SolGent

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SolGent

Molecular Diagnostics

(Version 15.1)

SolGent Co., Ltd.
Solutions for Genetic Technologies

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"SolGent's one-stop production and development system will improve the objectivity and accuracy of the result and it will satisfy all the customers' needs from the original material to the reagents for Molecular diagnostics."

SolGent is a molecular diagnostics company based on research reagent and genome analysis service. Adhering to global standards (ISO9001:2008, ISO13485:2003) we produce and maintain directly the most important element in the reagent, high-quality enzyme for enhancing the precision and price competitiveness. Furthermore, SolGent keeps pace with the rapid changes in the market by cooperating with the various internal and external organizations such as Korean national institutions, hospitals, universities and research companies.

SolGent has been keep growing steady with customers' encouragement and advices. We really appreciate of your interest and kind advice for company system development. According to customer reaction, we can promoted a variety of cooperative study and business, developing internal competence and new technique through numerous efforts. From a lot of trial and error, we learned that an open-minded and cooperative company is better than isolated and competitive in global business environment. So, we're going to strive more for the cooperative development with related organizations and businesses continuously.

In return for all your attention and advices for SolGent, all the executives and staff members will do our best to make SolGent be an outstanding bio company in the world.

SolGent co., Ltd. Co Representation **Hyun Kun Myong, Sung Jun Lee**

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Q Real-Time PCR C Conventional PCR

Overview

SolGent Overview

Located in South Korea, SolGent was founded in 2000 and has been growing for over a decade based on our strong relationships with valued customers who trust in our quality products. Since our foundation, SolGent has been manufacturing important raw materials for molecular biology, such as DNA polymerase. Utilizing our expertise, SolGent launched a series of molecular diagnostic kits in 2012. Now, as well as distributing throughout the world, we are providing our kits and raw materials to diagnostic and research related institutes based in Korea like the KCDC (Korean Centre for Disease Control), Korean National Institutions and Hospitals.

SolGent has a well-established manufacturing center with its own research institute equipped with state-of-the-art facilities, covering 2,000sqm in Daejeon, South Korea. In February 2014, SolGent opened an International Business Office based in Pangyo, near Seoul. All products including the molecular diagnostic kits are manufactured in-house and adhere to global standards ISO9001:2008 and ISO13485:2003. Many of our diagnostic kits have received CE-IVD certification with additional products launching in late 2015 currently processing certification.

ISO13485:2003

ISO9001:2008

Conformite European (CE-IVD)

Business Model

SolGent has established a number of strategic alliances with companies and organizations in order to improve the efficiency of our operations, ensuring the high quality of our products is maintained. SolGent is continuing to develop new products from existing and emerging technologies with prospective clients being molecular diagnostic, pharmaceutical and manufacturing companies, commercial laboratories, and distributors.

- Molecular Diagnostic Kits

We provide molecular diagnostic kits both to detect highly prevalent pathogens that cause serious diseases like tuberculosis, pneumonia or dengue fever and to reveal genetic abnormalities to prevent exacerbation of existing conditions like ACD (Avellino Corneal Dystrophy). We are looking to establish further partnerships to represent our diagnostic products in the global market.

- Raw Materials (PCR Enzyme)

We have acquired over a decade of experience supplying raw materials for molecular diagnosis to pharmaceutical companies, clinical laboratories and government organizations. We provide the core materials but are also capable of supplying our end products or customized products as OEM systems for your business.

- Outsourcing and Distribution Development

We have supplied customized molecular diagnostic kits and reagents to detect pathogens such as viral and bacterial genomes to government organizations and companies.

SolGent Overview

Headquarters and R&D
(Daejeon in Korea)

International Business
Department (Pangyo in Korea)

SolGent Customer Service

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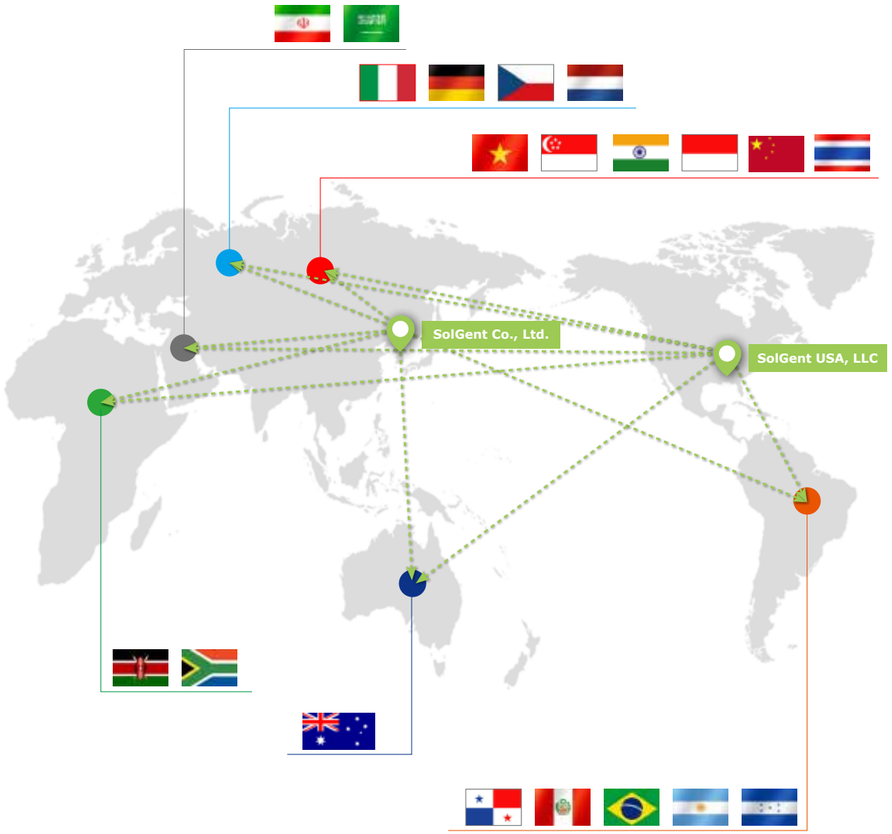
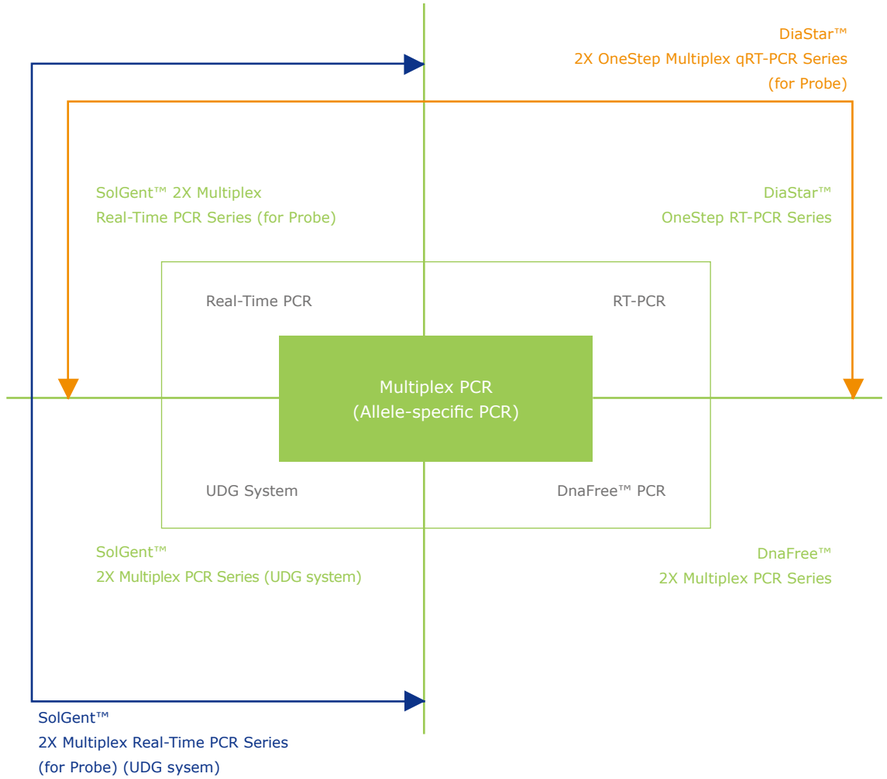


SolGent PCR Technology

The basis of SolGent's technology is the Multiplex PCR using a HotStart DNA Polymerase. SolGent's HotStart Polymerase has ultra-high sensitivity and specificity with an innovative buffer system which enables coverage of a broad range of annealing temperatures for various primers and minimization of non-specific target binding or formation of primer dimers. This enables an easy setup of the Multiplex PCR without multiple procedures and complex study.

Based on SolGent's Multiplex PCR technology and products, Real-Time PCR, RT-PCR and DnaFree PCR products were developed at our customers request allowing for greater convenience for a variety of PCR systems. This has enabled our customers to create customized PCR systems.



