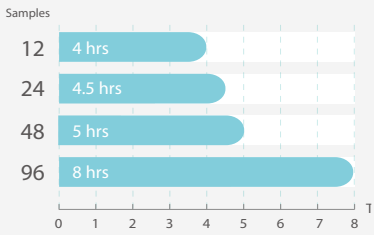
- Enable to distinguish or identify TB and drug-resistant TB within clinically meaningful timeframe
- Eliminate need for additional sample collection and nucleic acid extraction to test drug-resistant TB when coupled with MTB/NTM screening
- Provide prompt diagnosis and appropriate treatment guideline for TB control

Features

1. Available for various specimen types

- **Sputum**
- **Cultured cell**
- **Bronchial washing**
- **Fresh tissue**

2. Reportable within one working day of sample receipt

Anyplex™ MTB/NTM Real-time Detection	Anyplex™ II MTB/MDR/XDR Detection	TAT* (for 24 samples)
		
DNA extraction and MTB/NTM screening in **3.5 hours**	Identification of mutations associated drug-resistant TB in **3 hours**	MTB/NTM screening and drug-resistant TB detection **in 7 hours**

* Turnaround time : nucleic acid extraction to result

3. Convenient result analysis and interpretation through Seegene Viewer

- Interface specialized for multiplex testing
- Easy readout for comprehensive information
- Interlocked with LIS

Workflow

Anyplex™ II

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MTB / MDR Detection

Simultaneous detection of *Mycobacterium tuberculosis* (MTB) and 25 mutations associated with MDR-TB

Analytes

- MTB
- Internal Control (IC)
- Multi-Drug Resistance (MDR)
  - Isoniazid-resistance (7 mutations)
  - Rifampicin-resistance (18 mutations)

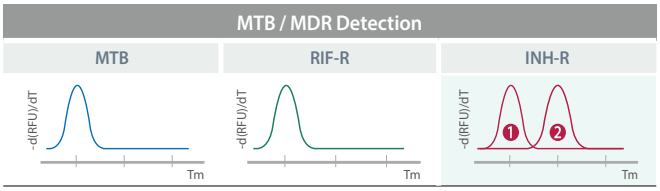
1. Broad coverage of MDR-TB point mutations

Target mutations of MDR-TB detection						
Drug resistance	Related gene	Target mutations				
RIF-R* (18 mutations)	*rpoB*	L511P (CTG ⇨ CCG) Q513K (CAA ⇨ AAA) Q513L (CAA ⇨ CTA) Q513P (CAA ⇨ CCA)	3 a.a. deletion in 513~516 D516V (GAC ⇨ GTC) D516Y (GAC ⇨ TAC) S522L (TCG ⇨ TTG)	S522Q (TCG ⇨ CAG) H526C (CAC ⇨ TGC) H526D (CAC ⇨ GAC) H526L (CAC ⇨ CTC)	H526N (CAC ⇨ AAC) H526R (CAC ⇨ CGC) H526Y (CAC ⇨ TAC) S531L (TCG ⇨ TTG)	S531W (TCG ⇨ TGG) L533P (CTG ⇨ CCG)
INH-R (7 mutations)	*katG*	S315I (AGC ⇨ ATC)	S315N (AGC ⇨ AAC)	S315T (AGC ⇨ ACC)	S315T (AGC ⇨ ACA)	
	inhA promoter	-15 (C ⇨ T)	-8 (T ⇨ A)	-8 (T ⇨ C)		

* It is possible to detect 9 additional RIF resistance mutations, which have the same codon site.

2. Anyplex™ II MTB/MDR Detection provides more information for appropriate treatment [1~3]

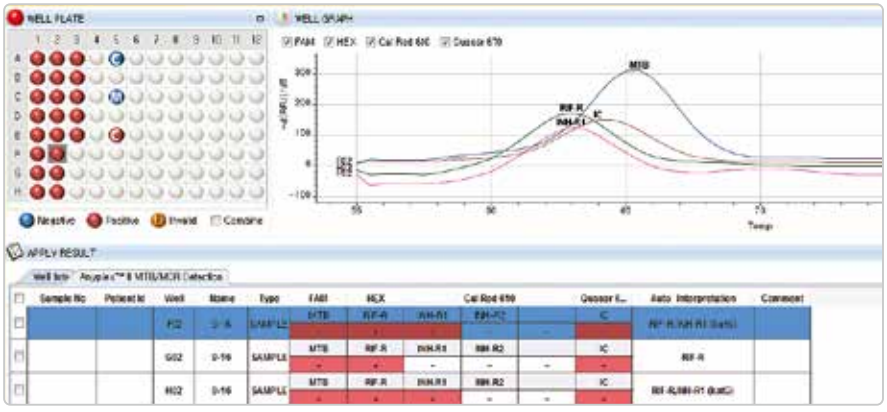
- Schematic diagram of test result



- Clinical implication according to melting temperature (INH-R)

