

MOLECULAR DIAGNOSTICS TOTAL SOLUTION

CATALOG 2019/2020

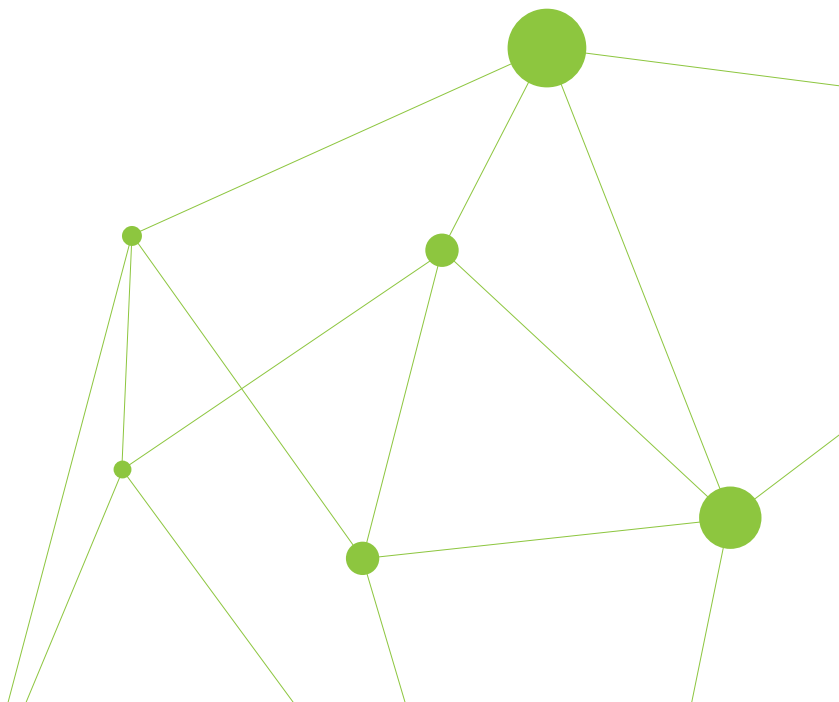
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A

Automatic Molecular Diagnostics System



ExiStation™ Universal Molecular Diagnostic System

Molecular diagnostics(MDx) is one of the *in vitro* diagnostic method composed with nucleic acid extraction, Real-Time PCR and results analysis. The features of MDx are high sensitivity and specificity. To maximize the features, MDx systems with superior performance is needed.

ExiStation™ series are the MDx system which have been developed BIONEER's patent technologies. This series is composed with ExiStation™, ExiStation™ 48 and ExiStation™ 48A.

All ExiStation™ system have a several common advantages.

- Various options according to scale of laboratory
- Able to detect tiny copies of pathogen in samples owing to built-in quality control system
- Simultaneous diagnosis of various targets since all AccuPower® kits have same thermal cycle condition using Exicycler™ 96
- User friendly process due to pre-installed protocol and streamlined workflow using ExiStation™ Manager software



ExiStation™

- Able to handle up to 48 samples with combination of 1-3 ExiPrep™ 16 Dx and an Exicycler™ 96
- Available for simultaneous diagnosis of various diseases: For example, HIV, STI and TB can be detected simultaneously since ExiPrep™ 16 Dx can extract nucleic acid from different specimen at the same time




ExiStation™ 48 / 48A

- Nucleic acid extraction from 48 samples within an hour
- Enhanced usability with built in automatic cartridge puncher and three options of sample volume, 200, 400 and 800 µl
- Use primary tube directly: all process is automated such as decapping/capping of sample tube and sample transfer*
- Input sample information automatically by using built-in barcoding system*

* Only apply to ExiStation™ 48A.

■ ExiStation™ Configuration

	<i>ExiStation™</i>	<i>ExiStation™ 48</i>	<i>ExiStation™ 48A</i>
Instruments	 <ul style="list-style-type: none"> ○ <i>ExiPrep™</i> 16 Dx (1-3 ea) ○ <i>Exicycler™</i> 96 (1 ea) ○ <i>ExiSpin™</i> (1 ea) ○ Notebook PC (1 ea) 	 <ul style="list-style-type: none"> ○ <i>ExiPrep™</i> 48 Dx (1 ea) ○ <i>Exicycler™</i> 96 (1 ea) ○ <i>ExiSpin™</i> (2 ea) 	 <ul style="list-style-type: none"> ○ <i>ExiLT</i> (1 ea) ○ <i>ExiPrep™</i> 48 Dx (1 ea) ○ <i>Exicycler™</i> 96 (1 ea) ○ <i>ExiSpin™</i> (2 ea)
Nucleic Acid Extraction Kit	<ul style="list-style-type: none"> ○ <i>ExiPrep™</i> Dx Kits 	<ul style="list-style-type: none"> ○ <i>ExiPrep™</i> 48 Kits 	
Real-Time PCR Kit	<ul style="list-style-type: none"> ○ <i>AccuPower®</i> Real-Time PCR Kits 		

■ Workflow

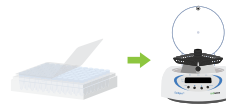
1 Sample Transfer



2 Nucleic Acid Extraction



3 Sealing & Centrifugation



4 Real-Time PCR



<i>ExiStation™</i>	<ul style="list-style-type: none"> ○ Transfer sample to sample tube ○ Insert components into <i>ExiPrep™</i> 16 Dx 	<ul style="list-style-type: none"> ○ Select protocol and run Use 1, 2 or 3 instruments 	<ul style="list-style-type: none"> ○ Seal PCR tube ○ Vortexing and Centrifugation using <i>ExiSpin™</i> 	<ul style="list-style-type: none"> ○ Run Real-Time PCR using <i>Exicycler™</i> 96 ○ Result analysis using <i>ExiStation™</i> Manager software
<i>ExiStation™ 48</i>	<ul style="list-style-type: none"> ○ Transfer sample to sample tube ○ Insert components into <i>ExiPrep™</i> 48 Dx 			
<i>ExiStation™ 48A</i>	<ul style="list-style-type: none"> ○ Input primary tube and components into <i>ExiLT</i> ○ Automatically transfer sample to <i>ExiPrep™</i> 48 Dx 	<ul style="list-style-type: none"> ○ Select protocol and run 		

■ Nucleic Acid Extractor



ExiPrep™ 16 Dx

- Simultaneous nucleic acid extraction from various types of clinical samples
 - Each of 3 ExiPrep™ 16 Dx extracts different targets at once
- Handle Max. 48 samples in 90 min
 - Each ExiPrep™ 16 Dx handles 16 samples in 90 min



ExiPrep™ 48 Dx

- Handle Max. 48 samples in an hour
- Various option of sample volume: 200, 400 and 800 µl
- Able to use primary tube by docking ExiLT
- Superior usability with built in auto-puncher and wide touch screen



ExiPrep™ 96 Lite

- Increased space efficiency by compact size
- High through-put and fast
 - Handle Max. 96 samples in a run
 - Outstanding walkaway time: approx. 40min
- Flexible sample volume
 - 24 test x 4 ml(cfDNA)
 - 96 test x 400 µl(genomic DNA)

* ExiPrep™ 96 Lite can not be used in ExiStation™ mode.

■ Real-Time PCR



Exicycler™ 96

- Superior sensitive optics by light polarization, which remove are flection light, allowing precise quantification and identification
- Improved thermal block ramping rate
 - Reduced run time by 25% (Max. 96 samples in 90 min)
 - Normal block (Max. 4.5°C/sec), Fast block (Max. 5.0°C /sec)
- 5 channel multiplex detection without use of a reference dye

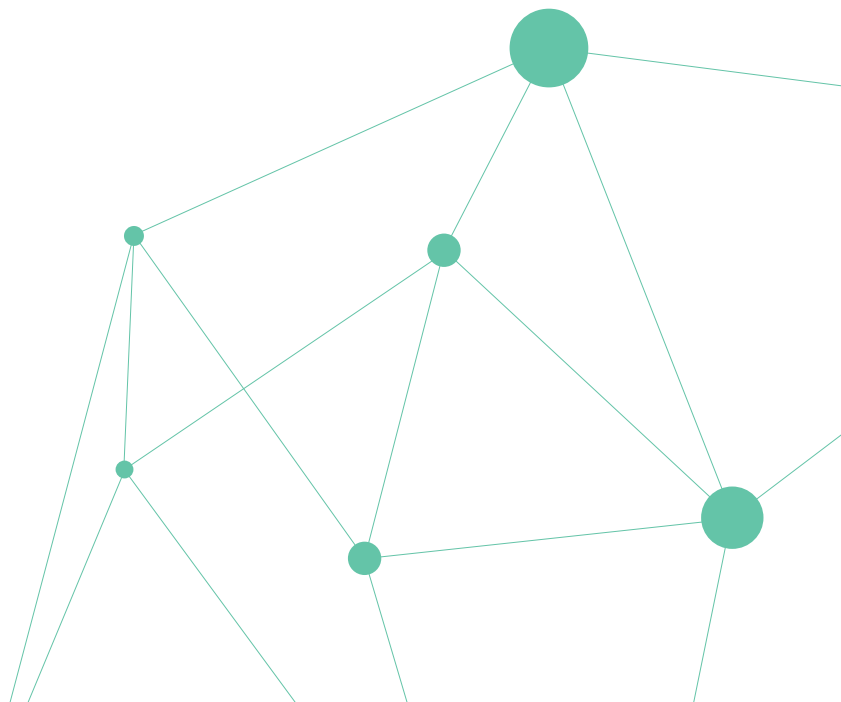
■ Related Products

Cat. No.	Product Name	Test/run
A-2200-N	ExiStation™	96
A-2400	ExiStation™ 48	96
A-2410	ExiStation™ 48A	96
A-5050	ExiPrep™ 16 Dx	16
A-5150	ExiPrep™ 48 Dx	48
A-5250	ExiPrep™ 96 Lite	96
A-2060-1	Exicycler™ 96	96
A-7040	ExiSpin™	32

B

Nucleic Acid Extraction Kits

01. <i>ExiPrep</i> [™] Nucleic Acid Extraction Kits	8
02. <i>ExiPrep</i> [™] Dx Nucleic Acid Extraction Kits	10
03. <i>ExiPrep</i> [™] 48 Nucleic Acid Extraction Kits	11
04. <i>ExiPrep</i> [™] 96 Nucleic Acid Extraction Kits	12
05. <i>MagListo</i> [™] cfDNA Extraction Kit	13



Success in molecular diagnostic detection and analysis requires effective method in the nucleic acid extraction from various sample types. For that, *ExiPrep™* Nucleic Acid Extraction Kit series provide a convenient and efficient method for the isolation and purification of nucleic acids from a variety of samples including blood, urine, sputum, BAL, swabs and so on.

And also, *MagListo™* cfDNA Extraction Kit allows cfDNA extraction with superior purity and yield. More convenient extraction than column type extraction since it does not need centrifugation due to using magnetic bead. Based on this, Bioneer's kits offer various isolation systems for special testing purpose, assuring high-quality nucleic acid purification.

■ Features & Benefits

- Many of target nucleic acids can be extracted simultaneously.
- Optimized protocols for nucleic acid extraction according to sample types are pre-installed for reproducible results*
- Using silica magnetic beads developed and produced with Bioneer's technology
- In case of using sputum specimen, EZ solution allows more efficient pretreatment process*

* The features does not apply to *MagListo™* Kit

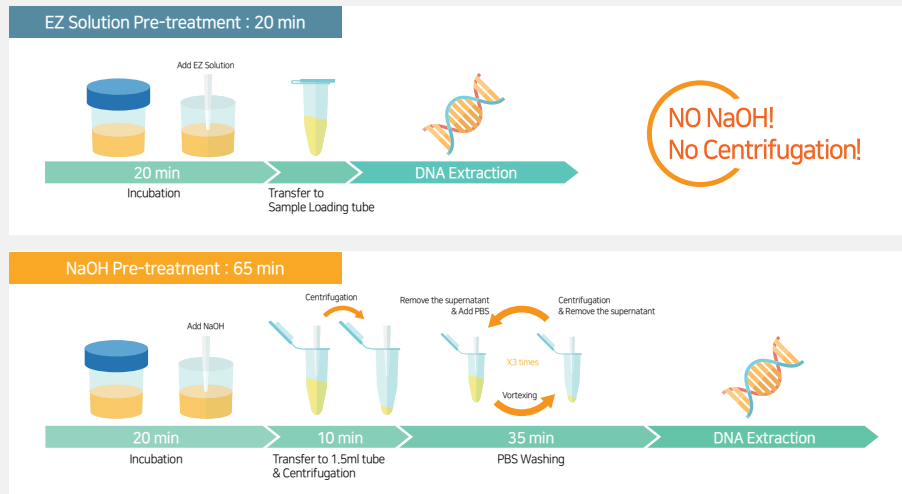
■ Selection Guide

Assay \ Nucleic Acid Extraction Kit	<i>ExiPrep™</i> 16 Dx				
	<i>ExiPrep™</i> Dx Viral DNA/RNA Kit	<i>ExiPrep™</i> Dx Viral DNA Kit	<i>ExiPrep™</i> Dx Viral RNA Kit	<i>ExiPrep™</i> Dx Blood Viral DNA Kit	<i>ExiPrep™</i> Dx Bacterial Genomic DNA Kit
HIV-1	●		●		
HBV	●	●			
HCV	●		●		
Tuberculosis					●
Sexually Transmitted Infection					●
Human Papillomavirus	●	●			
Respiratory Virus	●		●		
Pneumonia					●
Gastrointestinal Virus	●		●		
CMV, EBV	●	●		●	
BKV	●	●			
ZIKV, DENV, CHIKV	●		●		
Human Genotyping					

EZ Solution

EZ Solution is easy sputum liquefying solution. The sputum pretreatment procedure using EZ Solution doesn't require time consuming Centrifugation and washing steps. This innovation makes the sputum treatment simpler, faster and even more effective compared to the method using NaOH.

EZ Solution vs NaOH: Sputum Pretreatment



Comparison of pretreatment of sputum using EZ Solution and 1N NaOH. The process using EZ Solution is simpler, faster and even effective. No Centrifugation and washing steps are required.