Multiplex PCR / Multiplex Allele-Specific PCR System is based on technology which enables simultaneous amplification of many interesting targets in a single reaction with multiple primers. The Multiplex PCR is well-known but usually it has several difficulties, such as poor sensitivity or specificity due to the formation of primer-dimers or non-specific binding. SolGent overcame these difficulties in the Multiplex PCR by using a premium grade HotStart polymerase and an innovative buffer system. This system enables detection of multiple targets with a Multiplex Allele-Specific PCR.

Based on SolGent's Multiplex PCR system, SolGent's molecular diagnostic kits have the following strengths:

1) Minimization of non-specific template binding or formation of primer-dimers
2) Accurate and highly-specific amplification of the target.

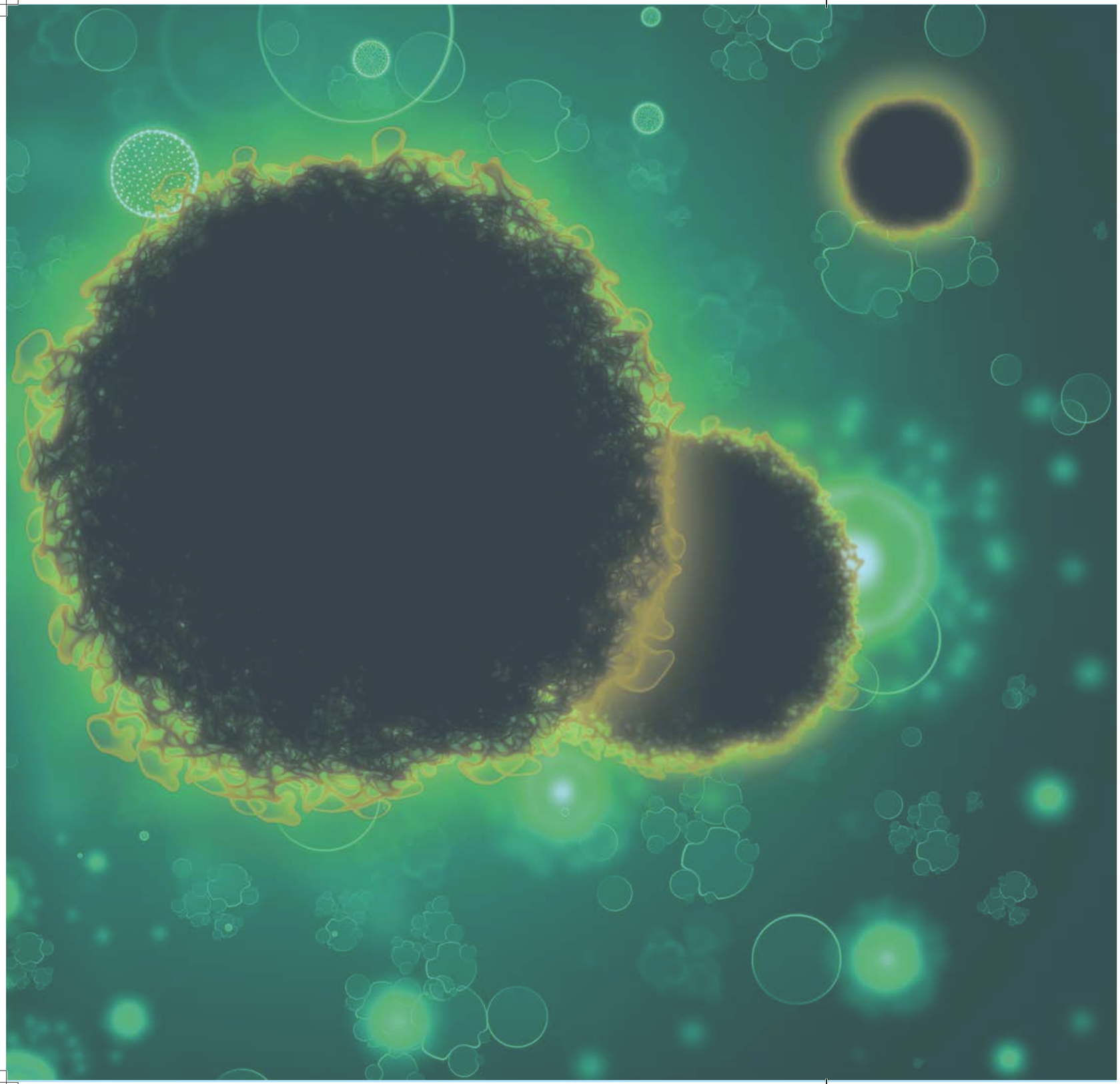
Technology	Cat. No.	Product	Size
Real-Time PCR	SRH22-M25h	SolGent™ 2X Multiplex Real-Time PCR Smart mix (for Probe)	0.5 ㎖ x 5 ea
	SRQ11-K050	DiaStar™ OneStep Multiplex qRT-PCR Kit (for Probe)	50 reaction
	SRQ11-M10h	DiaStar™ 2X OneStep Multiplex qRT-PCR Smart mix (for Probe)	1 ㎖
End-Point PCR	SMP01-M25h	SolGent™ 2X Multiplex PCR Smart mix, with dye	0.5 ㎖ x 5 ea
	SUH06-R250	SolGent™ *Uh-Taq* DNA Polymerase	250 U
	DR61-K050	DiaStar™ OneStep RT-PCR Kit	50 reaction
	DR31-M10h	DiaStar™ OneStep RT-PCR Smart mix	1 ㎖

DnaFree™ PCR System for bacterial infection such as tuberculosis, is a unique technology created by SolGent, maintaining absolute internal quality control by removing the host genomic DNA from E.Coli in the process of enzyme formation and purification. The main problem in the diagnosis of infection or screening is the enzyme contamination, which can cause a false-positive or false-negative error due to inappropriate binding of the primer. To prevent this contamination problem, most researchers use specifically designed primers focusing to optimize their PCR conditions. However, these methods require more time and additional cost, and it is not easy to apply. SolGent's DnaFree PCR system allows you to carry out accurate experiments in the same conditions without those additional labors through the absolute removal of host genomic DNA (DnaFree). This is a powerful and innovative technology saving time and cost, leading to accurate results.

Technology	Cat. No.	Product	Size
End-Point PCR	DD36-R250	DnaFree™ *h-Taq* DNA Polymerase	250 U
	MDF01-M25h	DnaFree™ 2X Multiplex PCR Smart mix, with dye	0.5 ㎖ x 5 ea

UDG (Uracil-DNA Glycosylase) System was developed to prevent carryover or cross contamination. PCR contamination remains a challenge for laboratories to perform accurate detection of infectious agents and genotyping of various gene-derived abnormalities. The single greatest source of PCR product contamination is the generation of aerosols created during the manipulation of PCR amplicons that are associated with the post-PCR analysis. In addition to post-PCR contamination, the target template itself can be the source of contamination. The UDG system is very effective at preventing carryover contamination in the PCR process when vigorously used for sample preparation by breaking the uracil-containing amplicon.

Technology	Cat. No.	Product	Size
Real-Time PCR	SRH41-M25h	SolGent™ 2X Multiplex Real-Time PCR Smart mix (for Probe) (UDG system)	500 U
End-Point PCR	SMP41-M25h	SolGent™ 2X Multiplex PCR Smart mix (UDG system), with dye	0.5 ㎖ x 5 ea



Molecular Diagnostics

Pathogen Detection

Ebola

Tuberculosis

Respiratory Disease

Sexually Transmitted Infection

Others

DiaPlexQ

Ebola Virus Detection Kit - Zaire

Real-Time

CE IVD

Real-Time OneStep RT-PCR based assay system for detection of Ebola Virus Zaire

Pathogen Information

Ebola virus (EBOV, formerly designated Zaire ebola virus) is one of five known viruses within the genus Ebola virus. Four of the five known ebola viruses, including EBOV-Zaire, cause a severe and often fatal hemorrhagic fever in humans and other mammals, known as Ebola virus disease (EVD). Ebola virus has caused the majority of human deaths from EVD, and is the cause of the 2013–2014 Ebola virus epidemic in West Africa, which has resulted in at least 15,935 suspected cases and 5,689 confirmed deaths.

Product Specification

Detection target	Ebola Virus Zaire (NP/GP)
Detection technology	Real-Time OneStep RT-PCR
Specimen type	Blood, Serum, Plasma
Analytical sensitivity	10 - 10^2 copies
Compatible instruments*	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)
PCR running time	~ 2 hrs

* Please inquire us for compatible instrument information before use.

Product Features

- Simple & Rapid detection system : OneStep Multiplex qRT-PCR based detection
- HotStart PCR system : Ultra high specific and sensitive result
- Reliable system : Automatic PCR control
- Positive control included
- CE certification

Reference

1. Gire SK et al. Genomic surveillance elucidates Ebola virus origin and transmission during the 2014 outbreak. Science. 2014;345(6202):1369-1372.
2. Jaax N et al. Transmission of Ebola virus (Zaire strain) to uninfected control monkeys in a biocontainment laboratory. The Lancet. 1995;346(8991-8992):1669-1671.
3. Francesconi P et al. Ebola hemorrhagic fever transmission and risk factors of contacts, Uganda. Emerging Infectious Diseases. 2003;9:1430-1437.
4. CDC, Ebola Hemorrhagic Fever Information Packet. 2009.
5. WHO, Ebola Response Roadmap Situation Report. 26 Nov 2014.

