

CEIVD

PowerChek[™] Clinical Dx Real-time PCR Kit series

Clinical Diagnostics

Influenza Virus - Respiratory Virus - Gastroenteritis - MTB/NTM - CT/NG

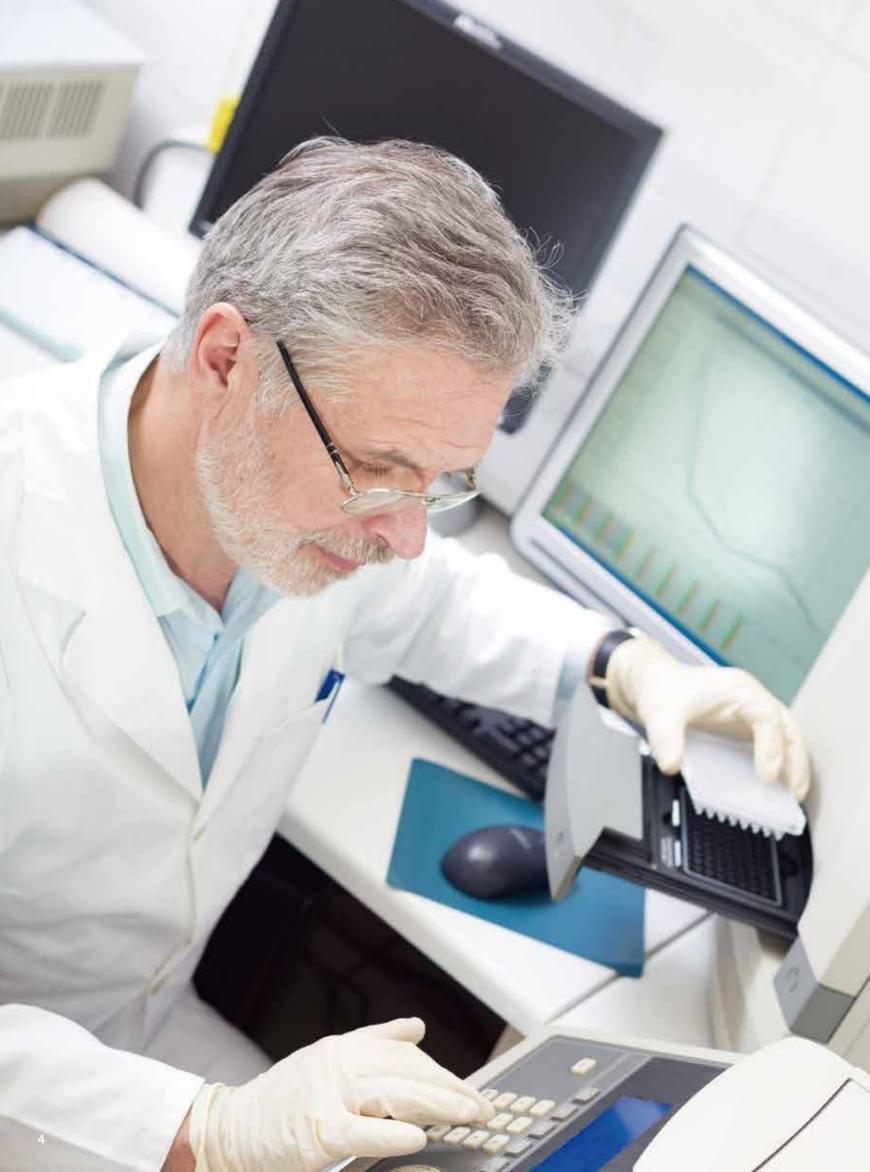






Clinical Diagnostics Kit

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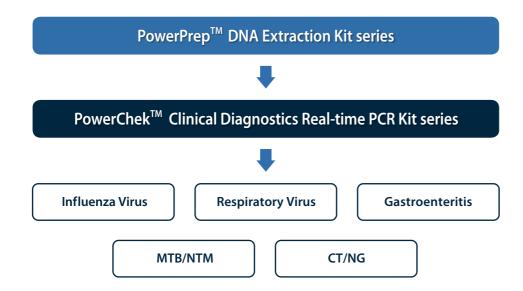
KogeneBiotech, Real-time PCR Kit company

KogeneBiotech has been approved as a manufacturer of Medical Device by MFDS (Ministry of Food and Drug Safety) for the diagnosis of infectious pathogen, like as gastroenteric pathogen, influenza virus, respiratory virus and so on. We provide complete and easy solution kits that help guide appropriate therapy by identifying pathogen.

Based on state-of-the-art Real-time PCR technologies, PowerChek™ Clinical Diagnostic Real-time PCR Kit series enable simple, fast and reliable detection of a wide range of Influenza virus, reapiratory virus, gastroenteritis, MTB/NTM and CT/NG.

PowerChek[™] System has instrument compatibility with major Real-time PCR instruments and is flexible, allowing rapid results from a broad spectrum of clinical matrices while simplifying the testing process.

Total Solution for Clinical Dx



F. A. C. E system

- FAST
- ACCURATE
- CUSTOMIZED
- EASY to USE



PowerChek[™] Clinical Diagnostic Real-time PCR Kit series **C€ №** Influenza Virus

Influenza A / B
Influenza A / pH1N1
pH1N1
pH1N1 / H3N2 / H5N1
Avian Influenza

Simple & Accurate testing for

Influenza Virus



Influenza, commonly referred to as the flu, is an infectious disease caused by RNA viruses of the family Orthomyxoviridae (the influenza viruses). Usually influenza is transmitted from infected mammals and birds through the air by coughs, sneezes or droppings containing the virus.

