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Diagnostics for Utopia

EuDx™ - Detection Kit



EuDx™ - MTB Detection Kit

Product Description and Components



Name : EuDx™-MTB Detection Kit

Category : High risk IVD reagents for infectious disease nucleic acid test

Core Technology : One tube Nested Real-Time PCR

Product Description : Targeting both *IS6110* and *rpoB* genes of the *M. tuberculosis* reduces the rate of false negative. Nested real-time PCR is used to show high sensitivity with low copy of target DNA.

Components

Component	CapColor	Amount	96 tests
2X qPCR Premix	Red	1.25 ml	
4X Reaction Mixture (Primer/Probe + Internal Control)	Green	400 ul	
Positive Control DNA	Yellow	20 ul	
Nuclease Free Water	Blue	1 ml	
DNA Extraction Solution	White	1.5ml x 4 tubes	

Clinical Test

Specimens	Sensitivity	Specificity
MTB positive	96%	100 %

The clinical test was performed at the Asan Clinical Trial Center.

*Specimens(N=400)

Specimens (N=400)		EuDx™-MTB Detection Kit	
		Undetected	Detected
<i>M. abscessus</i>	NTM	100%	0%
<i>M. abscessus</i> + <i>M. fortuitum</i>	NTM	100%	0%
<i>M. avium</i>	NTM	100%	0%
<i>M. avium</i> + <i>M. fortuitum</i>	NTM	100%	0%
<i>M. avium</i> + <i>M. intracellulare</i>	NTM	100%	0%
<i>M. Chelonae</i>	NTM	100%	0%
<i>M. fortuitum</i>	NTM	100%	0%
<i>M. Intracellulare</i>	NTM	100%	0%
<i>M. kansasii</i>	NTM	100%	0%
<i>M. peregrinum</i>	NTM	100%	0%
<i>M. tuberculosis</i>	TB	4%	96%
NTM, un-ID	NTM	100%	0%

EuDx™ - MDR TB Detection Kit

Product Description and Components

Name : EuDx™-MDR TB Detection Kit

Category : High risk IVD reagents for infectious disease nucleic acid test

Core technology : One tube Multiplex Real-Time PCR

Product Description : EuDx™-MDR TB Detection Kit qualitatively detects the multidrug (RIF and INH)-resistant tuberculosis from sputum of tuberculosis patients by multiplex real-time PCR. EuDx™-MDR TB Detection Kit can identify high risk strain for drug resistant which is Beijing lineage.



Components

Component	CapColor	Amount	
2X qPCR Premix	Red	1250 ul	
10X Reaction Mixture 1 (Primer/Probe + Internal Control)	Green	250 ul	48 tests
10X Reaction Mixture 2 (Primer/Probe + Internal Control)	Green	250 ul	
Positive Control DNA 1	Yellow	100 ul	
Positive Control DNA 2	Yellow	100 ul	
Nuclease-Free Water	Blue	1 ml	

Data

- Figures 1 & 2 indicates example of RIF, INH, MTB and negative amplification curve.

Target		Dye
10X Reaction Mixture 1	10X Reaction Mixture 2	
RIF-1 (516A, 526A, 531)	RIF-2 (511, 516B, 526B)	FAM (MGB application)
INH-1 (katG315, inhA-15)	INH-2 (inhA-8, ahpC-6)	VIC (MGB application)
MTB-1 (IS6110)	MTB-2 (Beijing lineage)	TEXAS RED
Internal control - 1	Internal control - 2	CY5

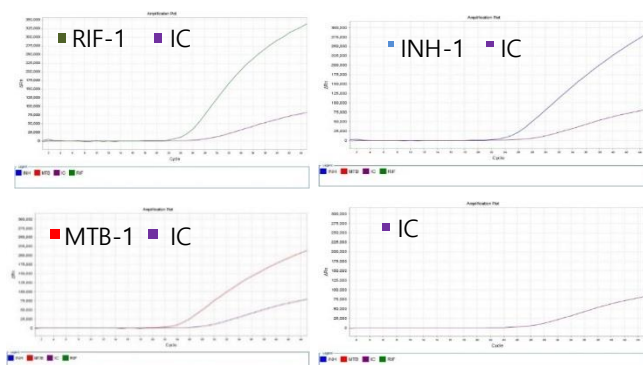


Figure 1 (Mixture 1)