Result & Data interpretation

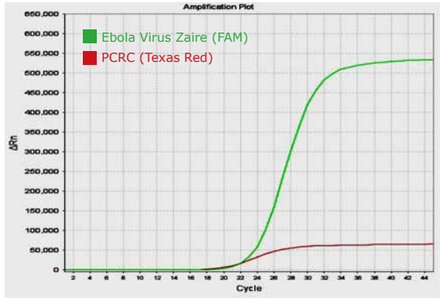


Fig. 1. Amplification Plot information (ABI7500 FAST)

Sample type	FAM	Texas Red / Cal Red 610	Result
Positive Control	+	+	Valid
Negative Control	-	+	Valid
NTC (Non-Template Control)	-	+	Valid
Sample case 1	+	+	Positive
Sample case 2	-	+	Negative
Sample case 3	+	-	Valid (Positive)
Sample case 4	-	-	Required re-experiment

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQD71-K020 (20 reaction)	*DiaPlexQ*™ Ebola Virus Detection Kit - Zaire	OneStep qRT-PCR Enzyme mix (Ebola-ZQ) 2X OneStep qRT-PCR Buffer (Ebola-ZQ) Primer & Probe Mixture (Ebola-ZQ) Control Template (Ebola-ZQ) RNase free Water
	SQD71-K100 (100 reaction)		

DiaPlexQ

MTC/NTM Detection Kit

Real-Time

DiaPlexC

MTC/NTM Detection Kit

Conventional

Real-Time PCR (or Multiplex PCR) based assay system for simultaneous detection of MTC and NTM complex

Pathogen Information

Mycobacterium tuberculosis (MTB) is a pathogenic bacteria species and the causative agent in most cases of tuberculosis. Along with MTB, 5 other species, which we call MTC are regarded as common infectious agents causing tuberculosis. That is why it is necessary to detect MTC, along with MTB. Although NTM is a group of non-tuberculosis related mycobacteria, it usually causes lung infections that mimic tuberculosis resulting in a potential misdiagnosis. Thus, the identification of a single infection or co-infection of MTC and NTM is required for appropriate treatment.

Product Specification

	***DiaPlexQ*™ MTC/NTM Detection Kit**	***DiaPlexC*™ MTC/NTM Detection Kit**
Detection target	MTC (5 species), NTM (13 species)	MTC (2 species), NTM (10 species)
Detection technology	Real-Time PCR	Conventional (End-point) Multiplex PCR
Specimen type	Sputum, Bronchoalveolar lavage (BAL), Cerebrospinal fluid, Urine, Body fluid, Blood, Tissue	Nasopharyngeal swab, Nasopharyngeal aspirate, Bronchoalveolar lavage (BAL), Nasal swab, Oropharyngeal swab, Sputum
Analytical sensitivity	10^2 - 10^3 copies	10^2 - 10^3 copies
Compatible instruments*	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)	ABI Veriti thermal Cycler (Applied Biosystems) recommended
PCR running time	~ 1 hr 30 min	~ 1 hr 30 min

* Please inquire us for compatible instrument information before use.

Product Features

- HotStart PCR system : Ultra high specific and sensitive result
- DnaFree™ system : No host genomic DNA contamination (*DiaPlexC*™)
- UDG system : No carryover contamination
- Multiplex PCR system : Multiple targets in a single reaction
- Reliable system : Automatic PCR control
- Positive control included
- DNA extraction solution included (Cat. No. SQD21-K100)
- Easy-to-use master mix
- CE certification

Reference

1. Korean J Clin microbial, Seong Deok Lee, Hye Young Lee, Hyun Chul Kim, Soo Young Kim, *Mycobacterium tuberculosis* and Non-Tuberculous Mycobacteria by PCR Assay.
2. Ryan KJ, Ray CG (Editors) (2004). Sherris Medical Microbiology (4th ed.). McGraw-Hill.
3. Sun-Pil Choi, M.D., Bong-Keun Lee M.D.1, Jin-Hong Min, M.D., Jin-Hee Kim, M.D. Pathogenic Classification and Clinical Characteristics of Non-Tuberculous Mycobacterial Pulmonary Disease in a National Tuberculosis Hospital.

CE IVD

Result & Data interpretation

DiaPlexQ™ MTC/NTM Detection Kit

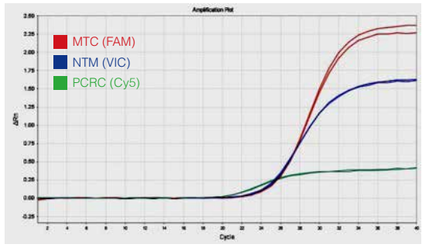
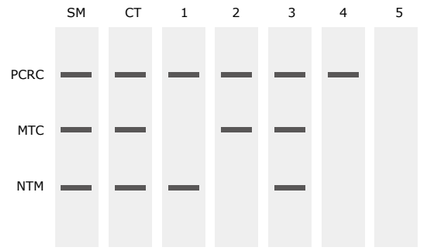


Fig. 1. Amplification Plot information (ABI7500 FAST)

Sample type	FAM	VIC/HEX	Cy5	Result
Positive Control	+	+	+	Valid
Negative Control	-	-	+	Valid
NTC (Non-Template Control)	-	-	+	Valid
Sample case 1	+	+	+/-	MTC, NTM (Co-infection)
Sample case 2	+	-	+/-	MTC
Sample case 3	-	+	+/-	NTM
Sample case 4	-	-	+	Negative
Sample case 5	-	-	-	Required re-experiment

DiaPlexC™ MTC/NTM Detection Kit



SM : Standard Marker
CT : Control Template
PCRC : PCR Control
NTC : Non-Template Control

Lane	Interpretation (detection)
1	NTM
2	MTC
3	MTC, NTM (Co-infection)
4	Negative (or NTC)
5	Required re-experiment

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQD21-K100[1] (100 reaction)	*DiaPlexQ*™ MTC/NTM Detection Kit (w/Ext.) + Kit for pre-treatment of specimen for PCR	DNA Extraction Solution Pre-Solution I (10X Concentration) Pre-Solution II (10X Concentration) 2X Multiplex Real-Time PCR Smart mix (with UDG) (MTC/NTM) Primer & Probe Mixture (MTC/NTM) Control Template (MTC/NTM) Nuclease free Water
	SQD20-K100[2] (100 reaction)	*DiaPlexQ*™ MTC/NTM Detection Kit	2X Multiplex Real-Time PCR Smart mix (with UDG) (MTC/NTM) Primer & Probe Mixture (MTC/NTM) Control Template (MTC/NTM) Nuclease free Water
Conventional (End-point) PCR	SMD21-K020 (20 reaction)	*DiaPlexC*™ MTC/NTM Detection Kit	2X Multiplex PCR Smart mix (with UDG) (MTC/NTM) Primer Mixture (MTC/NTM) Standard Marker (MTC/NTM) Control Template (MTC/NTM) Nuclease free Water
	SMD21-K100 (100 reaction)		

[1] *DiaPlexQ*™ MTC/NTM Detection Kit (w/Ext.), Cat. No. SQD21-K100, includes the kit for the detection of MTC/NTM, and an extension for the pre-treatment of specimens for the PCR and an extraction reagent (DNA Extraction Solution)
[2] *DiaPlexQ*™ MTC/NTM Detection Kit, Cat. No. SQD20-K100 is composed only of the Real-Time Detection Kit for the diagnosis of MTC/NTM.

DiaPlexC

MTB/M.Bovis Detection Kit

Conventional

Multiplex PCR based assay system for simultaneous detection of MTB and *M. bovis* among MTC complex

Pathogen Information

Mycobacterium tuberculosis (TB) is one of the most ubiquitously found dominant infectious agents around the world especially in developing countries that cause tuberculosis for almost 8 million and the death of 2 million people each year. Though there is a prevention method, the BCG (Bacillus Calmette-Guerin) TB vaccination, its disadvantage is that it cannot protect after 5 years from immunization and there is also possibility of diagnostic error for actual TB because there is a high chance of a false-positive result in the tuberculin test.

Product Specification

Detection target	*Mycobacterium tuberculosis* (MTB), *Mycobacterium bovis* (*M. bovis*)
Detection technology	Conventional (End-point) Multiplex PCR
Specimen type	Nasopharyngeal swab, Nasopharyngeal aspirate, Bronchoalveolar lavage (BAL), Nasal swab, Oropharyngeal swab, Sputum
Analytical sensitivity	10^2 copies
Compatible instruments*	ABI Veriti thermal Cycler (Applied Biosystems) recommended
PCR running time	~ 2 hrs

* Please inquire us for compatible instrument information before use.