Influenza viruses are classified A, B and C. Influenza A virus has a wide variety unlike influenza B virus or influenza C virus. Some variants of influenza A viruses (like H1N1, H5N1) are most virulent human pathogens among the three influenza types and cause the most severe disease.

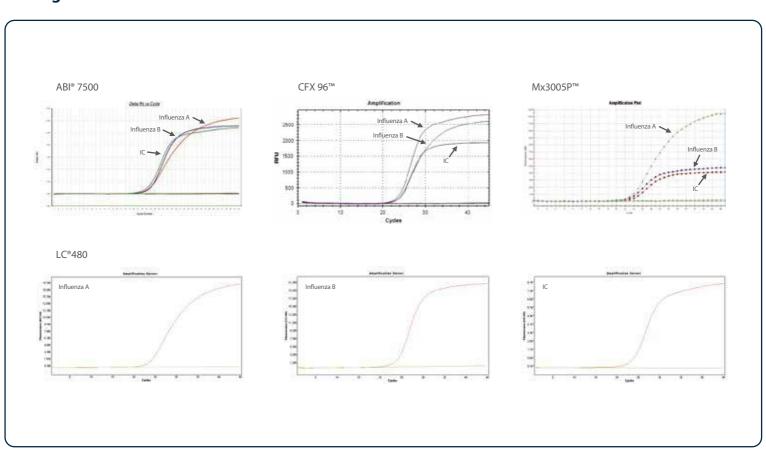
Applications

- Nasopharyngeal swabs
- Nasal aspirates
- Bronchoalveolar lavage
- Sputum

Intended Use

- Identifying test for diagnosis
- Confirmation of medical test
- Assistance of an examination in clinical samples

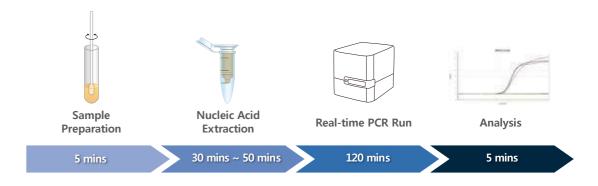
Testing Results: Influenza A / B Real-time PCR Kit



Work Flow

E0007

PowerChek™ Viral DNA/RNA Extraction Kit



Features & Benefits

- High sensitivity & specificity
- One-step Real-time RT-PCR assay
- Includes all necessary reagents
- Compatibility Flexible open system

- Time-to-Result: about 2 hr
- Easy to use
- CE marked

ower	Chek™ Influenza Virus Real-time PC	R Kit series ← 🚾			l °7500 se	ABI °7500 se BioRad CFX(BioRad iCycle		Qiagen RotorGeneQ	Roche LightCycler®	Roche LightCycler ®9	OCCUPA PROLICE
Cat #	PowerChek™ Influenza Virus Real-time PCR Kit series	Analyte	Size	Fluorophore	ABI			9.5	Ro Lig	S. E.	-
R2100E	PowerChek™ Influenza A Real-time PCR Kit	Influenza A, IC	100	FAM, Cy5	•	•	•	•	•	•	•
R2200E	PowerChek™ Influenza B Real-time PCR Kit	Influenza B, IC	100	VIC(HEX), Cy5	•	•	•	•	•	•	
R2800	PowerChek™ Pandemic H1N1 Real-time PCR Kit	Pandemic Influenza H1N1, IC	100	FAM, Cy5	•	•	•	•	•	•	
R2700	PowerChek™ Influenza A / Pandemic H1N1 Real-time PCR Kit	- Seasonal Influenza A - Pandemic Influenza H1N1 - IC	100	FAM, VIC(HEX), Cy5	•	•	•	•	•	•	
R3300T	PowerChek™ Influenza A / B Real-time PCR Kit	- Seasonal Influenza A - Seasonal Influenza B - IC	100	FAM, VIC(HEX), Cy5	•	•	•	•	•	•	
R3400	PowerChek™ Pandemic H1N1 / H3N2 Real-time PCR Kit	- Pandemic Influenza H1N1 - Seasonal Influenza H3N2 - IC	100	FAM, VIC(HEX), Cy5	•	•	•	•	•	•	
R3500T	PowerChek™ Pandemic H1N1 / H3N2 / H5N1 Real-time PCR Kit	- Pandemic Influenza H1N1 - Seasonal Influenza H3N2 - Avian Influenza H5N1 - IC	100	FAM, VIC(HEX), NED, Cy5	•						
R3000E	PowerChek™ AI H5N1 Real-time PCR Kit	Avian Influenza Virus H5N1	100	FAM, VIC(HEX)	•	•	•	•	•	•	
R3100E	PowerChek™ AI H7N7 Real-time PCR Kit	Avian Influenza Virus H7N7	100	FAM, VIC(HEX)	•	•	•	•	•	•	
R3200E	PowerChek™ AI H9N2 Real-time PCR Kit	Avian Influenza Virus H9N2	100	FAM, VIC(HEX)	•	•	•	•	•	•	
Cat #	PowerPrep™ Extraction Kit series	Size		Purification Module				Sample	e Matr	ces	
								• Cell, ti	issue, cı	ılture	

