TOCE™ Technology

Anyplex™ II

High Multiplex Real-time PCR

- High multiplicity in a single channel using Catcher-Tm analysis
- Controllable Catcher-Tm profile
- Consistent Catcher-Tm values regardless of target sequence variations
- As sensitive as singleplex real-time PCR
- Multiple quantitative analysis using cyclic-CMTA in a single channel
- High multiple point mutations detection in a single tube

Ordering Information

Not Available in U.S.A.

Product	Package Volume	Cat No.
Anyplex™ II MTB/MDR Detection	50 rxns	TB7301Y
Anyplex™ II MTB/XDR Detection	50 rxns	TB7302Y
Instrument & Extraction reagent	**Description**	**Cat No.**
CFX96™	Real-time PCR _ Optical Reaction Module	1845097-IVD
	Real-time PCR _ Thermal Cycler	1841000-IVD

Seegene

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TB75-EN160205B - 01

Anyplex™II

TB-DR Detection

Simultaneous detection for MTB infection & anti-TB drug resistance by Real-time PCR

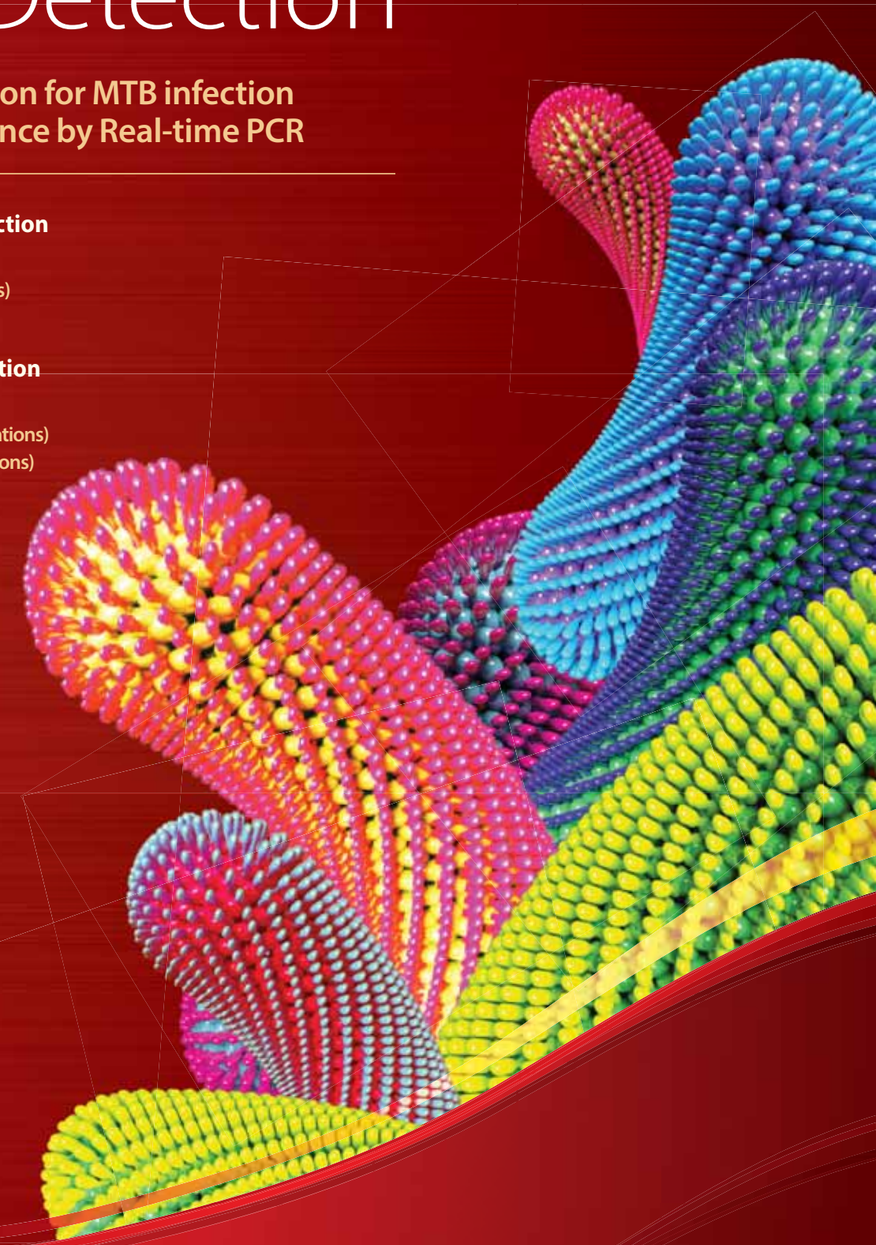
• Anyplex™ II MTB/MDR Detection

- MTB + Multi-Drug Resistance
- Rifampicin-resistance (18 mutations)
- Isoniazid-resistance (7 mutations)

• Anyplex™ II MTB/XDR Detection

- MTB + Extensively Drug Resistance
- Fluoroquinolone-resistance (7 mutations)
- Injectable drug-resistance (6 mutations)

CE-IVD Marked



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Anyplex™ II

REAL TIME | CE-IVD Marked

MTB / MDR Detection

Features

a. Simultaneous detection of *Mycobacterium tuberculosis* and 25 mutations associated with MDR-TB*

b. WTC**(Wild-type Control) and Internal Control(IC) for assay validity

c. Utilization of the UDG system to prevent carry-over contamination

d. Convenient result analysis and interpretation through the Seegene viewer

* MDR-TB - *Mycobacterium tuberculosis* and its resistance to first-line anti-tuberculosis drugs (Isoniazid and Rifampicin)

** WTC - The specificity of mutation-targeted oligos in the Anyplex™ II MTB/MDR Detection can be confirmed by Wild-type Control (WTC). The WTC is designed to be exhibited the same result pattern with drug-susceptible *M. tuberculosis* sample. The WTC reaction should be always performed in each testing run, and the drug-resistant result of unknown samples is analyzed on the basis of the result of WTC.