Product Features

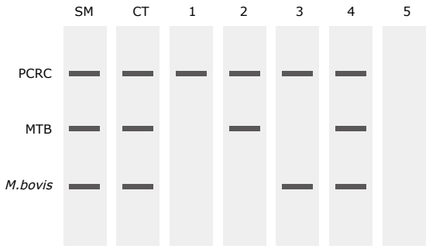
- HotStart PCR system : Ultra high specific and sensitive result
- DnaFree™ system : No host genomic DNA contamination
- UDG system : No carryover contamination
- Multiplex PCR system : Multiple targets in a single reaction
- Reliable system : Automatic PCR control
- Positive control included
- Easy-to-use master mix
- CE certification

Reference

1. "Mycobacterium tuberculosis" Sanger Institute. 2007-03-29 http://www.sanger.ac.uk/projects/M_tuberculosis/. Retrieved 2008-11-16
2. Frothingham R, Meeker-Meeker-O'Connell WA. (1998). "Genetic diversity in the *Mycobacterium tuberculosis* complex based on variable numbers of tandem DNA repeats.". Microbiology 144 (Pt 5): 1189-96.
3. Teo, SS ; Shingadia, DV (2006 Jun). "Does BCG have a role in tuberculosis control and prevention in the United Kingdom?". Archives of Disease in Childhood 91 (6) : 529-31.

CE IVD

Result & Data interpretation



SM : Standard Marker
CT : Control Template
PCRC : PCR Control
NTC : Non-Template Control

Lane	Interpretation (detection)
1	Negative (or NTC)
2	MTB
3	*M. bovis*
4	MTB, *M. bovis* (Co-infection)
5	Required re-experiment

Ordering Information

Technology	Cat. No.	Product	Contents
Conventional (End-point) PCR	SMD22-K020 (20 reaction)	*DiaPlexC*™ MTB/M.Bovis Detection Kit	2X Multiplex PCR Smart mix (with UDG) (MTB/M.Bovis) Primer Mixture (MTB/M.Bovis) Standard Marker (MTB/M.Bovis) Control Template (MTB/M.Bovis) Nuclease free Water
	SMD22-K100 (100 reaction)		

DiaPlexC

M.Avium/M.Intracellulare Detection Kit

Conventional

Multiplex PCR based assay system for simultaneous detection of *M. avium* and *M. intracellulare* among NTM complex

Pathogen Information

Mycobacterium avium and *Mycobacterium intracellulare* complex (MAC) is the atypical mycobacterium most commonly associated with human disease. MAC is primarily a pulmonary pathogen that affects individuals whose immune systems have been compromised (e.g. from AIDS, hairy cell leukemia, immunosuppressive chemotherapy). In this clinical setting, MAC has been associated with osteomyelitis, tenosynovitis and synovitis. MAC comprises two genetically distinct but difficult to discriminate species. *M. avium* predominates (87 % - 98 %) in AIDS patients with no anti-retroviral therapy and *M. intracellulare* is more frequent among non-AIDS patients.

Product Specification

Detection target	*Mycobacterium avium*, *Mycobacterium intracellulare*
Detection technology	Conventional (End-point) Multiplex PCR
Specimen type	Sputum, Bronchial lavage, Lung biopsy, Gastric lavage, Urine, Body fluid, Blood, Tissue, Pus, Stool
Analytical sensitivity	10^2 copies
Compatible instruments*	ABI Veriti thermal Cycler (Applied Biosystems) recommended
PCR running time	~ 2 hrs

* Please inquire us for compatible instrument information before use.

Product Features

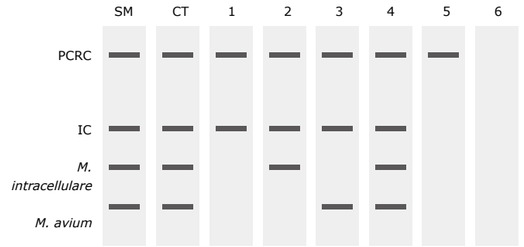
- HotStart PCR system : Ultra high specific and sensitive result
- DnaFree™ system : No host genomic DNA contamination
- UDG system : No carryover contamination
- Multiplex PCR system : Multiple targets in a single reaction
- Reliable system : Automatic PCR control & Internal control
- Positive control included
- Easy-to-use master mix
- CE certification

Reference

1. The NTM handbook: A Guide for Patients with Non-Tuberculous Mycobacterial Infections Including MAC.
2. Horsburgh CR Jr. Epidemiology of *Mycobacterium avium* complex. In: Korvick JA, Benson CA, eds. Mycobacterium Avium Complex Infection: Progress in Research and Treatment. New York, NY: Marcel Dekker; 1996:1-22.
3. Tortoli E. Impact of genotypic studies on mycobacterial taxonomy: the new mycobacteria of the 1990s. Clin Microbiol Rev. 2003; 16:319-354.
4. Griffith, David, E.; Aksamit, Timothy; & A. Brown-Elliott, Barbara et al. (2007). American Thoracic Society Guidelines: Diagnosis, Treatment and Prevention of Non-tuberculous Mycobacterial Diseases. AM. J. Respiratory and Critical Care Medicine, Vol. 175, pp. 367-417.
5. Grange, J.M. (2007). "Environmental mycobacterial". In Greenwood, David; Slack, Richard; peitherer, John; & Barer, Mike (Eds.), Medical Microbiology (17th Ed.), pp. 221-227. Elsevier. ISBN 978-0-443-10209-7. Evans AJ, Crisp AJ, Hubbard RB, Colville A, Evans SA, Johnston IDA. Pulmonary Mycobacterium kansasii infection: comparision of radiological appearances with pulmonary tuberculosis. Thorax. 1996;51:1243-1247.

CE IVD

Result & Data interpretation



SM : Standard Marker
PCRC : PCR Control
NTC : Non-Template Control
CT : Control Template
IC : Internal Control

Lane	Interpretation (detection)
1	Negative
2	*M. intracellulare*
3	*M. avium*
4	*M. intracellulare*, *M. avium* (Co-infection)
5	NTC
6	Required re-experiment

Ordering Information

Technology	Cat. No.	Product	Contents
Conventional (End-point) PCR	SMD23-K020 (20 reaction)	*DiaPlexC*™ M.Avium/M.Intracellulare Detection Kit	2X Multiplex PCR Smart mix (with UDG) (M.Av/M.Int) Primer Mixture (M.Avium/M.Intra) Standard Marker (M.Avium/M.Intra) Control Template (M.Avium/M.Intra) Nuclease free Water
	SMD23-K100 (100 reaction)		

DiaPlexQ

RV16 Detection Kit

Real-Time

Real-Time OneStep RT-PCR based assay system for simultaneous detection of 16 major respiratory viruses

Pathogen Information

Viral infections are among the leading causes of respiratory disease in children. Most of these infections are caused by respiratory syncytial virus (RSV), influenza virus A or B (Inf A or Inf B), parainfluenza virus (hPIV-I, II, III and IV), rhinovirus (RV) or adenovirus (AdV). Several recently discovered viruses, such as human metapneumovirus (hMPV), human bocavirus (hBoV), Enterovirus (EV) and the human coronaviruses (hCoVs) 229E and OC43, have been identified as potential respiratory pathogens.

Product Specification

Detection target	Set I : Parainfluenza-I (PIV-I) Parainfluenza-II (PIV-II) Parainfluenza-III (PIV-III) Set II : Influenza virus A (Inf A) Parainfluenza-IV (PIV-IV) Influenza virus B (Inf B) Set III : Adenovirus (AdV) Respiratory syncytial virus (RSV A & B) Rhinovirus (RV A/B/C) Set IV : Enterovirus (EntV) Bocavirus (BoV) Metapneumovirus (MPV) Set V : Beta Coronavirus OC43 (CoV OC43) Alpha Coronavirus 229E/NL63 (CoV 229E/NL63) MERS-CoV
Detection technology	Real-Time OneStep RT-PCR
Specimen type	Nasopharyngeal swab, Nasopharyngeal aspirate, Bronchoalveolar lavage (BAL), Nasal swab, Oropharyngeal swab, Sputum
Analytical sensitivity	10 - 10^2 copies
Compatible instruments*	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)
PCR running time	~ 2 hrs

* Please inquire us for compatible instrument information before use.

Product Features

- Simple & Rapid detection system : OneStep Multiplex qRT-PCR based detection
- HotStart PCR system : Ultra high specific and sensitive result
- Reliable system : Automatic PCR control
- Positive control included

Reference

1. Fouchier RAV, Munster A, Wallenstein TM, Bestebroer S, Herfst D, Smith GF, et al. J Virol. 2002;79:2814-2822
2. Lamb RA, Krug R. Field Virology, third ed. Lippincott-Raven Philadelphia. 1996; 1353-1395.
3. Ha Y, Stevens, DJ, Wiley DC. The EMBO Journal. 2002;21;865-875.
4. Russell RJ, Gamblin SJ, Haire LF, Stevens DJ, Xiao B, Ha Y, et al. Virology. 2004;287-296.

