

# MOLECULAR DIAGNOSTICS TOTAL SOLUTION

CATALOG 2022



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**Our goal is to give you the confidence  
to diagnose patients anytime, anywhere.**



**BIONEER** is the first biotech company in Korea established in 1992. We have focused on developing full next-generation technologies in the post-genome era by inventing new biochemistry technologies and instruments based on over 500 patents worldwide.

Since our establishment, we have expanded in magnetic beads, sample preparation, PCR enzymes, primers/probes, automated extractors, Real-Time PCR instruments.

We developed state-of-the-art molecular biology products and technologies, including PoCT, fully automated molecular diagnostics systems, and instruments for gene manipulation such as automated nucleic acid extractors, thermal cyclers, and Real-Time qPCR instruments.

We provide state-of-art solutions to the global community of life science researchers in academia, biotech, and pharmaceutical companies.



## Timeline



**1992**

Est. Korea Biotech Inc.  
(1<sup>st</sup> KRIBB spin-off)  
First in Korea to  
develop and supply  
enzymes and primers  
for PCR

**1995**

First in Korea to  
launch  
Real-Time PCR  
instrument



**2001**

Constructed the  
world's largest DNA  
synthesis center



**2003**

Exported SARS  
diagnostic kit  
to China



**2009**

Influenza A (H1N1)  
More than 2 million  
tests with the  
diagnostic kit



**2014**

Development of Ebola  
Virus Diagnostic Kit  
with Nigeria  
Government

## BIONEER GLOBAL



Europe



China



South Korea  
HQ



**2016**

The world's first multiplex kit on Zika WHO EUAL



**2017**

4<sup>th</sup> Africa Healthcare Awards winner for the Medical Technology Company of the Year

**2018**

Asia's first CE-IVD List A HIV-1 Quantitative RT-PCR Kit approved



**2019**

CE-IVD List listed in Global Fund A approved for HCV, HBV Viral Load Assay, and HIV-1 Kit



**2020**

CE approved for COVID-19 assay



**2021**

Attracted PoC MDx investment from Global Fund



U.S.A

3



Global Offices

80+

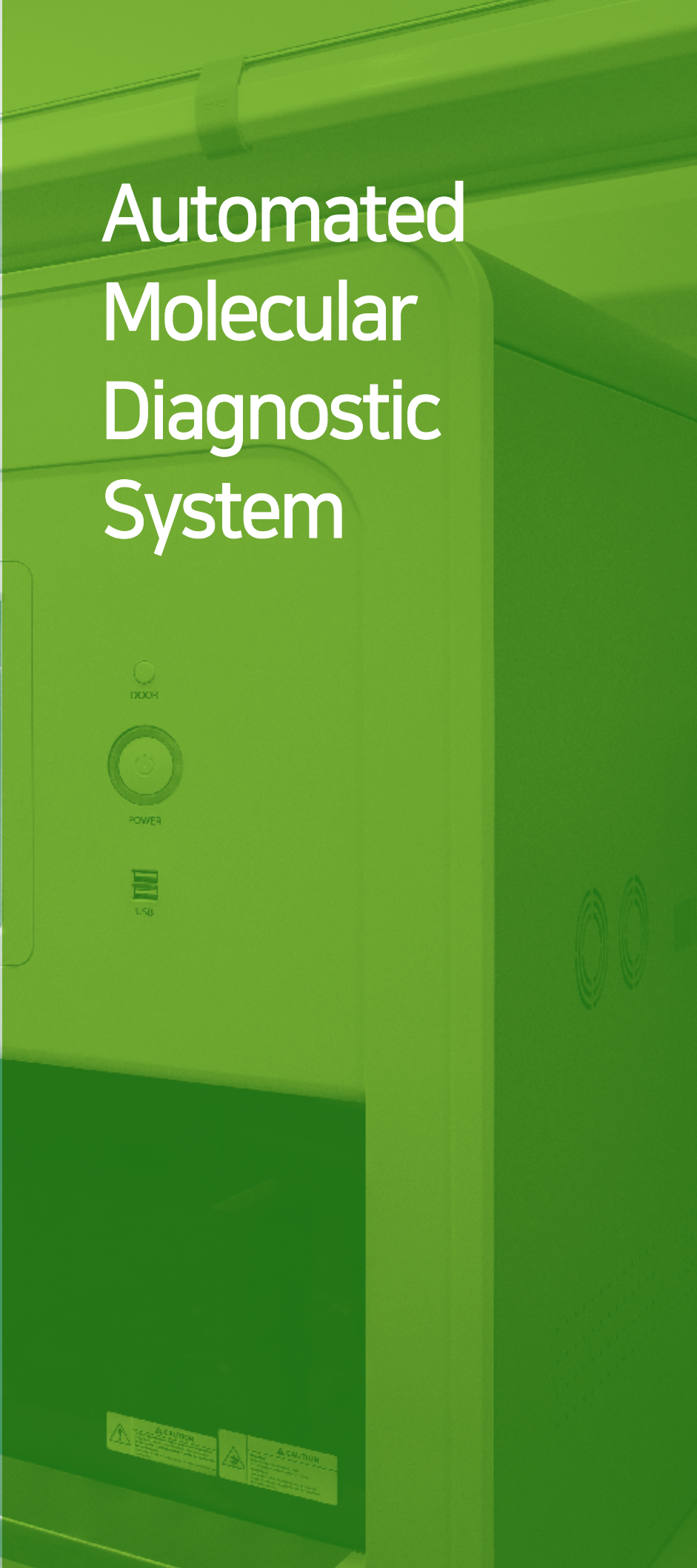


Global Partners





# Automated Molecular Diagnostic System



# ExiStation™ Universal Molecular Diagnostic System

Molecular Diagnostics (MDx) is one of the *in vitro* diagnostic methods consisting of nucleic acid extraction, Real-Time PCR, and analyzing results. Compared to other diagnostic methods, MDx is characterized by high sensitivity and specificity. The *ExiStation™* series is a high-performance MDx system developed with our patent-based technology. There are *ExiStation™* and *ExiStation™ 48* in this series and they have below in common.

- **Scalable Testing Capacity:** Adjustable testing capacity depending on the laboratory size
- **Built-in Quality Control System:** Allows the detection of tiny copies of pathogens in samples
- **Diagnose Various Diseases:** All *AccuPower®* kits are applicable with our thermal cycler, *Exicycler™96*
- **User-friendly Process:** Pre-installed protocol and workflow with the *ExiStation™* Manager Software



## ExiStation™

- *ExiStation™* is configured with *ExiPrep™ 16 Dx* and *Exicycler™96*.
- *ExiPrep™* can integrate from 1-3 *ExiPrep™* and handles from 16 - 48 samples
- Each *ExiPrep™ 16 Dx* is capable of simultaneous nucleic acid extraction for different samples such as HIV, HBV and HCV.



## ExiStation™ 48

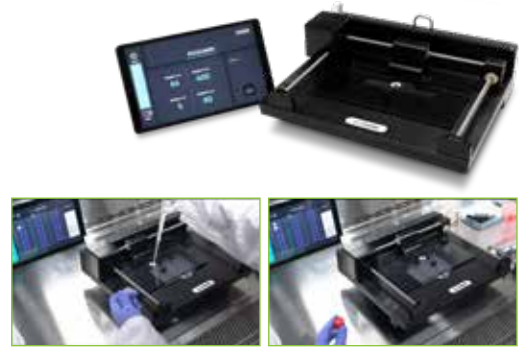
- Nucleic acid extraction of 48 samples in 60 minutes
- Enhanced user experience with built-in automatic cartridge puncher and three options of sample volume – 200, 400, and 800 µl

Configuration	Single set	Dual set	Triple set
<i>ExiStation™</i>	<i>ExiPrep™ 16 Dx</i> (1 ea) <i>Exicycler™96</i> (1 ea) <i>ExiSpin™</i> (1 ea)	<i>ExiPrep™ 16 Dx</i> (2 ea) <i>Exicycler™96</i> (1 ea) <i>ExiSpin™</i> (1 ea)	<i>ExiPrep™ 16 Dx</i> (3 ea) <i>Exicycler™96</i> (1 ea) <i>ExiSpin™</i> (1 ea)
<i>ExiStation™ 48</i>	<i>ExiPrep™ 48 Dx</i> (1 ea) <i>Exicycler™96</i> (1 ea) <i>ExiSpin™</i> (1 ea)	<i>ExiPrep™ 48 Dx</i> (2 ea) <i>Exicycler™96</i> (1 ea) <i>ExiSpin™</i> (2 ea)	-

## ■ Sample Loading Guide

### AccuLoader™

- Reads the sample barcode and automatically positions the dispensing site over the appropriate well
- Prevents cross-contamination with a sample shield and contamination prevention filter
- Easily change the loading conditions using the AccuLoader app for Android tablets
- Compatible with *ExiPrep™* plates and other plates such as MagnaPure96, KingFisher Flex, and more.



## ■ Nucleic Acid Extractor



### ExiPrep™ 16 Dx

- Simultaneous nucleic acid extractions from various clinical samples
- Each *ExiPrep™* 16 Dx processes 16 samples in 90 minutes and process up to 48 samples when 3 *ExiPrep™* 16 Dx instruments are used



### ExiPrep™ 48 Dx

- Process up to 48 samples in 60 minutes
- Multiple sample volume options: 200, 400 and 800 µl
- Excellent usability with a built-in auto puncher and wide touch screen



### ExiPrep™ 96 Lite

- Compact size
- Fast and high throughput
  - Process up to 96 samples per run
  - Fast walkaway time: less than 50 minutes
- Sample volume flexibility
  - 24 test x 4 ml (cfDNA only)
  - 96 test x 400 µl

\* *ExiStation™* mode is not available for *ExiPrep™* 96

## ■ Real-Time PCR



### Exicycler™96

- Excellent sensitivity optics by eliminating reflected light through polarization for accurate quantification and identification
- Improved thermal block ramping rate
  - Normal block (Max. 4.5°C/sec), Fast block (Max. 5.0°C/sec)
- 5 channel multiplex detection without a reference dye



*ExiPrep™ Dx Kit*

Extraction kit		Viral DNA /RNA Kit	Viral DNA Kit	Viral RNA Kit	Blood Viral DNA Kit	Bacterial Genomic DNA Kit	Mycobac. Genomic DNA Kit	Blood Genomic DNA Kit
		19p	19p	19p	20p	21p	22p	23p
Assay	COVID-19 44p							
	HIV-1 52p							
	HBV 53p							
	HCV 54p							
	TB 55p							
	STI 60p							
	HPV 67p							
	RV 69p							
	Pneumonia 70p							
	GI 73p							
	Transplantation related Virus 64p					* Except for BKV-1111		
	Mosquito borne Diseases 75p							
	Human Genotyping 76p							



B

Sample: Standard Protocol  
00:28:00  
0%

BIONEER





# Nucleic Acid Extraction Kits

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## Overview

### ExiPrep™ Dx Nucleic Acid Extraction Kits

Cat.no	Product List	Target	Sample Type	Initial Volume	Elution Volume	Number of Tests	Page
K-4471	ExiPrep™ Dx Viral DNA/RNA Kit	Virus	Serum, Plasma, Swab, Urine, Saliva, Body Fluids	400 ul	50 ul – 100 ul	96	19p
K-4472	ExiPrep™ Dx Viral DNA Kit					96	19p
K-4473	ExiPrep™ Dx Viral RNA Kit					96	19p
K-4474	ExiPrep™ Dx Blood Viral DNA Kit		Human Whole Blood	200 ul	50 ul	96	20p
K-4414	ExiPrep™ Dx Bacteria Genomic DNA Kit	Bacteria	Sputum, Body fluids, Urine, Swab, Stool	400 ul		96	21p
K-4418	ExiPrep™ Dx Mycobacteria Genomic DNA Kit	Mycobacteria	Sputum, Urine, Body Fluids			96	22p
K-4411	ExiPrep™ Dx Blood Genomic DNA Kit	Human Cell	Human Whole Blood	200 ul	70 ul	96	23p

### ExiPrep™ 48 Nucleic Acid Extraction Kits

Cat.no	Product List	Target	Sample Type	Initial Volume	Elution Volume	Number of Tests	Page
K-4571	ExiPrep™ 48 Viral DNA/RNA Kit	Virus	Serum, Plasma, Urine, Swab, Saliva, Body Fluids	400 ul, 800 ul	50 ul	96	24p
			Human Whole Blood	200 ul			
K-4573	ExiPrep™ 48 Viral RNA Kit		Saliva, Serum, Plasma, Swab, Stool, Body Fluids	400 ul, 800 ul		96	24p
K-4574	ExiPrep™ 48 Genomic DNA Kit	Bacteria	Sputum, Urine, Swab	400 ul, 800 ul		96	25p
		Mycobacteria	Sputum, Urine, BAL				
		Human Cell	Human Whole Blood	200ul			
K-4575	ExiPrep™ 48 Fast Viral RNA Kit	Virus	Saliva, Sputum, Nasopharyngeal & Oropharyngeal Swab	400 ul	96	26p	

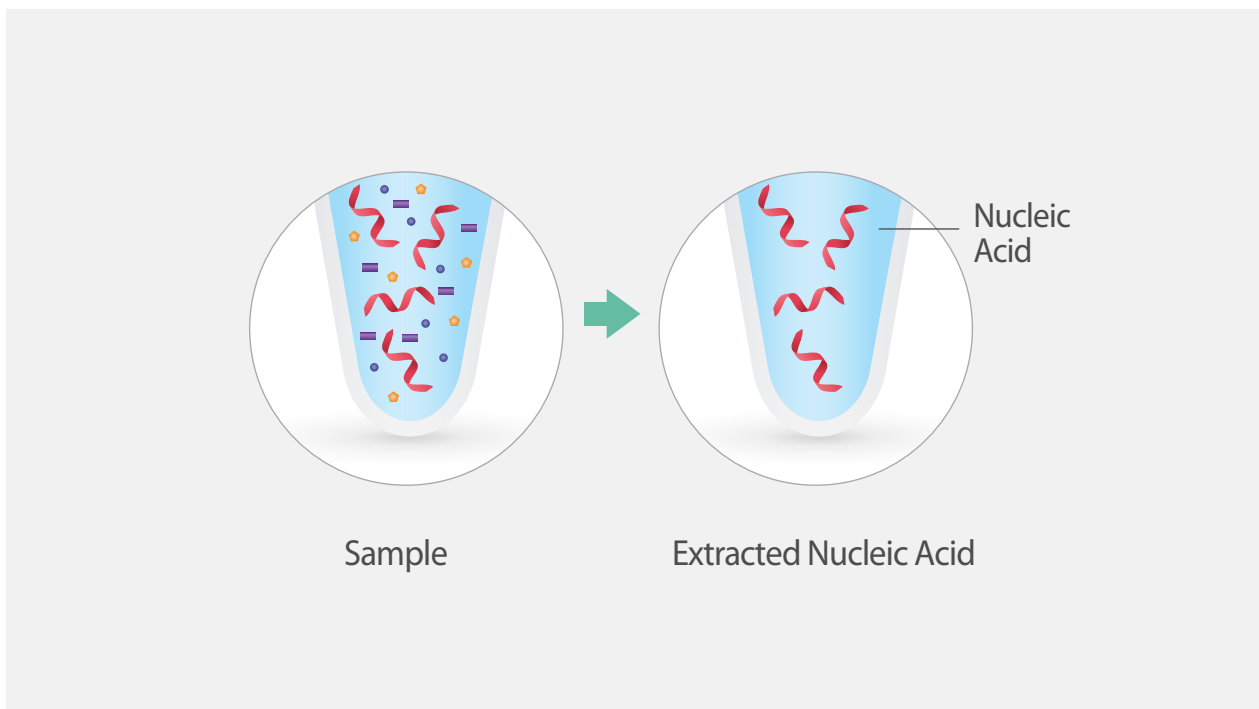
### ExiPrep™ 96 Nucleic Acid Extraction Kits

Cat.no	Product List	Target	Sample Type	Initial Volume	Elution Volume	Number of Tests	Page
K-4611	ExiPrep™ 96 Genomic DNA Kit	Bacteria	Sputum, Body Fluids, Urine, Nasopharyngeal & Oropharyngeal Swab	400 ul	100 ul	384	27p
			Human Whole Blood	200 ul			
			Stool	50 mg – 200 mg			
K-4612	ExiPrep™ 96 cDNA Kit	cfDNA	Plasma, Serum, Urine, Saliva	1 ml – 4 ml	100 ul	96	28p
K-4613	ExiPrep™ 96 Blood Genomic DNA Kit	Human Cell	Human Whole Blood	200 ul – 400 ul	150 ul	384	29p
K-4614	ExiPrep™ 96 Viral DNA/RNA Kit	Virus	Sputum, Nasopharyngeal & Oropharyngeal Swab	200 ul – 400 ul	100 ul	384	30p
K-4731	Protonion™ 96 Viral RNA Kit	Virus	Saliva, Sputum, Nasopharyngeal & Oropharyngeal Swab	400 ul	100 ul	384	31p



## ExiPrep™ Nucleic Acid Extraction

The success of molecular diagnostic detection and analysis is determined by methods of nucleic acid extraction from various sample types. *ExiPrep™* Nucleic Acid Extraction Kit series provides a convenient and efficient method for isolating and purifying nucleic acids from multiple samples including blood, urine, sputum, BAL, and swabs. In addition, *MagListo™* cfDNA Extraction Kit allows you to extract cfDNA with excellent purity and yield. The use of magnetic beads eliminates the need for centrifugation, making extraction more convenient than columnar extraction. Based on this, BIONEER kits offer different isolation systems for different testing purposes, ensuring high-quality nucleic acid purification.



### ■ Features & Benefits

- Multiple target nucleic acids can be extracted simultaneously
- Pre-installed nucleic acid extraction protocols optimized for each sample type for reproducible results\*
- Use of silica magnetic beads developed and produced with BIONEER technology
- If sputum specimens are used, the EZ solution allows for a more efficient pretreatment process

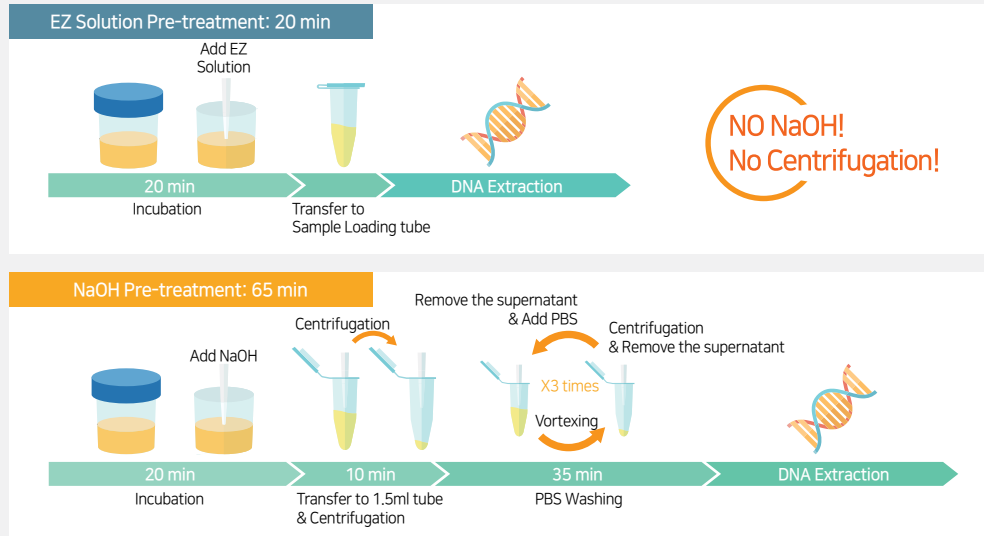
\* These features do not apply to Manual Handling kits

# I Nucleic Acid Extraction Technology

## EZ Solution

EZ Solution is an easy sputum liquefaction solution. The sputum pretreatment procedure with EZ Solution eliminates time-consuming centrifugation and washing steps. This makes sputum treatment simpler, faster, and more effective than methods using NaOH.

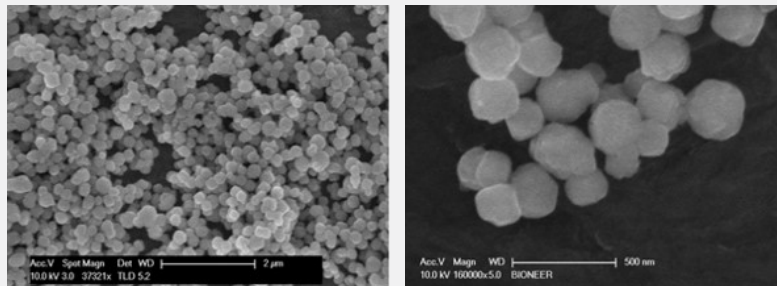
### EZ Solution vs NaOH: Sputum Pretreatment



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

## Silica Magnetic Nanobeads

There has been much applying magnetic beads in biology in recent years, from cellular experiments and DNA purification to disease monitoring and even disease treatment. The surface of magnetic beads is coated with functional groups that allow the binding of DNA, RNA, proteins, and specific cells. Afterward, the beads are moved or attached to the desired position through external magnetic fields to perform purification. In addition, while conventional magnetic beads are micro-sized, these silica magnetic beads are nano-sized. They bear the advantages of high binding capacity due to their relatively large surface area.



