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EuqPia
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	Cap Color	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

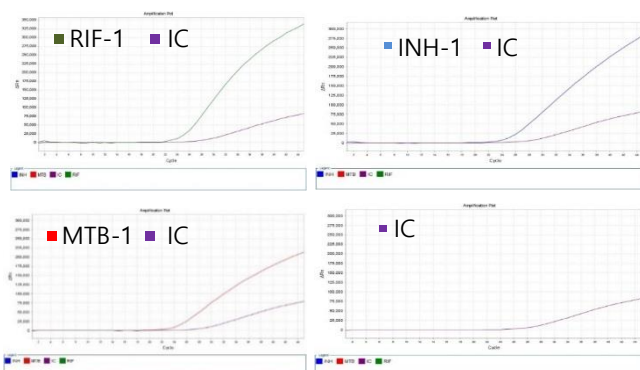


Figure 1 (Mixture 1)

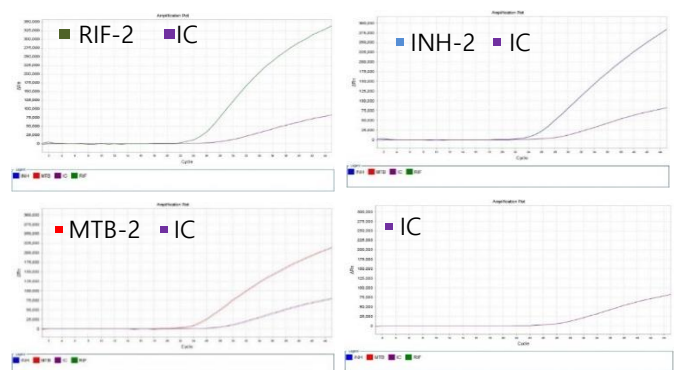


Figure 2 (Mixture 2)

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

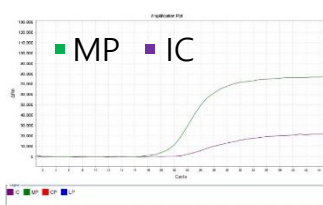


Figure 1

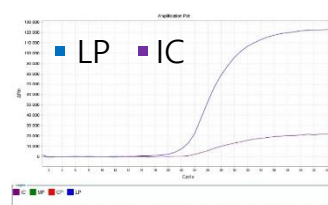


Figure 2

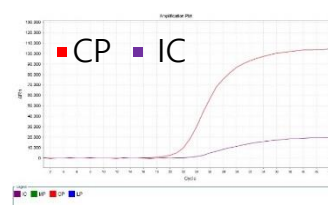


Figure 3

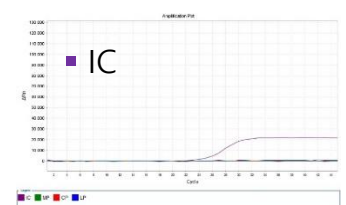


Figure 4

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EuDx™ Bordetella Detection Kit

Product Description and Components



Name : EuDx™ Bordetella Detection Kit

Core Technology : One tube Multiplex Real-Time PCR

Catalog No. : RT01-48T

Product Description : EuDx™ Bordetella Detection Kit is an in vitro diagnostic medical device that qualitatively detects two species of bacteria that cause pertussis (*Bordetella pertussis*, *Bordetella parapertussis*) using multiplex real-time PCR method in nucleic acid extracted from human nasopharyngeal swab. To detect pertussis causing bacteria, IS481, IS1001 and IS1002 genes were simultaneously amplified to improve false positives and false negatives that may occur in a single gene test.

Components

Component	Cap Color	Amount	
2X qPCR Premix	Red	500 µL	
4X Reaction Mixture (Primer/Probe + Internal Control)	Green	250 µL	48 tests
Positive Control DNA	Yellow	100 µL	
Nuclease-Free Water	Blue	1000 µL	

Data

- Figure 1 indicates an example of *B. pertussis* amplification curve.
- Figure 2 indicates an example of *B. parapertussis* curve.
- Figure 3 indicates an example of negative amplification curve.

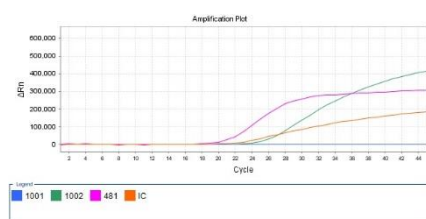


Figure 1

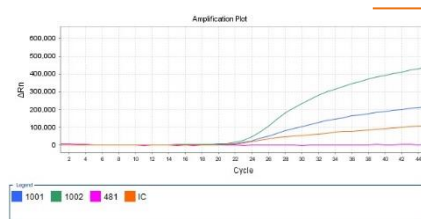


Figure 2

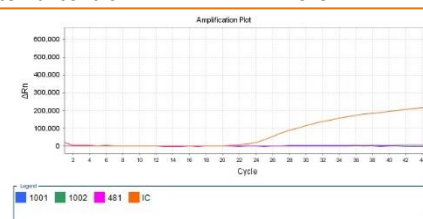


Figure 3

Target	Dye
BP (IS481)	FAM
BP, BPP (IS1002)	JOE
BPP (IS1001)	TEXAS RED
Internal control	CY5

Analytical Sensitivity

Genomic DNA isolated from *Bordetella pertussis* (DSMZ 5571), *Bordetella parapertussis* (DSMZ 13415) were diluted in five levels and repeatedly tested three times for each concentration to measure the detection limit. The test results showed $\geq 95\%$ positive detection rates in DNA until 10 copies/ μL which thus confirmed the product's limit of detection as 10 copies/ μL .

Analytical Specificity

Specificity tests were performed on genomic DNA from 35 different pathogens including eight *Bordetella* genus that could act as potential cross-reactants.

Cross reaction was not occurred.

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EuDx™

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
EuDx™ Bordetella	48 tests	RT-01-48T

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This information is subject to change without notice

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