		ExiPrep™ 48 Dx			ExiPrep™ 96 Lite
ExiPrep™ Dx Mycobacteria Genomic DNA Kit	ExiPrep™ Dx Blood Genomic DNA Kit	ExiPrep™ 48 Viral DNA/RNA Kit	ExiPrep™ 48 Viral RNA Kit	ExiPrep™ 48 Genomic DNA Kit	ExiPrep™ 96 Genomic DNA Kit
		●	●		
		●			
		●	●		
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	●			●	

ExiPrep™ Dx Nucleic Acid Extraction Kits

Specifications

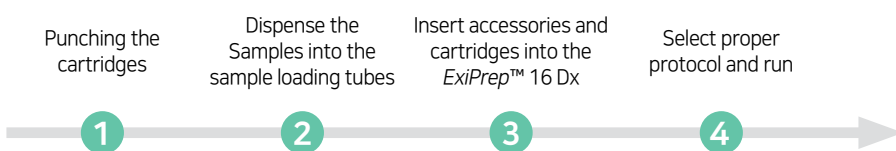
Cat. no.	Product Name	Target	Sample types	Initial volume	Elution volume	Certification
K-4471	ExiPrep™ Dx Viral DNA/RNA Kit	Virus	Serum, Plasma, Swab, Urine, Stool, CSF	400 µℓ	50 µℓ	CE
K-4472	ExiPrep™ Dx Viral DNA Kit					
K-4473	ExiPrep™ Dx Viral RNA Kit					
K-4474	ExiPrep™ Dx Blood Viral DNA Kit		Human whole blood	200 µℓ		
K-4414	ExiPrep™ Dx Bacteria Genomic DNA Kit	Bacteria	Sputum, Urine, Swab	400 µℓ		
K-4418	ExiPrep™ Dx Mycobacteria Genomic DNA Kit	Mycobacteria	Sputum, Urine, BAL			
K-4411	ExiPrep™ Dx Blood Genomic DNA Kit	Human Cell	Human whole blood	200 µℓ	70 µℓ	

Component

No.	Name	Composition
1	Buffer cartridge ① & ②	Each 6ea
2	Disposable filter tip (32ea)	3 packs
3	Elution tube (12ea) & Contamination shield filter paper (12ea)	Each 1 pack
4	Sample loading tube	6 packs
5	Protection cover (3ea)	4 packs
6	Waste tray (3ea)	1 pack



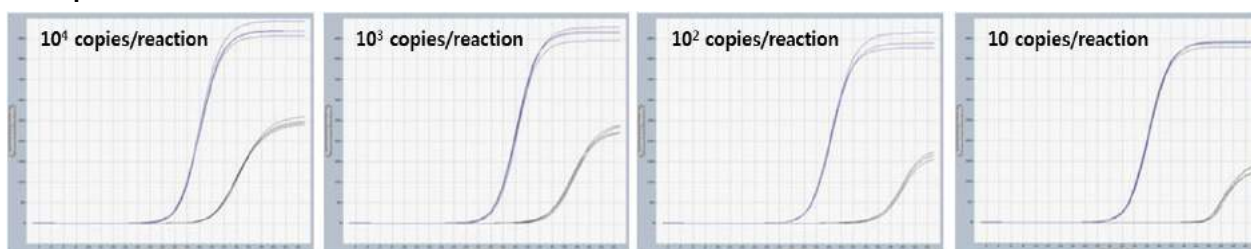
Workflow



After 90 Min!

Completion of extraction from 16 samples and automated dispensing of DNA/RNA into the PCR tube

Experimental Data



Quantification of HBV viral load was performed to evaluate ExiPrep™ Dx Viral DNA Kit. Viral DNA was extracted from serum using the kit, and Real-Time PCR was performed with the HBV Quantitative PCR Kit on Exicycler™ 96 (Black signal; HBV, Blue signal; IPC).

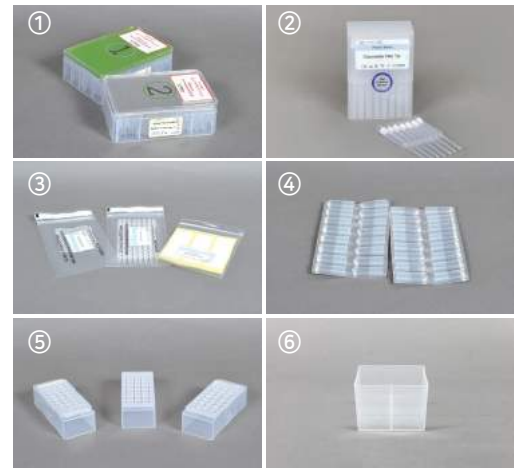
ExiPrep™ 48 Nucleic Acid Extraction Kits

■ Specification

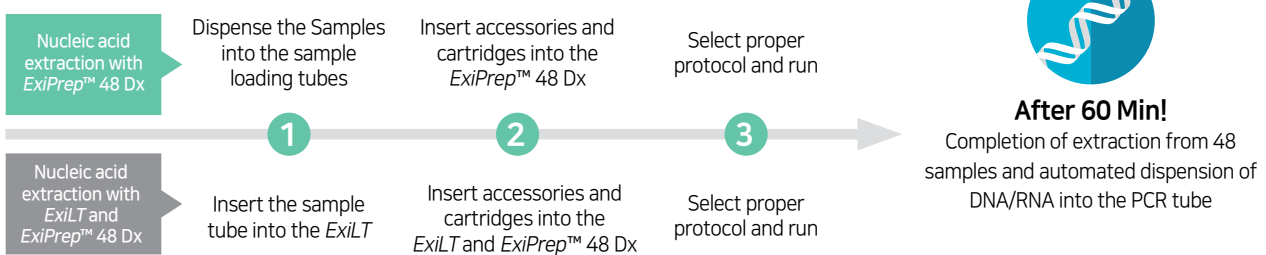
Cat. no.	Product Name	Target	Sample types	Initial volume	Elution volume	Certification
K-4571	ExiPrep™ 48 Viral DNA/RNA Kit	Virus	Serum, Plasma, Swab, Urine, Stool, CSF	400 µl, 800 µl	50 µl	CE
			Human whole Blood	200 µl		
K-4573	ExiPrep™ 48 Viral RNA Kit		Serum, Plasma, Swab, Urine, Stool, CSF	400 µl, 800 µl		
K-4574	ExiPrep™ 48 Genomic DNA Kit	Bacteria	Sputum, Urine, Swab	400 µl, 800 µl		
		Mycobacteria	Sputum, Urine, BAL			
		Human Cell	Human whole blood	200 µl, 400 µl		

■ Component

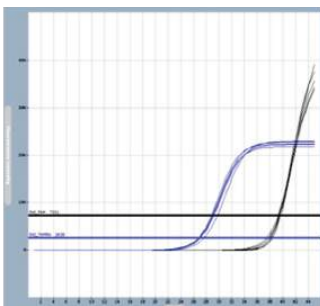
No.	Name	Composition
1	Buffer cartridge ① & ②	Each 6ea
2	Disposable filter tip (32ea)	6 packs
3	Elution tube (12ea) & Contamination shield filter paper (12ea)	Each 1 pack
4	Sample loading tube	6 packs
5	Protection cover (3ea)	4 packs
6	Waste tray (3ea)	2 packs



■ Workflow



■ Experimental Data



	HCV	IPC
Replicate 1	39.43	27.11
Replicate 2	39.72	26.97
Replicate 3	39.54	27.7
Replicate 4	39.5	26.81
Replicate 5	39.29	27.02

The HCV RNA extracted by ExiPrep™ 48 DNA/RNA Kit was used for panel test of AccuPower® HCV Quantitative RT-PCR Kit. The regular results indicate that nucleic acids extraction produce high reproducibility. (Black signal; HCV, Blue signal; IPC).

ExiPrep™ 96 Nucleic Acid Extraction Kits

■ Specification

Cat. no.	Product Name	Target	Sample types	Initial volume	Elution volume	Tests
K-4611	ExiPrep™ 96 Genomic DNA Kit	Bacteria	Sputum, Urine, Swab, Body fluid, Stool	400 µl	100 µl	384
K-4612	ExiPrep™ 96 cfDNA Kit	cfDNA	Plasma, Serum, Urine, Saliva	400 µl - 4 ml	100 µl	96

■ Component

- for Genomic DNA Extraction

No.	Name	Composition
1	Buffer Cartridge ① - ⑦	Each 4ea
2	Resuspension buffer	4ea
3	Magnetic Rod Cover	12ea
4	Sealing Film	8ea

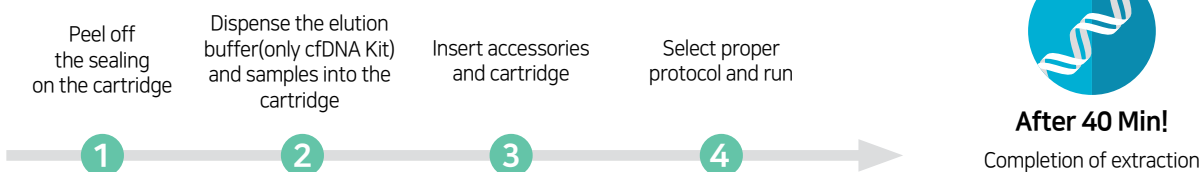


- for cfDNA Extraction

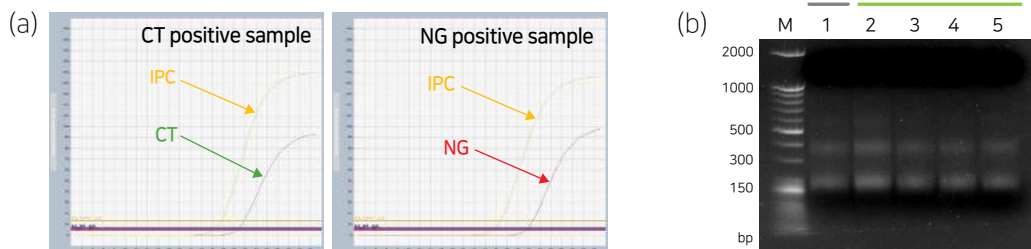
No.	Name	Composition
1	Buffer Cartridge ① - ⑦	Each 4ea
2	Elution buffer	1ea
3	Proteinase K	4ea
4	Magnetic Rod Cover	12ea
5	Sealing Film	8ea



■ Workflow



■ Experimental Data



(a) The CT and NG DNA extracted by ExiPrep™ 96 Genomic DNA Kit were used for test of AccuPower® CT&NG Real-Time PCR Kit on Exicycler™ 96. (Red signal; NG, Green signal; CT, Yellow signal; IPC)

(b) Result of cfDNA extraction test using ExiPrep™ 96 cfDNA Kit. 4ml serum samples were used. (cfDNA size: 175~180 bp, 330~350 bp)

MagListo™ cfDNA Extraction Kit

Specifications

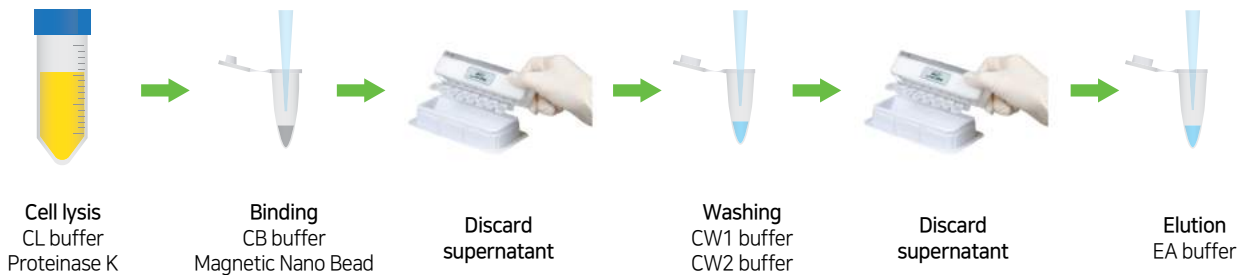
Cat. no.	Product Name	Target	Sample types	scale	Initial volume	Elution volume
K-3619M	MagListo™ cfDNA Extraction Kit	cfDNA	Plasma, Serum, Urine, Saliva	Mini	1 ml	30 µl
				Midi	3 ml	50 µl
				Maxi	5 ml	70 µl

Component

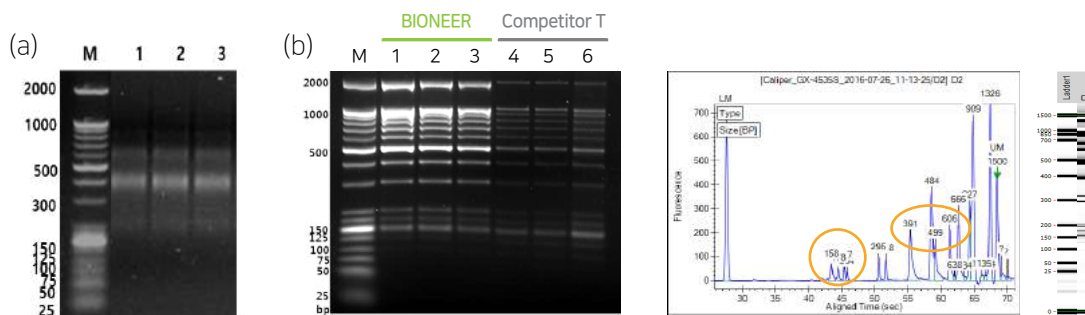
No.	Name	Composition
1	CL buffer, CB buffer, CW1 buffer, CW2 buffer, EA buffer	Each 1ea
2	Magnetic Nano Bead-DNA	6ea
3	Proteinase K powder	2ea



Workflow



Experimental Data

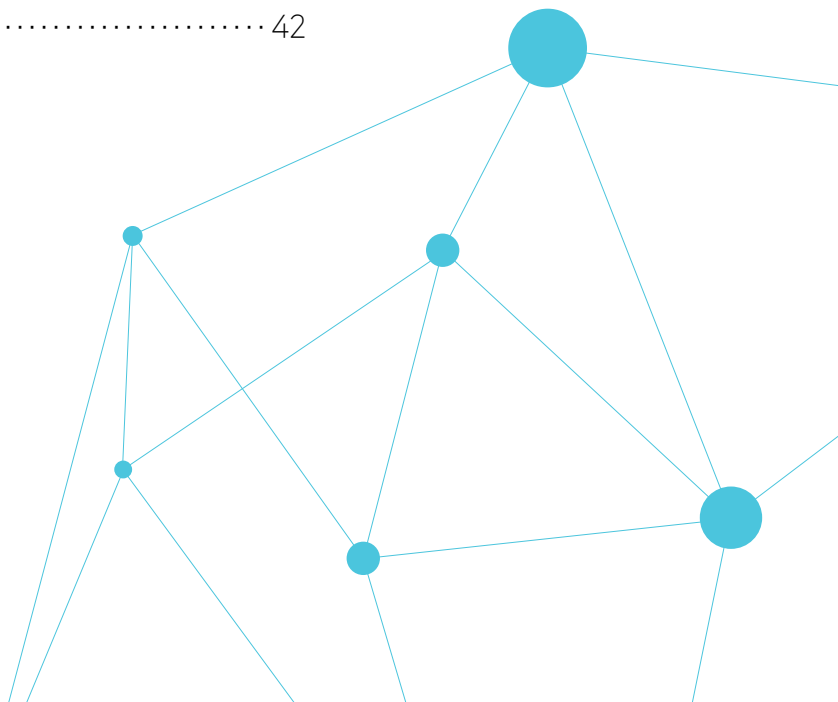


(a) Extracted cfDNA using MagListo™ cfDNA Extraction Kit from serum.

(b) Comparison of cfDNA purification yield between MagListo™ kit and competitor's kit using EDTA plasma sample.