Result

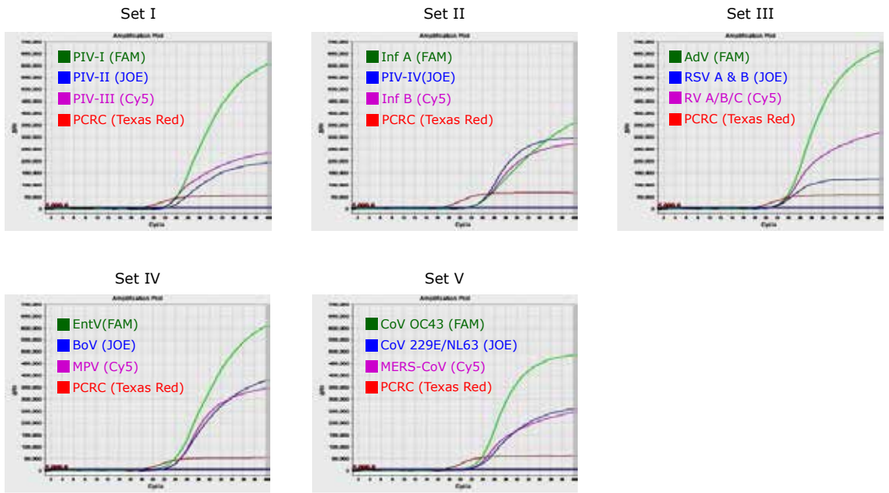


Fig. 1. Amplification Plot information (ABI7500 FAST)

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQD50-K020 (20 reaction)	*DiaPlexQ*™ RV16 Detection Kit	OneStep qRT-PCR Enzyme mix (RV16) 2X OneStep qRT-PCR Buffer (RV16) Primer & Probe Mixture I (RV16) Primer & Probe Mixture II (RV16) Primer & Probe Mixture III (RV16) Primer & Probe Mixture IV (RV16) Primer & Probe Mixture V (RV16) Control Template (RV16) RNase free Water
	SQD50-K100 (100 reaction)		

DiaPlexC

RV13 Detection Kit

Conventional

CE IVD

OneStep Multiplex RT-PCR based assay system for simultaneous detection of 13 major respiratory viruses

Pathogen Information

Viral infections are among the leading causes of respiratory disease in children. Most of these infections are caused by respiratory syncytial virus (RSV), influenza virus A or B (Inf A or Inf B), parainfluenza virus (hPIV-I, II and III), rhinovirus (RV) or adenovirus (AdV). Several recently discovered viruses, such as human metapneumovirus (hMBV), human bocavirus (hBoV), Enterovirus (EV) and the human coronaviruses (hCoVs) 229E and OC43, have been identified as potential respiratory pathogens.

Product Specification

Detection target	Set Ⅰ : Metapneumovirus (MPV) Coronavirus OC43(CoV OC43) Coronavirus 229E (CoV 229E) Enterovirus (EntV) Parainfluenza-Ⅰ (PIV-Ⅰ) Parainfluenza-Ⅱ (PIV-Ⅱ) Parainfluenza-Ⅲ (PIV-Ⅲ) Set Ⅱ : Respiratory syncytial virus (RSV A & B) Adenovirus (AdV) Bocavirus (BoV) Rhinovirus (RV A/B/C) Influenza virus A (Inf A) Influenza virus B (Inf B)
Detection technology	Conventional (End-point) OneStep Multiplex RT-PCR
Specimen type	Nasopharyngeal swab, Nasopharyngeal aspirate, Bronchoalveolar lavage (BAL), Nasal swab, Oropharyngeal swab, Sputum
Analytical sensitivity	10 - 10^2 copies
Compatible instruments*	ABI Veriti thermal Cycler (Applied Biosystems) recommended
PCR running time	~ 3 hrs

* Please inquire us for compatible instrument information before use.

Product Features

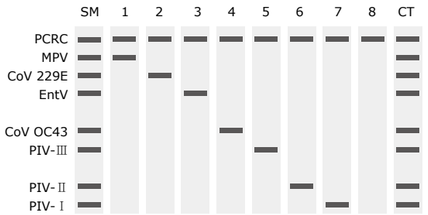
- Simple & Rapid detection system : OneStep Multiplex RT-PCR based detection
- HotStart PCR system : Ultra high specific and sensitive result
- Reliable system : Automatic PCR control
- Positive control included
- CE certification

Reference

1. Fouchier RAV, Munster A, Wallenstein TM, Bestebroer S, Herfst D, Smith GF, et al. J Virol. 2002;79:2814-2822
2. Lamb RA, Krug R. Field Virology, third ed. Lippincott-Raven Philadelphia. 1996; 1353-1395.
3. Ha Y, Stevens, DJ, Wiley DC. The EMBO Journal. 2002;21;865-875.
4. Russell RJ, Gamblin SJ, Haire LF, Stevens DJ, Xiao B, Ha Y, et al. Virology. 2004;287-296.

Result & Data interpretation

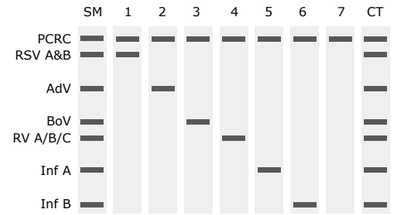
Set Ⅰ



SM : Standard Marker
PCRC : PCR Control
CT : Control Template Ⅰ (RV13)
NTC : Non-Template Control

Lane	Interpretation (detection)
1	MPV
2	CoV 229E
3	EntV
4	CoV OC43
5	PIV-Ⅲ
6	PIV-Ⅱ
7	PIV-Ⅰ
8	Negative (or NTC)

Set Ⅱ



SM : Standard Marker
PCRC : PCR Control
CT : Control Template Ⅱ (RV13)
NTC : Non-Template Control

Lane	Interpretation (detection)
1	RSV A&B
2	AdV
3	BoV
4	RV A/B/C
5	Inf A
6	Inf B
7	Negative (or NTC)

Ordering Information

Technology	Cat. No.	Product	Contents
Conventional (End-point) PCR	SMD50-K020 (20 reaction) SMD50-K100 (100 reaction)	*DiaPlexC*™ RV13 Detection Kit	OneStep RT-PCR Enzyme mix (RV13) 2X OneStep RT-PCR Buffer (RV13) Primer Mixture Ⅰ (RV13) Primer Mixture Ⅱ (RV13) Standard Marker Ⅰ (RV13) Standard Marker Ⅱ (RV13) Control Template Ⅰ (RV13) Control Template Ⅱ (RV13) RNase free Water

DiaPlexQ

MERS Virus Detection Kit

Real-Time

Real-Time OneStep RT-PCR based assay system for detection of MERS-CoV

Pathogen Information

MERS (Middle East respiratory syndrome) is an respiratory virus which was detected from Saudi Arabia on 24th Sep, 2012. The factor virus is MERS-CoV. People suspect that cause of virus come from bat and spread the infection to other animals. The symptom shows very similar with SAS that disease coming from same coronavirus origin. Initial symptom can be distinguish such as influenza because the symptom is very similar with it also. So just symptom diagnostic is really difficult. However, MERS has low infectivity so we can consider possibility of overwhelming disease is kind of low at this moment. But we need to preventive measures against the MERS because virus can be mutate and possible to being highly contagious disease. We should prepare strict prevent measures for early infection block. There is no medicine development yet for MERS virus so far.

Product Specification

	DiaPlexQ™ MERS Virus Detection Kit I (upE)	DiaPlexQ™ MERS Virus Detection Kit II (upE/ORF1a/ORF1b)
Detection target	*upE*	*upE, ORF1a, ORF1b*
Detection technology	Real-Time OneStep RT-PCR	
Specimen type*	Nasopharyngeal swab, Nasopharyngeal aspirate, Bronchoalveolar lavage (BAL), Nasal swab, Oropharyngeal swab, Sputum	
Analytical sensitivity	10 copies	10 copies
Compatible instruments**	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)	
PCR running time	~ 2 hrs	~ 2 hrs

*Sputum is recommended specimen type by KCDC (Korea Centers for Disease Control and Prevention).
** Please inquire us for compatible instrument information before use.