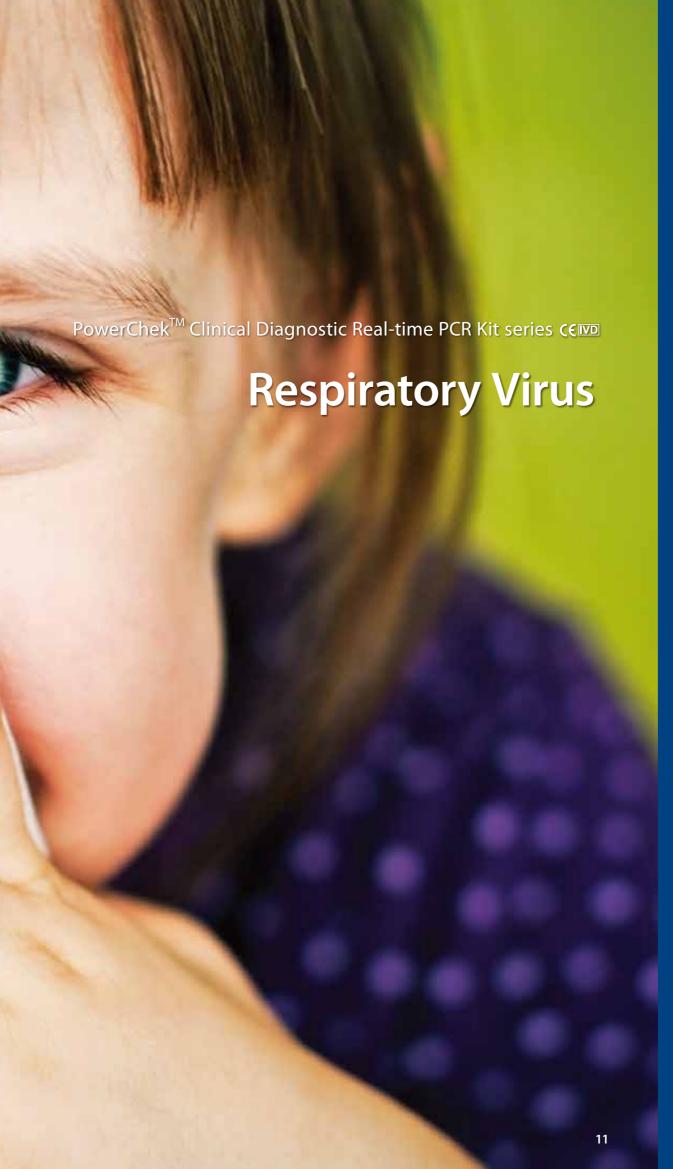
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Virus-infected samples

Swab

Silica spin column





Adenovirus / Bocavirus
PIV type 1, 2, 3
RSV A / B / HMV
Coronavirus
Rhinovirus

Simple & Accurate testing for

Respiratory Virus



The major causes of acute respiratory infections in children and adults are Adenovirus, Bocavirus, Parainfluenza virus (subtype1, 2, 3), Respiratory Syncytial Virus (A, B), Coronavirus (229E, OC43, NL63) and Rhinovirus. Rapid diagnosis of these viral pathogens is important for infection control and therapeutic purposes.

PowerChek™ Respiratory Virus Real-time PCR Kit series are intended for the qualitative detection and discrimination of respiratory viruses in clinical samples.

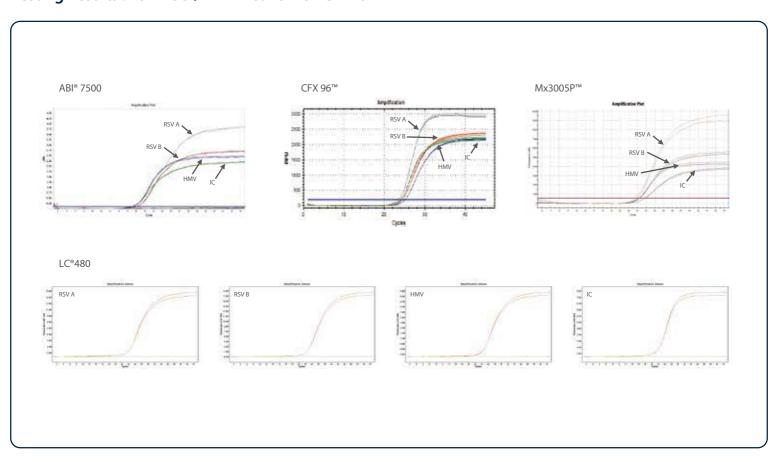
Applications

- Nasopharyngeal swabs
- Nasal aspirates
- Bronchoalveolar lavage
- Sputum

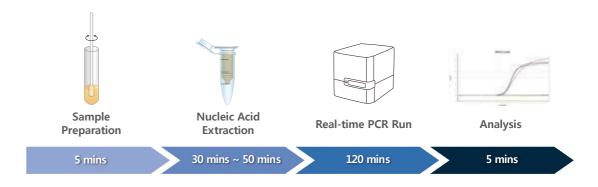
Intended Use

- Identifying test for diagnosis
- Confirmation of medical test
- Assistance of an examination in clinical samples