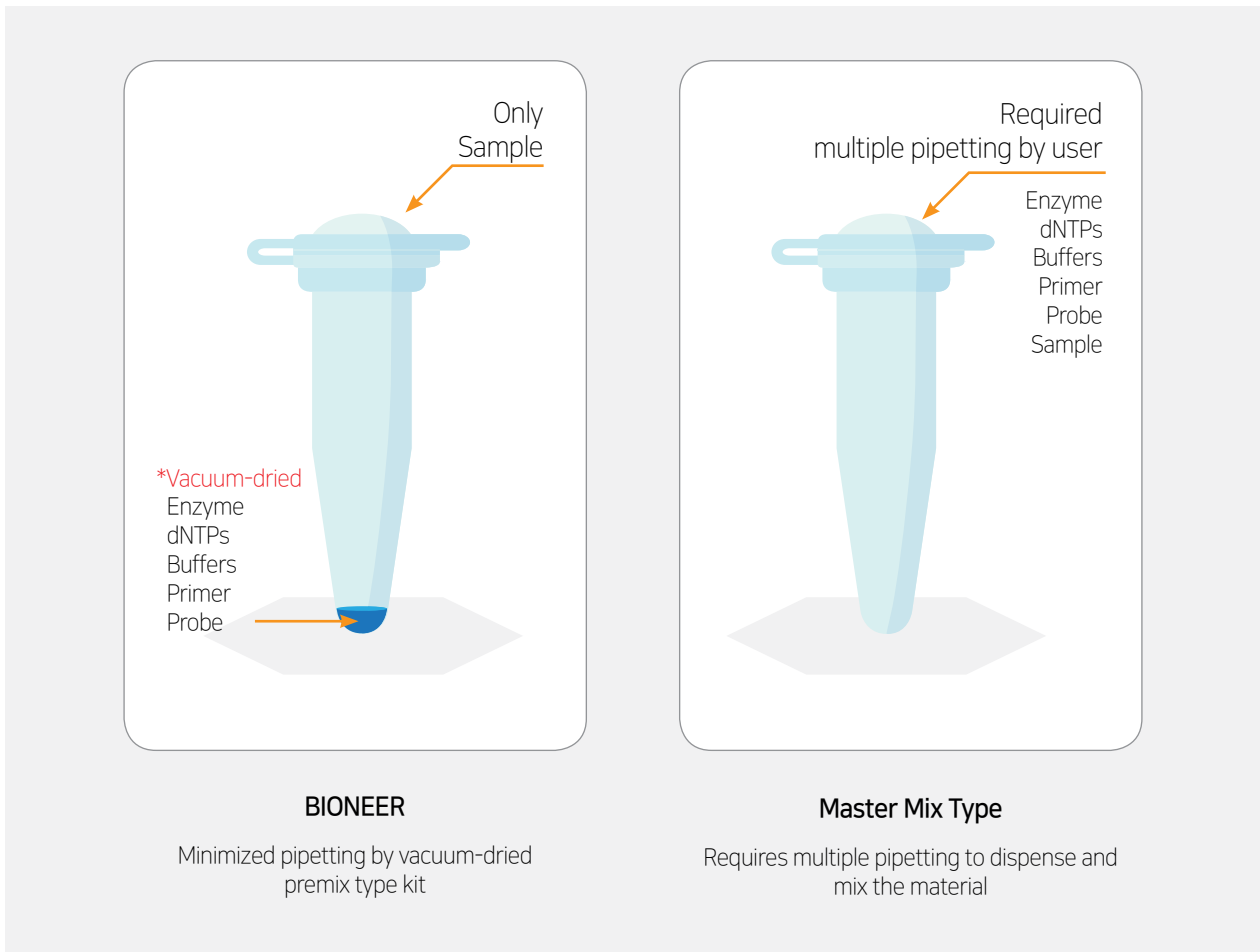
C Real-Time PCR Diagnostic Kits

01. <i>AccuPower</i> [®] Real-Time PCR Diagnostic Kits	16
02. Human Immunodeficiency Virus	18
03. Hepatitis Virus	19
04. <i>Mycobacterium Tuberculosis</i>	21
05. Sexually Transmitted Infection	26
06. Transplantation-related Virus	31
07. Human Papillomavirus	34
08. Respiratory Pathogen	35
09. Gastrointestinal Virus	39
10. Mosquito borne disease (ZIKV, DENV and CHIKV)	41
11. Human Genotyping	42



AccuPower® Real-Time PCR Diagnostic Kits

AccuPower® Real-Time PCR Diagnostic Kits are vacuum-dried qPCR and RT-qPCR premixes. All components necessary for Real-Time PCR are contained within one tube, which increases the stability of reagents and simplifies reaction setup. Due to this simplified setup, AccuPower® technology is ideal for automated molecular diagnostics. Furthermore, AccuPower® Real-Time PCR Diagnostic Kits use proprietary stabilization technology that preserves the full activity of the mixed reagents, and patented HotStart technology (US 14383793) that enhances sensitivity and specificity of the kits.



I MDx Technology

Dual-HotStart[™] Technology

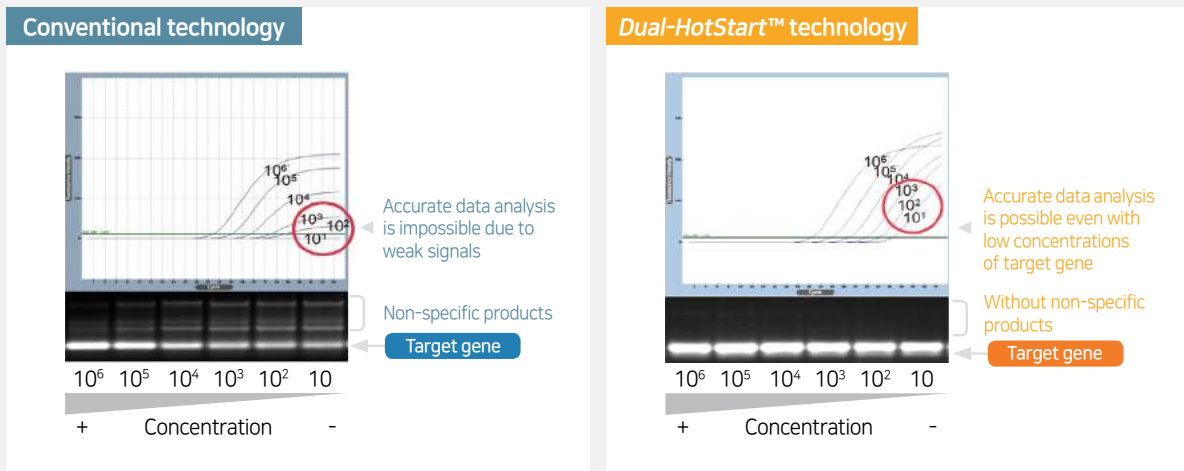
The most important aspects in diagnosis are specificity and sensitivity, which decide accuracy of diagnosis. Since accurate diagnosis will lead to proper treatment, it is directly related to patient's health and even lives.

Dual-HotStart[™] technology is unique diagnostic technology developed by Bioneer in order to enhance quality and save millions of lives. This technology is a method to detect RNA target from clinical samples with high sensitivity and specificity. This technology utilizes Bioneer's unique enzyme-mediated HotStart method for both reverse transcription and PCR amplification.

Dual-HotStart[™] eliminates non-specific cDNA synthesis and non-specific DNA amplification and allows for the most sensitive one-step RT-qPCR assays available.

■ Features

- *Dual-HotStart*[™] RT-qPCR reactions is key technology of accurate diagnosis with Pyro-HotStart RT and HotStart PCR
- Maximize sensitivity by extending the reaction through pyrophosphate cleanup with pyrophosphatase
- Increase specificity by preventing non-specific zero-cycle product formation



Serial dilutions of HCV RNA were amplified by conventional RT-PCR (left panel) and *Dual-HotStart*[™] RT-PCR (right panel). The results suggest that *Dual-HotStart*[™] RT-PCR enables highly sensitive detection of low copies of RNA target by eliminating non-specific cDNA synthesis and nonspecific PCR amplification.

AccuPower® HIV-1 Quantitative RT-PCR Kit CE 0197

Human immunodeficiency virus (HIV) is recognized as a known viral agent that causes Acquired Immune Deficiency Syndrome (AIDS). Thus, monitoring of viral load in HIV-1 infection patients is an essential test for establishment of therapeutic strategy and determination of therapeutic progress. The AccuPower® HIV-1 Quantitative RT-PCR Kit is an *in vitro* diagnostic kit designed for the quantification of HIV-1 RNA in human EDTA-plasma samples through Real-Time polymerase chain reaction (PCR) using ExiStation™ MDx System.

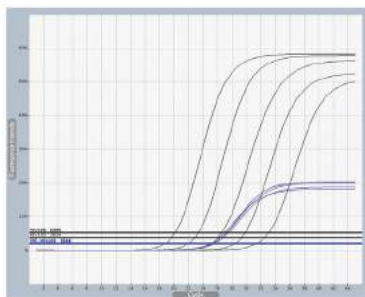
Specification

Target	Sample Type	Components	Instruments
HIV-1	EDTA-Plasma	PCR Premix(96 rxn), SPCs(S1~S5), PCs(LPC, HPC), NTC, SL Buffer, Optical sealing film	ExiStation™

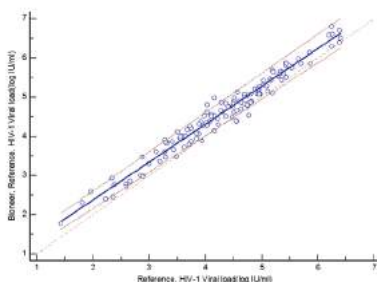
Features & Benefits

- Simultaneous diagnostics with Bioneer’s HBV and HCV Kits via ExiStation™ Manager software
- Highly sensitive detection of various HIV-1 subtypes including group M (A, B, C, D, AE, F, AG, G, H, and several CRFs), N and O
- Superior repeatability and reproducibility
- High reliability through Internal Positive Control and Low/High Positive Controls
- Simultaneous combination IVD test with Bioneer’s TB and STIs series kits by ExiStation™ Manager software

Testing results



Standard Positive Controls (S1 ~ S5) of AccuPower® HIV-1 Quantitative RT-PCR Kit. Black signal; HIV-1, Blue signal; IPC



Regression analysis between AccuPower® HIV-1 Quantitative RT-PCR Kit and CE-IVD approved HIV-1 NAT assay. ($R^2= 0.96$ ($p<0.001$))

*Blue Solid line: Regression line, Dashed line: 95% CI, Dotted line : Y=X

Diagnostic Sensitivity (Percent positive agreement)	96.99% (95% C.I 92.52 – 98.82)
Diagnostic Specificity (Percent negative agreement)	100% (95% C.I 96.92 – 100)

The performance of AccuPower® HIV-1 Quantitative RT-PCR Kit was compared to that of CE-IVD approved HIV-1 NAT assay by analysis of paired clinical specimen from 254 samples.

Related Products

Cat. No.	Kit name	Target	Tests
HIV-1211	AccuPower® HIV-1 Quantitative RT-PCR Kit (CE List A Ver.)	HIV	96
HIV-1111	AccuPower® HIV-1 Quantitative RT-PCR Kit		

Hepatitis Virus

AccuPower® HBV Quantitative PCR Kit CE 0197

Hepatitis B is a viral infection that attacks the liver and can cause both acute and chronic liver disease. Hepatitis B is transmitted through blood and infected bodily fluids. Thus, the quantification of hepatitis B virus (HBV) DNA in blood is essential for monitoring of HBV infection. The *AccuPower*® HBV Quantitative PCR Kit is an *in vitro* diagnostic kit designed for the quantification of HBV DNA in human EDTA-plasma samples through Real-Time PCR using *ExiStation*™ MDx System or *Exicycler*™ 96.

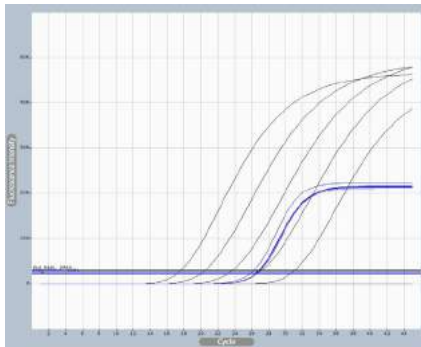
Specification

Target	Sample Type	Components	Instruments
HBV	Serum, EDTA-Plasma	PCR Premix(96 rxn), SPCs(S1~S5), PCs(LPC, HPC), IPC, NTC, DEPC-D.W, SL Buffer, Optical sealing film	<i>ExiStation</i> ™

Features & Benefits

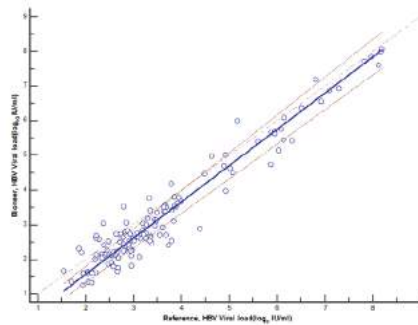
- Simultaneous diagnostics with Bioneer's HIV-1 and HCV Kits via *ExiStation*™ Manager software
- Superior repeatability and reproducibility
- High reliability through Internal Positive Control
- Specific Real-Time PCR reaction using Enzyme-mediated *HotStart*™ technology

Testing results



Standard Positive Controls (S1 ~ S5) of *AccuPower*® HBV Quantitative PCR Kit.

Black signal; HBV, Blue signal; IPC



Regression analysis between *AccuPower*® HBV Quantitative PCR Kit and CE-IVD approved HBV viral load NAT assay. ($R^2 = 0.936$)

*Blue Solid line : Regression line, Dashed line: 95 % CI, Dotted line : Y=X

Diagnostic Sensitivity (Percent positive agreement)	100 % (95% C.I 97.19 - 100)
Diagnostic Specificity (Percent negative agreement)	100 % (95% C.I 96.65 - 100)

The performance of *AccuPower*® HBV Quantitative PCR Kit was compared to that of CE-IVD approved HBV viral load assay by analysis of paired clinical specimens from 244 samples.

Related Products

Cat. No.	Kit name	Target	Tests
HBV-1211	<i>AccuPower</i> ® HBV Quantitative PCR Kit (CE List A Ver.)	HBV	96
HBV-1111	<i>AccuPower</i> ® HBV Quantitative PCR Kit		
HCV-1211	<i>AccuPower</i> ® HCV Quantitative RT-PCR Kit (CE List A Ver.)	HCV	96
HCV-1111	<i>AccuPower</i> ® HCV Quantitative RT-PCR Kit		

Hepatitis Virus

AccuPower® HCV Quantitative RT-PCR Kit CE 0197

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV). About 80% of those exposed to the virus develop a chronic infection. Guidelines for the management and treatment of HCV recommend quantitative testing for HCV RNA before, during and after the antiviral therapy. The *AccuPower*® HCV Quantitative RT-PCR Kit is an *in vitro* diagnostic kit designed for the quantification of HCV RNA in clinical samples through Real-Time PCR using *ExiStation*™ MDx System.