Product Features

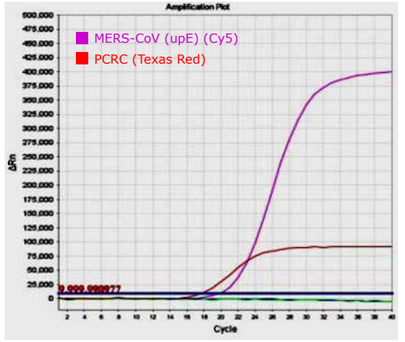
- Simple & Rapid detection system : OneStep Multiplex qRT-PCR based detection
- HotStart PCR system : Ultra high specific and sensitive result
- UDG system : No carryover contamination
- Reliable system : Automatic PCR control
- Positive control included

Reference

1. Victor Max Corman, Ndapewa Laudika Ithete, et al. Rooting the Phylogenetic Tree of Middle East Respiratory Syndrome Coronavirus by Characterization of a Conspecific Virus from an African Bat. Journal of Virology. 2014;88 (19):11297-11303
2. WHO guidelines for investigation of cases of human infection with Middle East Respiratory Syndrome Coronavirus (MERS-CoV). WHO. 2013
3. Novel Coronavirus 2012 Real-Time RT-PCR Assay (Instructions for Use - International Ver. 001). CDC. 2012

Result

DiaPlexQ™ MERS Virus Detection Kit I (upE)



DiaPlexQ™ MERS Virus Detection Kit II (upE/ORF1a/ORF1b)

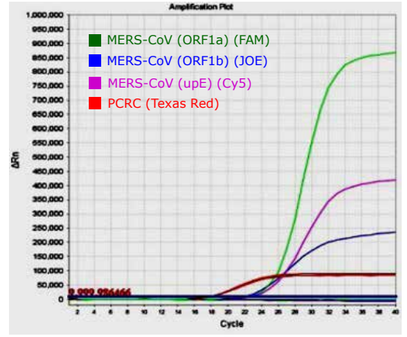


Fig. 1. Amplification Plot information (ABI7500 FAST)

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQD53-K020 (20 reaction)	*DiaPlexQ*™ MERS Virus Detection Kit I (upE)	OneStep qRT-PCR Enzyme mix (MERS) 2X OneStep qRT-PCR Buffer (MERS) Primer & Probe Mixture (upE) Control Template (upE) RNase free Water
	SQD53-K100 (100 reaction)		
	SQD54-K020 (20 reaction)	*DiaPlexQ*™ MERS Virus Detection Kit II (upE/ORF1a/ORF1b)	OneStep qRT-PCR Enzyme mix (MERS) 2X OneStep qRT-PCR Buffer (MERS) Primer & Probe Mixture (upE/ORF1a/ORF1b) Control Template (upE/ORF1a/ORF1b) RNase free Water
	SQD54-K100 (100 reaction)		

DiaPlexQ

Influenza Virus A/B & A Subtype Detection Kit

Real-Time

Real-Time OneStep RT-PCR based assay system for simultaneous detection of influenza virus A and B, A subtypes

Pathogen Information

Influenza is a family of RNA enveloped viruses that affects mammals and birds. Among three types of influenza viruses A, B &C, Influenza A is the most important in human infection. Influenza is a huge public health concern that occurs in seasonal epidemics and has caused pandemic level infections. There are three types of influenza viruses; A, B and C, in which specificity is conferred by internal nucleoprotein and matrix protein antigens. Influenza A and B are the major causative agents of human acute respiratory disease worldwide, while Influenza virus C occurs much less frequently than A and B, That is why only influenza A and B are included in seasonal influenza vaccines.

Product Specification

Detection target	Set I (Influenza Virus A Subtype) : H1N1-Seasonal H1N1-Pandemic (2009) H3N2 Set II (Influenza Virus A Subtype) : H5N1 H7 common H9N2 Set III (Influenza Virus A/B) : Influenza A Influenza B
Detection technology	Real-Time OneStep RT-PCR
Specimen type	Nasopharyngeal swab, Nasopharyngeal aspirate, Bronchoalveolar lavage (BAL), Nasal swab, Oropharyngeal swab, Sputum
Analytical sensitivity	10 - 10^2 copies
Compatible instruments*	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)
PCR running time	~ 2 hrs

* Please inquire us for compatible instrument information before use.

Product Features

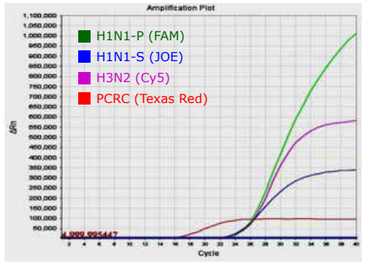
- Simple & Rapid detection system : OneStep Multiplex qRT-PCR based detection
- HotStart PCR system : Ultra high specific and sensitive result
- Reliable system : Automatic PCR control
- Positive control included

Reference

1. Fouchier RAV, Munster A, Wallenstein TM, Bestebroer S, Herfst D, Smith GF, et al. J Virol. 2002;79:2814-2822
2. Lamb RA, Krug R. Field Virology, third ed. Lippincott-Raven Philadelphia. 1996; 1353-1395.
3. Ha Y, Stevens, DJ, Wiley DC. The EMBO Journal. 2002;21;865-875.
4. Russell RJ, Gamblin SJ, Haire LF, Stevens DJ, Xiao B, Ha Y, et al. Virology. 2004;287-296.

Result

Set I



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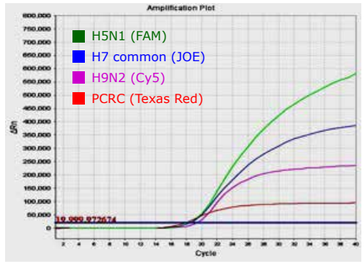

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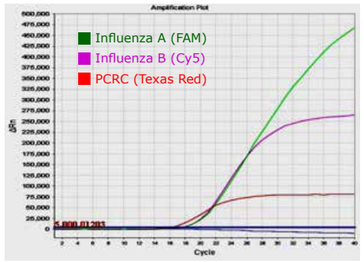


Fig. 1. Amplification Plot information (ABI7500 FAST)

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQD43-K020 (20 reaction)	*DiaPlexQ*™ Influenza Virus A/B & A Subtype Detection Kit	OneStep qRT-PCR Enzyme mix (Influenza) 2X OneStep qRT-PCR Buffer (Influenza) Primer & Probe Mixture I (Inf A Sub) Primer & Probe Mixture II (Inf A Sub) Primer & Probe Mixture III (Inf A/B) Control Template I (Inf A Sub) Control Template II (Inf A Sub) Control Template III (Inf A/B) RNase free Water
	SQD43-K100 (100 reaction)		

DiaPlexQ

Influenza Virus A/B Detection Kit

Real-Time

DiaPlexC

Influenza Virus A/B Detection Kit

Conventional

Real-Time OneStep RT-PCR (or Multiplex PCR) based assay system for simultaneous detection of influenza virus A and B

Pathogen Information

Influenza is a family of RNA enveloped viruses that affects mammals and birds. Among three types of influenza viruses A, B &C, Influenza A is the most important in human infection. Influenza is a huge public health concern that occurs in seasonal epidemics and has caused pandemic level infections. There are three types of influenza viruses; A, B and C, in which specificity is conferred by internal nucleoprotein and matrix protein antigens. Influenza A and B are the major causative agents of human acute respiratory disease worldwide, while Influenza virus C occurs much less frequently than A and B, That is why only influenza A and B are included in seasonal influenza vaccines.

Product Specification

	***DiaPlexQ*™ Influenza Virus A/B Detection Kit**	***DiaPlexC*™ Influenza Virus A/B Detection Kit**
Detection target	Influenza virus A, Influenza virus B	
Detection technology	Real-Time OneStep RT-PCR	Conventional (End-point) OneStep Multiplex RT-PCR
Specimen type	Nasopharyngeal swab, Nasopharyngeal aspirate, Bronchoalveolar lavage (BAL), Nasal swab, Oropharyngeal swab, Sputum	
Analytical sensitivity	10 - 10^2 copies	10 - 10^2 copies
Compatible instruments*	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)	ABI Veriti thermal Cycler (Applied Biosystems) recommended
PCR running time	~ 3 hrs	~ 2 hrs 30 min

* Please inquire us for compatible instrument information before use.

Product Features

- Simple & Rapid detection system : OneStep Multiplex qRT-PCR (or RT-PCR) based detection
- HotStart PCR system : Ultra high specific and sensitive result
- Reliable system : Automatic PCR control & Internal control (*DiaPlexQ*™ : only PCR control)
- Positive control included
- CE certification

Reference

1. Fouchier RAV, Munster A, Wallenstein TM, Bestebroer S, Herfst D, Smith GF, et al. J Virol. 2002;79:2814-2822
2. Lamb RA, Krug R. Field Virology, third ed. Lippincott-Raven Philadelphia. 1996; 1353-1395.
3. Ha Y, Stevens, DJ, Wiley DC. The EMBO Journal. 2002;21;865-875.
4. Russell RJ, Gamblin SJ, Haire LF, Stevens DJ, Xiao B, Ha Y, et al. Virology. 2004;287-296.