Testing Results: RSV A&B / HMV Real-time PCR Kit



Work Flow

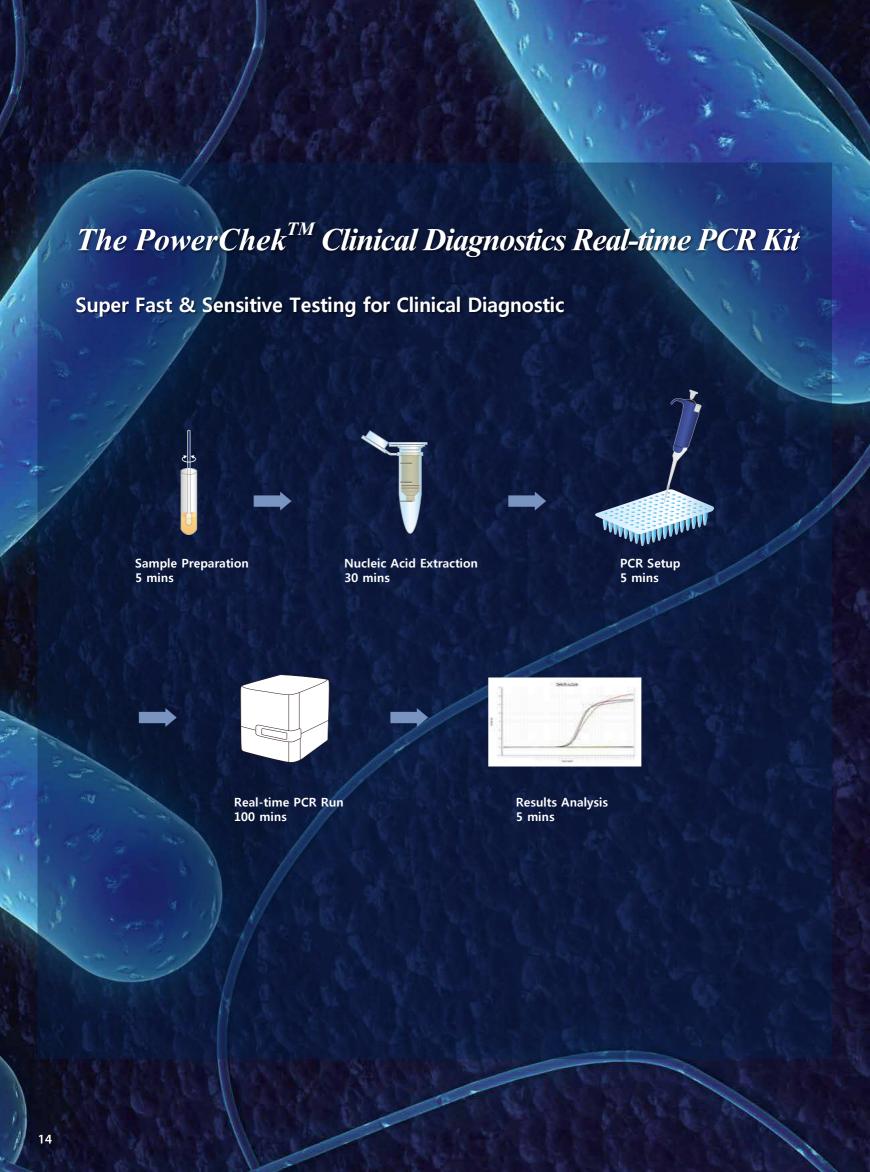


Features & Benefits

- High sensitivity & specificity
- One-step Real-time RT-PCR assay
- Includes all necessary reagents
- Compatibility Flexible open system

- Time-to-Result: about 2 hr
- Easy to use
- CE marked

PowerCl	nek™ Respiratory Virus Real-time PCI	R Kit series ← 🚾			ABI ®7500 series			Qiagen RotorGeneQ™	Roche LightCycler®480	Roche LightCycler ®96	Agilent Mx3005P™
Cat #	PowerChek™ Respiratory Virus Real-time PCR Kit series	s Analyte Fluorophore Size						Qia Rot	Roc	Roc Ligh	Agil
R6000 NEW	PowerChek™ 14 RV Panel Kit	- Adenovirus / Bocavirus / IC - Parainfluenza Virus type 1/2/3/IC - RSV A & B / Human Metapneumovirus / IC - Coronavirus 229E / OC43 / NL63 / IC - Human Rhinovirus / IC - Influenza A / Influenza B / IC	- FAM - VIC(HEX) - NED/ROX - Cy5	100	•	•	•	•	•	•	•
R6100T	PowerChek™ Human Adenovirus / Bocavirus Real-time PCR Kit	- Human Adenovirus - Human Bocavirus - IC	- FAM - VIC(HEX) - Cy5	100	•	•	•	•	•	•	•
R6200T	PowerChek™ Parainfluenza Virus 1 / 2 / 3 Real-time PCR Kit	- Parainfluenza Virus type 1 - Parainfluenza Virus type2 - Parainfluenza Virus type3 - IC	- FAM - VIC(HEX) - NED/ROX - Cy5	100	•	•	•	•	•	•	•
R6300T	PowerChek™ RSV A & B / HMV Real-time PCR Kit	- RSV A - RSV B - Human Metaneumo Virus - IC	- FAM - VIC(HEX) - NED/ROX - Cy5	100	•	•	•	•	•	•	•
R6400T	PowerChek™ Coronavirus 229E / OC43 / NL63 Real-time PCR Kit	- Coronavirus 229 - Coronavirus OC43 - Coronavirus NL63 - IC	- VIC(HEX) - FAM - NED/ROX - Cy5	100	•	•	•	•	•	•	•
R6600T	PowerChek™ Rhinovirus Real-time PCR Kit	- Rhinovirus - IC	- FAM - Cy5	100	•	•	•	•	•	•	•
Cat #	PowerPrep™ Nucleic Acid Extraction Kit series	Size	Purificatio	n Module				Sample	Matri	ces	
E0007	PowerChek™ Viral DNA/RNA Extraction Kit	50	Silica spin	Cell, tissue, cultureSwabVirus-infected samples							



Gastroenteric Bacteria

Gastroenteritis is a common infection caused by a variety of bacteria in children and adult.