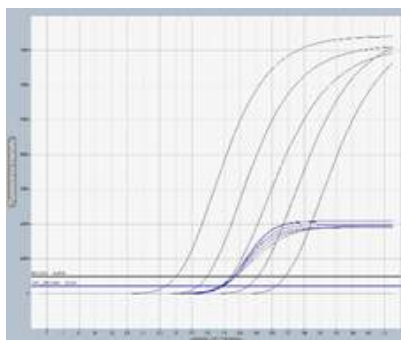
Specification

Target	Sample Type	Components	Instruments
HCV	Serum, EDTA-Plasma	PCR Premix(96 rxn), SPCs(S1~S5), PCs(LPC, HPC), NTC, SL Buffer, Optical sealing film	<i>ExiStation</i> ™

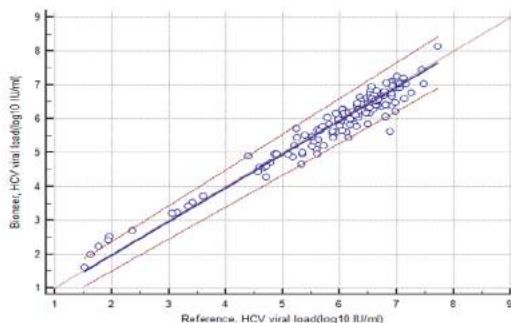
Features & Benefits

- Simultaneous diagnostics with Bioneer's HIV-1 and HBV Kits via *ExiStation*™ Manager software
- Superior repeatability and reproducibility
- High reliability through Internal Positive Control
- One-Step Real-Time RT-PCR reaction using *RocketScript*™ Reverse Transcriptase and *Dual-HotStart*™ technology

Testing results



Standard Positive Controls (S1 ~ S5) of *AccuPower*® HCV Quantitative RT-PCR Kit. **Black signal;** HCV, **Blue signal;** IPC



Regression analysis between *AccuPower*® HCV Quantitative RT-PCR Kit and CE-IVD approved HCV viral load NAT assay. ($R^2 = 0.9435$)

*Blue Solid line : Regression line, Dashed line : 95 % CI, Dotted line : Y=X

Diagnostic Sensitivity (Percent positive agreement)	99.26 % (95% C.I 95.92 – 99.87)
Diagnostic Specificity (Percent negative agreement)	99.12 % (95% C.I 95.21 – 99.84)

The performance of *AccuPower*® HCV Quantitative RT-PCR Kit was compared to that of CE-IVD approved HCV NAT assay by analysis of paired clinical specimens from 250 samples.

Related Products

Cat. No.	Kit name	Target	Tests
HBV-1211	<i>AccuPower</i> ® HBV Quantitative PCR Kit (CE List A Ver.)	HBV	96
HBV-1111	<i>AccuPower</i> ® HBV Quantitative PCR Kit		
HCV-1211	<i>AccuPower</i> ® HCV Quantitative RT-PCR Kit (CE List A Ver.)	HCV	96
HCV-1111	<i>AccuPower</i> ® HCV Quantitative RT-PCR Kit		

*Mycobacterium Tuberculosis***AccuPower® MTB&NTM Real-Time PCR Kit** 

Tuberculosis (TB) is caused by a bacterium called *M.tuberculosis*. The bacteria usually attack the lungs, but TB can attack any part of the body such as the kidney, spine, and brain. It can affect mainly the lungs (pulmonary TB). Nontuberculous mycobacteria (NTM) are a group of bacteria, normally found in soil and water and some domestic and wild animals that can cause severe lung disease. The *AccuPower®* MTB&NTM Real-Time PCR Kit is an *in vitro* diagnostic kit designed for the simultaneous detection of *M. tuberculosis* and NTM DNA in clinical samples through Real-Time PCR using *ExiStation™* MDx System or *Exicycler™* 96.

Specification

Target	Sample Type	Components	Instruments
<i>Mycobacterium tuberculosis</i> Non-tuberculous mycobacteria	Sputum, BAL, Urine	PCR Premix(96 rxn), MTB&NTM PC, IPC, NTC, DEPC-D.W, Optical sealing film	<i>ExiStation™</i> , <i>Exicycler™</i> 96

Features & Benefits

- Highly sensitive detection of TB
- A broad range of detection of 57 NTM species including the most common 8 species listed below
 - *M.avium*, *M.intracellulare*, *M.abscessus*, *M.chelonae*,
M.kansasii, *M.fortuitum*, *M.gordonae*, *M.massiliense*
- Simplified procedure of sputum pretreatment with EZ Solution

Testing results

Detection of TB and NTM Positive Control using *Exicycler™* 96. **Black signal**; MTB, **Red signal**; NTM, **Blue signal**; IPC

Related Products

Cat. No.	Kit name	Target	Tests
MTN-1111	<i>AccuPower®</i> MTB&NTM Real-Time PCR Kit	<i>Mycobacterium tuberculosis</i> , Non-tuberculous mycobacteria	96
MTB-1111	<i>AccuPower®</i> MTB Real-Time PCR Kit	<i>Mycobacterium tuberculosis</i>	96
TBMDR-1111	<i>AccuPower®</i> TB&MDR Real-Time PCR Kit	<i>Mycobacterium tuberculosis</i> , Multidrug-resistant Tuberculosis	48
XDRA-1111	<i>AccuPower®</i> XDR-TB Real-Time PCR Kit-A	Extensively drug-resistant tuberculosis	48
XDRB-1111	<i>AccuPower®</i> XDR-TB Real-Time PCR Kit-B	<i>Mycobacterium tuberculosis</i> , Extensively drug-resistant tuberculosis	96

AccuPower® MTB Real-Time PCR Kit C €

Tuberculosis (TB) is an infection caused by the bacteria called the tubercle bacillus or *Mycobacterium tuberculosis* (MTB). Until effective anti-tuberculosis drugs were introduced about 50 years ago, TB was one of the main causes of death. TB is still a major problem in many countries, especially developing countries.

It can affect mainly the lungs (pulmonary TB). In most cases, lung infection is well controlled by the immune system, and shows no symptoms. Active lung disease occurs if the immune system becomes less effective. Symptoms of pulmonary TB include fever, fatigue, loss of appetite and weight, night sweats and persistent cough. Tuberculous pleurisy leads to an accumulation of fluid in the pleural cavity and partial collapse of the lung.

The AccuPower® MTB Real-Time PCR Kit is an *in vitro* diagnostic kit designed for the simultaneous detection of *M. tuberculosis* DNA in clinical samples through Real-Time PCR using ExiStation™ MDx System or Exicycler™ 96.

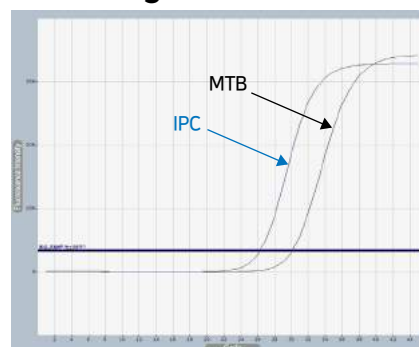
Specification

Target	Sample Type	Components	Instruments
<i>Mycobacterium tuberculosis</i>	Sputum, BAL, Urine	PCR Premix(96 rxn), MTB PC, IPC, NTC, DEPC-D.W, Optical sealing film	ExiStation™, Exicycler™ 96

Features & Benefits

- Highly sensitive detection of TB
- Highly reliability through IPC, PC and NTC
- Simplified procedure of sputum pretreatment with EZ Solution

Testing results



Detection of TB Positive Control using Exicycler™ 96. Black signal; MTB, Blue signal; IPC

Related Products

Cat. No.	Kit name	Target	Tests
MTN-1111	AccuPower® MTB&NTM Real-Time PCR Kit	<i>Mycobacterium tuberculosis</i> , Non-tuberculous mycobacteria	96
MTB-1111	AccuPower® MTB Real-Time PCR Kit	<i>Mycobacterium tuberculosis</i>	96
TBMDR-1111	AccuPower® TB&MDR Real-Time PCR Kit	<i>Mycobacterium tuberculosis</i> , Multidrug-resistant Tuberculosis	48
XDRA-1111	AccuPower® XDR-TB Real-Time PCR Kit-A	Extensively drug-resistant tuberculosis	48
XDRB-1111	AccuPower® XDR-TB Real-Time PCR Kit-B	<i>Mycobacterium tuberculosis</i> , Extensively drug-resistant tuberculosis	96

Mycobacterium Tuberculosis

AccuPower® TB&MDR Real-Time PCR Kit C €

Multidrug-resistant tuberculosis (MDR-TB) is caused by an organism that is resistant to the two most potent TB drugs: isoniazid (INH) and rifampicin (RIF). However, spontaneous mutations in the *Mycobacterium tuberculosis* genome can give rise to proteins that make the bacterium drug resistant. Since almost 2~3% of new TB patients have MDR-TB, early detection is the top priority for proper treatment. AccuPower® TB & MDR Real-Time PCR Kit is an *in vitro* diagnostic kit designed for the simultaneous detection of *M. tuberculosis* and MDR-TB DNA extracted from clinical samples.

Specification

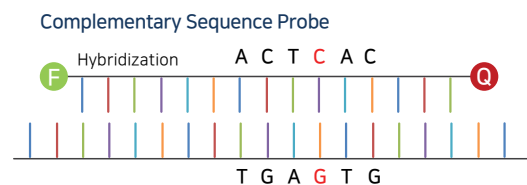
Target	Sample Type	Components	Instruments
Tuberculosis Multidrug-resistant Tuberculosis (RIF and INH)	Sputum, BAL, Culture specimen	PCR Premix(48 rxn), TB&MDR PC, IPC, NTC, DEPC-D.W, Optical sealing film	ExiStation™, Exicycler™ 96

Features & Benefits

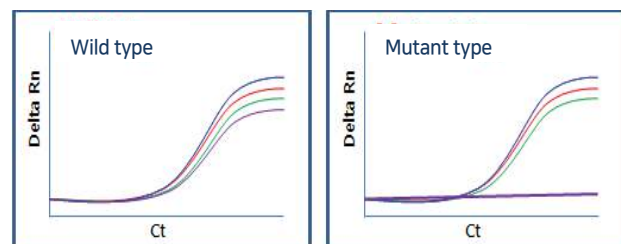
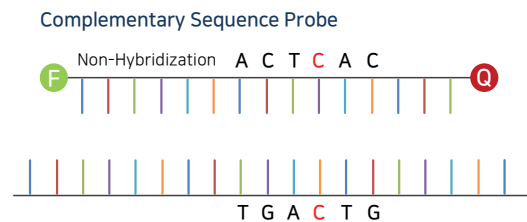
- Multiplex detection of TB and MDR-TB (RIF and INH resistance)
- Simplified procedure of sputum pretreatment with EZ Solution
- Highly sensitive detection of TB and MDR-TB

Method

A. Wild MTB Genomic DNA



B. Mutant MTB Genomic DNA



Wild type : All detection of 4 dyes

Mutant type : No detection either delayed CT Values of 1 or more dyes

Multidrug-resistance detection method: Allele-Specific PCR

Related Products

Cat. No.	Kit name	Target	Tests
MTN-1111	AccuPower® MTB&NTM Real-Time PCR Kit	<i>Mycobacterium tuberculosis</i> , Non-tuberculous mycobacteria	96
MTB-1111	AccuPower® MTB Real-Time PCR Kit	<i>Mycobacterium tuberculosis</i>	96
TBMDR-1111	AccuPower® TB&MDR Real-Time PCR Kit	<i>Mycobacterium tuberculosis</i> , Multidrug-resistant Tuberculosis	48
XDRA-1111	AccuPower® XDR-TB Real-Time PCR Kit-A	Extensively drug-resistant tuberculosis	48
XDRB-1111	AccuPower® XDR-TB Real-Time PCR Kit-B	<i>Mycobacterium tuberculosis</i> , Extensively drug-resistant tuberculosis	96

AccuPower® XDR-TB Real-Time PCR Kit C E

Extensively drug-resistant TB (XDR-TB) is a rare type of multidrug-resistant tuberculosis (MDR-TB) that is resistant to isoniazid and rifampin, plus any fluoroquinolone and at least one of three injectable second-line drugs (i.e., amikacin, kanamycin, or capreomycin). Because XDR-TB is resistant to most potent TB drugs, the remaining treatment options are less effective, have more side effects, and are more expensive. XDR-TB is a special concern for persons with HIV infection or other conditions that can weaken the immune system. These people are more likely to develop TB once they are infected, and they also have a higher risk of death if they develop TB. The AccuPower® XDR-TB Real-Time PCR Kits are *in vitro* diagnostic kit designed for the simultaneous detection of *M. tuberculosis* and various TB drug resistance in clinical samples through Real-Time PCR using ExiStation™ MDx System or Exicycler™ 96.

■ Specification

Kit	Target	Sample Type	Components	Instruments
AccuPower® XDR-TB Real-Time PCR Kit-A	Extensively drug resistant tuberculosis (Fluoroquinolone , Aminoglycosides)	Sputum, BAL, Culture specimen	PCR premix(48rxn), XDR-TB PC, IPC, NTC, DEPC D.W., Optical sealing film	ExiStation™, Exicycler™ 96
AccuPower® XDR-TB Real-Time PCR Kit-B	<i>M.tuberculosis</i> , Extensively drug resistant tuberculosis (Ethambutol, streptomycin)		PCR premix(96rxn), XDR-TB PC, IPC, NTC, DEPC D.W., Optical sealing film	

■ Features & Benefits

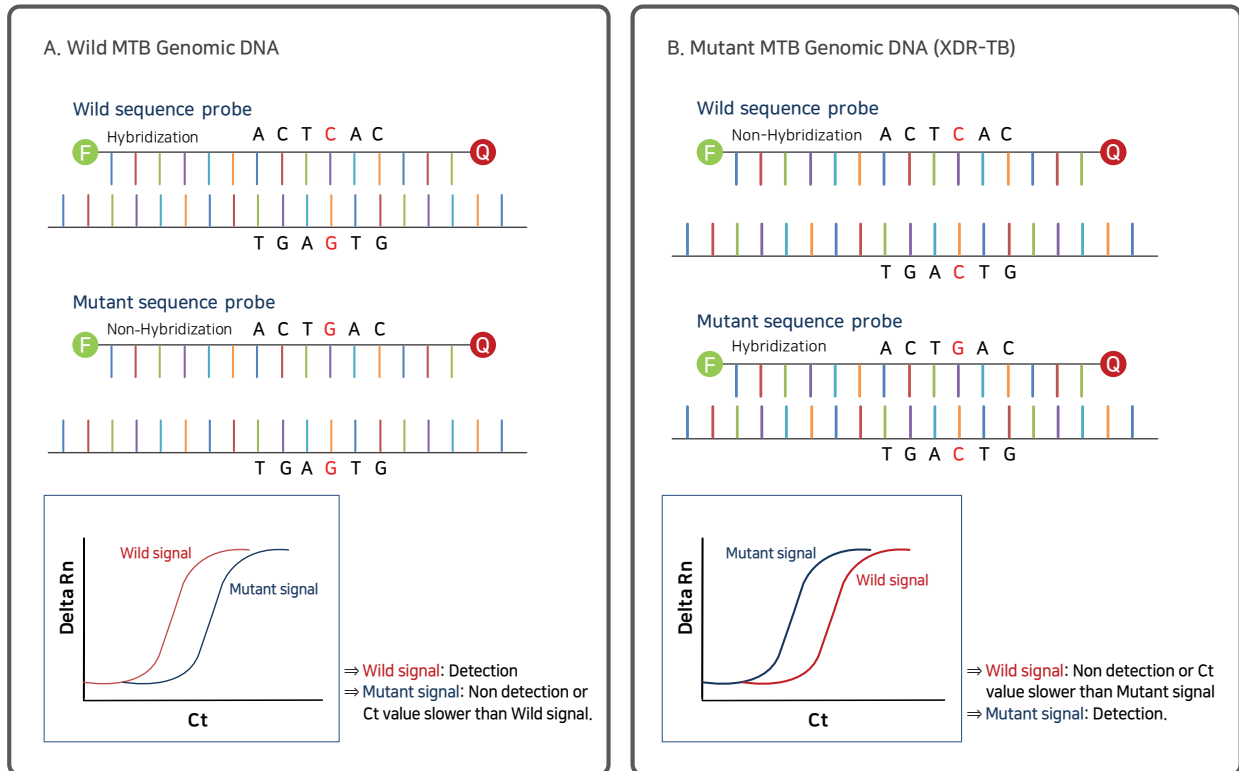
- Outstanding sensitivity and specificity
- Simultaneous detection of TB and XDR-TB using XDR-TB Kit A and B on ExiStation™ MDx System
 - Fluoroquinolone, Aminoglycosides, Ethambutol resistance, Streptomycin resistance
- Simplified procedure of sputum pretreatment with EZ Solution