Interpretation	Melting temp. (Tm)	Corresponding gene / mutations	Clinical implication (general aspect)
INH-R	❶ Low Tm	4 mutations in *katG*	High-level INH resistance
	❷ High Tm	3 mutations in *inhA* promoter	Low-level INH resistance

Result / Seegene Viewer



References

1. Guo H. *et al*, J. Med. Microbiology (2006) 55:1527–31
2. Johnson R. *et al*, Curr Issues Mol Biol. (2006) 8:97-111
3. Ando H. *et al*, Antimicrob Agents Chemother. (2010) 54:1793-9

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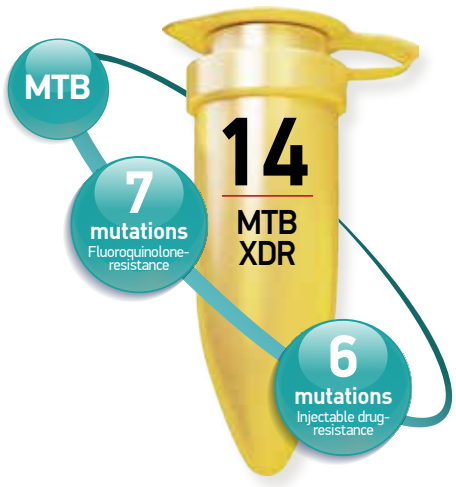
MTB / XDR Detection

Simultaneous detection of *Mycobacterium tuberculosis* (MTB) and 13 mutations associated with XDR-TB



Analytes

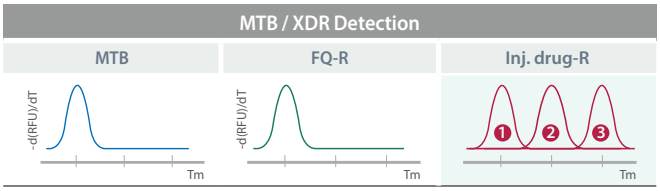
- MTB
- Internal Control (IC)
- Extensively Drug Resistance (XDR)
  - Fluoroquinolone-resistance (7 mutations)
  - Injectable drug-resistance (6 mutations)

1. Broad coverage of XDR-TB point mutations

Target mutations of XDR-TB detection						
Drug resistance	Related gene	Target mutations				
FQ-R (7 mutations)	*gyrA*	A90V (GCG ⇨ GTG) S91P (TCG ⇨ CCG)	D94A (GAC ⇨ GCC) D94G (GAC ⇨ GGC)	D94H (GAC ⇨ CAC)	D94N (GAC ⇨ AAC)	D94Y (GAC ⇨ TAC)
Injectable drug-R (6 mutations)	*rrs*	1401 (A ⇨ G)	1402 (C ⇨ T)	1484 (G ⇨ T)		
	eis promoter	-37 (G ⇨ T)	-14 (C ⇨ T)	-10 (G ⇨ A)		

2. Anyplex™ II MTB/XDR Detection provides more information for appropriate treatment [4~6]

- Schematic diagram of test result

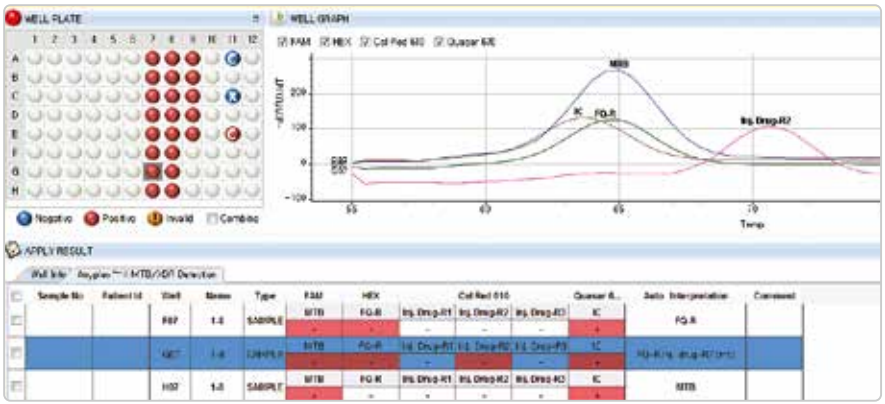


- Clinical implication according to melting temperature (Injectable drug-R)

Interpretation	Melting temp. (Tm)	Corresponding gene / mutations	Clinical implication (general aspect)
Injectable drug-R	❶ Low Tm	3 mutations in *eis* promoter	Low-level KAN resistance
	❷ Middle Tm	2 mutations in *rrs* (1401G/1484T)	High-level KAN/AMI/CAP resistance
	❸ High Tm	1 mutation in *rrs* (1402T)	Low-level KAN resistance High-level CAP resistance

KAN : Kanamycin, AMI : Amikacin, CAP : Capreomycin

Result / Seegene Viewer



References

4. Johnson R. *et al*, Curr Issues Mol Biol. (2006) 8:97-111
5. Zaunbrecher MA. *et al*, Proc Natl Acad Sci USA (2009) 106:20004-9
6. Gikalo MB *et al*, J Antimicrob Chemother. (2012) 67:2107-9