FE-SEM picture of Magnetic Nanobeads. The electron microscope picture shows spherical magnetic nanobeads.

- **ExiPrep™ Dx Viral DNA/RNA Kit (K-4471)**
- **ExiPrep™ Dx Viral DNA Kit (K-4472)**
- **ExiPrep™ Dx Viral RNA Kit (K-4473)**

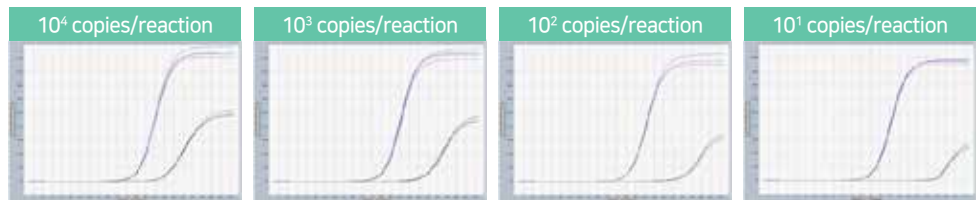


Target	Virus
Specimen	Serum, Plasma, Swab, Urine, Stool, CSF
Starting Volume	400 ul
Elution Volume	50 ul - 100 ul
Number of Test	96 tests
Turnaround Time	90 minutes

### ■ Components

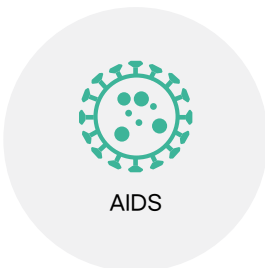
No.	Name	Quantity
1	Buffer Cartridges ① & ②	6 cartridges each
2	Disposable Filter Tip	32 ea x 3 packs
3	Elution Tubes & Contamination Shield Filter Paper	12 ea x 1 pack
4	Sample Loading Tube	16 ea x 6 packs
5	Protection Cover	3 ea x 4 packs
6	Waste Tray	3 ea x 1 pack

### ■ 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 *AccuPower®* HBV Quantitative PCR Kit with *ExiStation™*

(Black signal: HBV, Blue signal: IPC)



Quantification of HIV type 1 viral load was performed to evaluate *ExiPrep™* Dx Viral RNA Kit. Viral RNA was extracted from serum using the kit, and Real-Time PCR was performed with the *AccuPower®* HIV-1 Quantitative RT-PCR Kit with *ExiStation™*

(Black signal: HIV-1, Blue signal: IPC)

## ExiPrep™ Dx Blood Viral DNA Kit (K-4474)

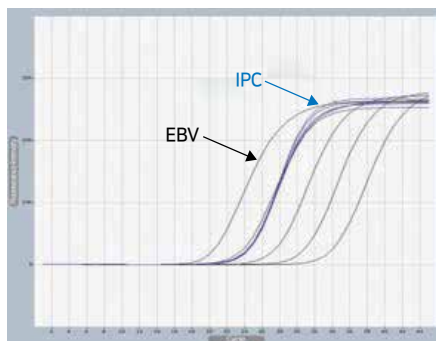
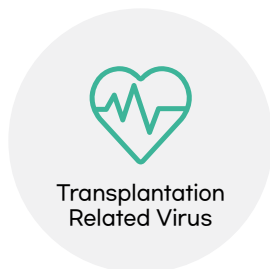


Target	Virus
Specimen	Human Whole Blood
Starting Volume	200 ul
Elution Volume	50 ul
Number of Test	96 tests
Turnaround Time	90 minutes

### Components

No.	Name	Quantity
1	Buffer Cartridges ① & ②	6 cartridges each
2	Disposable Filter Tip	32 ea x 3 packs
3	Elution Tubes & Contamination Shield Filter Paper	12 ea x 1 pack
4	Sample Loading Tube	16 ea x 6 packs
5	Protection Cover	3 ea x 4 packs
6	Waste Tray	3 ea x 1 pack

### Experimental Data



Serial dilutions of blood samples ( $5 \times 10^3 \sim 5 \times 10^7$  copies/ml) containing EBV was processed according to the ExiPrep™ Dx Blood Viral DNA Kit protocol.

## ExiPrep™ Dx Bacteria Genomic DNA Kit (K-4414)

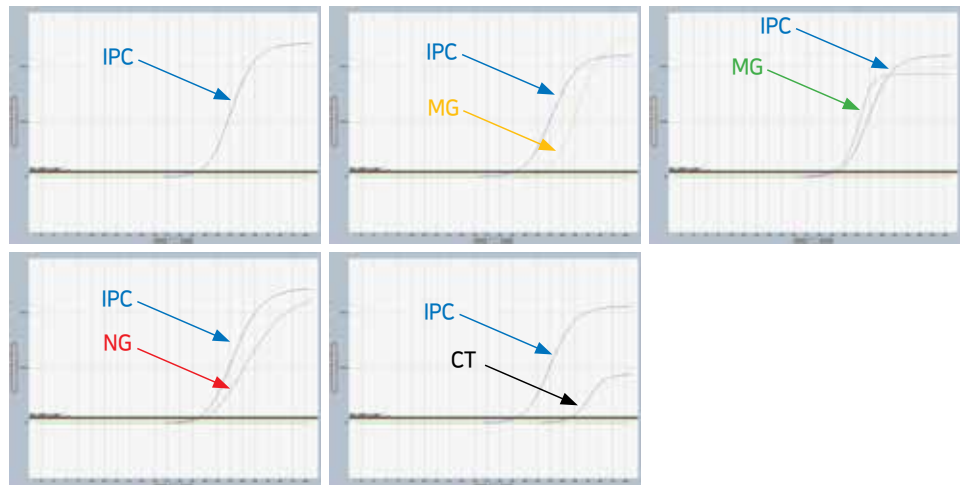
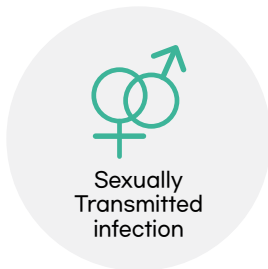


Target	Bacteria
Specimen	Sputum, Body fluids, Urine, Swab, Stool
Starting Volume	400 ul
Elution Volume	50 ul
Number of Test	96 tests
Turnaround Time	90 minutes

### Components

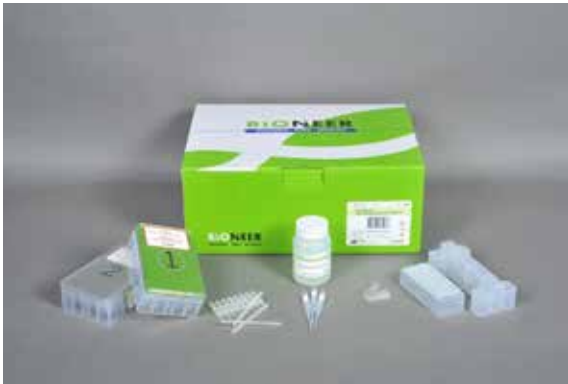
No.	Name	Quantity
1	Buffer Cartridges ① & ②	6 cartridges each
2	Disposable Filter Tip	32 ea x 3 packs
3	Elution Tubes & Contamination Shield Filter Paper	12 ea x 1 pack
4	Sample Loading Tube	16 ea x 6 packs
5	Protection Cover	3 ea x 4 packs
6	Waste Tray	3 ea x 1 pack

### Experimental Data



Bacterial genomic DNA extracted by ExiPrep™ Dx Bacteria Genomic DNA Kit for clinical test with AccuPower® STI8A-Plex Real-Time PCR Kit

# ExiPrep™ Dx Mycobacteria Genomic DNA Kit (K-4418)

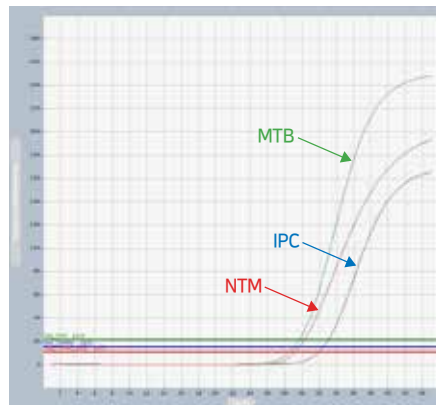
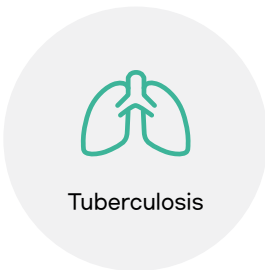


Target	Mycobacteria
Specimen	Sputum, Urine, BAL, Body Fluids
Starting Volume	400 ul
Elution Volume	50 ul
Number of Test	96 tests
Turnaround Time	90 minutes

## Components

No.	Name	Quantity
1	Buffer Cartridges ① & ②	6 cartridges each
2	Disposable Filter Tip	32 ea x 3 packs
3	Elution Tubes & Contamination Shield Filter Paper	12 ea x 1 pack
4	Sample Loading Tube	16 ea x 6 packs
5	Protection Cover	3 ea x 4 packs
6	Waste Tray	3 ea x 1 pack

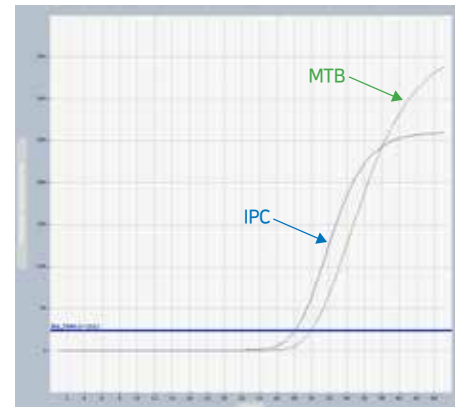
## Experimental Data



The mycobacterial genomic DNA extracted by ExiPrep™ Dx Mycobacterial Genomic DNA Kit was used for tests of AccuPower® MTB & NTM Real-Time RT-PCR Kit.

(Red signal: NTM,

Green signal: MTB, Blue signal: IPC)



The mycobacterial genomic DNA extracted by ExiPrep™ Dx Mycobacterial Genomic DNA Kit was used for tests of AccuPower® MTB Real-Time RT-PCR Kit.

(Green signal: MTB, Blue signal: IPC)

## ExiPrep™ Dx Blood Genomic DNA Kit (K-4411)

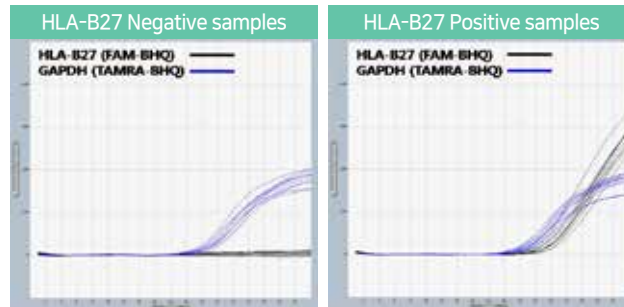


Target	Human Cell
Specimen	Human Whole Blood
Starting Volume	200 ul
Elution Volume	70 ul
Number of Test	96 tests
Turnaround Time	90 minutes

### Components

No.	Name	Quantity
1	Buffer Cartridges ① & ②	6 cartridges each
2	Disposable Filter Tip	32 ea x 3 packs
3	Elution Tubes & Contamination Shield Filter Paper	12 ea x 1 pack
4	Sample Loading Tube	16 ea x 6 packs
5	Protection Cover	3 ea x 4 packs
6	Waste Tray	3 ea x 1 pack

### Experimental Data



Genomic DNA extracted by *ExiPrep™* Blood Genomic DNA Kit was used for comparison test of *AccuPower®* HLA-B27 Real-Time PCR Kit

<i>AccuPower®</i> 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%)

The above table indicates comparison result from A and B University hospitals using clinical samples.

## ExiPrep™ 48 Viral DNA/RNA Kit (K-4571)

## ExiPrep™ 48 Viral RNA Kit (K-4573)

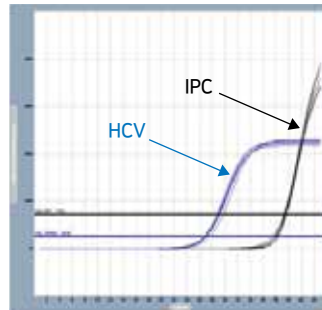


Target	Virus
Specimen	Serum, Plasma, Swab, Urine, Saliva, Stool, Body Fluids, Human Whole Blood
Starting Volume	400 ul, 800 ul (200 ul for Human Whole Blood)
Elution Volume	50 ul
Number of Test	96 tests
Turnaround Time	60 minutes

### Components

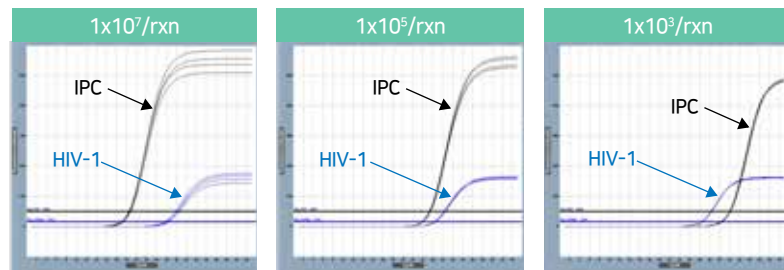
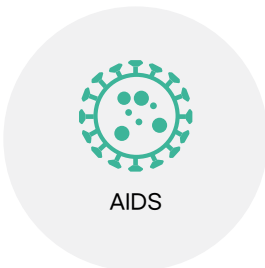
No.	Name	Quantity
1	Buffer Cartridges ① & ②	6 cartridges each
2	Disposable Filter Tip	32 ea x 6 packs
3	Elution Tubes & Contamination Shield Filter Paper	8 tubes x 12 strips
4	Sample Loading Tube	6 packs x 1 box
5	Protection Cover	3 ea x 4 packs
6	Waste Tray	3 ea x 1 pack

### 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 acid extraction produce high reproducibility. (Blue signal: HCV, Black signal: IPC)



Quantification of HIV viral load was performed to evaluate of ExiPrep™ 48 Viral RNA Kit. Viral RNA was extracted from serum using the kit, and Real-Time PCR was performed with the AccuPower® HIV-1 Quantitative RT-PCR Kit on Exicycler™96. (Blue signal: HIV-1, Black signal: IPC)



## ExiPrep™ 48 Genomic DNA Kit (K-4574)

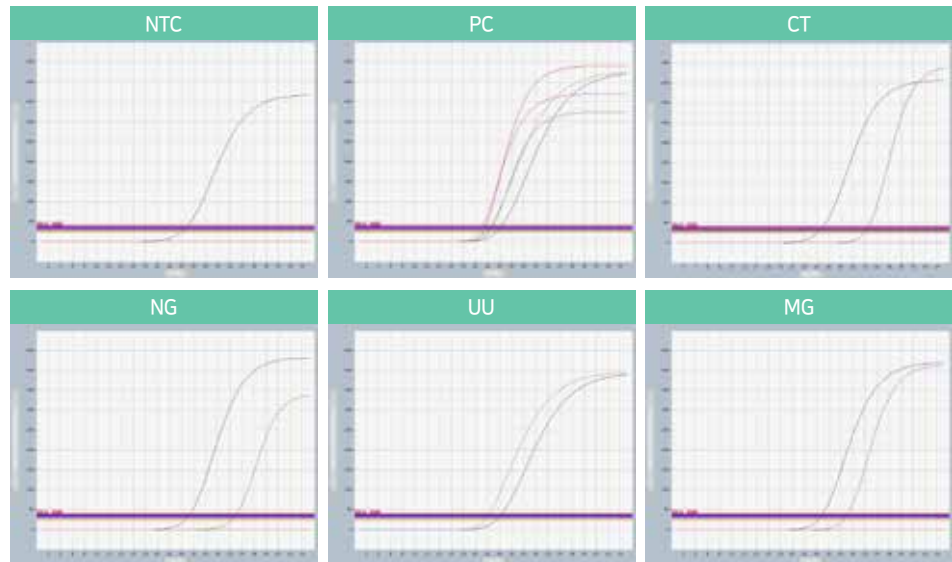


Target	Bacteria, Mycobacteria, Human Cell
Specimen	Sputum, Urine, Swab, BAL, Human Whole Blood
Starting Volume	400 ul, 800 ul for Bacteria, Mycobacteria 200 ul for Human Whole Blood
Elution Volume	50 ul
Number of Test	96 tests
Turnaround Time	60 minutes

### Components

No.	Name	Quantity
1	Buffer Cartridges ① & ②	6 cartridges each
2	Disposable Filter Tip	32 ea x 6 packs
3	Elution Tubes & Contamination Shield Filter Paper	8 tubes x 12 strips
4	Sample Loading Tube	6 packs x 1 box
5	Protection Cover	3 ea x 4 packs
6	Waste Tray	3 ea x 1 pack

### Experimental Data



Bacterial genomic DNA extracted by ExiPrep™ 48 Genomic DNA Kit was used for tests of AccuPower® STI8A-Plex Real-Time PCR Kit.

# ExiPrep™ 48 Fast Viral RNA Kit (K-4575)



Target	Virus
Specimen	Saliva, Sputum, Nasopharyngeal & Oropharyngeal Swab
Starting Volume	400 ul
Elution Volume	50 ul
Number of Test	96 tests
Turnaround Time	30 minutes

## Components

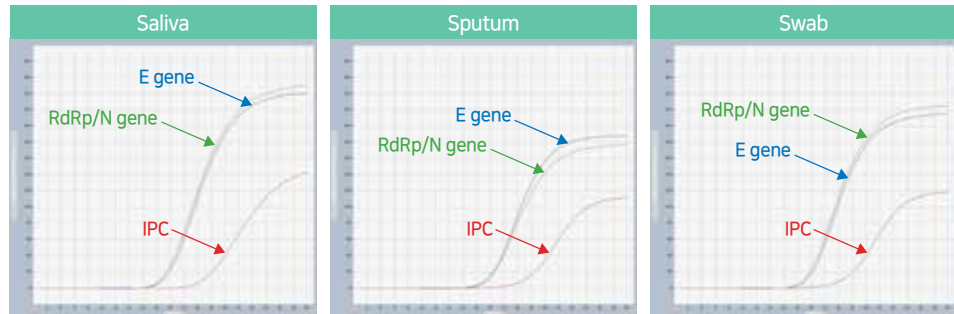
No.	Name	Quantity
1	Buffer Cartridge	6 cartridge
2	Disposable Filter Tip	16 ea x 6 packs
3	Elution Tubes & Contamination Shield Filter Paper	8 tubes x 12 strips
4	Sample Loading Tube	6 packs x 1 box
5	Protection Cover	3 ea x 4 packs
6	Waste Tray	3 ea x 1 pack

EtOH

## EtOH-free Extraction Kits

- More accurate diagnosis by not using EtOH as PCR inhibitor
- More rapid extraction without EtOH dry step

## Experimental Data



The SARS-CoV-2 RNA extracted by ExiPrep™48 Fast Viral RNA Kit was used for AccuPower® SARS-CoV-2 Multiplex Real-Time RT-PCR Kit. (Red signal: IPC, Blue signal: E gene, Green signal: RdRp/N gene)

## ExiPrep™ 96 Genomic DNA Kit (K-4611)

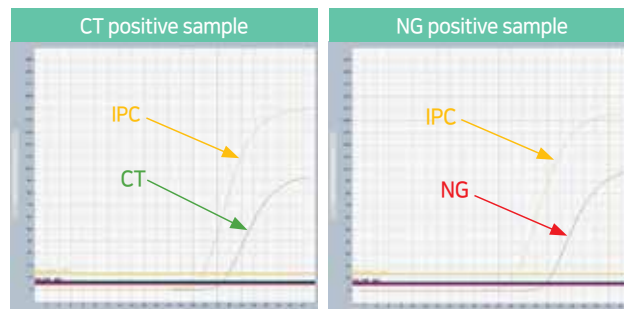
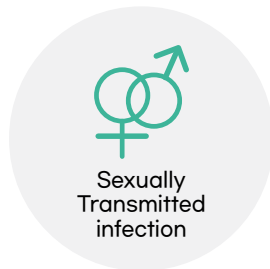


Target	Bacteria
Specimen	Sputum, Body Fluids, Urine, Stool, Swab, Human Whole Blood
Starting Volume	400 ul 200 ul for Human Whole Blood 50 mg - 200 mg for Stool
Elution Volume	100 ul
Number of Test	384 tests
Turnaround Time	50 minutes

### Components

No.	Name	Quantity
1	Buffer Cartridge ①-⑦	4 cartridge each
2	Resuspension Buffer	100 ml x 4 ea
3	Magnetic Rod Cover	12 ea x 1 pack
4	Sealing Film	8 ea x 1 pack

### Experimental Data



The eluent extracted with the ExiPrep™ 96 Genomic DNA Kit was used for testing with the AccuPower® CT & NG Real-Time PCR Kit on the Exicycler™96.