■ Related Products

Cat. No.	Kit name	Target	Tests
MTN-1111	AccuPower® MTB&NTM Real-Time PCR Kit	<i>Mycobacterium tuberculosis</i> , Non-tuberculous mycobacteria	96
MTB-1111	AccuPower® MTB Real-Time PCR Kit	<i>Mycobacterium tuberculosis</i>	96
TBMDR-1111	AccuPower® TB&MDR Real-Time PCR Kit	<i>Mycobacterium tuberculosis</i> , Multidrug-resistant Tuberculosis	48
XDRA-1111	AccuPower® XDR-TB Real-Time PCR Kit-A	Extensively drug-resistant tuberculosis	48
XDRB-1111	AccuPower® XDR-TB Real-Time PCR Kit-B	<i>Mycobacterium tuberculosis</i> , Extensively drug-resistant tuberculosis	96

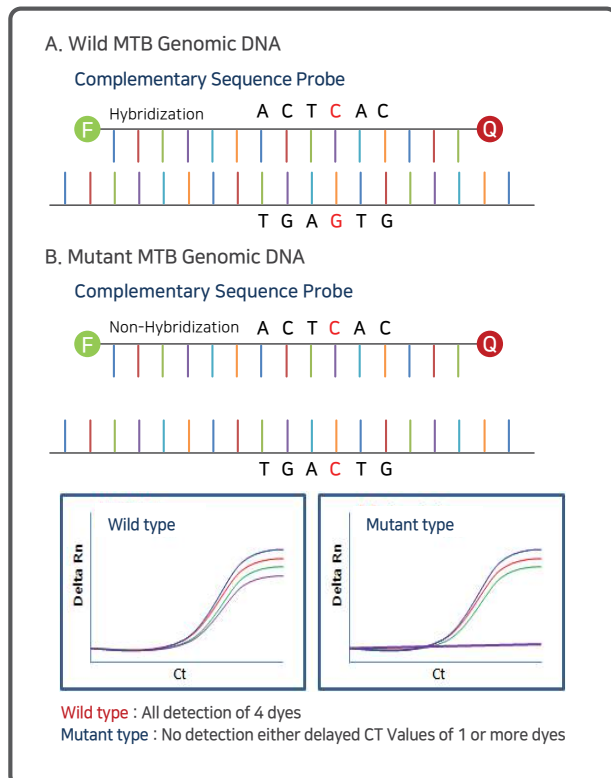
Method

XDR-TB Kit-A



Extensively drug-resistant detection method: Allele-Specific PCR

XDR-TB Kit-B



Extensively drug-resistant detection method: Allele-Specific PCR

AccuPower® STI8A-Plex Real-Time PCR Kit CE 0197

Sexually Transmitted Infection (STI) is an infection that can be transferred from one person to another by means of sexual contact, including oral sex, anal sex, and sharing sex toys. Chlamydia infection is a common sexually transmitted infection in human caused by the *Chlamydia trachomatis*. *Neisseria gonorrhoeae* is pathogenic to humans who are its only natural host, and it is responsible for the disease Gonorrhoea. Symptoms of infection with *N. gonorrhoeae* differ, depending on the site of infection. *Ureaplasma urealyticum* is part of the normal genital flora of both men and women. It is found in about 70% of sexually active humans. *Mycoplasma genitalium* is an emerging sexually transmitted pathogen implicated in urethritis in men and several inflammatory reproductive tract syndromes in women. Depending on the disease, some untreated STIs can lead to infertility, chronic pain or even death. Early identification and treatment results in less chance to spread disease and for some conditions may improve the outcomes of treatment. The AccuPower® STI8A-Plex Real-Time PCR Kit is an *in vitro* diagnostic kit designed for the simultaneous diagnosis of CT, NG, UU and MG in clinical samples using ExiStation™ MDx System.

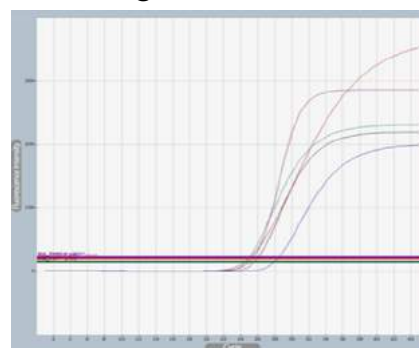
Specification

Target	Sample Type	Components	Instruments
CT, NG, UU, MG	Urine, Vaginal swab	PCR Premix(96 rxn), STI8A PC, IPC, NTC, DEPC-D.W, Optical sealing film	ExiStation™

Features & Benefits

- Highly sensitive detection of STI pathogens
- Simultaneous detection of 12 STI pathogens with STI8B & STI4C Real-Time PCR Kit using ExiStation™ MDx System
- High reliability through Internal Positive Control, Positive Control and No Template Control

Testing results



Detection of STI8A-Plex Positive Control using Exicycler™ 96.
Black signal; CT, **Red signal;** NG, **Purple signal;** UU, **Green signal;** MG, **Blue signal;** IPC

Related Products

Cat. No.	Kit name	Target	Tests
STI8A-1111	AccuPower® STI8A-Plex Real-Time PCR Kit	CT, NG, UU, MG	96
STI8B-1111	AccuPower® STI8B-Plex Real-Time PCR Kit	TV, MH, HSV1, HSV2	96
STI4C-1111	AccuPower® STI4C-Plex Real-Time PCR Kit	UP, TP, CA, GV	96
STD2A-1211	AccuPower® CT&NG Real-Time PCR Kit	CT, NG	96
CHT-1111	AccuPower® CT Real-Time PCR Kit	CT	96

Sexually Transmitted Infection

AccuPower® STI8B-Plex Real-Time PCR Kit C €

Trichomoniasis is one of the most common STIs caused by a small organism called *Trichomonas vaginalis*. Women are most often affected by this disease, although men can become infected and pass the infection to their partners through sexual contact. *Mycoplasma hominis* is a strain of bacteria that is present in the urogenital area. Infection is usually asymptomatic, but for pregnant women, infection can lead to premature birth. Herpes simplex type 1, which is transmitted through oral secretions or sores on the skin, can be spread through kissing or sharing objects such as toothbrushes or eating utensils. In general, a person can only get Herpes simplex type 2 infections during sexual contact with someone who has a genital HSV-2 infection. Depending on the disease, some untreated STIs can lead to infertility, chronic pain or even death. Early identification and treatment results in less chance to spread disease and for some conditions may improve the outcomes of treatment. The AccuPower® STI8B-Plex Real-Time PCR Kit is an *in vitro* diagnostic kit designed for the simultaneous diagnosis of TV, MH, HSV1 and HSV2 in clinical samples using ExiStation™ MDx System.

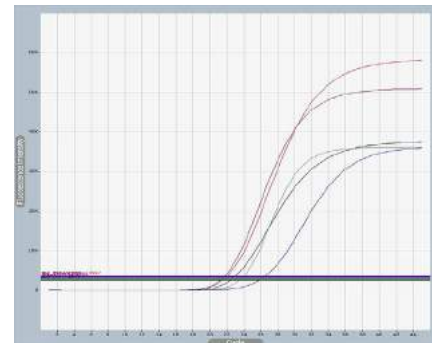
Specification

Target	Sample Type	Components	Instruments
TV, MH, HSV1, HSV2	Urine, Vaginal swab, Urethral swab	PCR Premix(96 rxn), STI8B PC, IPC, NTC, DEPC-D.W, Optical sealing film	ExiStation™

Features & Benefits

- Highly sensitive detection of STI pathogens
- Simultaneous detection of 12 STI pathogens with STI8A & STI4C Real-Time PCR Kit using ExiStation™ MDx System
- High reliability through Internal Positive Control, Positive Control and No Template Control

Testing results



Detection of STI8B-Plex Positive Control using Exicycler™ 96.

Black signal; TV, Red signal; HSV1, Purple signal; HSV2, Green signal; MH, Blue signal; IPC

Related Products

Cat. No.	Kit name	Target	Tests
STI8A-1111	AccuPower® STI8A-Plex Real-Time PCR Kit	CT, NG, UU, MG	96
STI8B-1111	AccuPower® STI8B-Plex Real-Time PCR Kit	TV, MH, HSV1, HSV2	96
STI4C-1111	AccuPower® STI4C-Plex Real-Time PCR Kit	UP, TP, CA, GV	96
STD2A-1211	AccuPower® CT&NG Real-Time PCR Kit	CT, NG	96
CHT-1111	AccuPower® CT Real-Time PCR Kit	CT	96

AccuPower® STI4C-Plex Real-Time PCR Kit

Ureaplasma parvum can cause asymptomatic infections or disease characterized by an exaggerated inflammatory response. *Treponema pallidum* cause Syphilis which have four different stage such as primary, secondary, latent, and tertiary. Each stage has different symptoms and it may also occur congenitally. *Candida albicans* is a fungus that is normally present on the skin and in mucous membranes. A common cause of infection may be the use of antibiotics that destroy beneficial, as well as harmful, microorganisms in the body, permitting candida to multiply in their place. *Gardnerella vaginalis* is a facultatively anaerobic Gram-variable rod that can cause bacterial vaginosis in some women as a result of a disruption in the normal vaginal microflora. The AccuPower® STI4C-Plex Real-Time PCR Kit is an *in vitro* diagnostic kit designed for the simultaneous detection of UP, TP, CA and GV DNA in clinical samples through Real-Time PCR using ExiStation™ MDx System.

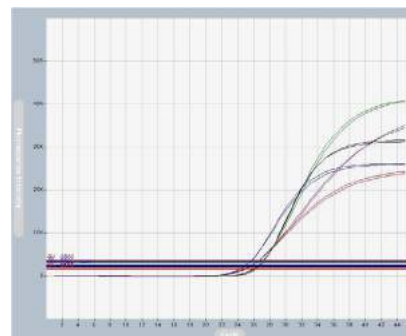
Specification

Target	Sample Type	Components	Instruments
UP, TP, CA, GV	Urine, Vaginal swab, Urethral swab	PCR Premix(96 rxn), STI4C PC, IPC, NTC, DEPC-D.W, Optical sealing film	ExiStation™

Features & Benefits

- Highly sensitive detection of STI pathogens
- Simultaneous detection of 12 STI pathogens with STI8A & STI8B Real-Time PCR Kit using ExiStation™ MDx System
- High reliability through Internal Positive Control, Positive Control and No Template Control

Testing results



Detection of STI4C-Plex Positive Control using Exicycler™ 96. Black signal; UP, Red signal; CA, Purple signal; GV, Green signal; TP, Blue signal; IPC

Related Products

Cat. No.	Kit name	Target	Tests
STI8A-1111	AccuPower® STI8A-Plex Real-Time PCR Kit	CT, NG, UU, MG	96
STI8B-1111	AccuPower® STI8B-Plex Real-Time PCR Kit	TV, MH, HSV1, HSV2	96
STI4C-1111	AccuPower® STI4C-Plex Real-Time PCR Kit	UP, TP, CA, GV	96
STD2A-1211	AccuPower® CT&NG Real-Time PCR Kit	CT, NG	96
CHT-1111	AccuPower® CT Real-Time PCR Kit	CT	96

Sexually Transmitted Infection

AccuPower® CT&NG Real-Time PCR Kit CE 0197

C. trachomatis and *N. gonorrhoeae* are two of the most prevalent sexually transmitted pathogens, with high rates of infection among female commercial sex workers in developing countries, a substantial proportion of whom have asymptomatic infections. *C. trachomatis* causes cervicitis, urethritis, salpingitis, proctitis and endometritis in women and urethritis, epididymitis and proctitis in men. Acute infections are reported more frequently in men because women often have no symptoms of infection. *N. gonorrhoeae* causes acute urethritis in males, which if untreated can develop into epididymitis, prostatitis, and urethral stricture. In females, the primary site of infection is the endocervix. An important complication in females is development of pelvic inflammatory disease which contributes to infertility. The AccuPower® CT&NG Real-Time PCR Kit is an *in vitro* diagnostic kit designed for the simultaneous detection of *C. trachomatis* and *N. gonorrhoeae* DNA in clinical samples through Real-Time PCR using ExiStation™ MDx System.

Specification

Target	Sample Type	Components	Instruments
CT, NG	Urine, Vaginal swab	PCR Premix(96 rxn), CT&NG PC, IPC, NTC, DEPC-D.W, Optical sealing film	ExiStation™

Features & Benefits

- Highly sensitive detection of *C. trachomatis* and *N. gonorrhoeae*
- High reliability through Internal Positive Control, Positive Control and No Template Control

Testing results



Detection of CT & NG Positive Control using Exicycler™ 96. Black signal; CT, Red signal; NG, Blue signal; IPC

Related Products

Cat. No.	Kit name	Target	Tests
ST18A-1111	AccuPower® ST18A-Plex Real-Time PCR Kit	CT, NG, UU, MG	96
ST18B-1111	AccuPower® ST18B-Plex Real-Time PCR Kit	TV, MH, HSV1, HSV2	96
ST14C-1111	AccuPower® ST14C-Plex Real-Time PCR Kit	UP, TP, CA, GV	96
STD2A-1211	AccuPower® CT&NG Real-Time PCR Kit	CT, NG	96
CHT-1111	AccuPower® CT Real-Time PCR Kit	CT	96

Sexually Transmitted Infection

AccuPower® CT Real-Time PCR Kit CE 0197

C. trachomatis is the most common curable sexually transmitted infection. Approximately 5-10% of sexually active women under 24 and men between 20-24 may be currently infected. Even though symptoms of chlamydia are usually mild or absent, serious complications that cause irreversible damage, including infertility. Chlamydia can occur “silently” before a woman ever recognizes a problem. Chlamydia can also cause discharge from the penis of an infected man. Chlamydia can be transmitted during vaginal, anal, or oral sex. Chlamydia can also be passed from an infected mother to her baby during vaginal childbirth. The AccuPower® CT Real-Time PCR Kit is an *in vitro* diagnostic kit designed for the detection of *C. trachomatis* DNA in clinical samples through Real-Time PCR using ExiStation™ MDx System.