PowerChek™ Gastroenteric Bacteria Real-time PCR Kit series enable simple, fast and reliable detection of major viral and bacterial contaminants in a complex sample like stool, environmental and food.



Gastroenteric Bacteria Real-time PCR assay

Multiplex Screening

Single Detection

Benefits & Key Features

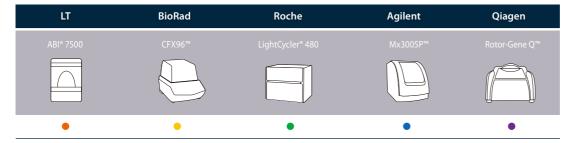
Super Fast, Simple and Easy

- Time-to-Result: 1.5 ~ 2.5 hrs.
- Easy to use

A Complete Solution Kit

- Included all reagents required to run Real-time PCR.
- As fast, easy and reliable as possible.

Compatibility - Flexible open system



PowerPrep™ Nucleic Acid Extraction Kit C€™

Cat No.	Size (Samples)	Product	Sample Matrices	Purification Module
E0101	100	PowerPrep™ DNA Extraction Kit	 Cell, tissue, culture Feces, swab Plasma, serum, swab, urine, stool, blood and infected samples 	Silica spin column

Campylobacter
Pathogenic E.coli
Listeria monocytogenes
Clostridium perfringenes
Vibrio

Bacillus cereus
Staphylococcus aureus

Yersinia enterocolitica etc.

PowerChek[™] Gastroenteric Bacteria Real-time PCR Kit series ເເໜ

Cat #	PowerChek™ Gastroenteric Bacteria Real-time PCR Kit series	Analyte
R0101E	PowerChek™ Campylobacter jejuni Real-time PCR Kit	Campylobacter jejuni, IC
R0102E	PowerChek™ E.coli O157 Real-time PCR Kit (VT2)	<i>E. coli</i> O157, IC
R0103E	PowerChek™ Staphylococcus aureus Real-time PCR Kit	Staphylococcus aureus, IC
R0104E	PowerChek™ Bacillus cereus Real-time PCR Kit	Bacillus cereus, IC
R0105E	PowerChek™ Vibrio parahaemolyticus Real-time PCR Kit	Vibrio parahaemolyticus, IC
R0106E	PowerChek™ Listeria monocytogenes Real-time PCR Kit	Listeria monocytogenes, IC
R0107E	PowerChek™ Yersinia enterocolitica Real-time PCR Kit	Yersinia enterocolitica, IC
R0108E	PowerChek™ Salmonella spp. Real-time PCR Kit	Salmonella spp., IC
R0109E	PowerChek™ Shigella spp. Real-time PCR Kit	Shigella spp. , IC
R0110E	PowerChek™ Vibrio cholerae Real-time PCR Kit	Vibrio cholerae, IC
R0111E	PowerChek™ Clostridium perfringens Real-time PCR Kit	Clostridium perfringens, IC
R0113E	PowerChek™ Vibrio vulnificus Real-time PCR Kit	Vibrio vulnificus, IC
R0115E	PowerChek™ EHEC Real-time PCR Kit	EHEC (stx1, stx2), IC
R0116E	PowerChek™ ETEC Real-time PCR Kit	ETEC (LT, ST), IC
R0121E	PowerChek™ EAEC/EIEC Real-time PCR Kit	EAEC (aggR), EIEC (ipaH)
R0122E	PowerChek™ EPEC Real-time PCR Kit	EPEC (bfpA, eaeA)
R0131T	PowerChek™ Diarrheal E.coli 4-plex Real-time PCR Kit I	EHEC (VT1, VT2), ETEC (LT, ST)
R0140T	PowerChek™ Diarrheal E.coli 4-plex Real-time PCR Kit II	EPEC (eaeA, bfpA), EIEC (ipaH), EAEC (aggR)
R0129E	PowerChek™ Campylobacter Triplex Real-time PCR Kit	Campylobacter spp., C. jejuni, C. coli, IC
R0136E	PowerChek™ E.coli O157 & Salmonella Real-time PCR Kit	E. coli O157, Salmonella spp. , IC
R0139E	PowerChek™ Vibrio parahaemolyticus Multiplex Real-time PCR Kit	Vibrio parahaemolyticus (toxR, trh, tdh) , IC
R0117E	PowerChek™ Vibrio Multi I Real-time PCR Kit	Vibrio parahaemolyticus, V. cholerae (ctx, hly), IC
R0118E	PowerChek™ Vibrio Multi II Real-time PCR Kit	Vibrio cholerae (ctx), V. parahaemolyticus, V. vulnificus, IC
R0123E	PowerChek™ Salmonella & Shigella Real-time PCR Kit	Salmonella spp., Shigella spp., IC
R0143E	PowerChek™ 20 Pathogen Multiplex Real-time PCR Kit	Campylobacter jejuni, C. coli, Clostridium perfringens (cpe, cpa) Vibrio cholerae, V. vulnificus, V. parahaemolyticus Listeria monocytogenes, Salmonella spp., IC Bacillus cereus, Yersinia enterocolitica, Staphylococcus aureus EHEC (VT1, VT2), ETEC (LT, ST) EAEC (aggR) EPEC (bfpaA, eaeA), EIEC (ipaH)
R1500 NEW	⊂ PowerChek™ 25 Gastroenteric Panel Kit	Campylobacter jejuni, C. coli, Clostridium perfringens (cpe, cpa) Vibrio cholerae, V. vulnificus, V. parahaemolyticus Listeria monocytogenes, Salmonella spp., IC Bacillus cereus, Yersinia enterocolitica, Staphylococcus aureus EHEC (VT1, VT2), ETEC (LT, ST) EAEC (aggR), EPEC (eaeA, bfpA), EIEC (ipaH) Norovirus G I / G II Adenovirus, Astrovirus, Rotavirus