(Green signal: CT, Red signal: NG, Yellow signal: IPC)

## ExiPrep™ 96 cfDNA Kit (K-4612)

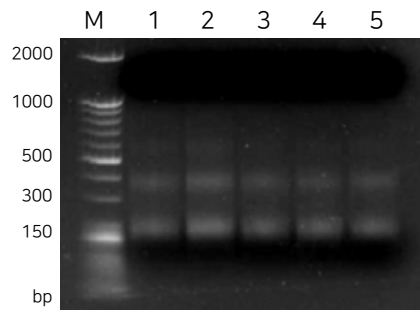
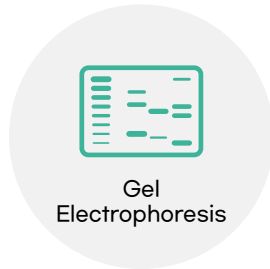


Target	cfDNA
Specimen	Plasma, Serum, Urine, Saliva
Starting Volume	1 ml – 4 ml
Elution Volume	100 ul
Number of Test	96 tests
Turnaround Time	50 minutes

### Components

No.	Name	Quantity
1	Buffer Cartridge ①-⑦	4 cartridge each
2	Elution Buffer	20 ml each
3	Proteinase K	4 tubes x 4 pack
4	Magnetic Rod Cover	12 ea x 1 pack
5	Sealing Film	8 ea x 1 pack

### Experimental Data



The result of electrophoresis of the eluent extracted by *ExiPrep*™ 96 cfDNA Kit. 4ml serum samples were used.

(cfDNA size: 175~180 bp, 330~350 bp)

## ExiPrep™ 96 Blood Genomic DNA Kit (K-4613)

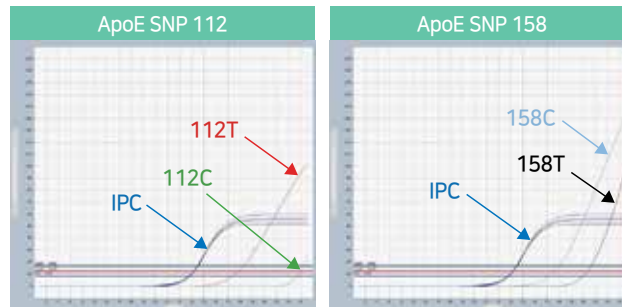


Target	Human Cell
Specimen	Human Whole Blood
Starting Volume	200 ul - 400 ul
Elution Volume	150 ul
Number of Test	384 tests
Turnaround Time	50 minutes

### Components

No.	Name	Quantity
1	Buffer Cartridge ①-⑦	4 cartridge each
2	Proteinase K	25 mg x 8 ea
3	Magnetic Rod Cover	12 ea x 1 pack
4	Sealing Film	8 ea x 1 pack

### Experimental Data



For panel testing of *AccuPower*® ApoE Real-Time PCR Kit, human genomic DNA extracted with *ExiPrep*™ 96 Blood Genomic DNA Kit was used.

# ExiPrep™ 96 Viral DNA/RNA Kit (K-4614)

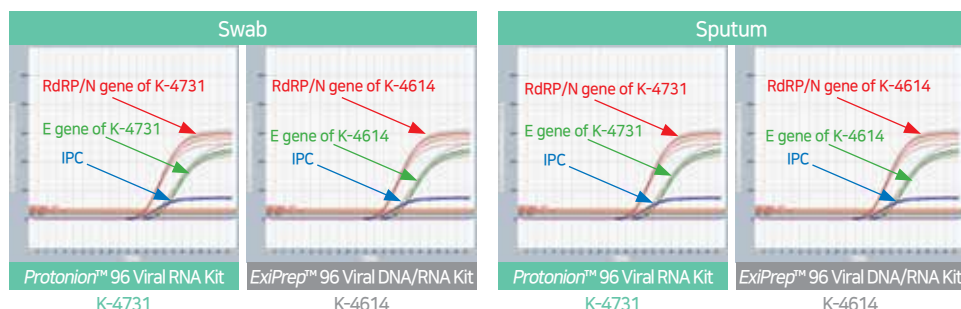


Target	Virus
Specimen	Sputum, Nasopharyngeal & Oropharyngeal Swab
Starting Volume	200 ul - 400 ul
Elution Volume	100 ul
Number of Test	384 tests
Turnaround Time	50 minutes

## Components

No.	Name	Quantity
1	Buffer Cartridge ①-⑦	4 cartridge each
2	Proteinase K	25 mg x 8 ea
3	Magnetic Rod Cover	12 ea x 1 pack
4	Sealing Film	8 ea x 1 pack

## Experimental Data



Panel	Kit	Ct								Average	SD	
		1	2	3	4	5	6	7	8			
E gene	VTM	K-4731	28.05	28.4	28.77	28.89	29.18	29.11	28.94	28	28.67	0.4317
		K-4614	30.81	31.43	30.54	32.03	31.36	33.61	31.4	32.34	31.69	0.9071
	Sputum	K-4731	27.25	27.18	28.07	27.41	28.9	28.99	29.55	28.05	28.18	0.8320
		K-4614	27.25	28.73	28.00	29.36	29.87	29.64	30.75	30.74	29.29	1.1639
RdRP/ N gene	VTM	K-4731	25.84	25.88	25.86	26.01	26.18	26.01	25.87	25.62	25.91	0.1528
		K-4614	26.25	26.31	26.34	26.34	26.29	26.48	26.54	26.66	26.40	0.1339
	Sputum	K-4731	24.8	24.44	24.88	24.77	25.66	25.27	25.48	25.02	25.04	0.3787
		K-4614	24.20	24.03	24.31	24.09	24.15	24.24	24.32	24.18	24.19	0.1008

The E gene, RdRp/N gene RNA extracted from two samples (Swab, Sputum) using Protonion™ 96 Viral RNA Kit and ExiPrep™ 96 Viral DNA/RNA Kit was used for panel test of AccuPower® RV1 Multiplex Kit (E gene, RdRp/N gene targeted). The regular results indicate that nucleic acids extraction produce high reproducibility.

(Red signal: RdRp/N gene, Green signal: E gene, Blue signal: IPC)

## Protonion™ 96 Viral RNA Kit (K-4731)

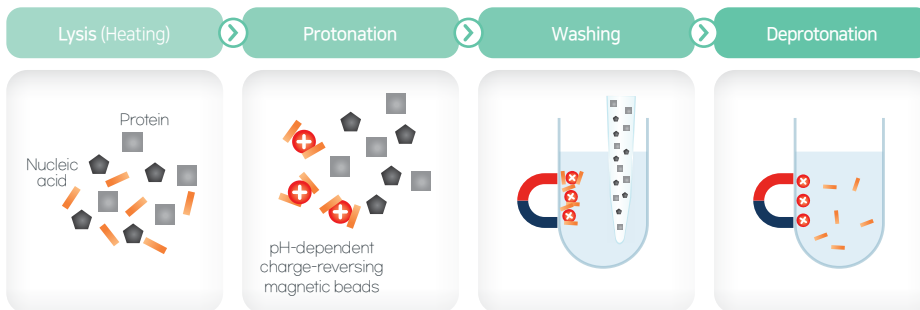


Target	Virus
Specimen	Sputum, Saliva, Nasopharyngeal & Oropharyngeal Swab
Starting Volume	400 ul
Elution Volume	100 ul
Number of Test	384 tests
Turnaround Time	28 minutes

### Components

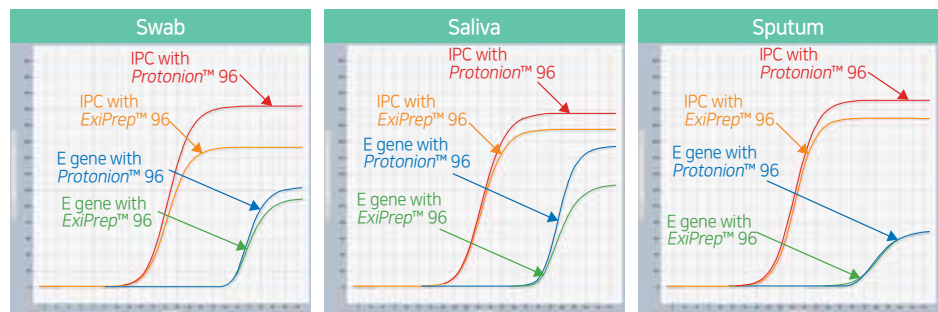
No.	Name	Quantity
1	Buffer Cartridge ①-⑤, ⑦	4 cartridge each
2	Viral RNA Enzyme Mix	8 ea
3	Magnetic Rod Cover	12 ea x 1 pack
4	Sealing Film	8 ea x 1 pack

### The Protonation in Protonion™ Kit



- Nucleic acids bind to protonated surface of magnetic beads
- Bound nucleic acids are eluted by deprotonation
- EtOH-Free: Ethanol, polymerase denaturant is not used in whole processes

### Experimental Data



Comparison between Protonion™ 96 Viral RNA Kit and ExiPrep™ 96 Viral DNA/RNA Kit. SARS-CoV-2 RNA extracted with Protonion™ 96 Viral RNA Kit and ExiPrep™ 96 Viral DNA/RNA Kit was used for AccuPower® SARS-CoV-2 Real-Time RT-PCR Kit testing.

(Red signal: IPC with Protonion™ 96, Blue signal: E gene with Protonion™ 96, Orange signal: IPC with ExiPrep™ 96, Green signal: E gene with ExiPrep™ 96)

# AccuPrep® Dx Viral RNA Extraction Kit (K-3033M)

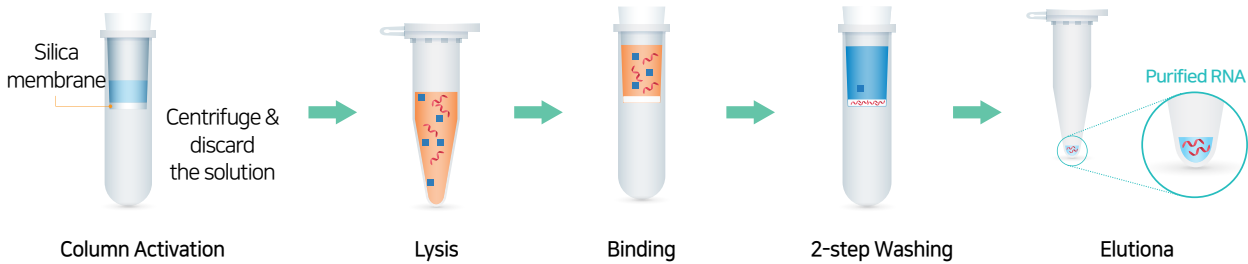


Target	Virus
Specimen	Sputum, Nasopharyngeal & Oropharyngeal Swab
Starting Volume	200 ul
Elution Volume	50 ul
Number of Test	100 tests

## Components

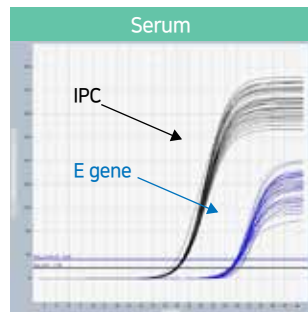
No.	Name	Quantity	No.	Name	Quantity
1	VB Buffer (Virus Binding)	50 ml X 1 ea	6	Poly (A), lyophilized	2 mg X 1 ea
2	VW1 Buffer (1 <sup>st</sup> Washing)	40 ml X 1 ea	7	Proteinase K, lyophilized	25 mg X 1 ea
3	RWA2 Buffer (2 <sup>nd</sup> Washing)	70 ml X 1 ea	8	AccuPrep Binding Column-I	100 ea
4	ER Buffer (Elution)	20 ml X 1 ea	9	Collection Tube (for filtration)	100 ea
5	BST Solution	40 ml X 1 ea	10	1.5 ml Tube (for elution)	100 ea

## Workflow



\*Please refer to User Guide for detail

## Experimental Data



	E gene				IPC			
Ct	32.80	33.17	33.26	33.04	24.02	24.82	25.14	24.93
	33.09	33.06	33.76	33.41	25.18	25.00	25.27	25.06
	32.77	33.25	33.02	33.03	25.13	24.86	24.97	24.81
	32.78	33.31	33.14	33.09	25.19	25.09	25.16	25.04
	32.83	33.33	33.18	33.30	25.12	25.10	24.90	24.96
	32.94	34.15	33.43	33.19	25.21	25.07	25.14	24.91
	32.84	34.49	33.18	34.16	25.24	25.06	25.19	24.85
	32.93	33.73	32.53	33.15	25.33	25.18	25.10	25.13
Average	33.22				25.03			
CV	1.25				0.88			

The E gene RNA extracted from Serum by AccuPrep® Dx Viral RNA Extraction Kit was used for particle test of AccuPower® SARS-CoV Real-Time RT-PCR Kit (E gene targeted). The regular results indicate that nucleic acids extraction produce high reproducibility.

(Blue signal: E gene, Black signal: IPC)



## MagListo™ 5M Viral DNA/RNA Extraction Kit (K-3617)



Target	Virus
Specimen	Sputum, Nasopharyngeal & Oropharyngeal Swab
Starting Volume	200 ul
Elution Volume	50 - 100 ul
Number of Test	100 tests

### Components

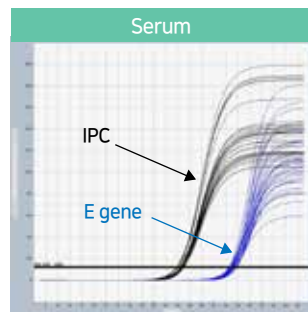
No.	Name	Quantity	No.	Name	Quantity
1	AccuNanoBead	22 ml X 1 ea	5	ER Buffer (Elution)	20 ml X 1 ea
2	VB Buffer (Virus Binding)	50 ml X 1 ea	6	Poly (A), lyophilized	2 mg X 1 ea
3	VW1 Buffer (1 <sup>st</sup> Washing)	50 ml X 2 ea	7	Proteinase K, lyophilized	25 mg X 1 ea
4	RWA2 Buffer (2 <sup>nd</sup> Washing)	100 ml X 1 ea			

### Workflow



\*Please refer to User Guide for detail

### Experimental Data



	E gene				IPC			
Ct	33.11	33.30	32.98	32.68	24.54	25.07	24.87	24.16
	33.01	33.44	33.34	32.74	24.61	24.99	24.65	24.17
	33.31	33.45	33.27	32.63	24.87	24.94	24.65	24.00
	32.58	33.24	32.94	32.55	24.52	24.89	24.56	23.78
	33.54	33.59	32.74	32.39	24.56	25.11	24.52	23.97
	32.78	33.20	33.08	32.88	24.55	24.97	24.49	24.31
	33.23	33.83	32.94	33.05	24.66	24.99	24.71	23.97
	33.29	33.66	32.70	32.54	24.84	24.77	24.82	24.24
	Average	33.06				24.59		
CV	1.07				1.39			

The E gene RNA extracted from Serum by MagListo™ 5M Viral DNA/RNA Extraction Kit was used for particle test of AccuPower® SARS-CoV Real-Time RT-PCR Kit (E gene targeted). The regular results indicate that nucleic acids extraction produce high reproducibility.

(Blue signal: E gene, Black signal: IPC)

# MagListo™ 5M cfDNA Extraction Kit (K-3619M)

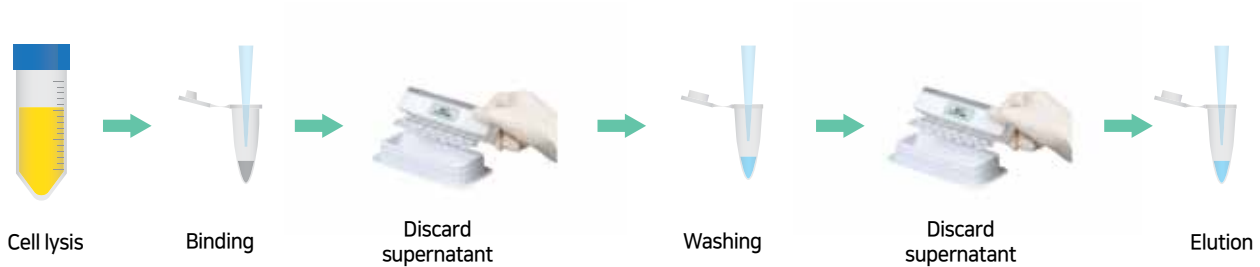


Target	cfDNA	
Specimen	Plasma, Serum, Urine, Saliva	
Starting Volume	Mini	1 ml
	Midi	3 ml
	Maxi	5 ml
Elution Volume	Mini	30 ul
	Midi	50 ul
	Maxi	70 ul

## Components

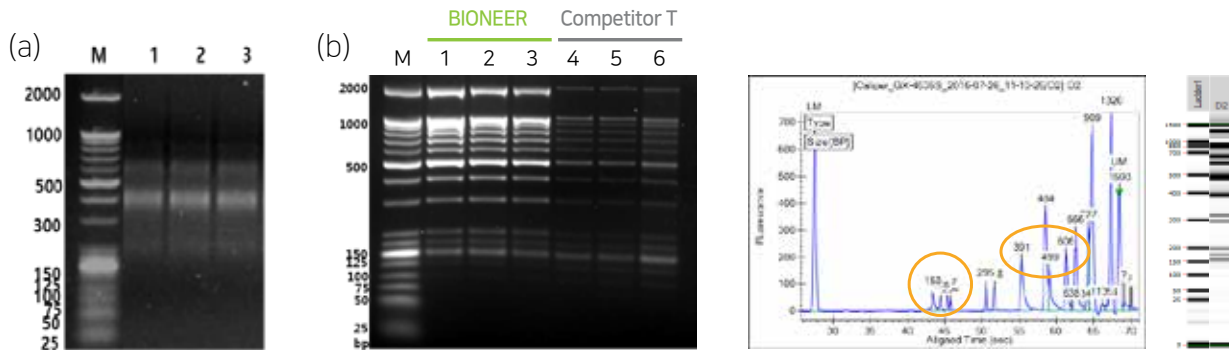
No.	Name	Quantity
1	CL buffer, CB buffer, CW1 buffer, CW2 buffer, EA buffer	1 buffer each
2	Magnetic Nano Bead-DNA	6 ea
3	Proteinase K powder	2 ea

## Workflow



\*Please refer to User Guide for detail

## 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

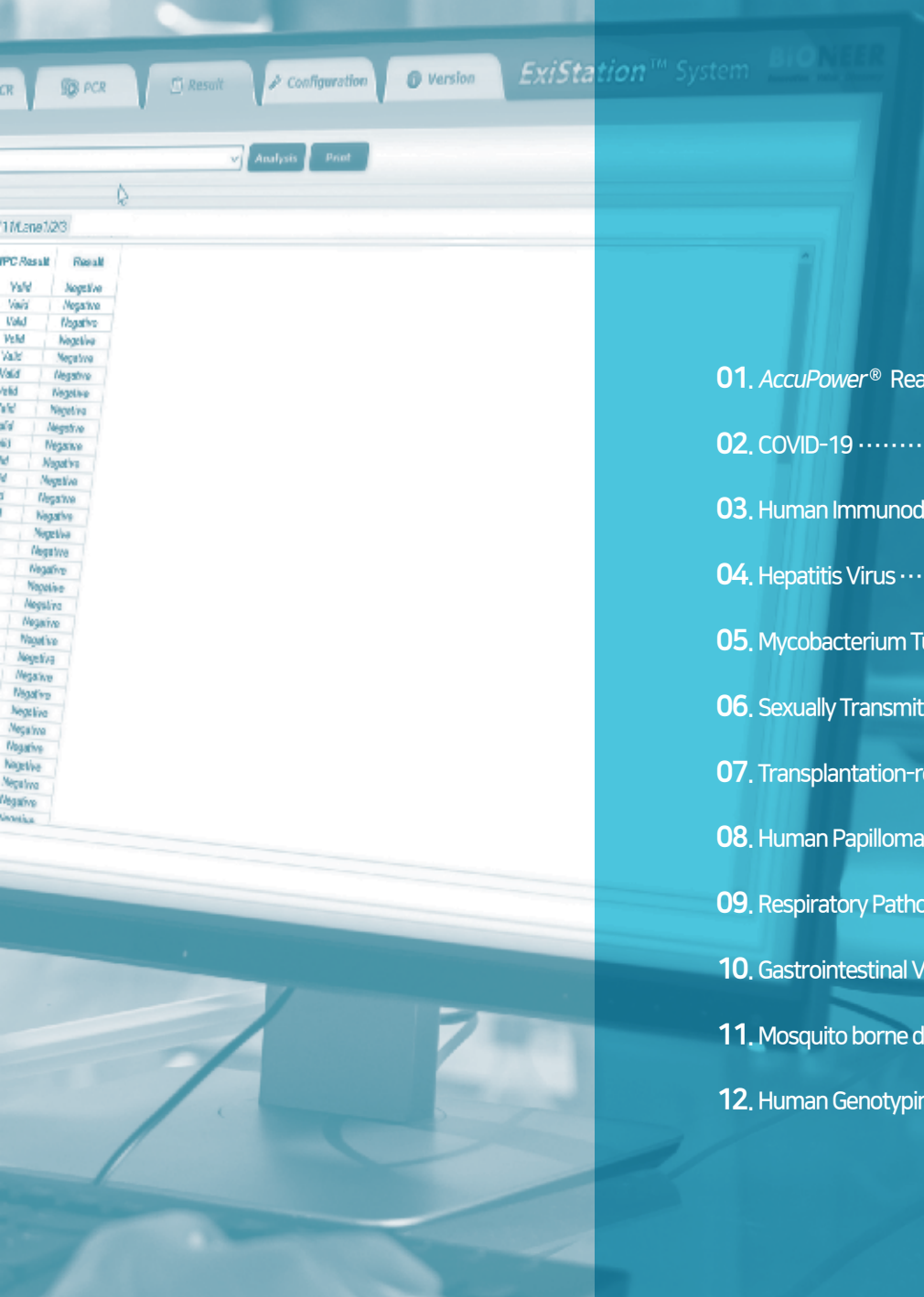
Pass Prop Assign P

Data File : NCVM-111

PCR Result (NCVM-111) Lane 123 NCVM-1

Sap	Sample ID	Yield/Lane	Val
1	15402	NCVM-111 Lane 123	
2	15403	NCVM-111 Lane 123	
3	15404	NCVM-111 Lane 123	
4	15405	NCVM-111 Lane 123	
5	15406	NCVM-111 Lane 123	
6	15407	NCVM-111 Lane 123	
7	15408	NCVM-111 Lane 123	
8	15409	NCVM-111 Lane 123	
9	15410	NCVM-111 Lane 123	
10	15411	NCVM-111 Lane 123	
11	15412	NCVM-111 Lane 123	
12	15413	NCVM-111 Lane 123	
13	15414	NCVM-111 Lane 123	
14	15415	NCVM-111 Lane 123	
15	15416	NCVM-111 Lane 123	
16	15417	NCVM-111 Lane 123	
17	15418	NCVM-111 Lane 123	
18	15419	NCVM-111 Lane 123	
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29	15430	NCVM-111 Lane 123	
30	15431	NCVM-111 Lane 123	
31	15432	NCVM-111 Lane 123	

# Real-Time PCR Diagnostic Kits



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# I SELECTION GUIDE

We offer a wide range of product selections from Nucleic Acid Extraction to PCR reagents with patented technology. All products are optimized for each other for our users to experience the best diagnosis with our selection guide below.