Analytes

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

Validated Specimen

- Sputum
- Cultured cell
- Bronchial washing
- Fresh tissue

Compatible Instrumentation

- Real-time PCR - CFX96™ (Bio-Rad) (CE-IVD Marked)

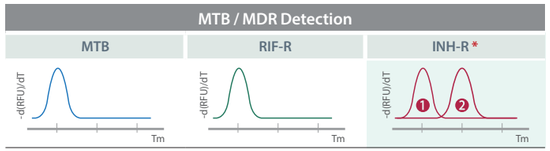
1. Broad coverage of MDR-TB point mutations

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

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

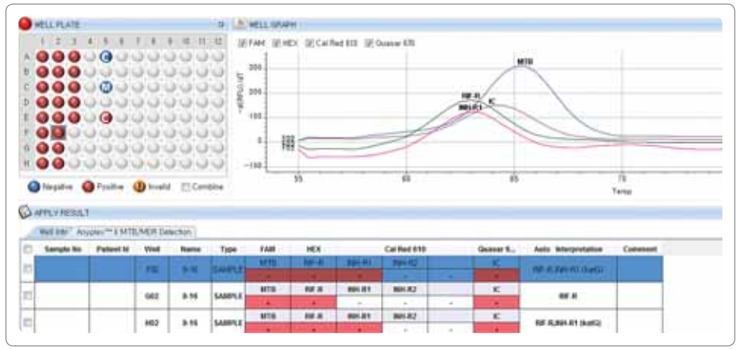
2. Anyplex™ II MTB/MDR Detection provides more information for appropriate treatment [1~3]

- 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-R1	1 Low Tm	4 mutations in *katG*	High-level INH resistance
INH-R2	2 High Tm	3 mutations in *inhA* promoter	Low-level INH resistance



Result / Seegene Viewer

a. Interface specialized for multiplex testing

b. Interlocked with LIS

c. Patient information input via barcode scanning system

d. Printable in various formats

e. Downloadable results in a CSV file

f. Convenient view for quantitative analysis result

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

Anyplex™ II

REAL TIME | CE-IVD Marked

MTB / XDR Detection

Features

a. Simultaneous detection of *Mycobacterium tuberculosis* and 13 mutations associated with XDR-TB*

b. WTC**(Wild-type Control) and Internal Control(IC) for assay validity

c. Utilization of the UDG system to prevent carry-over contamination

d. Convenient result analysis and interpretation through the Seegene viewer

* XDR-TB - *Mycobacterium tuberculosis* and its resistance to second-line anti-tuberculosis drugs (fluoroquinolones and injectable drugs)

** WTC - The specificity of mutation-targeted oligos in the Anyplex™ II MTB/XDR Detection can be confirmed by Wild-type Control (WTC). The WTC is designed to be exhibited the same result pattern with drug-susceptible *M. tuberculosis* sample. The WTC reaction should be always performed in each testing run, and the drug-resistant result of unknown samples is analyzed on the basis of the result of WTC.

Analytes

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

Validated Specimen

- Sputum
- Cultured cell
- Bronchial washing
- Fresh tissue

Compatible Instrumentation

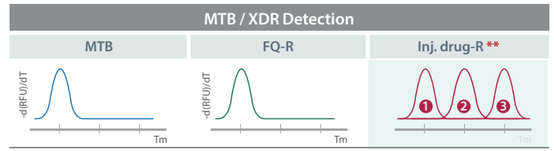
- Real-time PCR - CFX96™ (Bio-Rad) (CE-IVD Marked)

1. Broad coverage of XDR-TB point mutations

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

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

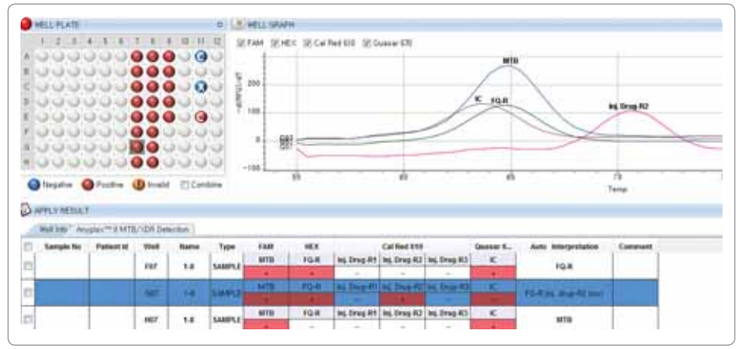
- Schematic diagram of test result



- Clinical Implication according to melting temperature (Injectable drug-R**)

Interpretation	Melting temp. (Tm)	Corresponding gene / mutations	Clinical implication (general aspect)
Inj.drug-R1	1 Low Tm	3 mutations in *eis* promoter	Low-level KAN resistance
Inj.drug-R2	2 Middle Tm	2 mutations in *rrs* (1401G/1484T)	High-level KAN/AMI/CAP resistance
Inj.drug-R3	3 High Tm	1 mutation in *rrs* (1402T)	Low-level KAN resistance High-level CAP resistance

KAN : Kanamycin, AMI : Amikacin, CAP : Capreomycin



Result / Seegene Viewer

a. Interface specialized for multiplex testing

b. Interlocked with LIS

c. Patient information input via barcode scanning system

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References

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