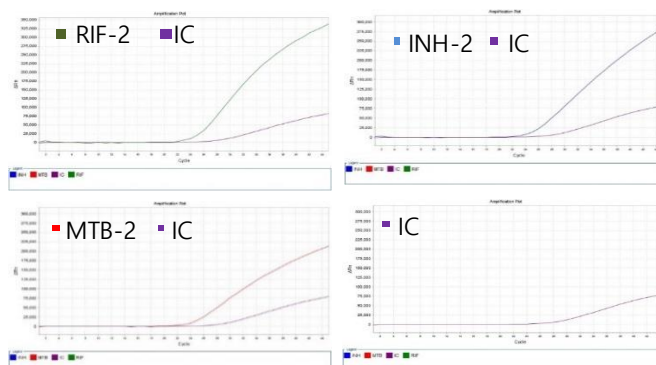


Figure 2 (Mixture 2)

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EuDx™ - PN MLC Detection Kit

Product Description and Components



Name : EuDx™-PN MLC Detection Kit

Category : High risk IVD reagents for infectious disease nucleic acid test

Core Technology : One tube Multiplex Real-Time PCR

Product Description : EuDx™-PN MLC Detection Kit qualitatively detects three types of causative bacteria Mycoplasma pneumoniae (MP), Legionella pneumophila (LP), Chlamydomphila pneumoniae (CP) existing in nasopharynx swab by the multiplex real-time PCR.

Components

Component	CapColor	Amount	
2X qPCR Premix	Red	500 ul	
4X Reaction Mixture (Primer/Probe + Internal Control)	Green	250 ul	48 tests
Positive Control DNA	Yellow	100 ul	
Nuclease-Free Water	Blue	1 ml	

Clinical Test

Specimens	Sensitivity	Specificity
<i>Mycoplasma pneumoniae</i> (MP)	97.56%	99.13%
<i>Legionella pneumophila</i> (LP)	93.33%	99.70%
<i>Chlamydomphila pneumoniae</i> (CP)	95.24%	100%

The clinical test was performed at the Chung-Ang Clinical Trial Center.

*Specimens(N=353)

Data

- Figures 1~3 indicates example of MP, LP, CP amplification curve.
- Figure 4 indicates an example of negative amplification curve.

Target	Dye
MP	FAM
LP	HEX
CP	TEXAS RED
Internal control	CY5

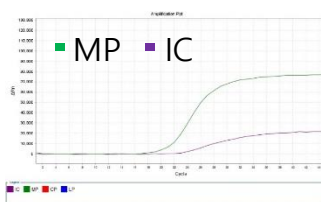


Figure 1

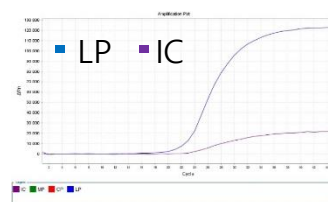


Figure 2

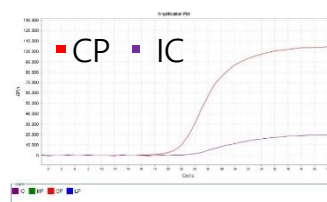


Figure 3

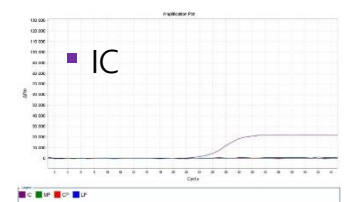


Figure 4

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EuDx™ - Detection Kit



❖ Ordering Information

Product	Unit	Category No.
EuDx™-MTB	96 tests	MC-01-96T
EuDx™-MDR TB	48 tests	TR-02-48T
EuDx™-PN MLC	48 tests	PN-02-48T

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This information is subject to change without notice

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