Category	Product List		Page	Kit type	Sample
	Name	Cat. No.			
COVID-19	AccuPower® RV1 Multiplex Kit	RV1-2112	46p	Mastermix	Sputum, Nasopharyngeal & Oropharyngeal swab
	AccuPower® RV1 Real-Time RT-PCR Kit	RV1-1111	46p	Premix	Sputum, Nasopharyngeal & Oropharyngeal swab
	AccuPower® COVID-19 Multiplex Real-Time RT-PCR Kit	NCVM-1111	44p	Premix	Saliva, Sputum, Nasopharyngeal & Oropharyngeal swab
	AccuPower® SARS-CoV-2 Multiplex Real-Time RT-PCR Kit	SCVM-2112	44p	Mastermix	Saliva, Sputum, Nasopharyngeal & Oropharyngeal swab
	AccuPower® SARS-CoV-2 Variants ID Real-Time RT-PCR Kit	SMVR-1111	49p	Premix	Sputum, Nasopharyngeal & Oropharyngeal swab
	AccuPower® SARS-CoV-2 Variants ID Kit -A	SMVR-2112	49p	Mastermix	Sputum, Nasopharyngeal & Oropharyngeal swab
	AccuPower® SARS-CoV-2 Variants ID Kit -B	SMVR-2113	49p	Mastermix	Sputum, Nasopharyngeal & Oropharyngeal swab
	AccuPower® SARS-CoV-2 Variants ID2 Real-Time RT-PCR Kit	SMVR2-1111	50p	Premix	Sputum, Nasopharyngeal & Oropharyngeal swab
	AccuPower® SARS-CoV-2 Variants ID2 Kit -A	SMVR2-2112	50p	Mastermix	Sputum, Nasopharyngeal & Oropharyngeal swab
	AccuPower® SARS-CoV-2 Variants ID2 Kit -B	SMVR2-2113	50p	Mastermix	Sputum, Nasopharyngeal & Oropharyngeal swab
	AccuPower® SARS-CoV-2 Variants ID3 Kit -A	SMVR3-2112	51p	Mastermix	Sputum, Nasopharyngeal & Oropharyngeal swab
	AccuPower® SARS-CoV-2 Variants ID3 Kit -B	SMVR3-2113	51p	Mastermix	Sputum, Nasopharyngeal & Oropharyngeal swab
AIDS	AccuPower® HIV-1 Quantitative RT-PCR kit	HIV-1211 HIV-1111 (Non-CE)	52p	Premix	EDTA-Plasma
Hepatitis	AccuPower® HBV Quantitative PCR Kit	HBV-1211 HBV-1111 (Non-CE)	53p	Premix	Serum, EDTA-Plasma
	AccuPower® HCV Quantitative RT-PCR kit	HCV-1211 HCV-1111 (Non-CE)	54p	Premix	Serum, EDTA-Plasma
Tuberculosis	AccuPower® XDR-TB Real-Time PCR Kit-A	XDRA-1111	58p	Premix	Sputum, BAL, Culture specimen
	AccuPower® XDR-TB Real-Time PCR Kit-B	XDRB-1111	58p	Premix	Sputum, BAL, Culture specimen
	AccuPower® TB & MDR Real-Time PCR Kit	TBMDR-1111	57p	Premix	Sputum, BAL, Culture specimen

\*Mastermix kits are available with various thermocyclers

Instrument		Extraction Kit	
Name	Cat.No.	Name	Cat.No.
Exicycler™96	A-2060-1	ExiPrep™ 96 Viral DNA/RNA Kit	K-4614
		Protonion™ 96 Viral RNA Kit	K-4731
ExiStation™	A-2200	ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
		ExiPrep™ Dx Viral RNA Kit	K-4473
ExiStation™ 48	A-2400	ExiPrep™ 48 Viral DNA/RNA Kit	K-4571
		ExiPrep™ 48 Viral RNA Kit	K-4573
		ExiPrep™ 48 Fast Viral RNA Kit	K-4575
ExiStation™	A-2200	ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
		ExiPrep™ Dx Viral RNA Kit	K-4473
ExiStation™ 48	A-2400	ExiPrep™ 48 Viral DNA/RNA Kit	K-4571
		ExiPrep™ 48 Viral RNA Kit	K-4573
		ExiPrep™ 48 Fast Viral RNA Kit	K-4575
Exicycler™96	A-2060-1	ExiPrep™ 96 Viral DNA/RNA Kit	K-4614
		Protonion™ 96 Viral RNA Kit	K-4731
ExiStation™	A-2200	ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
		ExiPrep™ Dx Viral RNA Kit	K-4473
ExiStation™ 48	A-2400	ExiPrep™ 48 Viral DNA/RNA Kit	K-4571
		ExiPrep™ 48 Viral RNA Kit	K-4573
		ExiPrep™ 48 Fast Viral RNA Kit	K-4575
Exicycler™96	A-2060-1	ExiPrep™ 96 Viral DNA/RNA Kit	K-4614
		Protonion™ 96 Viral RNA Kit	K-4731
-	-	ExiPrep™ 96 Viral DNA/RNA Kit	K-4614
		Protonion™ 96 Viral RNA Kit	K-4731
ExiStation™	A-2200	ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
		ExiPrep™ Dx Viral RNA Kit	K-4473
ExiStation™ 48	A-2400	ExiPrep™ 48 Viral DNA/RNA Kit	K-4571
		ExiPrep™ 48 Viral RNA Kit	K-4573
		ExiPrep™ 48 Fast Viral RNA Kit	K-4575
Exicycler™96	A-2060-1	ExiPrep™ 96 Viral DNA/RNA Kit	K-4614
		Protonion™ 96 Viral RNA Kit	K-4731
-	-	ExiPrep™ 96 Viral DNA/RNA Kit	K-4614
		Protonion™ 96 Viral RNA Kit	K-4731
Exicycler™96	A-2060-1	ExiPrep™ 96 Viral DNA/RNA Kit	K-4614
		Protonion™ 96 Viral RNA Kit	K-4731
-	-	ExiPrep™ 96 Viral DNA/RNA Kit	K-4614
		Protonion™ 96 Viral RNA Kit	K-4731
ExiStation™	A-2200	ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
		ExiPrep™ Dx Viral RNA Kit	K-4473
ExiStation™ 48	A-2400	ExiPrep™ 48 Viral DNA/RNA Kit	K-4571
		ExiPrep™ 48 Viral RNA Kit	K-4573
ExiStation™	A-2200	ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
		ExiPrep™ Dx Viral DNA Kit	K-4472
ExiStation™ 48	A-2400	ExiPrep™ 48 Viral DNA/RNA Kit	K-4571
		ExiPrep™ 48 Viral RNA Kit	K-4573
ExiStation™	A-2200	ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
		ExiPrep™ Dx Viral RNA Kit	K-4473
ExiStation™ 48	A-2400	ExiPrep™ 48 Viral DNA/RNA Kit	K-4571
		ExiPrep™ 48 Viral RNA Kit	K-4573
ExiStation™	A-2200	ExiPrep™ Dx Mycobacteria Genomic DNA Kit	K-4418
ExiStation™ 48	A-2400	ExiPrep™ 48 Genomic DNA Kit	K-4574
ExiStation™	A-2200	ExiPrep™ Dx Mycobacteria Genomic DNA Kit	K-4418
ExiStation™ 48	A-2400	ExiPrep™ 48 Genomic DNA Kit	K-4574
ExiStation™	A-2200	ExiPrep™ Dx Mycobacteria Genomic DNA Kit	K-4418
ExiStation™ 48	A-2400	ExiPrep™ 48 Genomic DNA Kit	K-4574

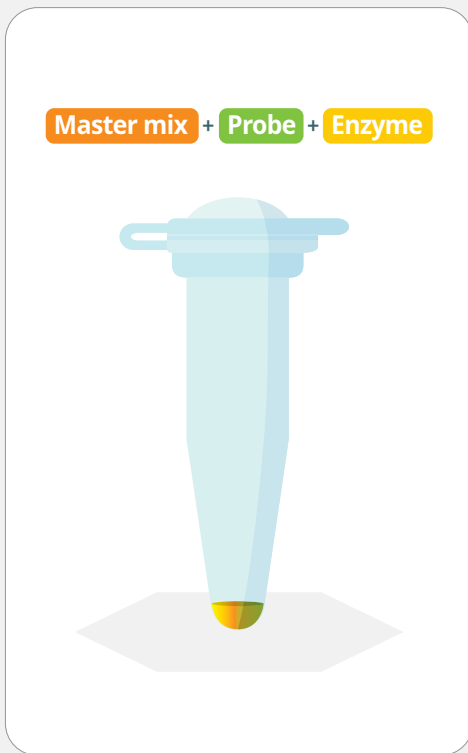
Category	Product List		Page	Kit type	Sample
	Name	Cat.No.			
Tuberculosis	AccuPower® MTB & NTM Real-Time PCR Kit	MTN-1111	55p	Premix	Sputum, BAL, Urine
	AccuPower® MTB Real-Time PCR Kit	MTB-1111	56p	Premix	Sputum, BAL, Urine
Sexually Transmitted Infection	AccuPower® STI8A-Plex Real-Time PCR Kit	STI8A-1111	60p	Premix	Urine, Vaginal swab
	AccuPower® STI8B-Plex Real-Time PCR Kit	STI8B-1111	61p	Premix	Urine, Vaginal swab
	AccuPower® STI4C-Plex Real-Time PCR Kit	STI4C-1111	62p	Premix	Urine, Vaginal swab
	AccuPower® CT & NG Real-Time PCR Kit	STD2A-1211	63p	Premix	Urine, Vaginal swab
Human Papillomavirus	AccuPower® HPV 16 & 18 Real-Time PCR Kit	HPM-1111	67p	Premix	Cervical swab
	AccuPower® hrHPV Genotyping & Screening Kit	HHP-1111	68p	Premix	Cervical swab
Transplantation-related Virus	AccuPower® CMV Quantitative PCR Kit	CMV-1111	64p	Premix	Whole blood, EDTA-plasma, Serum, Urine
	AccuPower® EBV Quantitative PCR Kit	EBV-1111	65p	Premix	Whole blood, EDTA-plasma, Serum
	AccuPower® BKV Quantitative PCR Kit	BKV-1111	66p	Premix	Serum, Urine
Respiratory Pathogens	AccuPower® New Inf A (H1N1) & Inf A Real-Time RT-PCR Kit	SIA-1111	69p	Premix	Nasopharyngeal swab, BAL
	AccuPower® CP Real-Time PCR Kit	CPN-1111	70p	Premix	Sputum, BAL
	AccuPower® MP Real-Time PCR Kit	MPN-1111	71p	Premix	Sputum, BAL
	AccuPower® MERS-CoV(upE&ORF1a) Real-Time RT-PCR Kit	COV-1112	72p	Premix	Sputum, Nasopharyngeal swab, BAL
Gastrointestinal Pathogens	AccuPower® Norovirus Real-Time RT-PCR Kit	NOR-1111	73p	Premix	Stool, Rectal swab
	AccuPower® EV Real-Time RT-PCR Kit	ENT-1111	74p	Premix	Stool, CSF
Mosquito borne disease	AccuPower® ZIKV (DENV, CHIKV) Multiplex Real-Time RT-PCR Kit	ZIK-1111	75p	Premix	Urine(for ZIKV only) Serum, Plasma
Human Genotyping	AccuPower® HLA-B27 Real-Time PCR Kit	HLB-1111	76p	Premix	Whole Blood, Buccal swab
	AccuPower® Warfarin genotyping Kit	WAF-1111	77p	Premix	Whole blood, Buccal swab
	AccuPower® JAK2 V617F Quantitative PCR Kit	JAK-1111	78p	Premix	Whole blood, Buccal swab
	AccuPower® ApoE Real-Time PCR Kit	APE-1111	79p	Premix	Whole blood, Buccal swab
	AccuPower® TPMT genotyping Real-Time PCR Kit	TPM-1111	80p	Premix	Whole blood, Buccal swab
	AccuPower® BCR-ABL Quantitative RT-PCR Kit	CML-1111	81p	Premix	Whole blood



Instrument		Extraction Kit	
Name	Cat. No.	Name	Cat. No.
Exicycler™96	A-2060-1	ExiPrep™ Dx Mycobacteria Genomic DNA Kit	K-4418
		ExiPrep™ 48 Genomic DNA Kit	K-4574
ExiStation™	A-2200	ExiPrep™ Dx Mycobacteria Genomic DNA Kit	K-4418
ExiStation™ 48	A-2400	ExiPrep™ 48 Genomic DNA Kit	K-4574
Exicycler™96	A-2060-1	ExiPrep™ Dx Mycobacteria Genomic DNA Kit	K-4418
		ExiPrep™ 48 Genomic DNA Kit	K-4574
ExiStation™	A-2200	ExiPrep™ Dx Mycobacteria Genomic DNA Kit	K-4418
ExiStation™ 48	A-2400	ExiPrep™ 48 Genomic DNA Kit	K-4574
ExiStation™	A-2200	ExiPrep™ Dx Bacteria Genomic DNA Kit	K-4414
ExiStation™ 48	A-2400	ExiPrep™ 48 Genomic DNA Kit	K-4574
ExiStation™	A-2200	ExiPrep™ Dx Bacteria Genomic DNA Kit	K-4414
ExiStation™ 48	A-2400	ExiPrep™ 48 Genomic DNA Kit	K-4574
ExiStation™	A-2200	ExiPrep™ Dx Bacteria Genomic DNA Kit	K-4414
ExiStation™ 48	A-2400	ExiPrep™ 48 Genomic DNA Kit	K-4574
ExiStation™	A-2200	ExiPrep™ Dx Bacteria Genomic DNA Kit	K-4414
Exicycler™96	A-2060-1	ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
		ExiPrep™ Dx Viral DNA Kit	K-4472
ExiStation™	A-2200	ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
		ExiPrep™ Dx Viral DNA Kit	K-4472
Exicycler™96	A-2060-1	ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
		ExiPrep™ Dx Viral DNA Kit	K-4472
		ExiPrep™ 96 Viral DNA/RNA Kit	K-4614
		ExiPrep™ 96 Genomic DNA Kit	K-4611
ExiStation™	A-2200	ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
		ExiPrep™ Dx Viral DNA Kit	K-4472
ExiStation™	A-2200	ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
		ExiPrep™ Dx Viral DNA Kit	K-4472
		ExiPrep™ Dx Blood Viral DNA Kit	K-4474
ExiStation™ 48	A-2400	ExiPrep™ 48 Viral DNA/RNA Kit	K-4571
		ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
Exicycler™96	A-2060-1	ExiPrep™ Dx Viral DNA Kit	K-4472
		ExiPrep™ Dx Blood Viral DNA Kit	K-4474
		ExiPrep™ 48 Viral DNA/RNA Kit	K-4571
		ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
ExiStation™	A-2200	ExiPrep™ Dx Viral DNA Kit	K-4472
		ExiPrep™ Dx Blood Viral DNA Kit	K-4474
ExiStation™ 48	A-2400	ExiPrep™ 48 Viral DNA/RNA Kit	K-4571
		ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
Exicycler™96	A-2060-1	ExiPrep™ Dx Viral DNA Kit	K-4472
		ExiPrep™ 48 Viral DNA/RNA Kit	K-4571
		ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
ExiStation™	A-2200	ExiPrep™ Dx Viral DNA Kit	K-4472
		ExiPrep™ Dx Blood Viral DNA Kit	K-4474
ExiStation™ 48	A-2400	ExiPrep™ 48 Viral DNA/RNA Kit	K-4571
		ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
Exicycler™96	A-2060-1	ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
		ExiPrep™ Dx Viral DNA Kit	K-4472
ExiStation™	A-2200	ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
		ExiPrep™ Dx Viral DNA Kit	K-4472
Exicycler™96	A-2060-1	ExiPrep™ Dx Viral RNA Kit	K-4473
Exicycler™96	A-2060-1	ExiPrep™ Dx Bacteria Genomic DNA Kit	K-4414
		ExiPrep™ Dx Mycobacteria Genomic DNA Kit	K-4418
ExiStation™	A-2200	ExiPrep™ Dx Bacteria Genomic DNA Kit	K-4414
		ExiPrep™ Dx Mycobacteria Genomic DNA Kit	K-4418
Exicycler™96	A-2060-1	ExiPrep™ Dx Bacteria Genomic DNA Kit	K-4414
		ExiPrep™ Dx Mycobacteria Genomic DNA Kit	K-4418
ExiStation™	A-2200	ExiPrep™ Dx Bacteria Genomic DNA Kit	K-4414
		ExiPrep™ Dx Mycobacteria Genomic DNA Kit	K-4418
Exicycler™96	A-2060-1	ExiPrep™ Dx Viral RNA Kit	K-4473
Exicycler™96	A-2060-1	ExiPrep™ Dx Viral RNA Kit	K-4473
Exicycler™96	A-2060-1	ExiPrep™ Dx Viral RNA Kit	K-4473
ExiStation™	A-2200	ExiPrep™ Dx Viral DNA/RNA Kit	K-4471
		ExiPrep™ Dx Viral RNA Kit	K-4473
Exicycler™96(ExiGenotyper™ S/W)	A-2060-1	ExiPrep™ Dx Blood Genomic DNA Kit	K-4411
Exicycler™96(ExiGenotyper™ S/W)	A-2060-1	ExiPrep™ Dx Blood Genomic DNA Kit	K-4411
Exicycler™96(ExiGenotyper™ S/W)	A-2060-1	ExiPrep™ Dx Blood Genomic DNA Kit	K-4411
Exicycler™96(ExiGenotyper™ S/W)	A-2060-1	ExiPrep™ Dx Blood Genomic DNA Kit	K-4411
Exicycler™96(ExiGenotyper™ S/W)	A-2060-1	ExiPrep™ Dx Blood Genomic DNA Kit	K-4411
Exicycler™96(ExiGenotyper™ S/W)	A-2060-1	ExiPrep™ Dx Blood Genomic DNA Kit	K-4411

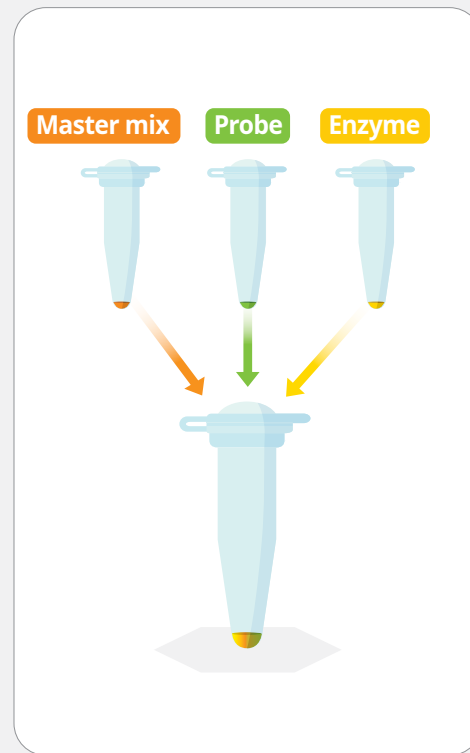
# AccuPower® Real-Time PCR Diagnostic Kits

AccuPower® Real-Time PCR Diagnostic Kit is a vacuum dried qPCR and RT-qPCR premix. All components needed for Real-Time PCR are included in a single tube, increasing reagent stability and simplifying the reaction setup. This simplified setup makes AccuPower® technology ideal for automated molecular diagnostics. The AccuPower® Real-Time PCR Diagnostic Kit also uses a proprietary stabilization technology that preserves the full activity of the mixed reagents and patented HotStart technology (US 14383793) that improves the sensitivity and specificity of the kit.