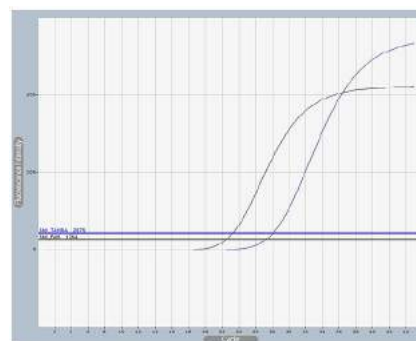
Specification

Target	Sample Type	Components	Instruments
CT	Urine, Vaginal swab	PCR Premix(96 rxn), CT PC, IPC, NTC, DEPC-D.W, Optical sealing film	ExiStation™

Features & Benefits

- Sensitive detection of *C. trachomatis*
- High reliability through Internal Positive Control, Positive Control and No Template Control

Testing results



Detection of CT Positive Control using Exicycler™ 96. Black signal; CT, Blue signal; IPC

Related Products

Cat. No.	Kit name	Target	Tests
ST18A-1111	AccuPower® ST18A-Plex Real-Time PCR Kit	CT, NG, UU, MG	96
ST18B-1111	AccuPower® ST18B-Plex Real-Time PCR Kit	TV, MH, HSV1, HSV2	96
ST14C-1111	AccuPower® ST14C-Plex Real-Time PCR Kit	UP, TP, CA, GV	96
STD2A-1211	AccuPower® CT&NG Real-Time PCR Kit	CT, NG	96
CHT-1111	AccuPower® CT Real-Time PCR Kit	CT	96

Transplantation-related Virus

AccuPower® CMV Quantitative PCR Kit

Human cytomegalovirus (HCMV) infection is acquired subclinically during childhood. It is usually transmitted via body fluid, blood, solid organ transplant and stem cell transplant recipients. Thus, monitoring of CMV viral load is essential for newborns and transplant recipients. The *AccuPower*® CMV Quantitative PCR Kit is an *in vitro* diagnostic kit designed for the quantification of CMV DNA in clinical samples through Real-Time PCR using *ExiStation*™ MDx System or *Exicycler*™ 96.

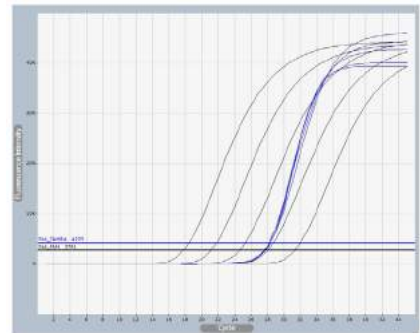
Specification

Target	Sample Type	Components	Instruments
CMV	Whole blood, EDTA-plasma, Serum, Urine	PCR Premix(96 rxn), SPCs(S1~S5), IPC, NTC, DEPC-D.W, SL Buffer, Optical sealing film	<i>ExiStation</i> ™, <i>Exicycler</i> ™ 96

Features & Benefits

- Highly sensitive detection of human cytomegalovirus
- Simplified procedure by eliminating clinical sample pretreatment step
 - Whole blood, urine and breast milk samples can be directly used for the quantification of CMV viral load using *ExiStation*™ MDx System
- Specific Real-Time PCR reaction by *Dual-HotStart*™ technology

Testing results



Standard Positive Controls (S1 ~ S5) of *AccuPower*® CMV Quantitative PCR Kit.
Black signal; CMV, Blue signal; IPC

Related Products

Cat. No.	Kit name	Target	Tests
CMV-1111	<i>AccuPower</i> ® CMV Quantitative PCR Kit	CMV	96
EBV-1111	<i>AccuPower</i> ® EBV Quantitative PCR Kit	EBV	96
BKV-1111	<i>AccuPower</i> ® BKV Quantitative PCR Kit	BKV	96

AccuPower® EBV Quantitative PCR Kit C €

Epstein-Barr virus (EBV) or HHV-4 is a ubiquitous virus that infects humans worldwide. EBV is associated with a spectrum of clinical presentations on transplant recipients, from fever to post-transplantation lymphoproliferative disorder (PTLD). Increasing EBV viral loads have been demonstrated to correlate with the development of EBV related diseases and quantitative PCR is considered a valuable tool to monitor patients with high risk of PTLD.

The AccuPower® EBV Quantitative PCR Kit is an *in vitro* diagnostic kit designed for the quantification of EBV DNA in human whole blood and EDTA-plasma samples through Real-Time PCR using *ExiStation™* MDx System or *Exicycler™* 96.

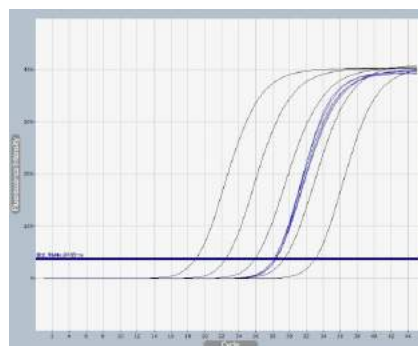
Specification

Target	Sample Type	Components	Instruments
EBV	Whole blood, EDTA-plasma, Serum	PCR Premix(96 rxn), SPCs(S1~S5), PCs(LPC, HPC), IPC, NTC, DEPC-D.W, SL Buffer, Optical sealing film	<i>ExiStation™</i> , <i>Exicycler™</i> 96

Features & Benefits

- Highly sensitive detection of human Epstein-Barr virus
- Simplified procedure by eliminating clinical sample pretreatment step
 - Whole blood, EDTA-plasma and serum samples can be directly used for the quantification of EBV viral load using *ExiStation™* MDx System
- Specific Real-Time PCR reaction by *Dual-HotStart™* technology

Testing results



Standard Positive Controls (S1 ~ S5) of AccuPower® EBV Quantitative PCR Kit.
Black signal; EBV, Blue signal; IPC

Related Products

Cat. No.	Kit name	Target	Tests
CMV-1111	AccuPower® CMV Quantitative PCR Kit	CMV	96
EBV-1111	AccuPower® EBV Quantitative PCR Kit	EBV	96
BKV-1111	AccuPower® BKV Quantitative PCR Kit	BKV	96

Transplantation-related Virus

AccuPower® BKV Quantitative PCR Kit

BK virus (BKV) was originally discovered and isolated from the urine of a renal allograft recipient. The source of BKV infection is due to decline in immunologic activity from either graft dysfunction and graft rejection in renal transplant recipients under immunosuppressed state. The *AccuPower*® BKV Quantitative PCR Kit is an *in vitro* diagnostic kit designed for the quantification of BKV DNA in urine and serum samples through Real-Time PCR using *ExiStation*™ MDx System or *Exicycler*™ 96.

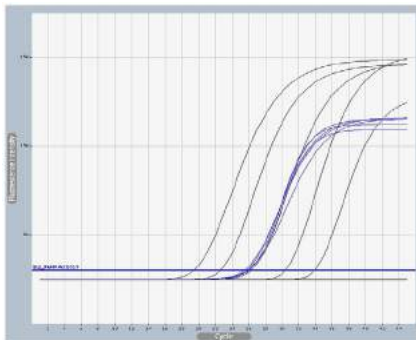
Specification

Target	Sample Type	Components	Instruments
BKV	Serum, Urine	PCR Premix(96 rxn), SPCs(S1~S5), IPC, NTC, DEPC-D.W, SL Buffer, Optical sealing film	<i>ExiStation</i> ™, <i>Exicycler</i> ™ 96

Features & Benefits

- Highly sensitive detection of human BK virus
- Simplified procedure by eliminating clinical sample pretreatment step
 - Serum and urine samples can be directly used for the quantification of BKV viral load using *ExiStation*™ MDx System
- High performance of repeatability and reproducibility

Testing results



Conc. (copies/rxn)	Within-run	Between-run	Between-day
	SD (copies/rxn)	SD (copies/rxn)	SD (copies/rxn)
10 ³	0.20	0.09	0.14
10 ⁵	0.20	0.08	0.24
10 ⁷	0.34	0.21	0.19

Repeatability and reproducibility of *AccuPower*® BKV Quantitative PCR Kit

Standard Positive Controls (S1 ~ S5) of *AccuPower*® BKV Quantitative PCR Kit.
 Black signal; BKV, Blue signal; IPC

Related Products

Cat. No.	Kit name	Target	Tests
CMV-1111	<i>AccuPower</i> ® CMV Quantitative PCR Kit	CMV	96
EBV-1111	<i>AccuPower</i> ® EBV Quantitative PCR Kit	EBV	96
BKV-1111	<i>AccuPower</i> ® BKV Quantitative PCR Kit	BKV	96

AccuPower® HPV 16 &18 Real-Time PCR Kit C E

The global incidence and death from cervical cancer rank the second and third highest respectively among women. The main cause of cervical cancer is Human papillomavirus (HPV) in the cervix. According to the study with 196 patients in cervical adenocarcinoma, HPV genotype 16 and 18 are responsible for cervical cancer in 44.1% and 54.2% of the patients respectively. The AccuPower® HPV 16&18 Real-Time PCR Kit is an *in vitro* diagnostic kit designed for the simultaneous detection of HPV type 16 and 18 DNA in human cervical swab samples using ExiStation™ MDx System or Exicycler™ 96.

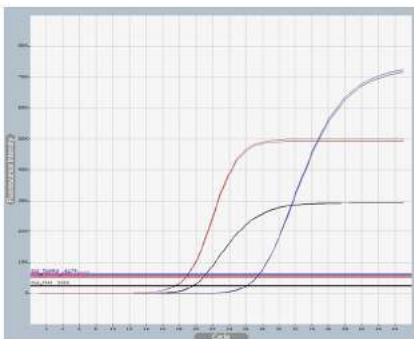
Specification

Target	Sample Type	Components	Instruments
HPV 16 &18	Cervical swab	PCR Premix(96 rxn),HPV 16&18 PC, IPC, DEPC-D.W, Optical sealing film	ExiStation™, Exicycler™ 96

Features & Benefits

- Highly sensitive detection of human HPV type 16 and 18
- High reliability through Internal Positive Control and Positive Control
- Simultaneous detection of high risk HPV type 16 and 18
- Specific Real-Time PCR reaction using Enzyme-mediated HotStart technology

Testing results



Detection of HPV 16 &18 Positive Control using Exicycler™ 96. Black signal; HPV16, Red signal; HPV18, Blue signal; IPC

Method	CE-IVD certification kit		Total
	Positive	Negative	
Bioneer HPV 16 &18	Positive	-	12
	Negative	10	10
Total	12	10	22

Diagnostic Evaluation and Correlation with Reference Method

The clinical evaluation of the AccuPower® HPV 16 &18 Real-Time PCR Kit was performed on 22 clinical samples. Out of 22 samples, the AccuPower® HPV16&18 Real-Time PCR Kit determined four specimens as HPV16-positive, another four as HPV18-positive, another four as HPV16 and 18-positive, the rest ten as negative. Those results agreed 100% with those from direct sequencing Results.

Related Products

Cat. No.	Kit name	Target	Tests
HPM-1111	AccuPower® HPV 16 &18 Real-Time PCR Kit	HPV 16 &18	96

Respiratory Pathogen

AccuPower® New InfA (H1N1) & InfA Real-Time RT-PCR Kit C €

Influenza occurs all over the world, with an annual global attack rate estimated at 5–10% in adults and 20–30% in children. In temperate regions, influenza is a seasonal disease occurring typically in winter months. The subtypes of influenza A viruses are determined by envelope glycoproteins possessing either haemagglutinin (HA) or neuraminidase (NA) activity. Influenza A (H1N1) virus emerged in 2009 is a new reassortment that has never before circulated among humans. This virus is not closely related to previous or current human seasonal influenza viruses.

The AccuPower® New InfA (H1N1) & InfA Real-Time RT-PCR Kit is an *in vitro* diagnostic kit designed for the detection of influenza A (H1N1-2009, common) virus RNA in clinical samples through Real-Time PCR using *Exicycler™ 96*.

Specification

Target	Sample Type	Components	Instruments
New InfA (H1N1) & InfA	Nasopharyngeal swab, BAL	New InfA(H1N1) PCR Premix (48 rxn), Influenza A PCR Premix (48 rxn), PC, IPC, DEPC-D.W, Optical sealing film	<i>Exicycler™ 96</i>

Features & Benefits

- Highly sensitive detection of influenza A and new influenza A (H1N1-2009)
- High reliability through Internal Positive Control and Positive Control
- One-Step Real-Time RT-PCR reaction using *RocketScript™* Reverse Transcriptase and *Dual-HotStart™* technology

Testing results



Detection of new Influenza A (H1N1) Positive Control using *Exicycler™ 96*.
Black signal; new InfA(H1N1), Blue signal; IPC



Detection of Influenza A Positive Control using *Exicycler™ 96*.
Black signal; InfA, Blue signal; IPC

Related Products

Cat. No.	Kit name	Target	Tests
SIA-1111	AccuPower® New InfA (H1N1) & InfA Real-Time RT-PCR Kit	New InfA (H1N1) & InfA	48
IFA-1111	AccuPower® Influenza A Real-Time RT-PCR Kit	Influenza A	96
SIV-1111	AccuPower® New InfA (H1N1) Real-Time PCR Kit	New InfA (H1N1)	96

AccuPower® CP Real-Time PCR Kit

Chlamydia pneumoniae is a species of Chlamydophila, an obligate intracellular bacterium that infects humans and is a major cause of pneumonia. Outbreaks of *C. pneumoniae* occur mostly in crowded environments, like schools, college dormitories, military barracks, and nursing homes, where transmission is possible through airborne droplets from close person-to-person contact. *C. pneumoniae* causes mild pneumonia or bronchitis in adolescents and young adults. Older adults may experience more severe disease and repeated infections. The AccuPower® CP Real-Time PCR Kit is an *in vitro* diagnostic kit designed for the detection of *C. pneumoniae* DNA in clinical samples through Real-Time PCR using ExiStation™ MDx System or Exicycler™ 96.