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		FAM, VIC(HEX), NED, Cy5	•										

 $[\]divideontimes$ IC : Internal Control \bigstar Compatible with fluorophore, but not validated on this machine



Gastroenteric Virus

Gastroenteritis is a common infection caused by a variety of viruses in children and adult. Especially the viruses, including Rotavirus, Norovirus, Astrovirus and enteric Adenovirus, are frequently associated with diarrhea and vomiting in children under 5 years of age, sporadic cases have been described for hospitalized children



PowerChek™ Gastroenteric Virus Real-time PCR Kit series enable simple, fast and reliable detection of major viral and bacterial contaminants in a complex sample like stool, environmental and food.

Benefits & Key Features

Super Fast, Simple and Easy

- Time-to-Result: 1.5 ~ 2.5 hrs.
- Easy to use
- One-step RT Real-time PCR Kit

A Complete Solution Kit

- Included all reagents required to run Real-time PCR.
- As fast, easy and reliable as possible.

Compatibility - Flexible open system

LT	BioRad	Roche	Agilent	Qiagen
ABI® 7500	CFX96™	LightCycler® 480	Mx3005P™	Rotor-Gene Q™
•	•	•	•	•

C€ IVI Gastı	roenteric Virus Real-time PCF	R Kit	series	ABI *7500 series			AB StepOne"	AB StepOne Plus"			Qiagen RotorGeneQ™	Roche LightCycler*480	Roche LightCycler *96	
Cat #	PowerChek™ Gastroenteric Virus Real-time PCR Kit series	Size	Fluorophore				AB Ste	AB Ste			Qiage Rotor(Roche Light(Roche LightC	
R0203E	PowerChek™ Norovirus G I Real-time PCR Kit	50	FAM, VIC(HEX)	•	•	•	•	•	•	•	•	•	•	
R0205E	PowerChek™ Norovirus G II Real-time PCR Kit	50	FAM, VIC(HEX)	•	•	•	•	•	•	•	•	•	•	
R0201E	PowerChek™ Adenovirus Real-time PCR Kit	50	FAM, VIC(HEX)	•	•	•	•	•	•	•	•	•	•	
R0202E	PowerChek™ Astrovirus Real-time PCR Kit	50	FAM, VIC(HEX)	•	•	•	•	•	•	•	•	•	•	
R0204E	PowerChek™ Rotavirus Real-time PCR Kit	50	FAM, VIC(HEX)	•	•	•	•	•	•	•	•	•	•	
R0210	PowerChek™ Norovirus GI / GII Multiplex Real-time PCR Kit	50	FAM, VIC(HEX), Cy5	•	•	•	•	•	•	*	•	•	*	
R0211	PowerChek™ Adeno/Astro/Rota Real-time PCR Kit	50	FAM, VIC(HEX), ROX, Cy5						•	*	•	•	*	
R0212	PowerChek™ Hepatitis A Virus Real-time PCR Kit	50	FAM, VIC(HEX)	•	•	•	•	•	•	•	•	•	•	
R1502	PowerChek™ 5 Viral Panel Kit	32 tests	FAM, VIC(HEX), NED/ROX, Cy5	•	•	•	•	•	•	•	•	•	•	Ī
Cat #	PowerPrep™ Extraction Kit	Size		Purit	ficatio	on Mo	dule		S	ampl	e Mat	rices		
E0007	PowerPrep™ Viral DNA/RNA Extraction Kit	50		9	Sili spin c	ca olumr	n			Swal	tissue, b s-infect			_

Norovirus GI/GII Adenovirus Heptitis A Virus



MTB / NTM

The differentiation of *Mycobacterium tuberculosis* (MTB) from non tuberculous mycobacteria (NTM) is of primary importance for infection control and choice of antimicrobial therapy.

PowerChek™ MTB/NTM Real-time PCR Kit is designed to simultaneously detect the specific genes for MTB and NTM using multiplex Real-time PCR assay.



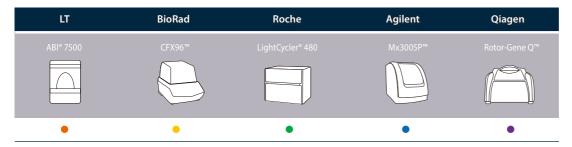
The kit targets the MTB complex-specific IS6110 and ITS, 16s rDNA region of mycobacterium. Therefore, the product allows for the qualitative detection and discrimination of MTB and NTM directly in clinical sample and culture.