**AccuPower® Premix Tube**

Minimized pipetting Premix reagent.



**Conventional**

Requires multiple pipetting to dispense and to mix the materials

## I MDx Technology

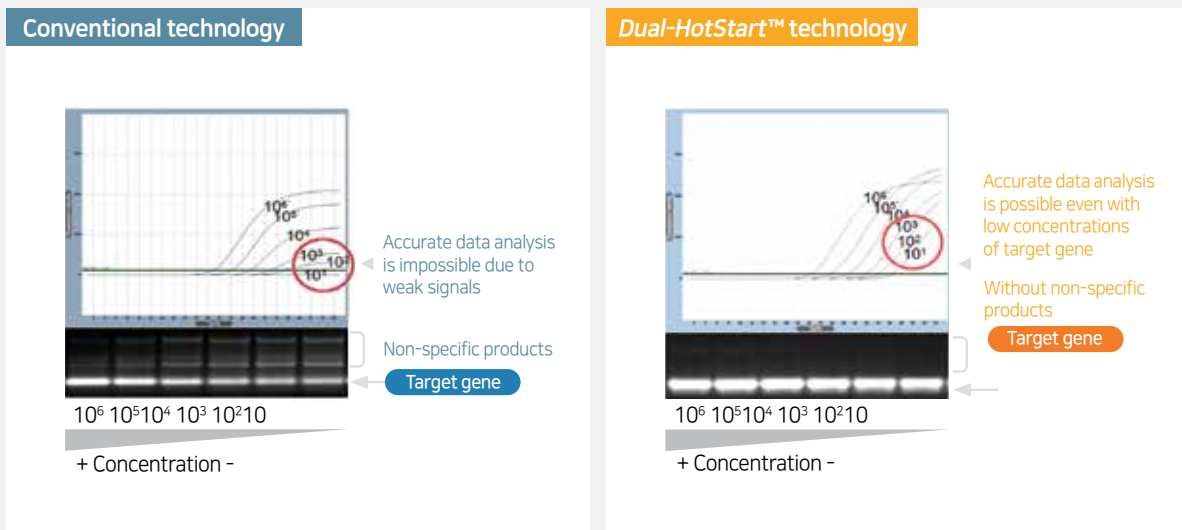
### *Dual-HotStart*<sup>™</sup> Technology

Two most critical aspects in diagnosis are specificity and sensitivity. Since accurate diagnosis results determine proper treatment, it is directly related to patients' health and even, lives.

*Dual-HotStart*<sup>™</sup> technology is a unique diagnostic technology developed by BIONEER to enhance quality of diagnosis and thus save millions of lives. This technology detects RNA targets from clinical samples with high sensitivity and specificity. This technology utilizes our unique enzyme-mediated HotStart method for both reverse transcription and PCR amplification. *Dual-HotStart*<sup>™</sup> eliminates non-specific cDNA synthesis and non-specific DNA amplification, allowing the most sensitive one-step RT-qPCR assays available.

### ■ Features

- *Dual-HotStart*<sup>™</sup> RT-qPCR reactions is the core technology of 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*<sup>™</sup> RT-PCR (right panel). The results suggest that *Dual-HotStart*<sup>™</sup> RT-PCR enables highly sensitive detection of low copies of RNA target by eliminating non-specific cDNA synthesis and nonspecific PCR amplification.

## COVID-19

### AccuPower® SARS-CoV-2 Multiplex Real-Time RT-PCR Kit

### AccuPower® COVID-19 Multiplex Real-Time RT-PCR Kit

Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered SARS-CoV-2. Most people infected with the virus will experience mild to moderate respiratory illness and recover without special treatment. Older people with underlying medical problems like cardiovascular disease, diabetes, chronic respiratory disease, and cancer are more likely to develop serious illnesses. So, a sensitive and accurate diagnosis is required. BIONEER provides three types of COVID-19 diagnostic kits that have different features. Users can choose the kit according to condition.

## Specification

	Master mix reagent	Vacuum dried premix reagent
Product	AccuPower® SARS-CoV-2 Multiplex Real-Time RT-PCR Kit	AccuPower® COVID-19 Multiplex Real-Time RT-PCR Kit
Cat. No.	SCVM-2112(100T)	NCVM-1111(96T)
Targets	E gene, RdRp/N gene	E gene, RdRp/N gene
Sample type	Saliva, Sputum, Nasopharyngeal & Oropharyngeal swab	Saliva, Sputum, Nasopharyngeal & Oropharyngeal swab
Tube	1 tube	1 tube
Components	Master mix, Enzyme mix, IPC, PC, NTC	NCVM Premix, PC, SL Buffer, Optical sealing film
Instruments	Exicycler™96 (BIONEER), CFX96 (Bio-Rad), ABI7500FAST (ThermoFisher), Quantstudio5 (ThermoFisher)	ExiStation™ (BIONEER), ExiStation™ 48 (BIONEER)

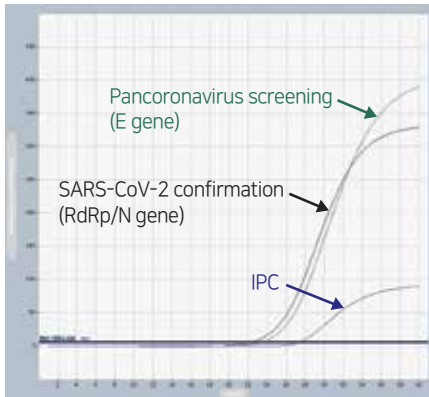
## Related Products

Cat. No.	Reagent type	Kit name	Target	Tests
NCVM-1111	Premix	AccuPower® COVID-19 Multiplex Real-Time RT-PCR Kit	E, RdRp/N gene	96
SCVM-2112	Master mix	AccuPower® SARS-CoV-2 Multiplex Real-Time RT-PCR Kit		100
RV1-1111	Premix	AccuPower® RV1 Real-Time RT-PCR Kit	COVID-19 (E, RdRp/N gene), Influenza A, B	96
RV1-2112	Master mix	AccuPower® RV1 Multiplex Kit		100

## ■ Features & Results

### AccuPower® SARS-CoV-2 Multiplex Real-Time RT-PCR Kit

- Decreased hands-on steps due to 3-target multiplex detection in a tube.
- 1 target for pancoronavirus screening (E gene) and 2 targets for COVID-19 confirmation (RdRp / N gene).
- Compatible with various Real-Time PCR machine



Results of SARS-CoV-2 diagnosis using Positive Control

**Green signal:** Pancoronavirus screening

**Black signal:** SARS-CoV-2 confirmation

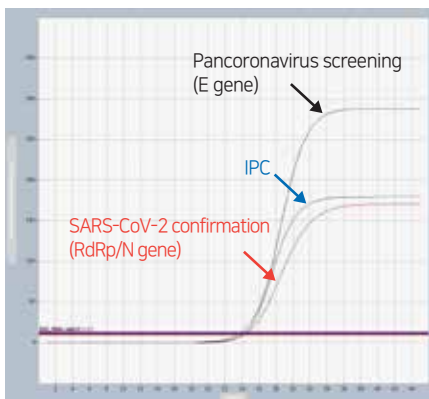
**Blue signal:** IPC

Nasopharyngeal Swab	Positive percent agreement	100 % (95% CI 89.57 - 100%)
	Negative percent agreement	100 % (95% CI 92.29- 100%)
Sputum	Positive percent agreement	100 % (95% CI 89.28 - 100%)
	Negative percent agreement	100 % (95% CI 91.43- 100%)

The performance of *AccuPower*® SARS-CoV-2 Multiplex Real-Time RT-PCR Kit was compared to that of KCDC EUA assay by analysis of paired clinical specimens from 126 samples.

### AccuPower® COVID-19 Multiplex Real-Time PCR Kit

- Reduced hands-on steps with 3-target multiplex detection in the tube.
- 1 target for pancoronavirus screening (E gene) and 2 targets for COVID-19 confirmation (RdRp / N gene).
- All components for the assay are included in the tube
- Compatible with *ExiStation*™ system



Results of SARS-CoV-2 diagnosis using Positive Control

**Black signal:** Pancoronavirus screening

**Red signal:** SARS-CoV-2 confirmation

**Blue signal:** IPC

Swab	Positive percent agreement	100 % (95% CI 88.65 - 100%)
	Negative percent agreement	100 % (95% CI 88.65 - 100%)
Sputum	Positive percent agreement	100 % (95% CI 88.65 - 100%)
	Negative percent agreement	100 % (95% CI 88.65 - 100%)

The performance of *AccuPower*® COVID-19 Multiplex Real-Time RT-PCR Kit was compared to that of KCDC EUA assay by analysis of paired clinical specimens from 60 samples.

## COVID-19

### AccuPower® RV1 Multiplex Kit

### AccuPower® RV1 Real-Time RT-PCR Kit

A warning has been issued about the possibility of a 'twin-demic', in which COVID-19 and the flu peak simultaneously as the pandemic continues. COVID-19 and the flu have similar symptoms but different causes and different treatments. Therefore, it is important to differentiate between COVID-19 and the flu during TwinDemic to take appropriate treatment and preventive measures. AccuPower® RV1 Multiplex Kit is an *in vitro* diagnostic kit that helps diagnose COVID-19 and influenza infections.

#### Specification

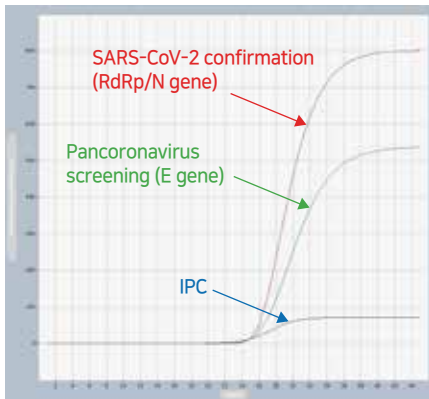
Product	AccuPower® RV1 Multiplex Kit	AccuPower® RV1 Real-Time RT-PCR Kit
Cat.No.	RV1-2112(100T)	RV1-1111(96T)
Reagent type	Mastermix type	Premix type
Target	COVID-19 (E, RdRp/N gene), Influenza A, B	
Sample type	Sputum, Nasopharyngeal & Oropharyngeal swab	
Tube	1 tube	
Components	Master Mix 1, Master Mix 2, Master Mix 3, Enzyme Mix, Positive Control, IPC, NTC	RV1 Premix, RV1 Positive Control RNA, SL buffer, Optical Sealing film
Instruments	Exicycler™96 (BIONEER), CFX96 (Bio-Rad), ABI7500FAST (ThermoFisher), Quantstudio5 (ThermoFisher)	ExiStation™ (BIONEER), ExiStation™ 48 (BIONEER)

#### Related Products

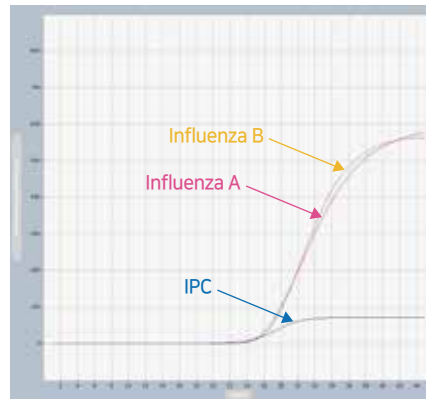
Cat. No.	Reagent type	Kit name	Target	Tests
NCVM-1111	Premix	AccuPower® COVID-19 Multiplex Real-Time RT-PCR Kit	E, RdRp/N gene	96
SCVM-2112	Master mix	AccuPower® SARS-CoV-2 Multiplex Real-Time RT-PCR Kit		100
RV1-1111	Premix	AccuPower® RV1 Real-Time RT-PCR Kit	COVID-19 (E, RdRp/N gene), Influenza A, B	96
RV1-2112	Master mix	AccuPower® RV1 Multiplex Kit		100

## ■ Features & Results

- Reduced hands-on steps with 5-target multiplex detection in the tube.
- The targets are COVID-19 (E, RdRp/N gene) and Influenza A, B.
- 2 types of reagents are available for user convenience



Results of SARS-CoV-2 diagnosis using Positive Control  
**Red Signal:** SARS-CoV-2 confirmation  
**Green signal:** Pancoronavirus screening  
**Blue signal:** IPC



Results of Influenza diagnosis using Positive Control  
**Pink Signal:** Influenza A  
**Yellow Signal:** Influenza B  
**Blue signal:** IPC

### SARS-CoV-2

Nasopharyngeal Swab	Positive percent agreement	100%(95% CI:88.65% - 100%)
	Negative percent agreement	100%(95% CI:88.65% - 100%)
Sputum	Positive percent agreement	100%(95% CI:88.65% - 100%)
	Negative percent agreement	100%(95% CI:88.65% - 100%)

The performance of *AccuPower*<sup>®</sup> RV1 Real-Time RT-PCR Kit and *AccuPower*<sup>®</sup> RV1 Multiplex PCR Kit were compared to that of Emergency Use Authorization Kit by analysis of paired clinical specimens from 120 samples.

### Influenza A, B

Nasopharyngeal Swab	Positive percent agreement	100%(95% CI:88.65% - 100%)
	Negative percent agreement	100%(95% CI:88.65% - 100%)

The performance of *AccuPower*<sup>®</sup> RV1 Real-Time RT-PCR Kit and *AccuPower*<sup>®</sup> RV1 Multiplex PCR Kit were compared to that of KFSA approval Kit(Influenza A, B) by analysis of paired clinical specimens from 120 samples.

## COVID-19

# AccuPower® SARS-CoV-2 Variants ID Kits

AccuPower® SARS-CoV-2 Variants ID Real-Time PCR Kit is an *in vitro* diagnostic kit that helps diagnose SARS-CoV-2 variants. The spike gene (S gene) is the key region to monitor the mutants with the recent emergence of variants from SARS-CoV-2. The kit can detect S gene mutation hot spots in 2 tubes. Sputum, nasopharyngeal swab and an oropharyngeal swab from the suspected infection patient's sample can be used.

## SARS-CoV-2 Variants

Product	SARS-CoV-2 Variants ID Kit	SARS-CoV-2 Variants ID Kit		
		ID1 Kit	ID2 Kit	ID3 Kit
SARS-CoV-2	-	●	●	●
B.1.1.7 (Alpha)	N501Y Hv 69/70 deletion P681H	●	●	
B.1.1.7 with E484K (Alpha)	N501Y Hv 69/70 deletion P681H, E484K	●	●	
B.1.351 (Beta)*	N501Y E484K K417N	●	●	
P.1 (Gamma)*	N501Y E484K K417T	●		
B.1.617.2 (Delta)*	L452R T478K P681R		●	●
B.1.1.529 (Omicron)*	E484A, N679K, S477N, N440K, Q493R, T478K, P681H and many more			●

\* Variants of Concern (ECDC)



COVID-19

AccuPower® SARS-CoV-2 Variants ID Real-Time RT-PCR Kit

AccuPower® SARS-CoV-2 Variants ID Kit-A

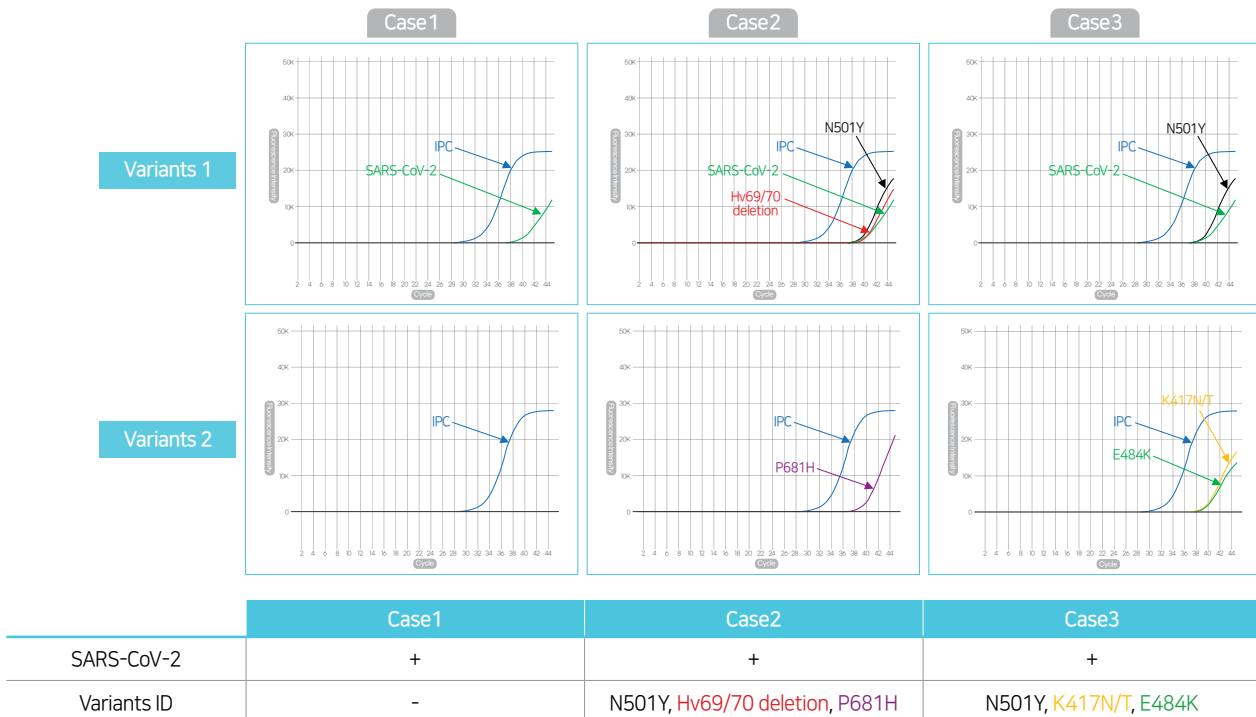
AccuPower® SARS-CoV-2 Variants ID Kit-B

Specification

Product	SARS-CoV-2 Variants ID Kit		
Product name	AccuPower® SARS-CoV-2 Variants ID Kit-A	AccuPower® SARS-CoV-2 Variants ID Kit-B	AccuPower® SARS-CoV-2 Variants ID Real-Time RT-PCR Kit
Cat.No.	SMVR-2112 (50T)	SMVR-2113 (50T)	SMVR-1111 (48T)
Reagent type	Master mix type		Premix type
Target	Variants 1: RdRp/N gene, Hv69/70 deletion, N501Y Variants 2: E484K, K417N/T, P681H		
Sample type	Sputum, Nasopharyngeal & Oropharyngeal swab		
Tube	2 tubes		
Components	Oligo Mix 1(Variants 1), Oligo Mix 2(Variants 2), Enzyme Mix, Positive Control 1, Positive Control 2, NTC		SMVR(Variants 1)-1111 Premix, SMVR(Variants 2)-1111 Premix, SL buffer, Positive Control, IPC, Optical Sealing film
Instruments	Exicycler™96 (BIONEER), ABI7500FAST (ThermoFisher), Quantstudio 5 (ThermoFisher)	CFX 96(Bio-Rad)	ExiStation™ (BIONEER), ExiStation™ 48 (BIONEER)