CE IVD

Result & Data interpretation

DiaPlexQ™ Influenza Virus A/B Detection Kit

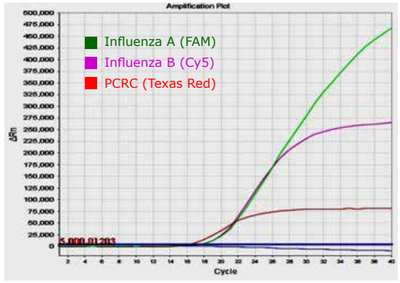
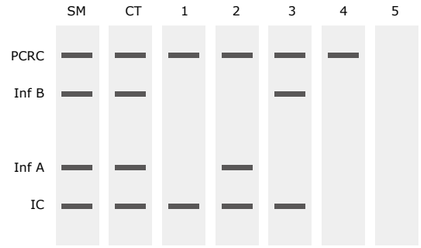


Fig. 1. Amplification Plot information (ABI7500 FAST)

Sample type	FAM	Cy5	Texas Red / Cal Red 610	Result
Positive Control	+	+	+	Valid
Negative Control	-	-	+	Valid
NTC (Non-Template Control)	-	-	+	Valid
Sample case 1	+	-	+/-	Influenza A
Sample case 2	-	+	+/-	Influenza B
Sample case 3	+	+	+/-	Influenza A&B (Co-infection)
Sample case 4	-	-	+	Negative
Sample case 5	-	-	-	Required re-experiment

DiaPlexC™ Influenza Virus A/B Detection Kit



SM : Standard Marker
PCRC : PCR Control
NTC : Non-Template Control
CT : Control Template
IC : Internal Control

Lane	Interpretation (detection)
1	Negative
2	Influenza virus A
3	Influenza virus B
4	NTC
5	Required re-experiment

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQD42-K020 (20 reaction)	*DiaPlexQ*™ Influenza Virus A/B Detection Kit	OneStep qRT-PCR Enzyme mix (Inf A/B) 2X OneStep qRT-PCR Buffer (Inf A/B) Primer & Probe Mixture (Inf A/B) Control Template (Inf A/B) RNase free Water
	SQD42-K100 (100 reaction)		
Conventional (End-point) PCR	SMD42-K020 (20 reaction)	*DiaPlexC*™ Influenza Virus A/B Detection Kit	OneStep RT-PCR Enzyme mix (Inf A/B) 2X OneStep RT-PCR Buffer (Inf A/B) Primer Mixture (Inf A/B) Standard Marker (Inf A/B) Control Template (Inf A/B) RNase free Water
	SMD42-K100 (100 reaction)		

DiaPlexQ

Influenza Virus A Subtype Detection Kit

Real-Time

DiaPlexC

Influenza Virus A Subtype Detection Kit

Conventional

Real-Time OneStep RT-PCR (or Multiplex PCR) based assay system for identification of influenza virus A subtypes

Pathogen Information

Influenza virus A (H1N1) is a subtype of Influenza virus A and the most common cause of influenza (flu) in humans. Some strains of H1N1 are endemic in humans and cause a small fraction of all influenza-like illness and a large fraction of all seasonal influenza. H3N2 is currently endemic in both human and pig populations. It evolved from H2N2 through an antigenic shift and caused the Hong Kong Flu pandemic of 1968 and 1969 that killed almost 750,000 people. The dominant strain of annual flu in January 2006 was H3N2. Since November 2003, nearly 400 cases of human infection with the highly pathogenic Avian Influenza A (H5N1) viruses have been reported by more than a dozen countries in Asia, Africa, the Pacific, Europe and the Near East. Highly pathogenic Avian Influenza A (H5N1) virus infections occur in both poultry and humans. Furthermore, although H7N2, H7N3, H7N7 and H9N2 are classified as relatively low pathogenic infections, they have been reported in humans in the past few years and they can potentially develop into pandemic infections.

Product Specification

	***DiaPlexQ*™ Influenza Virus A Subtype Detection Kit**	***DiaPlexC*™ Influenza Virus A Subtype Detection Kit**
Detection target	Set I : H1N1-Seasonal H1N1-Pandemic (2009) H3N2 Set II : H5N1 H7 common H9N2	H1N1-Seasonal, H1N1-Pandemic (2009), H3N2, H5N1, H7 common, H9N2
Detection technology	Real-Time OneStep RT-PCR	Conventional (End-point) OneStep Multiplex RT-PCR
Specimen type	Nasopharyngeal swab, Nasopharyngeal aspirate, Bronchoalveolar lavage (BAL), Nasal swab, Oropharyngeal swab, Sputum	
Analytical sensitivity	10 - 10^2 copies	10 - 10^2 copies
Compatible instruments*	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)	ABI Veriti thermal Cycler (Applied Biosystems) recommended
PCR running time	~ 2 hrs 30 min	~ 3 hrs

* Please inquire us for compatible instrument information before use.

Product Features

- Simple & Rapid detection system : OneStep Multiplex qRT-PCR based detection
- HotStart PCR system : Ultra high specific and sensitive result
- Reliable system : Automatic PCR control
- Positive control included

Reference

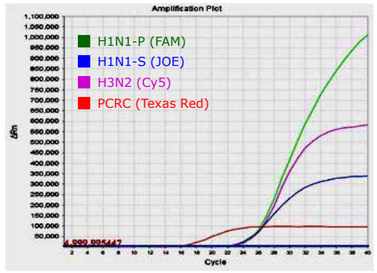
1. Grist NR, Bell EJ, Assaad F. Enteroviruses in human disease. Prog Med Virol. 1978;24:114-57
2. Muir P, Nicholson F, Illavia SJ, et al. Serological and molecular evidence of enterovirus infection in patients with end-stage dilated cardiomyopathy. Heart. 1996;76(3):243-9.
3. Tebruegge M, Curtis N. Enterovirus infections in neonates. Semin Fetal Neonatal Med. 2009;14(4):222-7.
4. Imamura T1, Fuji N, Suzuki A, et al. Enterovirus 68 among children with severe acute respiratory infection, the Philippines. Emerg Infect Dis. 2011;17(8):1430-5.

CE IVD

Result & Data interpretation

DiaPlexQ™ Influenza Virus A Subtype Detection Kit

Set I



Set II

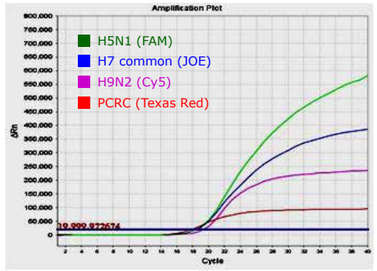
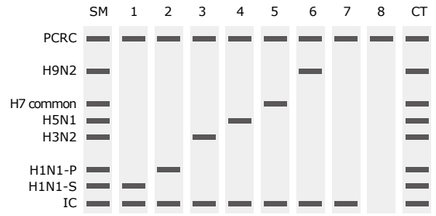


Fig. 1. Amplification Plot information (ABI7500 FAST)

DiaPlexC™ Influenza Virus A Subtype Detection Kit



SM : Standard Marker
PCRC : PCR Control
NTC : Non-Template Control
CT : Control Template
IC : Internal Control

Lane	Interpretation (detection)
1	H1N1-Seasonal
2	H1N1-Pandemic
3	H3N2
4	H5N1
5	H7 common
6	H9N2
7	Negative
8	NTC

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQD41-K020 (20 reaction)	*DiaPlexQ*™ Influenza Virus A Subtype Detection Kit	OneStep qRT-PCR Enzyme mix (Inf A Sub) 2X OneStep qRT-PCR Buffer (Inf A Sub) Primer & Probe Mixture I (Inf A Sub) Primer & Probe Mixture II (Inf A Sub) Control Template I (Inf A Sub) Control Template II (Inf A Sub) RNase free Water
	SQD41-K100 (100 reaction)		
Conventional (End-point) PCR	SMD41-K020 (20 reaction)	*DiaPlexC*™ Influenza Virus A Subtype Detection Kit	OneStep RT-PCR Enzyme mix (Inf A Sub) 2X OneStep RT-PCR Buffer (Inf A Sub) Primer Mixture (Inf A Sub) Standard Marker (Inf A Sub) Control Template (Inf A Sub) RNase free Water
	SMD41-K100 (100 reaction)		

DiaPlexQ

Entero Virus (Respiratory) Detection Kit

Real-Time

Real-Time OneStep RT-PCR based assay system for detection of enterovirus

Pathogen Information

Enterovirus (EV) is positive sense single-strand RNA (+ssRNA) virus of icosahedral symmetry. Poliovirus, coxsackie A, B virus and Eco virus and Enterovirus are group of them. The virus firstly multiply in the mucosal cells from gastrointestinal tract, GI tract. And then show the pathogenic reaction through the central nervous system reaction and extend the infection. Additionally multiplied virus expose as a stool and being the one of infection factor. The symptom of Enterovirus is normally shows similar as influenza or general repiratory illness, however, part of virus can be the cause of herpangina, aseptic meningitis, hand-foot- and mouth disease, myocarditis, acute hemorrhagic conjunctivitis virus. Rarely the virus infect to central nervous system and being the factor of encephalitis or encephalomeningitis. In a serious case it remains after effects or death of factor.