Benefits & Key Features

- KFDA approved
- High sensitivity & specificity
- Time to results: 100 min after DNA ext.
- Includes all necessary reagents

- Compatibility Flexible open system
- Reliable internal control
- Easy to use
- CE marked

Compatibility - Flexible open system



Ordering information C€ IVD Cat # Product Size Fluorophore R0120 PowerChek™ MTB/NTM Real-time PCR Kit 100 FAM, VIC(HEX), Cy5 Cat # PowerPrep™ Extraction Kit Size Sample Matrices Purification Module E0104 PowerPrep™ TB Extraction Kit 100 FAM, VIC(HEX), Cy5 Boiling Boiling

 $[\]star$ Compatible with fluorophore, but not validated on this machine



CT/NG

Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) are the two most prevalent bacterial sexually transmitted infections (STIs) reported to the Centers for Disease Control and Prevention. Chlamydia trachomatis infections are often asymptomatic in both males and females. Children born to infected mothers are at significantly higher risk for inclusion conjunctivitis and chlamydial pneumonia.



Neisseria gonorrhoeae is pathogenic to humans who are its only natural host, it is responsible for the disease Gonorrhea. Gonorrhea is a sexually transmitted disease of worldwide importance. Host-related factors contribute to the incidence of Gonorrhea.

PowerChek™ CT/NG Real-time PCR Kit is designed to simultaneously detect the specific genes for CT and NG using multiplex Real-time PCR assay.

Benefits & Key Features

- High sensitivity & specificity
- Time to results: 100 min after DNA ext.
- Includes all necessary reagents
- KGMP

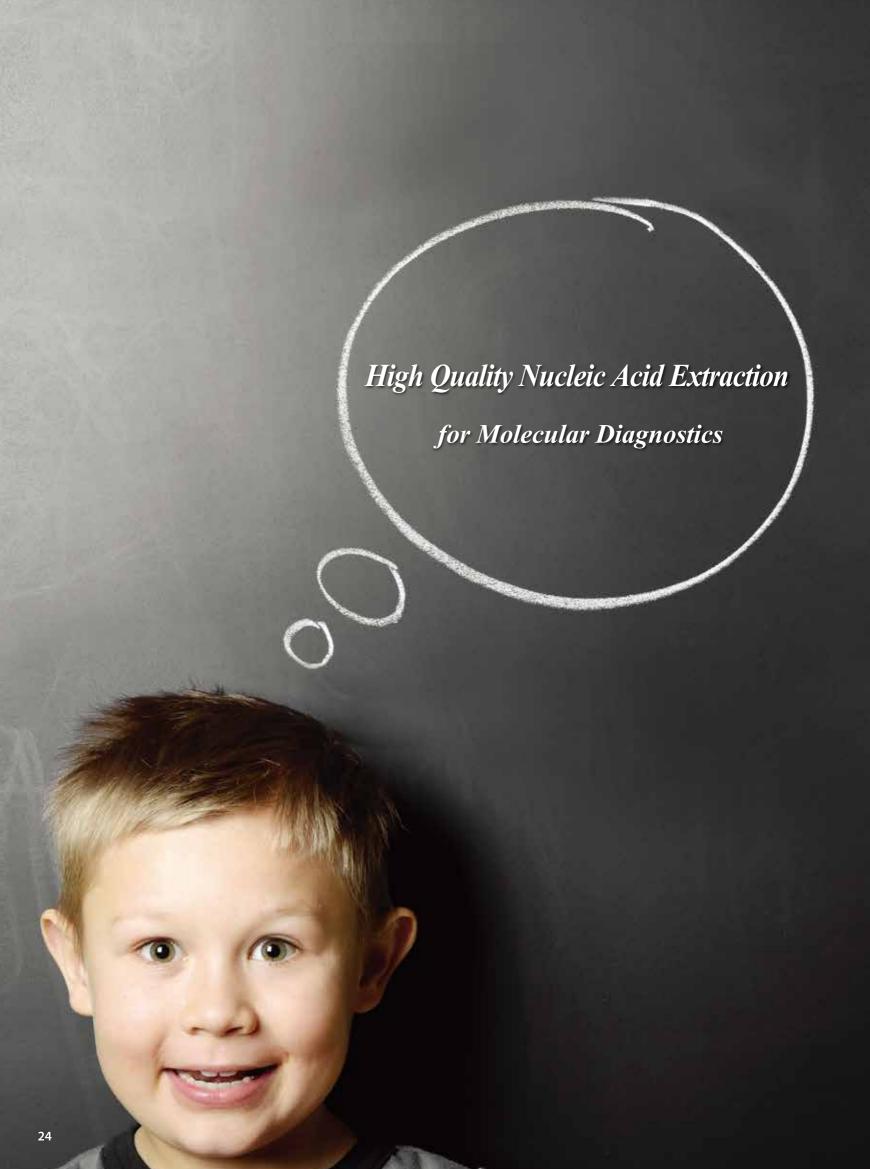
- Compatibility Flexible open system
- Reliable internal control
- Easy to use
- CE marked

Compatibility - Flexible open system

LT	BioRad	Roche	Agilent	Qiagen
ABI® 7500		LightCycler® 480		Rotor-Gene Q™
•	•	•	•	•

Ordering information C€IVD Fluorophore PowerChek™ CT/NG Real-time PCR Kit R0110 100 FAM, VIC(HEX), Cy5 • \star Purification Module PowerPrep™ Extraction Kit Sample Matrices PowerPrep™ DNA Extraction Kit E0101 100 • Feces, swab Silica Plasma, serum. Urine, spin column stool, blood and virus infected samples

[★] Compatible with fluorophore, but not validated on this machine



PowerPrep[™] Nucleic Acid Extraction Kit series

The success of molecular diagnostic analysis requires effective methods for the nucleic acid extraction from various sample types.