Results

SARS-CoV-2 Variants ID Kit



## COVID-19

### AccuPower® SARS-CoV-2 Variants ID2 Real-Time-RT-PCR Kit

### AccuPower® SARS-CoV-2 Variants ID2 Kit-A

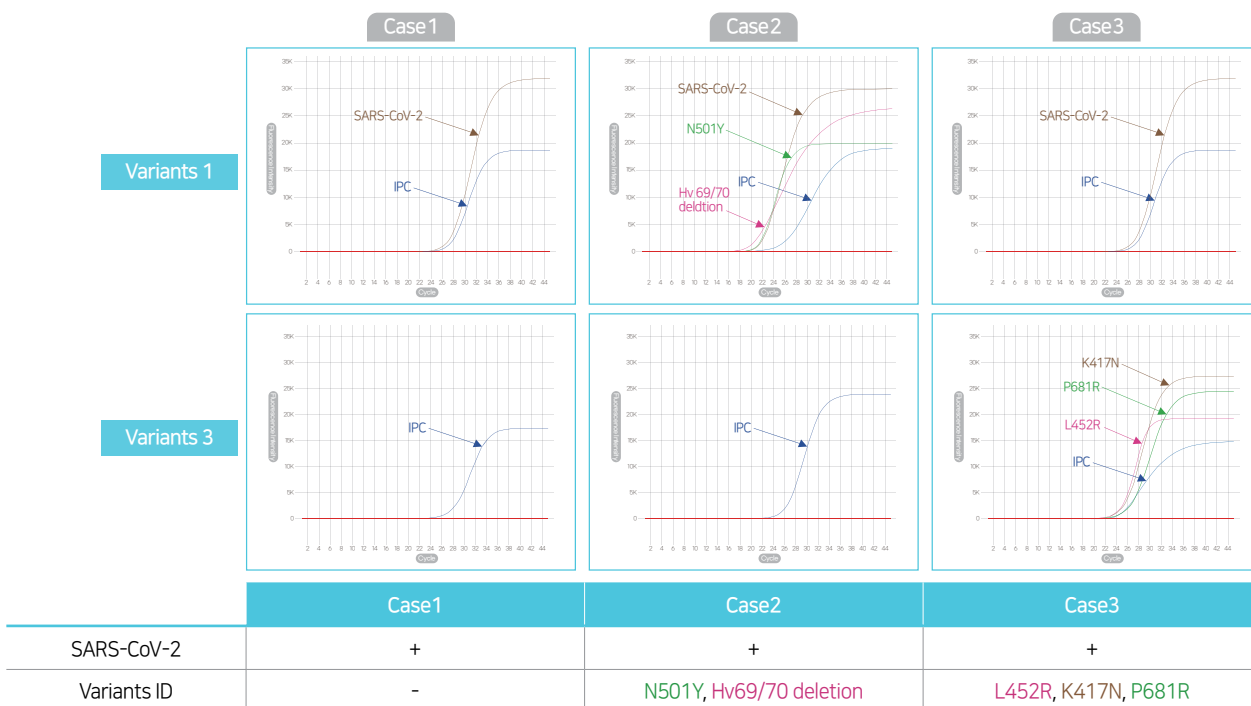
### AccuPower® SARS-CoV-2 Variants ID2 Kit-B

## Specification

Product	SARS-CoV-2 Variants ID2 Kit		
Product name	AccuPower® SARS-CoV-2 Variants ID2 Kit-A	AccuPower® SARS-CoV-2 Variants ID2 Kit-B	AccuPower® SARS-CoV-2 Variants ID2 Real-Time-RT-PCR Kit
Cat.No.	SMVR2-2112(50T)	SMVR2-2113(50T)	SMVR2-1111(48T)
Reagent type	Master mix type		Premix type
Target	Variants 1: RdRp/N gene, Hv69/70 deletion, N501Y Variants 3: K417N, L452R, P681R		
Sample type	Sputum, Nasopharyngeal & Oropharyngeal swab		
Tube	2 tubes		
Components	Oligo Mix 1(Variants 1), Oligo Mix 3(Variants 3), Enzyme Mix, Positive Control 1, Positive Control 2, NTC		SMVR2(Variants 1)-1111 Premix, SMVR3(Variants 3)-1111 Premix, SL buffer, Positive Control, IPC, Optical Sealing film
Instruments	Exicycler™96 (BIONEER), ABI7500FAST (ThermoFisher), Quantstudio 5 (ThermoFisher)	CFX 96(Bio-Rad)	ExiStation™ (BIONEER), ExiStation™ 48 (BIONEER)

## Results

### SARS-CoV-2 Variants ID2 Kit



COVID-19

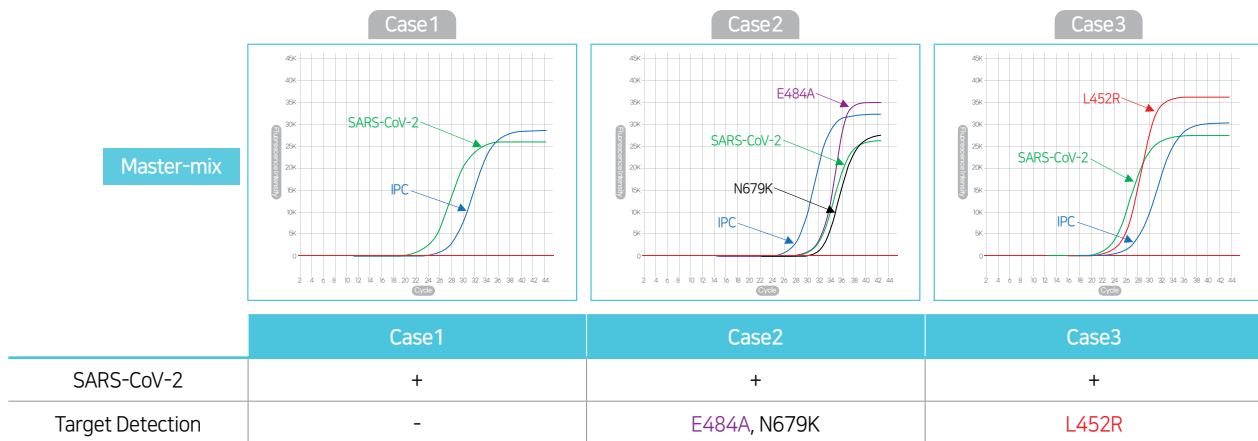
AccuPower® SARS-CoV-2 Variants ID3 Kit-A  
 AccuPower® SARS-CoV-2 Variants ID3 Kit-B

Specification

Product	SARS-CoV-2 Variants ID3 Kit	
Product name	AccuPower® SARS-CoV-2 Variants ID 3 Kit-A	AccuPower® SARS-CoV-2 Variants ID 3 Kit-B
Cat.No.	SMVR3-2112 (100T)	SMVR3-2113 (100T)
Reagent type	Master mix type	
Target	SARS-CoV-2 Detection: RdRp/N gene Variants Detection: E484A, N679K, L452R	
Sample type	Sputum, Nasopharyngeal & Oropharyngeal Swab	
Tube	1 tube	
Components	Master Mix, Enzyme Mix, Positive Control, NTC	
Instruments	ExiStation™ 96 (BIONEER), ABI 7500 FAST (ThermoFisher)	CFX 96 (Bio-Rad)

Results

SARS-CoV-2 Variants ID3 Kit



## Human Immunodeficiency Virus

# AccuPower® HIV-1 Quantitative RT-PCR Kit

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 establishing therapeutic strategy and determining therapeutic progress. The *AccuPower*® HIV-1 Quantitative RT-PCR Kit is an *in vitro* diagnostic kit designed to quantify HIV-1 RNA in human EDTA-plasma samples through Real-Time polymerase chain reaction (PCR) using *ExiStation*™ MDx System.

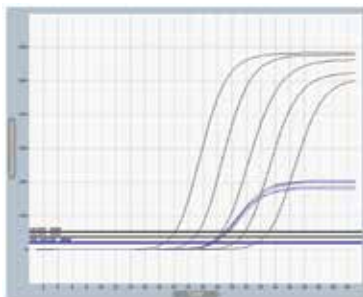
## Specification

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	<i>ExiStation</i> ™, <i>ExiStation</i> ™ 48

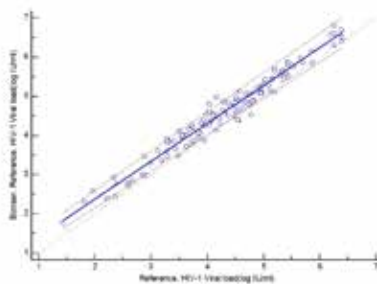
## Features & Benefits

- Simultaneous diagnosis of our HBV and HCV Kit through *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
- Excellent repeatability and reproducibility
- High reliability through Internal Positive Control and Low/High Positive Controls

## 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	<i>AccuPower</i> ® HIV-1 Quantitative RT-PCR Kit (CE List A Ver.)	HIV	96
HIV-1111	<i>AccuPower</i> ® HIV-1 Quantitative RT-PCR Kit		

## Hepatitis Virus

### AccuPower® HBV Quantitative PCR Kit

Hepatitis B is a viral infection that attacks the liver and can cause acute and chronic liver disease. Hepatitis B is transmitted through blood and infected body fluids. Therefore, quantifying hepatitis B virus (HBV) DNA in blood is essential for monitoring HBV infection. *AccuPower*® HBV Quantitative PCR Kit is an *in vitro* diagnostic kit that can quantify HBV DNA in human EDTA-plasma samples through Real-Time PCR using *ExiStation*™ MDx System.

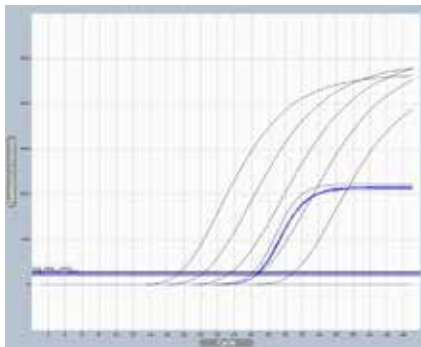
#### ■ Specification

Target	Sample Type	Components	Instruments
HBV	Serum, EDTA-Plasma	PCR Premix(96 rxn), SPCs(S1~S5), PCs(LPC, HPC), NTC, DEPC-D.W, SL Buffer, Optical sealing film	<i>ExiStation</i> ™, <i>ExiStation</i> ™ 48

#### ■ Features & Benefits

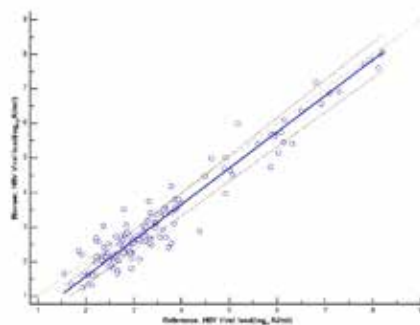
- Our HIV-1 and HCV Kit simultaneous diagnosis through *ExiStation*™ Manager software
- Excellent repeatability and reproducibility
- High reliability with internal positive control
- Specific Real-Time PCR Reactions Using Enzyme-Mediated *HotStart*™ Technology

#### ■ 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

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 managing and treating 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 to quantify HCV RNA in clinical samples through Real-Time PCR using *ExiStation*™ MDx System.

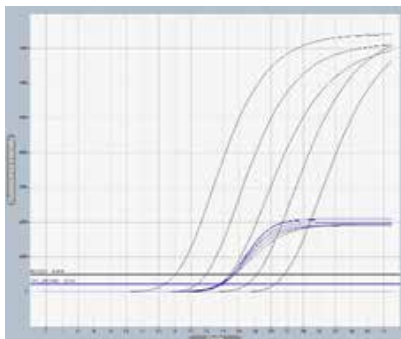
### Specification

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> ™, <i>ExiStation</i> ™ 48

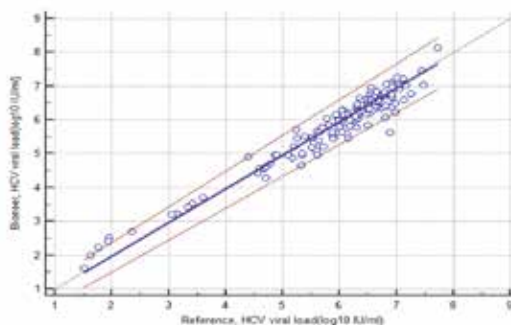
### Features & Benefits

- Our HIV-1 and HBV Kit simultaneous diagnosis through *ExiStation*™ Manager software
- Excellent repeatability and reproducibility
- High reliability with 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

### I 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.

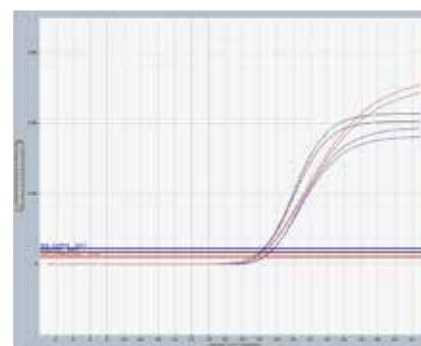
#### ■ Specification

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	Exicycler™96, ExiStation™, ExiStation™ 48

#### ■ 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	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

### I **AccuPower®** MTB Real-Time PCR Kit

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.

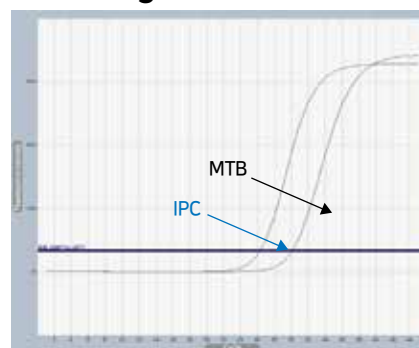
#### ■ Specification

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	<i>Exicycler™</i> 96, <i>ExiStation™</i> , <i>ExiStation™</i> 48

#### ■ 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	<b>AccuPower®</b> MTB&NTM Real-Time PCR Kit	<i>Mycobacterium tuberculosis</i> , Non-tuberculous mycobacteria	96
MTB-1111	<b>AccuPower®</b> MTB Real-Time PCR Kit	<i>Mycobacterium tuberculosis</i>	96
TBMDR-1111	<b>AccuPower®</b> TB&MDR Real-Time PCR Kit	<i>Mycobacterium tuberculosis</i> , Multidrug-resistant Tuberculosis	48
XDRA-1111	<b>AccuPower®</b> XDR-TB Real-Time PCR Kit-A	Extensively drug-resistant tuberculosis	48
XDRB-1111	<b>AccuPower®</b> 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

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™, ExiStation™ 48

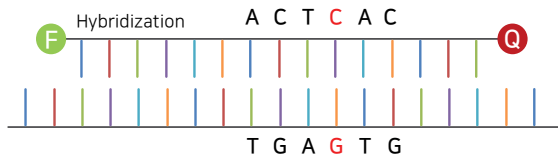
#### Features & Benefits

- 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

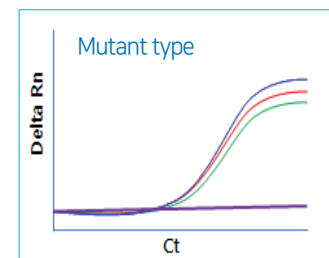
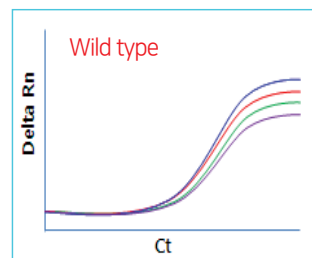
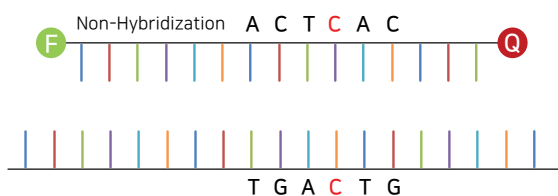
##### A. Wild MTB Genomic DNA

###### Complementary Sequence Probe



##### B. Mutant MTB Genomic DNA

###### Complementary Sequence Probe



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

## Mycobacterium Tuberculosis

### I AccuPower® XDR-TB Real-Time PCR Kit

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.

#### ■ 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™, ExiStation™ 48
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

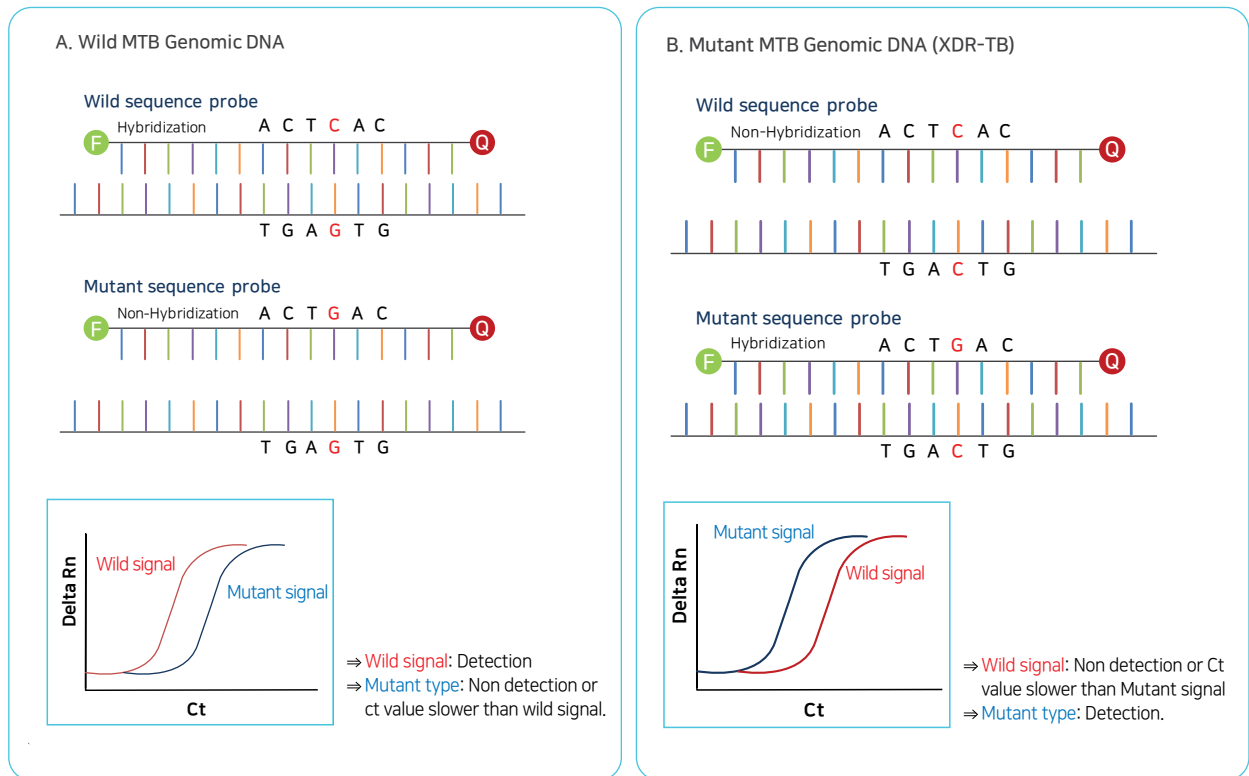
- Outstanding sensitivity and specificity
- Simultaneous detection of TB and XDR-TB using XDR-TB Kit A and B on ExiStation™ MDx System
  - Fluoroquinolone, Aminoglycosides, Ethambutol resistance, Streptomycin resistance
- Simplified procedure of sputum pretreatment with EZ Solution

#### ■ 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

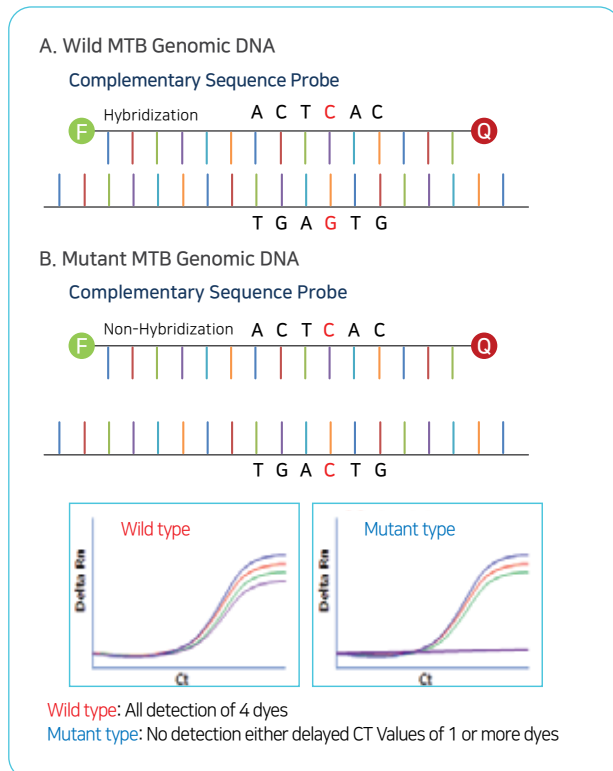
## Method

### XDR-TB Kit-A



Extensively drug-resistant detection method: Allele-Specific PCR

### XDR-TB Kit-B



Extensively drug-resistant detection method: Allele-Specific PCR

## Sexually Transmitted Infection

### AccuPower® STI8A-Plex Real-Time PCR Kit

Sexually Transmitted Infection (STI) is an infection that can be transferred from one person to another through sexual contact, including oral sex, anal sex, and sharing sex toys. Chlamydia infection is a common sexually transmitted infection in humans 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. Some untreated STIs can lead to infertility, chronic pain, or even death, depending on the disease. Early identification and treatment results in less chance to spread disease and may improve treatment outcomes for some conditions. 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.