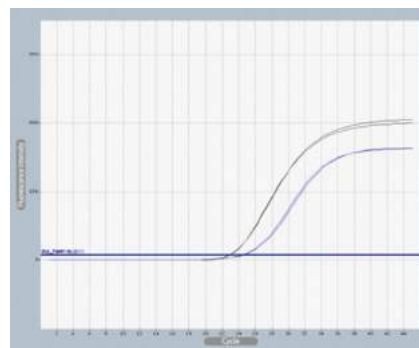
Specification

Target	Sample Type	Components	Instruments
CP	Sputum, BAL	PCR Premix (96 rxn), PC, IPC, DEPC-D.W, Optical sealing film	ExiStation™, Exicycler™ 96

Features & Benefits

- Highly sensitive detection of *C. pneumoniae*
- Simplified procedure of sputum pretreatment with EZ Solution
- Low coefficient of variation (CV) for between-day precision and inter-instrument trueness within 1.74 %
- No interference observed in the presence of the interfering substances such as blood and hemoglobin

Testing results



Detection of CP Positive Control using Exicycler™ 96. Black signal; CP, Blue signal; IPC

Related Products

Cat. No.	Kit name	Target	Tests
CPN-1111	AccuPower® CP Real-Time RT-PCR Kit	CP	96
MPN-1111	AccuPower® MP Real-Time RT-PCR Kit	MP	96

Respiratory Pathogen

| **AccuPower® MP Real-Time PCR Kit** C €

Mycoplasma pneumoniae is a form of atypical bacterial pneumonia caused by the bacterial species *Mycoplasma pneumoniae*. In general, *M. pneumoniae* infection is a mild illness that is most common in young adults and school-aged children. The most common type of illness, that is caused by the bacteria, especially in children, is tracheobronchitis, commonly called a chest cold. Diagnosis of *M. pneumoniae* infections is complicated by the delayed onset of symptoms and the similarity of symptoms to other pulmonary conditions. Among other diagnostic tools, PCR is the most rapid and effective way to determine the presence of *M. pneumoniae*. The AccuPower® MP Real-Time PCR Kit is an *in vitro* diagnostic kit designed for the detection of *M. pneumoniae* DNA in sputum, BAL and throat swab samples through Real-Time PCR using ExiStation™ MDx System or Exicycler™ 96.

■ Specification

Target	Sample Type	Components	Instruments
MP	Sputum, BAL	PCR Premix (96 rxn), PC, IPC, DEPC-D.W, Optical sealing film	ExiStation™ , Exicycler™ 96

■ Features & Benefits

- Highly sensitive detection of *M. pneumoniae*
- Simplified procedure of sputum pretreatment with EZ Solution
- Low coefficient of variation (CV) for between-day precision and inter- instrument trueness within 1.89 %
- No interference observed in the presence of the interfering substances such as blood and hemoglobin

■ Testing results



Detection of MP Positive Control using Exicycler™ 96. Black signal; MP, Blue signal; IPC

■ Related Products

Cat. No.	Kit name	Target	Tests
CPN-1111	AccuPower® CP Real-Time RT-PCR Kit	CP	96
MPN-1111	AccuPower® MP Real-Time RT-PCR Kit	MP	96

AccuPower® MERS-CoV (upE&ORF1a) Real-Time PCR Kit C €

Middle East respiratory syndrome (MERS) is a viral respiratory illness caused by a coronavirus called MERS-CoV. It was first reported in Saudi Arabia in 2012 and has spread to other countries including South Korea. Camels and bats are suspected to be the primary source of the infection for humans. MERS causes high fever, cough, and severe shortness of breath, and can also lead up to kidney failure and even death in patients who had a history of other medical conditions. There are currently no vaccines for MERS and no treatments available to cure the infection.

The AccuPower® MERS-CoV Real-Time RT-PCR Kit is an *in vitro* diagnostic kit designed for the detection of MERS-CoV upstream of E gene (upE) and Open reading frame 1a (ORF1a) gene in human sputum, nasopharyngeal swab and bronchial alveolar lavage (BAL) through real-time polymerase chain reaction (PCR) using ExiStation™ MDx System or Exicycler™ 96.

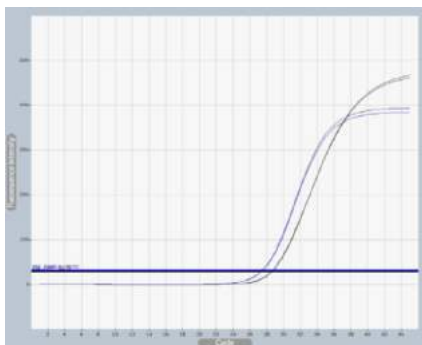
Specification

Target	Sample Type	Components	Instruments
MERS-CoV(upE&ORF1a)	Sputum, Nasopharyngeal swab, BAL	PCR Premix (48 rxn), PC, IPC, NTC, DEPC-D.W, Optical sealing film	ExiStation™, Exicycler™ 96

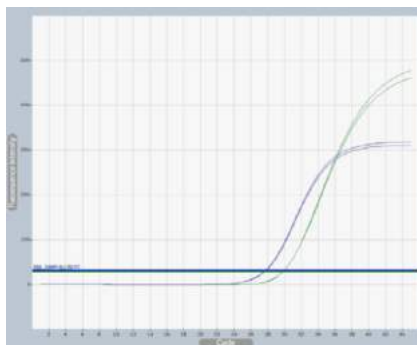
Features & Benefits

- Sensitive detection of MERS-CoV (upE and ORF1a)
- High reliability through IPC, PC and NTC
- Specific one-step Real-Time RT-PCR reaction using *Dual-HotStart™* technology

Testing results



Detection of MERS-CoV (upE) Positive Control using Exicycler™ 96.
Black signal; MERS-CoV(upE), Blue signal; IPC



Detection of MERS-CoV (ORF1a) Positive Control using Exicycler™ 96
Green signal; MERS-CoV(ORF1a), Blue signal; IPC

Related Products

Cat. No.	Kit name	Target	Tests
COV-1112	AccuPower® MERS-CoV (upE&ORF1a) Real-Time RT-PCR Kit	MERS-CoV (upE&ORF1a)	48

Gastrointestinal Virus

AccuPower® Norovirus Real-Time RT-PCR Kit

Norovirus is an RNA virus of the Caliciviridae family and infects people regardless of age and infection occurs sporadically throughout the world. The potential for norovirus infection can occur in food poisoning even with very low virus numbers, and transmission through bodily fluids. The *AccuPower*® Norovirus Real-Time RT-PCR Kit is an *in vitro* diagnostic kit designed for the detection of norovirus GI/GII RNA in human stool or rectal swab samples through Real-Time PCR using *Exicycler*™ 96.

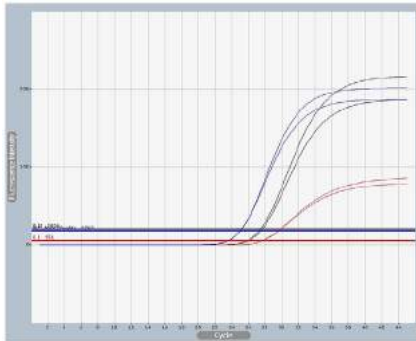
Specification

Target	Sample Type	Components	Instruments
Norovirus	Stool, Rectal swab	PCR Premix (96 rxn), PC, IPC, NTC, DEPC-D.W, Optical sealing film	<i>Exicycler</i> ™ 96

Features & Benefits

- Highly sensitive detection of norovirus (GI:1 to 9, GII:1 to 22)
- Multiplex detection of norovirus GI and GII in one tube
- Specific one-step Real-Time RT-PCR reaction using *Dual-HotStart*™ technology

Testing results



Detection of Norovirus Positive Control using *Exicycler*™ 96.
Red signal; GI, Black signal; GII, Blue signal; IPC

Genotyping	No. of sample	No. of detected by <i>AccuPower</i> ® Real-Time PCR kit	Detection rate
GL1	1	1	100%
GL3	1	1	100%
GIL3	14	14	100%
GIL4	72	72	100%
GIL6	1	1	100%
GIL12	3	3	100%
GII untyped or no sample for genotyping	113	13	
RIDAGENE PCR positive, no sample for genotyping	1	0	

Detectability of norovirus genotypes by *AccuPower*® Real-Time PCR kits
*J. Hyun et al. / Diagnostic Microbiology and Infectious Disease 78(2014) 40-44

Related Products

Cat. No.	Kit name	Target	Tests
NOR-1111	<i>AccuPower</i> ® Norovirus Real-Time RT-PCR Kit	Norovirus	96

AccuPower® EV Real-Time RT-PCR Kit C €

Enterovirus can be classified into one of five major groups, including polioviruses, echoviruses, coxsackieviruses A, coxsackieviruses B and other enteroviruses. Infected persons who become ill usually develop mild upper respiratory symptoms (a “cold”), a flu-like illness with fever and muscle aches, or an illness with rash. Rarely, a person may develop an illness that affects the heart (myocarditis) or the brain (encephalitis) or causes paralysis. The *AccuPower*® EV Real-Time RT-PCR Kit is an *in vitro* diagnostic kit designed for the detection of enterovirus RNA in human stool or cerebrospinal fluid (CSF) samples through Real-Time PCR using *Exicycler*™ 96.

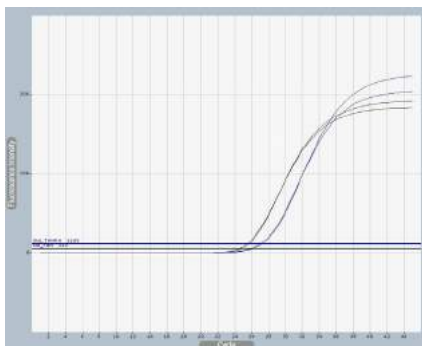
Specification

Target	Sample Type	Components	Instruments
Enterovirus	Stool, CSF	PCR Premix (96 rxn), PC, IPC, NTC, DEPC-D.W, Optical sealing film	<i>Exicycler</i> ™ 96

Features & Benefits

- Highly sensitive detection of various enterovirus serotypes
- Specific one-step Real-Time RT-PCR reaction using *Dual-HotStart*™ technology

Testing results



Detection of Enterovirus Positive Control using *Exicycler*™ 96.

Black signal; Enterovirus, Blue signal; IPC

Detectable Enterovirus Serotypes

	Detectable serotype
Enterovirus	71, 76, 77, 79, 80, 82, 83, 87, 97, 101, B, yanjian96-83
Coxsackievirus A	A2, A3, A4, A5, A6, A8, A9, A10, A12, A14, A15, A16, A18, A20, A24
Coxsackievirus B	B1, B2, B3, B4, B5
Echovirus	3, 4, 6, 7, 9, 11, 13, 14, 16, 17, 18, 21, 24, 25, 30, 32, 33
Poliovirus	1, 2, 3
Total	52 serotypes

Related Products

Cat. No.	Kit name	Target	Tests
ENT-1111	<i>AccuPower</i> ® EV Real-Time RT-PCR Kit	Enterovirus	96

Mosquito borne disease

AccuPower® ZIKV (DENV, CHIKV) Multiplex Real-Time RT-PCR Kit C €

Infection of Zika(ZIKV), Dengue(DENV) and Chikungunya(CHIKV) viruses are referred to as mosquito-borne diseases since they are transmitted by mosquitoes. Over one million people die from these diseases every year. ZIKV, DENV and CHIKV have similar symptoms and a common vector, *Aedes aegypti*. Especially, the risk of microcephaly is increased in newborn baby borned from mother who had ZIKV infection. Therefore simultaneous diagnosis of these viruses is important. The AccuPower® ZIKV (DENV, CHIKV) Multiplex Real-Time RT-PCR Kit is an *in vitro* diagnostic kit designed for qualification of ZIKV, DENV and CHIKV RNA simultaneously in human samples, such as serum and plasma samples, through Real-Time polymerase chain reaction (RT-PCR).

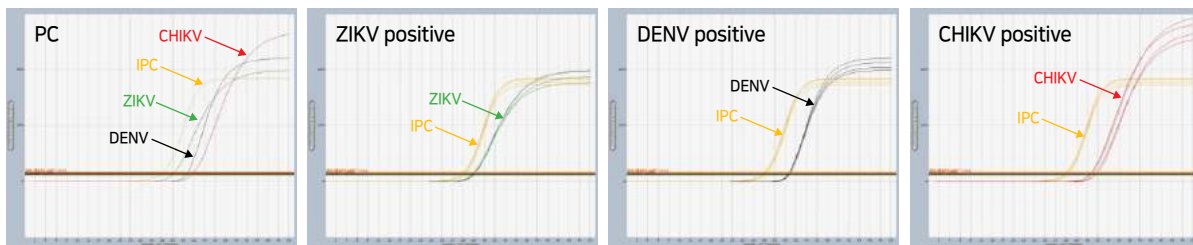
Specification

Target	Sample Type	Components	Instruments
ZIKV, DENV, CHIKV	Serum, Plasma (for ZIKV,DENV and CHIKV), Urine (for ZIKV only)	PCR Premix (96 rxn), PC, IPC, NTC, DEPC-D.W, Optical sealing film	ExiStation™, Exicycler™ 96

Features & Benefits

- Multiplex detection of ZIKV, DENV and CHIKV in a tube
- Highly sensitive detection of each viruses
- Specific one-step Real-Time RT-PCR reaction using *Dual-HotStart™* Technology No interference observed in the presence of the interfering substances

Testing results



Detection of ZIKV, DENV and CHIKV Positive Control using Exicycler™ 96
Green signal : ZIKV, Black signal : DENV, Red signal : CHIKV, Yellow signal : IPC

Related Products

Cat. No.	Kit name	Target	Tests
ZIK-1111	AccuPower® ZIKV (DENV, CHIKV) Multiplex Real-Time RT-PCR Kit	ZIKV, DENV, CHIKV	96

AccuPower® HLA-B27 Real-Time PCR Kit

The function of the human leukocyte antigen (HLA) system is to present antigen molecules to a variety of cell types including most immune cells. The HLA system plays a large role in infectious diseases, graft rejection and auto-immunity. HLA-B27 serotype is found in more than 90% of ankylosing spondylitis patients. HLA genes have been extensively investigated in the clinic and are screened for organ transplant fitness screening or DNA fingerprinting. AccuPower® HLA-B27 Real-Time PCR Kit is designed to detect HLA-B27 gene and configured for use with Exicycler™ 96 (ExiGenotyper™ software).

Specification

Target	Sample Type	Components	Instruments
HLA-B27	Whole Blood, Buccal swab	PCR Premix (96 rxn), PC, NC, NTC, DEPC-D.W, Optical sealing film	Exicycler™ 96 (ExiGenotyper™ software)

Features & Benefits

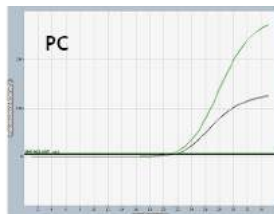
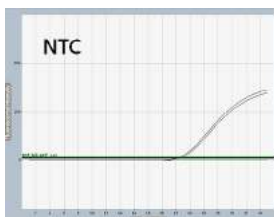
- Specific detection of HLA-B27 gene
- Highly sensitive detection of HLA-B27 gene
- No interference observed in the presence of the interfering substances such as EDTA, hemoglobin, albumin, cholesterol, etc.

Testing results

AccuPower® HLA-B27 Real-Time PCR kit	A Univ. Hospital	B Univ. Hospital
Sensitivity	39/40(97.5%)	20/20(100%)
Specificity	66/66(100%)	40/40(100%)
Positive predictive value	39/39(100%)	20/20(100%)
Negative predictive value	66/67(98.5%)	40/40(100%)

Diagnostic Evaluation and Correlation with Reference Method

The clinical evaluation of the AccuPower® HLA-B27 Real-Time PCR Kit was performed on 166 clinical samples. AccuPower® HLA-B27 Real-Time PCR kit was showed sensitivity of 98%, specificity of 100 %.