PowerPrep™ Nulceic Acid Extraction Kit series provide a rapid and efficient method for the isolation and purification of DNA from a variety of samples including infected samples, tissue and culture cell so on. The kits offer various isolation systems available to suit your special testing purpose, assuring high-quality nucleic acid purification.



PowerPrep™ Nucleic Acid Extraction Kit series

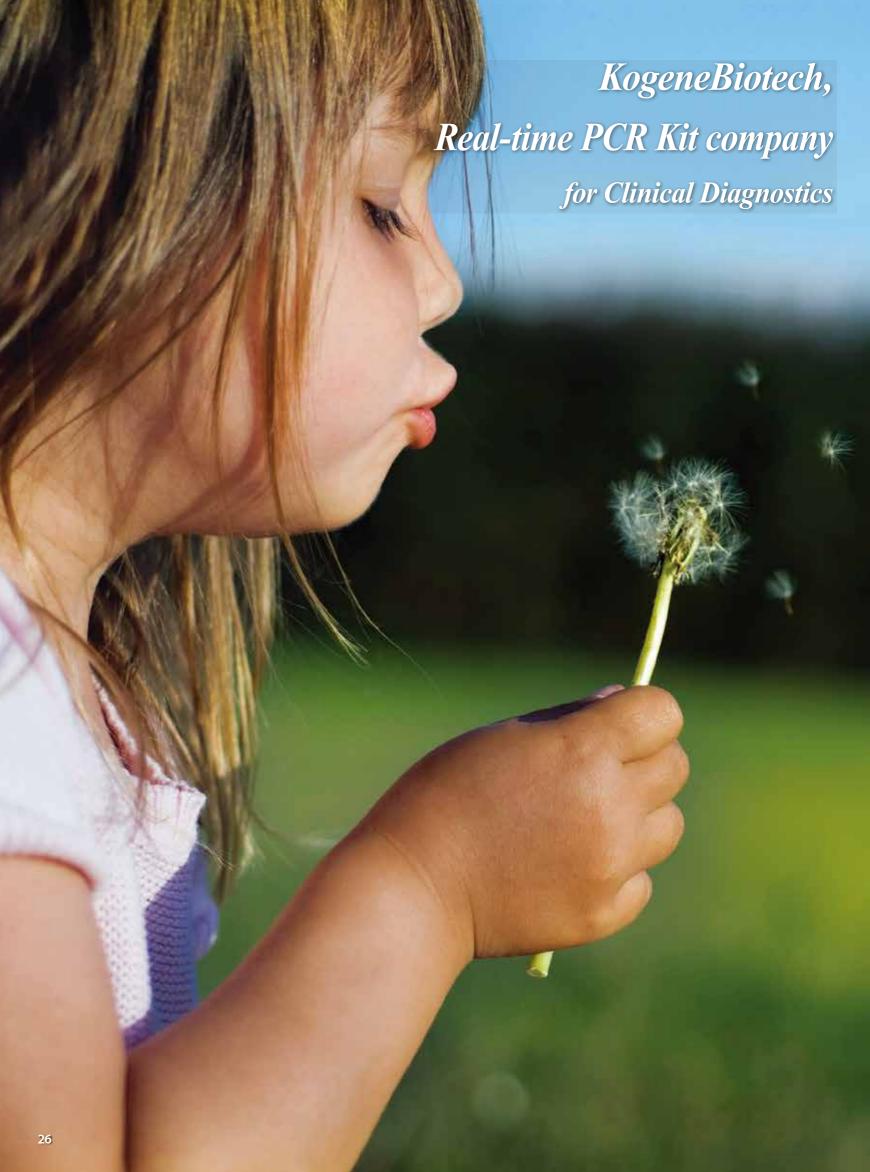
- Simple & fast procedure : less than 100 mins
- Efficient extraction & purification from complex food matrices
- Efficient removal of PCR inhibitors
- Especially for highly processed food

Sample Procedure & High Quality



Applications & Products C€ ™

Application	Sample material	Cat #	Product	Size	Purification Module	Sample scale
• MTB/NTM	Sputum Bronchial wash, bronchoalveolar lavage	E0104	PowerPrep™TB Extraction Kit	100	Boiling	Small
Influenza VirusRespiratory VirusGastroenteric Virus	Cell, tisse, cultureSwabVirus infected samples	E0007	PowerPrep™ Viral DNA/RNA Extraction Kit	50	Silica spin column	Small
Gastoenteric Bacteria MTB/NTM CT/NG	 Cell, tisse, culture Feces, swab Plasma, serum, swab, urine, stool, blood and virus infected samples 	E0101	PowerPrep™ DNA Extraction Kit	100	Silica spin column	Small



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