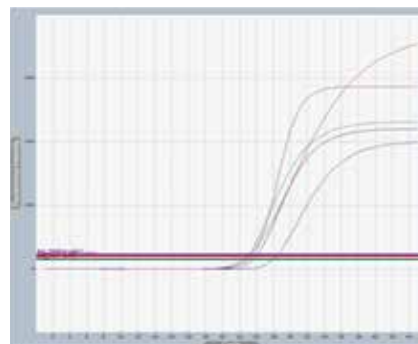
#### Specification

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™, ExiStation™ 48

#### 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

Trichomoniasis is one of the most common STIs caused by a small organism called *Trichomonas vaginalis*. Women are most often affected by this disease. However, 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, the infection can lead to premature birth. Herpes simplex type 1, transmitted through oral secretions or sores on the skin, can be spread by 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 may improve the outcomes of treatment for some conditions. The AccuPower® STI8B-Plex Real-Time PCR Kit is an *in vitro* diagnostic kit designed to simultaneously diagnose TV, MH, HSV1, and HSV2 in clinical samples using ExiStation™ MDx System.

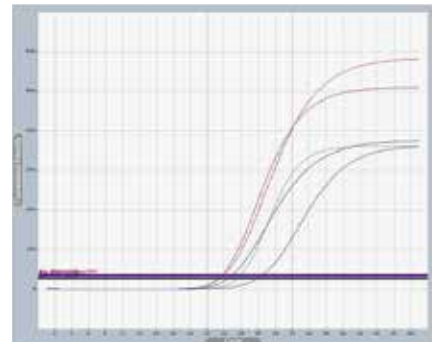
#### Specification

Target	Sample Type	Components	Instruments
TV, MH, HSV1, HSV2	Urine, Vaginal swab	PCR Premix(96 rxn), STI8B PC, IPC, NTC, DEPC-D.W, Optical sealing film	ExiStation™, ExiStation™ 48

#### 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

## Sexually Transmitted Infection

# AccuPower® STI4C-Plex Real-Time PCR Kit

*Ureaplasma parvum* can cause asymptomatic infections or diseases characterized by an exaggerated inflammatory response. *Treponema pallidum* causes Syphilis, which has four stages: 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 and 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 due to 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.

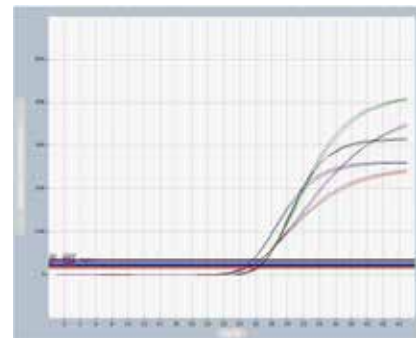
### Specification

Target	Sample Type	Components	Instruments
UP, TP, CA, GV	Urine, Vaginal swab	PCR Premix(96 rxn), STI4C PC, IPC, NTC, DEPC-D.W, Optical sealing film	ExiStation™, ExiStation™ 48

### 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

### I **AccuPower® CT & NG Real-Time PCR Kit**

*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.

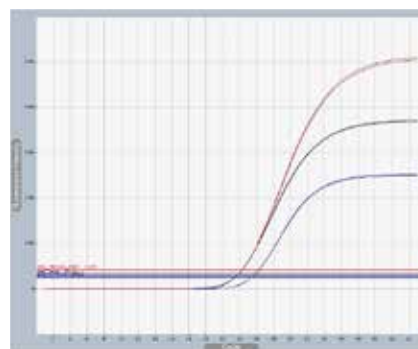
#### ■ Specification

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	<i>ExiStation™</i>

#### ■ 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	<b>AccuPower®</b> ST18A-Plex Real-Time PCR Kit	CT, NG, UU, MG	96
ST18B-1111	<b>AccuPower®</b> ST18B-Plex Real-Time PCR Kit	TV, MH, HSV1, HSV2	96
ST14C-1111	<b>AccuPower®</b> ST14C-Plex Real-Time PCR Kit	UP, TP, CA, GV	96
STD2A-1211	<b>AccuPower®</b> CT&NG Real-Time PCR Kit	CT, NG	96
CHT-1111	<b>AccuPower®</b> CT Real-Time PCR Kit	CT	96

## Transplantation-related Virus

### I **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.

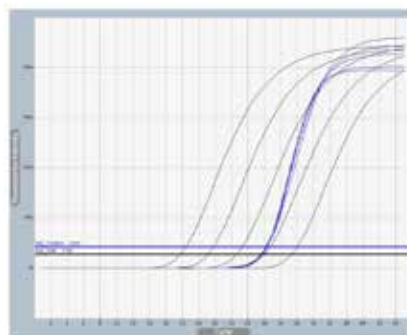
#### ■ Specification

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>ExiStation™</i> 48

#### ■ 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



## Transplantation-related Virus

### AccuPower® EBV Quantitative PCR Kit

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.

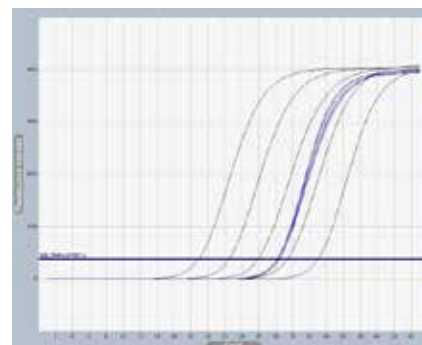
#### ■ Specification

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	Exicycler™96, ExiStation™, ExiStation™ 48

#### ■ 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.

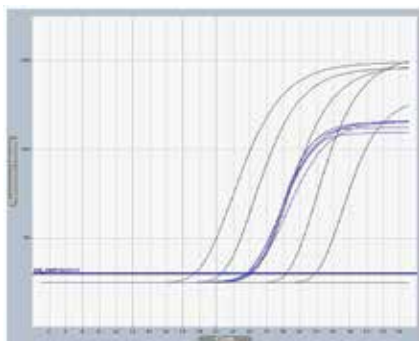
#### Specification

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>Exicycler</i> ™96, <i>ExiStation</i> ™

#### 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



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

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

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

#### 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

## Human Papillomavirus

### AccuPower® HPV 16 &18 Real-Time PCR Kit

The worldwide incidence and mortality rates from cervical cancer are second and third highest in women, respectively. The leading 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. 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.

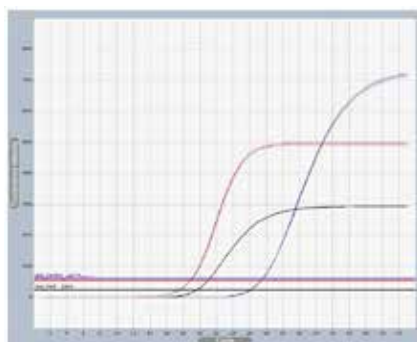
#### Specification

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	Exicycler™96, ExiStation™

#### 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	-	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

## Human Papillomavirus

# AccuPower® hrHPV Genotyping & Screening Kit

The AccuPower® hrHPV Genotyping & Screening Kit is an *in vitro* diagnostic kit designed for the simultaneous detection of 14 High-risk Human *papillomavirus* (hrHPV) DNA(16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68) from human Cervical swab and liquid based cytology specimen through Real-Time polymerase chain reaction (PCR).

### ■ Specification

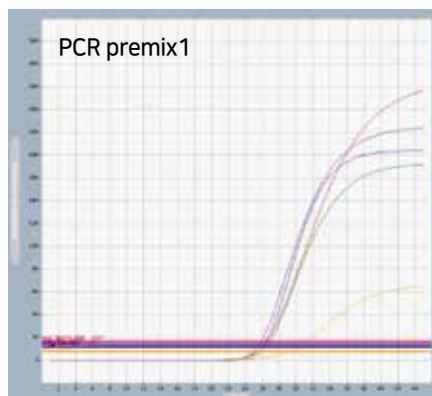
Target	Sample Type	Components	Instruments
High-risk Human <i>papillomavirus</i>	Cervical swab	PCR premix, PC, NTC, DEPC D.W., Optical sealing film 150 ul	Exicycler™96, ExiStation™

### ■ Features & Benefits

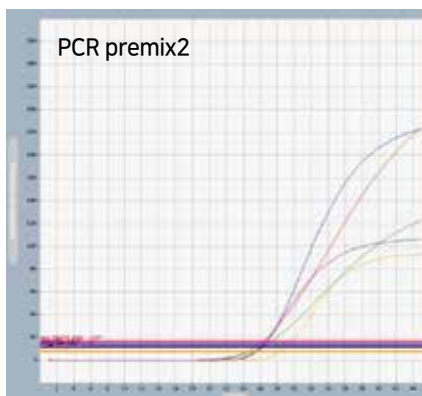
- Multiplex detection of High-risk Human *papillomavirus* in a tube
- Highly sensitive detection of High-risk Human *papillomavirus*
- Vacuum-dried premix allows stable and reproducible results

### ■ Testing results

Result of diagnosis of High-risk Human papillomavirus using Positive Control.



Red signal: HPV33,39,66,68  
Blue signal: HPV18  
Purple signal: HPV45  
Green signal: HPV16  
Yellow signal: IPC



Red signal: HPV51,56,58,59  
Blue signal: HPV52  
Purple signal: HPV35  
Green signal: HPV31  
Yellow signal: IPC

### ■ Related Products

Cat. No.	Kit name	Target	Tests
HHP-1111	AccuPower® hrHPV Genotyping & Screening Kit	High-risk Human <i>papillomavirus</i>	48

## Respiratory Pathogen

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

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.

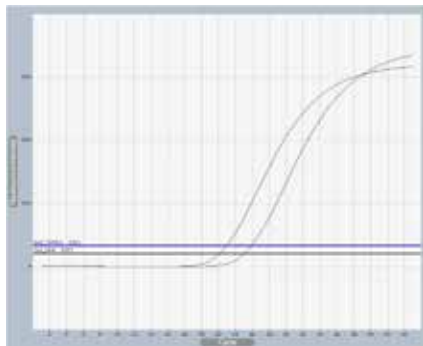
#### Specification

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</i> ™96

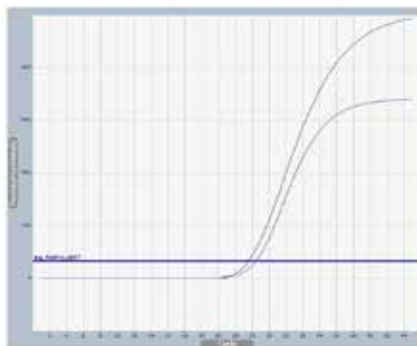
#### Features & Benefits

- 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

## Respiratory Pathogen

# AccuPower® CP Real-Time PCR Kit

*Chlamydia pneumoniae* is a species of Chlamydia, 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.

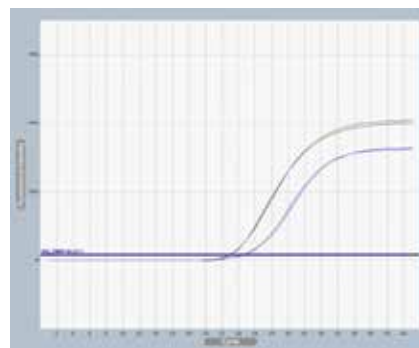
## Specification

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

## 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

*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 most common in young adults and school-aged children. The most common type of illness 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 similar 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 to detect *M. pneumoniae* DNA in sputum, BAL, and throat swab samples through Real-Time PCR using ExiStation™ MDx System or Exicycler™96.

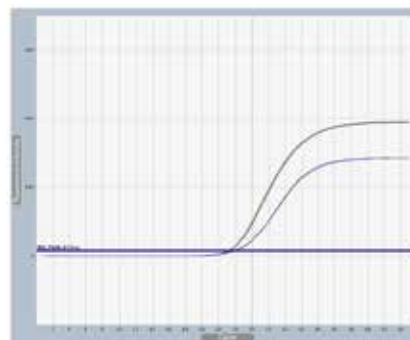
#### Specification

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

#### 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

## Respiratory Pathogen

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

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 Exicycler™96.

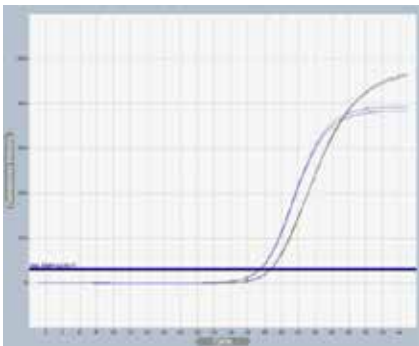
## Specification

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	Exicycler™96

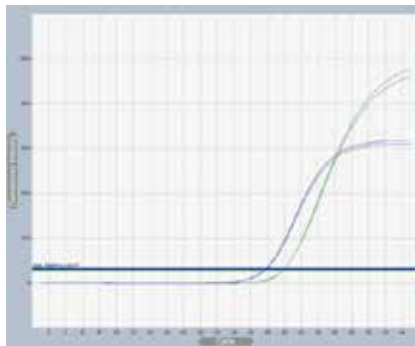
## Features & Benefits

- 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. Norovirus infection can occur in food poisoning even with low virus numbers and transmission through bodily fluids. The AccuPower® Norovirus Real-Time RT-PCR Kit is an *in vitro* diagnostic kit designed to detect norovirus GI/GII RNA in the human stool or rectal swab samples through Real-Time PCR using Exicycler™96.

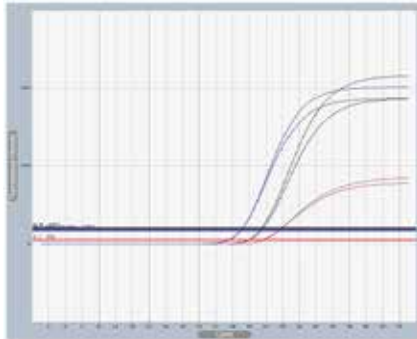
#### Specification

Target	Sample Type	Components	Instruments
Norovirus	Stool, Rectal swab	PCR Premix (96 rxn), PC, IPC, NTC, DEPC-D.W, Optical sealing film	Exicycler™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 AccuPower® 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	AccuPower® Norovirus Real-Time RT-PCR Kit	Norovirus	96

## Gastrointestinal Virus

### AccuPower® EV Real-Time RT-PCR Kit

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.

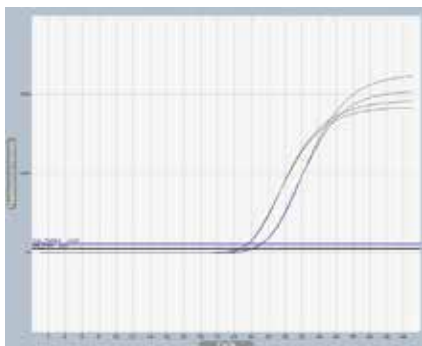
#### Specification

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 serotype	
Enterovirus	71, 76, 77, 79, 80, 82, 83, 87, 97, 101, B, yanbian96-83
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

Detectable Enterovirus 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

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

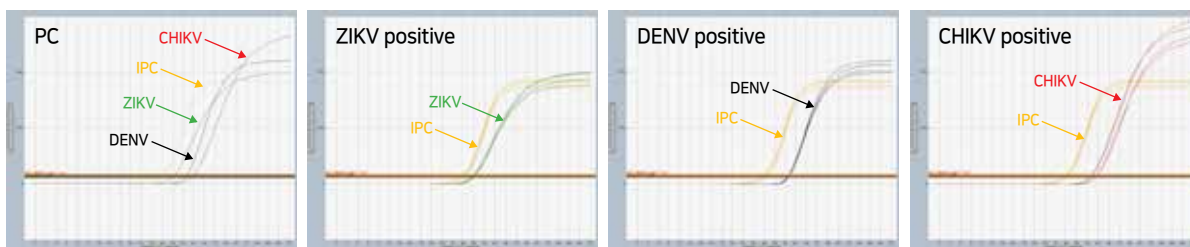
#### Specification

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™

#### 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

## Human Genotyping

# 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 autoimmunity. 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	<i>Exicycler</i> ™96 ( <i>ExiGenotyper</i> ™ software)

### ■ Features & Benefits

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

### ■ Testing results

<i>AccuPower</i> ® 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%)

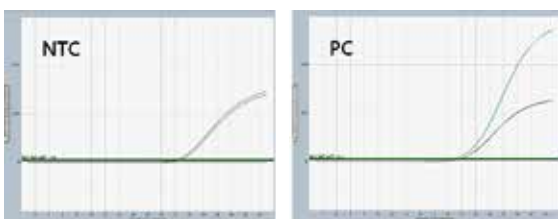
#### Diagnostic Evaluation and Correlation with Reference Method

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	<i>AccuPower</i> ® HLA-B27 Real-Time PCR Kit	HLA-B27	96

## Human Genotyping

# AccuPower® Warfarin genotyping Kit

Warfarin as a coumarin derivative is an anticoagulant that inhibits the biosynthesis of coagulant factor. Determining an optimal warfarin dose is essential to reduce side effect like hemorrhage. With this, analysis of SNPs in the genes, VKORC1 and CYP2C9, is shown to be closely related to the metabolism of anticoagulation drugs such as warfarin in individuals. This is why a fast and reliable test method is essential for prompt dose adjustment to prevent serious over- or under-dosing effects. *AccuPower®* Warfarin genotyping Kit is designed to determine the genotype of warfarin SNPs within VKORC1 and CYP2C9 gene. The kit is configured for use with *Exicycler™96* (*ExiGenotyper™* software).

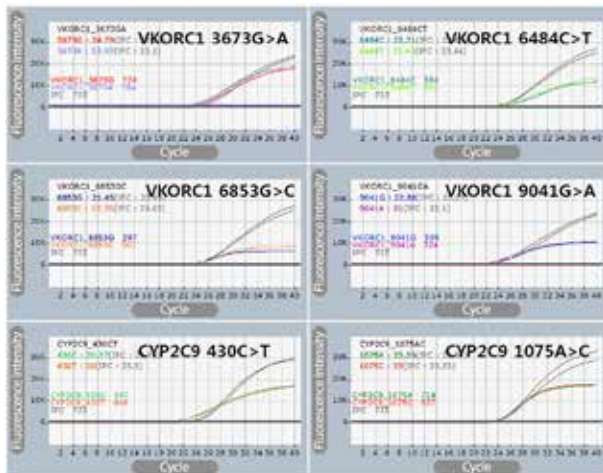
### ■ Specification

Target	Sample Type	Components	Instruments
Human VKORC1 gene SNP (3673 G>A, 6484 C>T, 6853G>C, 9041 G>A) Human CYP2C9 gene SNP (430 C>T, 1075 A>C)	Whole blood, Buccal swab	Warfarin Premix, Warfarin PC DNA(W1~8), DEPC-D.W, Optical sealing film	<i>Exicycler™96</i> ( <i>ExiGenotyper™</i> S/W)

### ■ Features & Benefits

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

### ■ Testing results



SNPs	Concordance(%)		SNPs	Concordance(%)	
	Sequencing	<i>ExiGenotyper</i>		Sequencing	<i>ExiGenotyper</i>
C430 C>T(*2)	CC (n=80)	80 (100)	G6484 C>T	CC (n=7)	7 (100)
	CT (n=2)	2 (100)		CT (n=20)	20 (100)
	TT (n=0)	NA		TT (n=55)	55 (100)
C1075 A>C(*3)	AA (n=71)	71 (100)	G6953 G>C	GG (n=7)	7 (100)
	AC (n=10)	10 (100)		GC (n=20)	20 (100)
	CC (n=1)	1 (100)		CC (n=55)	55 (100)
G3674 G>A	GG (n=7)	7 (100)	G9041 G>A	GG (n=59)	59 (100)
	GA (n=20)	20 (100)		GA (n=23)	23 (100)
	AA (n=55)	55 (100)		AA (n=0)	NA

#### Diagnostic Evaluation and Correlation with Reference Method

\*Thrombosis Research Volume 130, Issue 1, Pages 104-109, July 2012

The clinical evaluation of the *AccuPower®* Warfarin genotyping Kit was performed on 82 clinical samples. *AccuPower®* Warfarin genotyping assay determined that 82 specimen results were 100% agreement with direct-sequencing method

Sample	VKORC1				CYP2C9	
	g.3673G>A	g.6484C>T	g.6853G>C	g.9041G>A	c.430C>T	c.1075A>C
IPC	GA	CT	GC	GA	CT	AC
1	AA	TT	CC	GG	CC	AA
2	AA	TT	CC	GG	CC	AA
3	GA	CT	GC	GA	CT	AA

*ExiGenotyper™* S/W automatically interprets warfarin SNP results.

### ■ Related Products

Cat. No.	Kit name	Target	Tests
WAF-1111	<i>AccuPower®</i> Warfarin genotyping Kit	Warfarin SNP	12

## Human Genotyping

# AccuPower® JAK2 V617F Quantitative PCR Kit

The JAK2 (Janus Kinase 2) gene has been reported to be related to MPD (Myeloproliferative Disorder). Studies has revealed that 90% mutation ratio of JAK2 V617F is found in PV (Polycythemia Vera) patients, 35%-70% mutation ratio in ET (Essential Thrombocythemia) patients, and 50% mutation ratio in Myelofibrisis patients. *AccuPower® JAK2 V617F* Quantitative PCR Kit is designed for the quantification of each JAK2 wild type and mutant type to determine the mutant ratio. The kit is configured for use with *Exicycler™96(ExiGenotyper™* software).