Anyplex™

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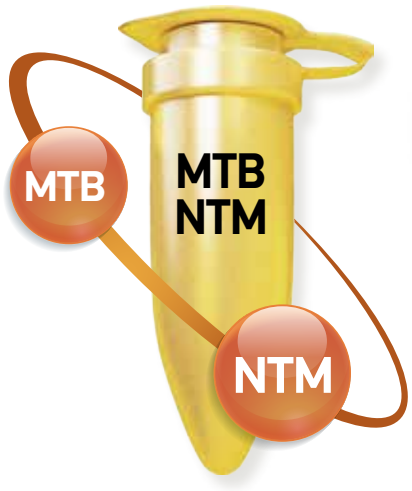
MTB / NTM Real-time Detection

Simultaneous detection of *Mycobacterium tuberculosis* (MTB) and non-tuberculosis mycobacteria (NTM)

Analytes

- MTB
- Mycobacteria
- Internal Control (IC)

Result / Seegene Viewer



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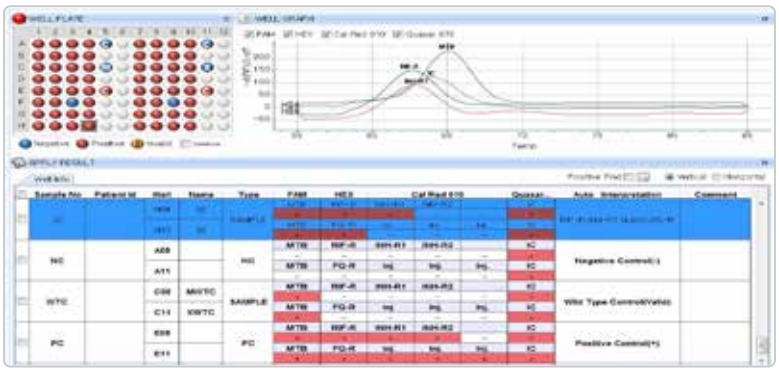
MTB / MDR / XDR Detection

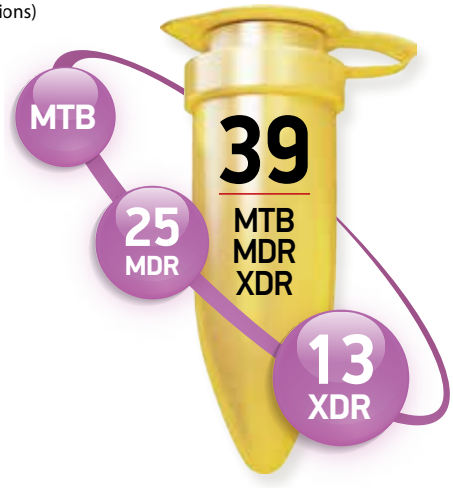
Simultaneous detection of MTB, 25 mutations associated with multi-drug-resistant tuberculosis (MDR-TB) and 13 mutations associated with extensively drug-resistant tuberculosis (XDR-TB)

Analytes

- MTB
- Internal Control (IC)
- **Multi-Drug Resistance**
  - Isoniazid-resistance (7 mutations)
  - Rifampicin-resistance (18 mutations)
- **Extensively Drug Resistance**
  - Fluoroquinolone-resistance (7 mutations)
  - Injectable drug-resistance (6 mutations)

Result / Seegene Viewer





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Benefits of Seegene's TB Solution

For Patients
- Be treated promptly
- Get personalized treatment

For Physician Clinics
- Give faster answers to patients
- Aid in selecting appropriate therapy (first-line or second-line anti-TB drugs)

For Technicians / Labs
- Reduce hands-on time with health-threatening specimen
- Provide comprehensive tests for MTB/NTM and MTB/MDR/XDR on one platform

For TB Controller
- Get more results (MTB, NTM, MDR and XDR) to deliver timely and targeted therapy
- Control secondary transmission of MTB and drug-TB resistance in the community

• Ordering information

Not Available for Sale in the United States

Product		Package Volume	Cat. No.
Anyplex™ MTB/NTMe Real-time Detection		50 rxns	TB7202Y
		100 rxns*	TB7202X
Anyplex™ MTB/NTM Real-time Detection (V2.0)		100 rxns	TB7200X
Anyplex™ II MTB/MDR/XDR Detection		50 rxns	TB7500Y
Anyplex™ II MTB/MDR Detection		50 rxns	TB7301Y
Anyplex™ II MTB/XDR Detection		50 rxns	TB7302Y
Instrument	**Type**		**Cat. No.**
CFX96™ Dx	Real-time PCR _ Optical Reaction Module		1845097-IVD
	Real-time PCR _ Thermal Cycler		1841000-IVD

*For use with NIMBUS IVD & STARlet IVD only

Seegene

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