Well	Omit	Sample ID	IPC_HLA-B27 Ct	IPC_HLA-B27 Result	HLA-B27 Ct	HLA-B27 Delta Rn	HLA-B27 Result
A1	False	NTC	21.44	Valid	Undetermined		Valid
B1	False	NTC	21.3	Valid	Undetermined		Valid
C1	False	PC	21.42	Valid	22.23	16,404	Valid
D1	False	PC	21.13	Valid	23.34	16,274	Valid
E1	False	NC	Undetermined	Valid	Undetermined		Valid
F1	False	NC	Undetermined	Valid	Undetermined		Valid

Automatic Analysis of HLA-B27 Detection Results

ExiGenotyper™ software automatically analyzes HLA-B27 gene detection results in real-time. The results are analyzed based on the Ct value calculated from each sample amplification result

Example of AccuPower® HLA-B27 Real-Time PCR Kit result
 Green signal; HLA-B27, Black signal; IPC

Related Products

Cat. No.	Kit name	Target	Tests
HLB-1111	AccuPower® HLA-B27 Real-Time PCR Kit	HLA-B27	96

Human Genotyping

AccuPower® MTHFR Real-Time PCR Kit C €

MTHFR is an enzyme that converts 5, 10-methylenetetrahydrofolate to 5-methyltetrahydrofolate, a substrate for homocysteine remethylation to methionine. If MTHFR enzyme activity is reduced, methionine synthesis metabolism is inhibited and homocysteine concentration is increased (hyperhomocysteinemia), which may result in vascular disease and venous thromboembolism. *AccuPower®* MTHFR Real-Time PCR Kit is designed to determine the genotype of MTHFR SNPs and configured for use with *Exicycler™* 96 (*ExiGenotyper™* software).

Specification

Target	Sample Type	Components	Instruments
MTHFR	Whole Blood, Buccal swab	PCR Premix (48 rxn), PCs(W/M), DEPC-D.W, Optical sealing film	<i>Exicycler™</i> 96 (<i>ExiGenotyper™</i> software)

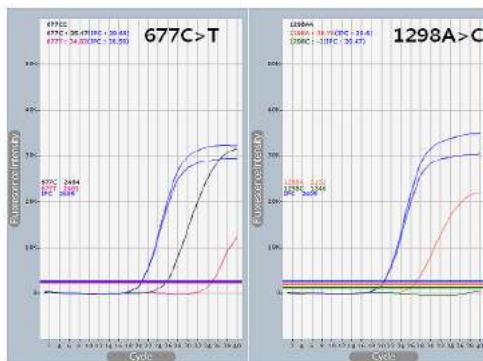
Features & Benefits

- Distinct and direct detection of MTHFR SNP genotype through allele-specific PCR method
- Highly sensitive detection of MTHFR SNP
- No interference observed in the presence of the interfering substances such as EDTA, hemoglobin, albumin, cholesterol, etc.

Testing results

	<i>AccuPower®</i> MTHFR Real-Time PCR Kit	Direct-sequencing	Conventional PCR (A Company)
CT/AA	7/7	7/7	7/7
CC/AA	8/8	8/8	8/8
TT/AA	1/1	1/1	1/1
CT/AC	2/2	2/2	2/2
CT/AC	1/1	1/1	1/1
CT/CC	1/1	1/1	0/1

Comparison results of *AccuPower®* MTHFR Real-Time PCR Kit, Direct-sequencing method and A company product



Flu. Graph	Well vs Ct	MTHFR Report	Reaction Summary															
		<table border="1"> <thead> <tr> <th>Sample</th> <th>677C>T</th> <th>1298A>C</th> </tr> </thead> <tbody> <tr> <td>PC</td> <td>CT</td> <td>AC</td> </tr> <tr> <td>1</td> <td>CC</td> <td>AA</td> </tr> <tr> <td>2</td> <td>CT</td> <td>AC</td> </tr> <tr> <td>3</td> <td>TT</td> <td>AA</td> </tr> </tbody> </table>	Sample	677C>T	1298A>C	PC	CT	AC	1	CC	AA	2	CT	AC	3	TT	AA	
Sample	677C>T	1298A>C																
PC	CT	AC																
1	CC	AA																
2	CT	AC																
3	TT	AA																

Automatic Analysis of MTHFR gene SNPs

ExiGenotyper™ software automatically interprets MTHFR SNP results in real-time. MTHFR SNP genotype(s) are analyzed based on the delta Ct value calculated from each allele specific amplification result

Related Products

Cat. No.	Kit name	Target	Tests
MTH-1111	<i>AccuPower®</i> MTHFR Real-Time PCR Kit	MTHFR	48

AccuPower® Factor V Leiden Real-Time PCR Kit C €

Factor V Leiden thrombophilia is characterized by a poor anticoagulant response to activated protein C (APC). The term "Factor V Leiden" refers to the specific G-to-A substitution at nucleotide 1691 of the gene for Factor V to result in a single amino acid replacement (R506Q) at one of three APC cleavage sites in the factor V molecule. *AccuPower®* Factor V Leiden Real-Time PCR Kit is designed to determine the genotype of Factor V SNP and configured for use with *Exicycler™ 96* (*ExiGenotyper™* software).

Specification

Target	Sample Type	Components	Instruments
Factor V Leiden	Whole Blood, Buccal swab	PCR Premix (48 rxn), PCs(W/M), DEPC-D.W, Optical sealing film	<i>Exicycler™ 96</i> (<i>ExiGenotyper™</i> software)

Features & Benefits

- Distinct and direct detection of Factor V SNP genotype through allele-specific PCR method
- Highly sensitive detection of Factor V SNP
- No interference observed in the presence of the interfering substances such as EDTA, hemoglobin, albumin, cholesterol, etc.

Testing results

		Direct-sequencing Method			Total
		Wild type	Heterozygous	Mutant	
Bioneer Factor V Leiden	Wild type	4	-	-	4
	Heterozygous	-	4	-	4
	Mutant	-	-	4	4
Total		4	4	4	12

Diagnostic Evaluation and Correlation with Reference Method
The clinical evaluation of the *AccuPower®* Factor V Leiden Real-Time PCR Kit was performed on 12 clinical samples. *AccuPower®* Factor V Leiden Real-Time PCR kit determined that 12 specimen results were 100% agreement with direct-sequencing method



Sample	Factor V>Factor V leiden
PC	GA
1	GG
2	GA
3	AA

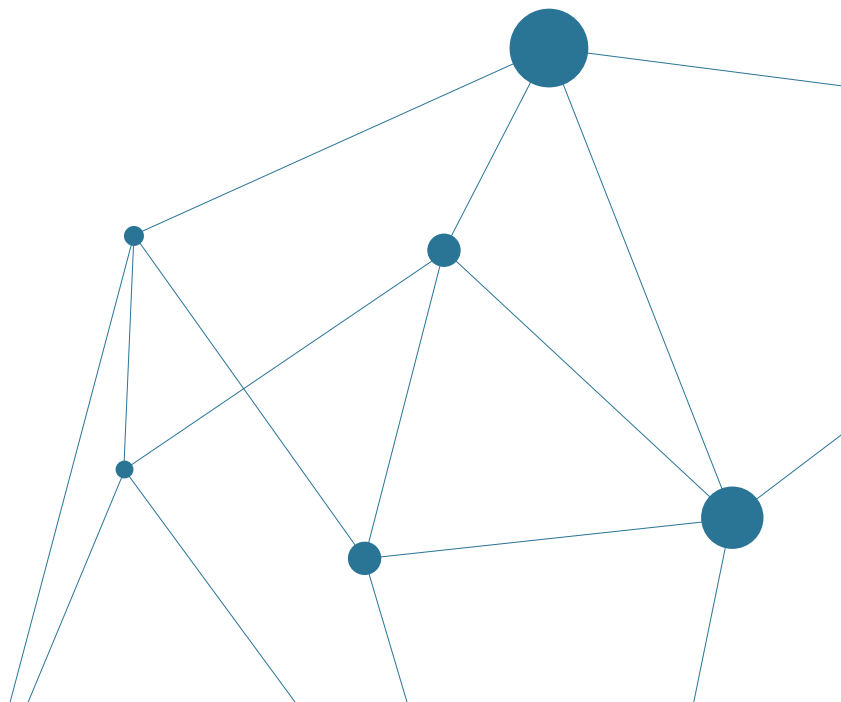
Automatic Analysis of Factor V SNP
ExiGenotyper™ software automatically analyzes Factor V SNP results in real-time. Factor V SNP genotype is analyzed based on the delta Ct value calculated from each allele specific amplification result.

Related Products

Cat. No.	Kit name	Target	Tests
FVL-1111	<i>AccuPower®</i> Factor V Leiden Real-Time PCR Kit	Factor V Leiden	48




D

Ordering Information



Ordering Information

A. Automatic Molecular Diagnostics System

Cat. No.	Product Name	Test/run
A-2200-N	ExiStation™ C €	96
A-2400	ExiStation™ 48 C €	96
A-2410	ExiStation™ 48A C €	96
A-5050	ExiPrep™ 16 Dx C € 	16
A-5150	ExiPrep™ 48 Dx C € 	48
A-5250	ExiPrep™ 96 Lite C €	96
A-2060-1	Exicycler™ 96 C € 	96
A-7040	ExiSpin™	32

B. Nucleic Acid Extraction Kits

- ExiPrep™ Dx Kit

*ExiPrep™ Dx Kit for use on the ExiPrep™ 16 Dx.

Cat. No.	Product Name	Target	Sample types	Test/Kit
K-4471	ExiPrep™ Dx Viral DNA/RNA Kit C €	Virus	Serum, Plasma, Swab, Urine, Stool, CSF	96
K-4472	ExiPrep™ Dx Viral DNA Kit C €			96
K-4473	ExiPrep™ Dx Viral RNA Kit C €			96
K-4474	ExiPrep™ Dx Blood Viral DNA Kit C €		Human whole blood	96
K-4414	ExiPrep™ Dx Bacteria Genomic DNA Kit C €	Bacteria	Sputum, Urine, Swab	96
K-4418	ExiPrep™ Dx Mycobacteria Genomic DNA Kit C €	Mycobacteria	Sputum, Urine, BAL	96
K-4411	ExiPrep™ Dx Blood Genomic DNA Kit C €	Human Cell	Human whole blood	96

- ExiPrep™ 48 Kit

*ExiPrep™ 48 Kit for use on the ExiPrep™ 48 Dx.

Cat. No.	Product Name	Target	Sample types	Test/Kit
K-4571	ExiPrep™ 48 Viral DNA/RNA Kit C €	Virus	Serum, Plasma, Swab, Urine, Stool, CSF Human whole Blood	96
K-4573	ExiPrep™ 48 Viral RNA Kit C €	Virus	Serum, Plasma, Swab, Urine, Stool, CSF	96
K-4574	ExiPrep™ 48 Genomic DNA Kit C €	Bacteria	Sputum, Urine, Swab	96
		Mycobacteria	Sputum, Urine, BAL	
		Human Cell	Human whole blood	

- ExiPrep™ 96 Kit

*ExiPrep™ 96 Kit for use on the ExiPrep™ 96 Lite.

Cat. No.	Product Name	Target	Sample types	Test/Kit
K-4611	ExiPrep™ 96 Genomic DNA Kit	Bacteria	Sputum, Urine, Swab, Body fluid, Stool	384
K-4612	ExiPrep™ 96 cfDNA Kit	cfDNA	Plasma, Serum, Urine, Saliva	96

- MagListo™ cfDNA Extraction Kit

*MagListo™ cfDNA Extraction Kit is Manual Type.

Cat. No.	Product Name	Target	Sample types	Test/Kit
K-3619M	MagListo™ 96 cfDNA Extraction Kit	cfDNA	Plasma, Serum, Urine, Saliva	50

C. Real-Time PCR Diagnostic Kits

*Diagnostic Kits for use on the *Exicycler™* 96.

Category	Cat. No.	Product name	Test/Kit
HIV	HIV-1211	AccuPower® HIV-1 Quantitative RT-PCR Kit €€ ⁰¹⁹⁷	96
	HIV-1111	AccuPower® HIV-1 Quantitative RT-PCR Kit	96
Hepatitis	HBV-1211	AccuPower® HBV Quantitative PCR Kit €€ ⁰¹⁹⁷	96
	HBV-1111	AccuPower® HBV Quantitative PCR Kit	96
	HCV-1211	AccuPower® HCV Quantitative RT-PCR Kit €€ ⁰¹⁹⁷	96
	HCV-1111	AccuPower® HCV Quantitative RT-PCR Kit	96
Tuberculosis	XDRA-1111	AccuPower® XDR-TB Real-Time PCR Kit-A €€	48
	XDRB-1111	AccuPower® XDR-TB Real-Time PCR Kit-B €€	96
	TBMDR-1111	AccuPower® TB&MDR Real-Time PCR Kit €€	48
	MTN-1111	AccuPower® MTB&NTM Real-Time PCR Kit €€	96
	MTB-1111	AccuPower® MTB Real-Time PCR Kit €€	96
Sexually Transmitted Infection	STI8A-1111	AccuPower® STI8A-Plex Real-Time PCR Kit €€ ⁰¹⁹⁷	96
	STI8B-1111	AccuPower® STI8B-Plex Real-Time PCR Kit €€	96
	STI4C-1111	AccuPower® STI4C-Plex Real-Time PCR Kit €€	96
	STD2A-1211	AccuPower® CT & NG Real-Time PCR Kit €€ ⁰¹⁹⁷	96
	CHT-1111	AccuPower® CT Real-Time PCR Kit €€ ⁰¹⁹⁷	96
Transplantation -related Virus	CMV-1111	AccuPower® CMV Quantitative PCR Kit	96
	EBV-1111	AccuPower® EBV Quantitative PCR Kit €€	96
	BKV-1111	AccuPower® BKV Quantitative PCR Kit €€	96
Human Papillomavirus	HPM-1111	AccuPower® HPV 16 & 18 Real-Time PCR Kit €€	96
Respiratory Pathogens	SIA-1111	AccuPower® New Inf A (H1N1) & Inf A Real-Time RT-PCR Kit €€	48
	IFA-1111	AccuPower® Influenza A Real-Time RT-PCR Kit €€	96
	SIV-1111	AccuPower® New Inf A (H1N1) Real-Time RT-PCR Kit €€	96
	CPN-1111	AccuPower® CP Real-Time PCR Kit	96
	MPN-1111	AccuPower® MP Real-Time PCR Kit €€	96
	COV-1112	AccuPower® MERS-CoV(upE&ORF1a) Real-Time RT-PCR Kit €€	48
Gastrointestinal Pathogens	NOR-1111	AccuPower® Norovirus Real-Time RT-PCR Kit €€	96
	ENT-1111	AccuPower® EV Real-Time RT-PCR Kit €€	96
Mosquito borne disease	ZIK-1111	AccuPower® ZIKV (DENV, CHIKV) Multiplex Real-Time RT-PCR Kit €€	96
Human Genotyping	HLB-1111	AccuPower® HLA-B27 Real-Time PCR Kit	96
	MTH-1111	AccuPower® MTHFR Real-Time PCR Kit €€	48
	FVL-1111	AccuPower® Factor V Leiden Real-Time PCR Kit €€	48

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