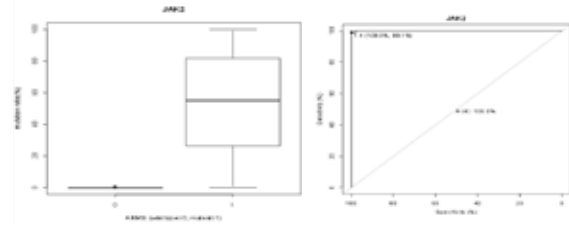
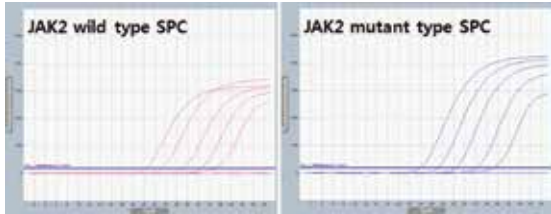
### Specification

Target	Sample Type	Components	Instruments
Human JAK2 gene V617F SNP	Whole Blood, Buccal swab	PCR premix (48rxn), SPCs (Wild type/Mutant) DEPC D.W., Optical sealing film	<i>Exicycler™96</i> ( <i>ExiGenotyper™ S/W</i> )

### Features & Benefits

- Reliable quantification of JAK2 SNP through allele-specific PCR method
- No interference observed in the presence of the interfering substances such as EDTA, hemoglobin, albumin, cholesterol, etc.

### Testing results



Flu. Graph	STD Curve	Well vs Ct	JAK2 Wild	JAK2 Mutant	Final Result
Sample	Wild type Concentration	Mutant type Concentration	Total Concentration	Counted Mutant ratio(%)	
Wild Control	21141607.06	0	0	0	
Mutant Control	0	26703696.76	1	100	
1	304746.17	493085.11	0.61	61.32	
2	408431.79	254592.54	0.38	38.4	
3	540153.43	69987.12	0.14	14.28	

Comparison test result of *AccuPower® JAK2 V617F* Quantitative PCR Kit and amplification refractory mutation system(ARMS).

*ExiGenotyper™* software automatically analyzes JAK2 V617F mutation ratio.

### Related Products

Cat. No.	Kit name	Target	Tests
JAK-1111	<i>AccuPower® JAK2 V617F</i> Quantitative PCR Kit	Human JAK2 gene	48

## Human Genotyping

### AccuPower® ApoE Real-Time PCR Kit

Human apolipoprotein E (ApoE) is a major component of lipoproteins and has an important role in lipoprotein metabolism. ApoE has 3 common alleles ( $\epsilon 2$ ,  $\epsilon 3$ ,  $\epsilon 4$ ) which encode three isoforms of ApoE protein E2, E3, and E4. *AccuPower*® ApoE Real-Time PCR Kit is designed to determine the genotype of ApoE codon change (112 Arg/Cys, 158 Cys/Arg). The kit is configured for use with *Exicycler*™96 (*ExiGenotyper*™ software).

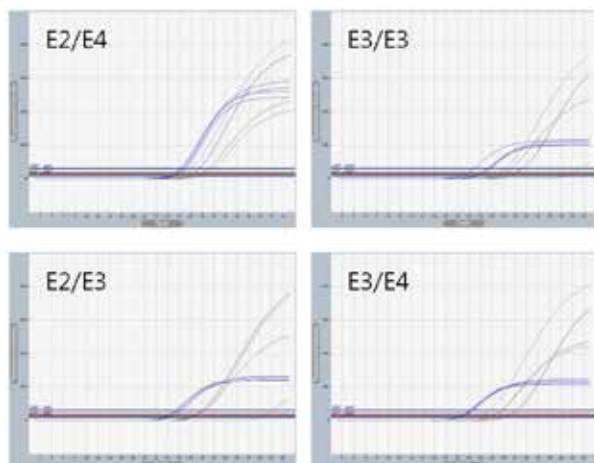
#### Specification

Target	Sample Type	Components	Instruments
Human ApoE SNP (Cys112Arg, Arg158Cys)	Whole blood, Buccal swab	PCR premix (24rxn), PCs (E1/E3), DEPC D.W., Optical sealing film	<i>Exicycler</i> ™96 ( <i>ExiGenotyper</i> ™ S/W)

#### Features & Benefits

- Distinct and direct detection of ApoE 6 genotype through allele-specific PCR method
- No interference observed in the presence of the interfering substances such as albumin, cholesterol, hemoglobin, etc.

#### Testing results



Method	Direct - sequencing			
	E2/E3	E2/E4	E3/E3	E4/E4
<i>AccuPower</i> ® ApoE Real-Time PCR Kit	1	2	1	2

Comparison test result of *AccuPower*® ApoE Real-Time PCR Kit and direct-sequencing

Flu. Graph	Well vs Ct	ApoE PCR Kit	Reaction Summary
112		158	Result
Hetero		Hetero	E2/E4
M.HOMO(T)		M.HOMO(C)	E3/E3
M.HOMO(T)		Hetero	E2/E3
Hetero		M.HOMO(C)	E3/E4

*ExiGenotyper*™ software automatically interprets ApoE SNP results

#### Related Products

Cat. No.	Kit name	Target	Tests
APE-1111	<i>AccuPower</i> ® ApoE Real-Time PCR Kit	Human ApoE SNP (Cys112Arg, Arg158Cys)	24

## Human Genotyping

# AccuPower® TPMT genotyping Real-Time PCR Kit

The TPMT (Thiopurine S-methyltransferase) gene encodes a protein that catalyses S-methylation of aromatic & heterocyclic sulfhydryl compounds. If a normal dose is prescribed to patients with a reduced TPMT activity, a side effect like a pancytopenia may occur. TPMT activity can be estimated through the SNP genotyping of the TPMT gene (238 G>C, 460 G>A, 719 A>G). *AccuPower®* TPMT genotyping Real-Time PCR Kit is designed to determine the genotype of TPMT SNPs and configured for use with *Exicycler™96* (*ExiGenotyper™* software).

## Specification

Target	Sample Type	Components	Instruments
Human TPMT gene SNP (*2, *3A, *3C)	Whole Blood, Buccal swab	PCR premix (12rxn), PC DEPC D.W., Optical sealing film	<i>Exicycler™96</i> ( <i>ExiGenotyper™</i> S/W)

## Features & Benefits

- Distinct and direct detection of TPMT SNP genotype through allelespecific PCR method
- No interference observed in the presence of the interfering substances such as albumin, cholesterol, bilirubin, etc.

## Testing results



Sample	238G>C	460G>A	719A>G
PC	GC	GA	AG
1	GC	GA	AG
2	GG	GG	AA
3	GG	GA	AA

*ExiGenotyper™* software automatically interprets TPMT SNP results.

SNPs		Concordance(%) Sequencing vs. <i>ExiGenotyper</i>
238	GG (n=11)	80 (100)
	GC (n=0)	2 (100)
	CC (n=0)	NA
460	GG (n=71)	71 (100)
	GA (n=10)	10 (100)
	AA (n=1)	1 (100)
719	AA (n=7)	7 (100)
	GA (n=20)	2 (100)
	GG (n=55)	55 (100)

Comparison test results of *AccuPower®* TPMT genotyping Real-Time PCR Kit and direct-sequencing.  
(BioMed Research International Vol. 2013, Pages 4, Jan 2013)

## Related Products

Cat. No.	Kit name	Target	Tests
TPM-1111	<i>AccuPower®</i> TPMT Genotyping Real-Time PCR Kit	Human TPMT gene	12



## Human Genotyping

### AccuPower® BCR-ABL Quantitative RT-PCR Kit

Philadelphia chromosome or Philadelphia translocation is a specific chromosomal abnormality that is associated with chronic myelogenous leukemia (CML). It is the result of a reciprocal translocation between chromosome 9 (region q34: ABL) and 22 (region q11: BCR). ABL gene expresses a membrane-associated protein, a tyrosine kinase, the BCR-ABL transcript is also translated into a tyrosine kinase, adding a phosphate group to tyrosine. In turn, BCR-ABL activates a number of cell cycle- controlling proteins and enzymes, speeding up cell division. Moreover, it inhibits DNA repair, causing genomic instability and potentially causing the feared blast crisis in CML. The AccuPower® BCR-ABL Quantitative RT-PCR Kit is designed for the quantification of BCR-ABL mutation and configured for use with Exicycler™96 (ExiGenotyper™ software).

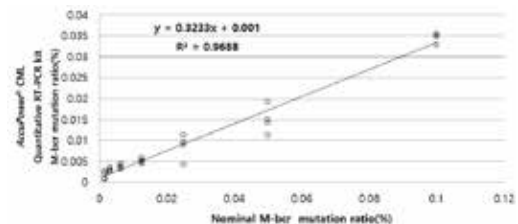
#### Specification

Target	Sample Type	Components	Instruments
ABL (reference gene), BCR-ABL (M-bcr) -b3a2, b2a2	Whole blood	ABL premix (48rxn), BCR-ABL premix (48rxn), SPCs, NTC, DEPC D.W., Optical sealing film	Exicycler™96 (ExiGenotyper™ S/W)

#### Features & Benefits

- Highly sensitive detection of M-bcr (b3a2, b2a2) mutation ratio
- One-Step Real-Time RT-PCR reaction using *Dual-HotStart™* technology

#### Testing results



Analytical sensitivity of AccuPower® BCR-ABL Quantitative RT-PCR Kit

Standard Positive Controls (S1 ~ S5) of AccuPower® BCR-ABL Quantitative RT-PCR Kit  
(Red signal: ABL, Green signal: M-bcr)

#### Related Products

Cat. No.	Kit name	Target	Tests
CML-1111	AccuPower® BCR-ABL Quantitative RT-PCR Kit	Human BCR-ABL gene	48



D

Gene Synthesis

ExiStation™ FA

ExiPrep

Accu

# Ordering Information



# Ordering Information

## A. Automatic Molecular Diagnostics System

Cat. No.	Product Name	Test/run
A-2200-N	<i>ExiStation</i> <sup>™</sup> CE-IVD	96
A-2400	<i>ExiStation</i> <sup>™</sup> 48 CE-IVD	96
A-5050	<i>ExiPrep</i> <sup>™</sup> 16 Dx CE-IVD US-IVD	16
A-5150	<i>ExiPrep</i> <sup>™</sup> 48 Dx CE-IVD US-IVD	48
A-5250	<i>ExiPrep</i> <sup>™</sup> 96 Lite CE-IVD US-IVD	96
A-2060-1	<i>Exicycler</i> <sup>™</sup> 96 CE-IVD	96
A-7040	<i>ExiSpin</i> <sup>™</sup>	32
A-5251	<i>AccuLoader</i> <sup>™</sup>	-

## B. Nucleic Acid Extraction Kits

### - *ExiPrep*<sup>™</sup> Dx Kit

\**ExiPrep*<sup>™</sup> Dx Kit for use on the *ExiPrep*<sup>™</sup> 16 Dx.

Cat. No.	Product Name	Target	Sample types	Test/Kit
K-4471	<i>ExiPrep</i> <sup>™</sup> Dx Viral DNA/RNA Kit CE-IVD US-IVD	Virus	Serum, Plasma, Swab, Urine, Saliva, Body Fluids	96
K-4472	<i>ExiPrep</i> <sup>™</sup> Dx Viral DNA Kit CE-IVD US-IVD			96
K-4473	<i>ExiPrep</i> <sup>™</sup> Dx Viral RNA Kit CE-IVD US-IVD			96
K-4474	<i>ExiPrep</i> <sup>™</sup> Dx Blood Viral DNA Kit CE-IVD		Human whole blood	96
K-4414	<i>ExiPrep</i> <sup>™</sup> Dx Bacteria Genomic DNA Kit CE-IVD US-IVD	Bacteria	Sputum, Body fluids, Urine, Swab, Stool	96
K-4418	<i>ExiPrep</i> <sup>™</sup> Dx Mycobacteria Genomic DNA Kit CE-IVD US-IVD	Mycobacteria	Sputum, Urine, Body Fluids	96
K-4411	<i>ExiPrep</i> <sup>™</sup> Dx Blood Genomic DNA Kit CE-IVD US-IVD	Human Cell	Human whole blood	96

### - *ExiPrep*<sup>™</sup> 48 Kit

\**ExiPrep*<sup>™</sup> 48 Kit for use on the *ExiPrep*<sup>™</sup> 48 Dx.

Cat. No.	Product Name	Target	Sample types	Test/Kit
K-4571	<i>ExiPrep</i> <sup>™</sup> 48 Viral DNA/RNA Kit CE-IVD US-IVD	Virus	Serum, Plasma, Urine, Swab, Saliva, Body Fluids, Human whole Blood	96
K-4573	<i>ExiPrep</i> <sup>™</sup> 48 Viral RNA Kit CE-IVD US-IVD	Virus	Saliva, Serum, Plasma, Swab, Stool, Body Fluids	96
K-4574	<i>ExiPrep</i> <sup>™</sup> 48 Genomic DNA Kit CE-IVD	Bacteria	Sputum, Urine, Swab	96
		Mycobacteria	Sputum, Urine, BAL	
		Human Cell	Human whole blood	
K-4575	<i>ExiPrep</i> <sup>™</sup> 48 Fast Viral RNA kit CE-IVD	Virus	Saliva, Sputum, Nasopharyngeal & Oropharyngeal Swab	96

**- 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 <b>CE-IVD US-IVD</b>	Bacteria	Sputum, Urine, Swab, Body fluid, Stool	384
K-4612	ExiPrep™ 96 cfDNA Kit	cfDNA	Plasma, Serum, Urine, Saliva	96
K-4613	ExiPrep™ 96 Blood Genomic DNA Kit <b>CE-IVD</b>	Human cell	Human whole blood	384
K-4614	ExiPrep™ 96 Viral DNA/RNA Kit <b>CE-IVD US-IVD</b>	Virus	Nasopharyngeal swab, Oropharyngeal swab	384
K-4731	Protonion™ 96 Viral RNA Kit <b>CE-IVD US-IVD</b>	Virus	Sputum, Saliva, Nasopharyngeal swab, Oropharyngeal swab	384

**- Manual type Kit**

Cat. No.	Product Name	Target	Sample types	Test/Kit
K-3033M	AccuPrep® Dx Viral RNA Extraction Kit <b>CE-IVD</b>	Virus	Sputum, Nasopharyngeal swab, Oropharyngeal swab	100
K-3619M	MagListo™ cfDNA Extraction Kit	cfDNA	Plasma, Serum, Urine, Saliva	50
K-3617	MagListo™ 5M Viral DNA/RNA Extraction Kit <b>CE-IVD US-IVD</b>	Virus	Sputum, Nasopharyngeal swab, Oropharyngeal swab	100
TM-1010	MagListo™ Separation rack	-	-	8
TM-1011		-	-	12

## C. Real-Time PCR Diagnostic Kits

Category	Cat. No.	Product name	Test/Kit	
COVID-19	SCVM-2112	AccuPower® SARS-CoV-2 Multiplex Real-Time RT-PCR Kit <b>CE-IVD</b>	100	
	RV1-2112	AccuPower® RV1 Multiplex Kit <b>CE-IVD</b>	100	
	SMVR-2112	AccuPower® SARS-CoV-2 Variants ID Real-Time PCR Kit (for Exicycler™96, ABI7500Fast, QuantStudio5) <b>CE-IVD</b>	50	
	SMVR-2113	AccuPower® SARS-CoV-2 Variants ID Real-Time PCR Kit (for CFX 96) <b>CE-IVD</b>	50	
	SMVR2-2112	AccuPower® SARS-CoV-2 Variants ID2 Kit-A (for Exicycler™96, ABI7500Fast, QuantStudio5) <b>CE-IVD</b>	50	
	SMVR2-2113	AccuPower® SARS-CoV-2 Variants ID2 Kit-B (for CFX 96) <b>CE-IVD</b>	50	
	SMVR3-2112	AccuPower® SARS-CoV-2 Variants ID3 Kit-A (for Exicycler™96, ABI7500Fast) <b>CE-IVD</b>	100	
	SMVR3-2113	AccuPower® SARS-CoV-2 Variants ID3 Kit-B (for CFX 96) <b>CE-IVD</b>	100	
	Vacuum dried Premix	NCVM-1111	AccuPower® COVID-19 Multiplex Real-Time RT-PCR Kit <b>CE-IVD</b>	96
		RV1-1111	AccuPower® RV1 Real-Time RT-PCR Kit <b>CE-IVD</b>	96
		SMVR-1111	AccuPower® SARS-CoV-2 Variants ID Real-Time-RT-PCR Kit <b>CE-IVD</b>	48
		SMVR2-1111	AccuPower® SARS-CoV-2 Variants ID2 Real-Time-RT-PCR Kit <b>CE-IVD</b>	48
	HIV	HIV-1211	AccuPower® HIV-1 Quantitative RT-PCR Kit <b>CE-IVD</b>	96
		HIV-1111	AccuPower® HIV-1 Quantitative RT-PCR Kit	96
Hepatitis	HBV-1211	AccuPower® HBV Quantitative PCR Kit <b>CE-IVD</b>	96	
	HBV-1111	AccuPower® HBV Quantitative PCR Kit	96	
	HCV-1211	AccuPower® HCV Quantitative RT-PCR Kit <b>CE-IVD</b>	96	
	HCV-1111	AccuPower® HCV Quantitative RT-PCR Kit	96	
Tuberculosis	XDRA-1111	AccuPower® XDR-TB Real-Time PCR Kit-A <b>CE-IVD</b>	48	
	XDRB-1111	AccuPower® XDR-TB Real-Time PCR Kit-B <b>CE-IVD</b>	96	
	TBMDR-1111	AccuPower® TB&MDR Real-Time PCR Kit <b>CE-IVD</b>	48	
	MTN-1111	AccuPower® MTB&NTM Real-Time PCR Kit <b>CE-IVD</b>	96	
	MTB-1111	AccuPower® MTB Real-Time PCR Kit <b>CE-IVD</b>	96	
Sexually Transmitted Infection	STI8A-1111	AccuPower® STI8A-Plex Real-Time PCR Kit <b>CE-IVD</b>	96	
	STI8B-1111	AccuPower® STI8B-Plex Real-Time PCR Kit <b>CE-IVD</b>	96	
	STI4C-1111	AccuPower® STI4C-Plex Real-Time PCR Kit <b>CE-IVD</b>	96	
	STD2A-1211	AccuPower® CT & NG Real-Time PCR Kit <b>CE-IVD</b>	96	
Human Papillomavirus	HPM-1111	AccuPower® HPV 16 &18 Real-Time PCR Kit <b>CE-IVD</b>	96	
	HHP-1111	AccuPower® hrHPV Genotyping & Screening Kit <b>CE-IVD</b>	48	

Category	Cat. No.	Product name	Test/Kit
Transplantation - related Virus	CMV-1111	AccuPower® CMV Quantitative PCR Kit <b>CE-IVD</b>	96
	EBV-1111	AccuPower® EBV Quantitative PCR Kit <b>CE-IVD</b>	96
	BKV-1111	AccuPower® BKV Quantitative PCR Kit <b>CE-IVD</b>	96
Respiratory Pathogens	SIA-1111	AccuPower® New Inf A (H1N1) & Inf A Real-Time RT-PCR Kit <b>CE-IVD</b>	48
	CPN-1111	AccuPower® CP Real-Time PCR Kit	96
	MPN-1111	AccuPower® MP Real-Time PCR Kit <b>CE-IVD</b>	96
	COV-1112	AccuPower® MERS-CoV(upE&ORF1a) Real-Time RT-PCR Kit <b>CE-IVD</b>	48
Gastrointestinal Pathogens	NOR-1111	AccuPower® Norovirus Real-Time RT-PCR Kit <b>CE-IVD</b>	96
	ENT-1111	AccuPower® EV Real-Time RT-PCR Kit <b>CE-IVD</b>	96
Mosquito borne disease	ZIK-1111	AccuPower® ZIKV (DENV, CHIKV) Multiplex Real-Time RT-PCR Kit <b>CE-IVD</b>	96
Human Genotyping	HLB-1111	AccuPower® HLA-B27 Real-Time PCR Kit	96
	WAF-1111	AccuPower® Warfarin genotyping Kit <b>CE-IVD</b>	12
	JAK-1111	AccuPower® JAK2 V617F Quantitative PCR Kit <b>CE-IVD</b>	48
	APE-1111	AccuPower® ApoE Real-Time PCR Kit <b>CE-IVD</b>	24
	TPM-1111	AccuPower® TPMT genotyping Real-Time PCR Kit <b>CE-IVD</b>	12
	CML-1111	AccuPower® BCR-ABL Quantitative PCR Kit <b>CE-IVD</b>	48

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