Product Specification

Detection target	Entero Virus (A/B/D type)
Detection technology	Real-Time OneStep RT-PCR
Specimen type	Nasopharyngeal swab, Nasopharyngeal aspirate, Bronchoalveolar lavage (BAL), Throat swab, Nasal aspirates, Sputum
Analytical sensitivity	10 copies
Compatible instruments*	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)
PCR running time	~ 2 hrs

* Please inquire us for compatible instrument information before use.

Product Features

- Simple & Rapid detection system : OneStep Multiplex qRT-PCR based detection
- HotStart PCR system : Ultra high specific and sensitive result
- Reliable system : Automatic PCR control
- Positive control included

Reference

1. Grist NR, Bell EJ, Assaad F. Enteroviruses in human disease. Prog Med Virol. 1978;24:114-57
2. Muir P, Nicholson F, Illavia SJ, et al. Serological and molecular evidence of enterovirus infection in patients with end-stage dilated cardiomyopathy. Heart. 1996;76(3):243-9.
3. Tebruegge M, Curtis N. Enterovirus infections in neonates. Semin Fetal Neonatal Med. 2009;14(4):222-7.
4. Imamura T1, Fuji N, Suzuki A, et al. Enterovirus 68 among children with severe acute respiratory infection, the Philippines. Emerg Infect Dis. 2011;17(8):1430-5.

Result & Data interpretation

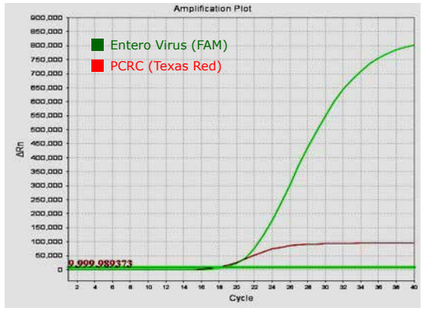


Fig. 1. Amplification Plot information (ABI7500 FAST)

Sample type	FAM	Texas Red / Cal Red 610	Result
Positive Control	+	+	Valid
Negative Control	-	+	Valid
NTC (Non-Template Control)	-	+	Valid
Sample case 1	+	+	Positive
Sample case 2	-	+	Negative
Sample case 3	+	-	Valid (Positive)
Sample case 4	-	-	Required re-experiment

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQD51-K020 (20 reaction)	*DiaPlexQ*™ Entero Virus (Respiratory) Detection Kit	OneStep qRT-PCR Enzyme mix (Entero-Res.) 2X OneStep qRT-PCR Buffer (Entero-Res.) Primer & Probe Mixture (Entero-Res.) Control Template (Entero-Res.) RNase free Water
	SQD51-K100 (100 reaction)		

DiaPlexQ

STI 12 Detection Kit
STI 6 Detection Kit

Real-Time

Real-Time PCR based assay system for simultaneous detection of sexually transmitted infections

Pathogen Information

STIs (Sexually Transmitted Infections) are an infection passed from person to person through intimate sexual contact. There are many kinds of STIs and they are very common. More than half of all of us will get one at some point in our lives.

Product Specification

	***DiaPlexQ*™ STI 12 Detection Kit**	***DiaPlexQ*™ STI 6 Detection Kit**
Detection target	Set I : *N. gonorrhoeae* (NG) *C. trachomatis* (CT) *M. hominis* (MH) Set II : *T. vaginalis* (TV) *U. urealyticum* (UU) *M. genitalium* (MG) Set III : Herpes simplex virus 1 (HSV-1) Herpes simplex virus 2 (HSV-2) *G. vaginalis* (GV) Set IV : *T. pallidum* (TP) *C. albicans* (CA) *H. ducreyi* (HD) *DiaPlexQ*™ STI 12 Detection Kit : All set (Set I ~ Set IV) *DiaPlexQ*™ STI 6 Detection Kit : Only major group (Set I and Set II)	
Detection technology	Real-Time PCR	
Specimen type	Urogenital swab specimen, Urine	
Analytical sensitivity	10 - 10^2 copies	10 - 10^2 copies
Compatible instruments*	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)	
PCR running time	~ 1 hr 30 min	~ 1 hr 30 min

* Please inquire us for compatible instrument information before use.

Product Features

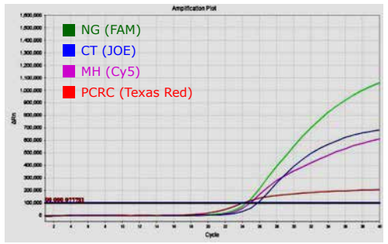
- HotStart PCR system : Ultra high specific and sensitive result
- UDG system : No carryover contamination
- Multiplex PCR system : Multiple targets in a single reaction
- Reliable system : Automatic PCR control
- Positive control included
- Easy-to-use master mix

Reference

1. Korean J Clin microbial, Seong Deok Lee, Hye Young Lee, Hyun Chul Kim, Soo Young Kim, Mycobacterium Tuberculosis and Non-Tuberculous Mycobacteria by PCR Assay.
2. Ryan KJ, Ray CG (Editors) (2004). Sherris Medical Microbiology (4th ed.). McGraw-Hill.
3.Sun-Pil Choi, M.D., Bong-Keun Lee M.D.1, Jin-Hong Min, M.D., Jin-Hee Kim, M.D. Pathogenic Classification and Clinical Characteristics of Non-Tuberculous Mycobacterial Pulmonary Disease in a National Tuberculosis Hospital.

Result

Set I



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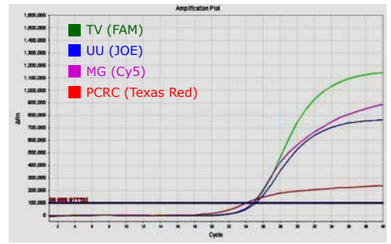

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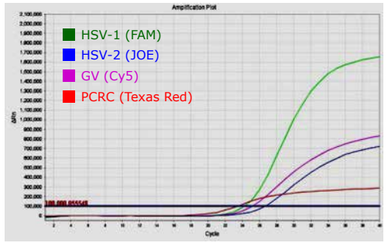


Set IV

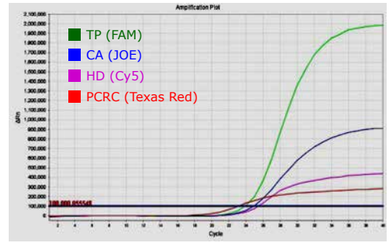


Fig. 1. Amplification Plot information (ABI7500 FAST)

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQD95-K020 (20 reaction)	*DiaPlexQ*™ STI 12 Detection Kit	2X Multiplex Real-Time PCR Smart mix (with UDG) (STI 12) Primer & Probe Mixture I (STI 12) Primer & Probe Mixture II (STI 12) Primer & Probe Mixture III (STI 12) Primer & Probe Mixture IV (STI 12) Control Template (STI 12) Nuclease free Water
	SQD95-K100 (100 reaction)		
	SQD94-K020 (20 reaction)	*DiaPlexQ*™ STI 6 Detection Kit	2X Multiplex Real-Time PCR Smart mix (with UDG) (STI 6) Primer & Probe Mixture I (STI 6) Primer & Probe Mixture II (STI 6) Control Template (STI 6) Nuclease free Water
	SQD94-K100 (100 reaction)		

DiaPlexQ

CT/NG Detection Kit

Real-Time

Real-Time PCR based assay system for simultaneous detection of *C. trachomatis* and *N. gonorrhoeae*

Pathogen Information

Chlamydia, caused by *Chlamydia trachomatis* (CT) and gonorrhea, caused by *Neisseria gonorrhoeae* (NG), are the most common sexually transmitted diseases. It is known that 70% of NG infected patients are co-infected with CT. These infections may be transmitted through vaginal, anal or oral sexual contact.

Product Specification

Detection target	*Chlamydia trachomatis*, *Neisseria gonorrhoeae*
Detection technology	Real-Time PCR
Specimen type	Urogenital swab specimen, Urine
Analytical sensitivity	10 - 10^2 copies
Compatible instruments*	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)
PCR running time	~ 2 hrs

* Please inquire us for compatible instrument information before use.

Product Features

- HotStart PCR system : Ultra high specific and sensitive result
- UDG system : No carryover contamination
- Multiplex PCR system : Multiple targets in a single reaction
- Reliable system : Automatic PCR control
- Positive control included
- Easy-to-use master mix

Reference

1. Grayston, J.T. 1990. Chlamydia pneumonia, strain TWAR. In: Chlamydia Infections: Proceedings of the Seventh International Symposium on Human Chlamydial Infections, eds. Bowie, W.R., et al., Cambridge University Press, New York, 389-401.
2. Guidelines for Treatment of Sexually Transmitted Diseases. Morbidity and Mortality Weekly Reports. 1998. (No.RR-1) : 1-118.
3. Thompson, S.E. and Washington, A.E. 1983. Epidemiology of sexually transmitted *Chlamydia trachomatis* infections. Epidemiologic Reviews 5:96-123.

Result & Data interpretation

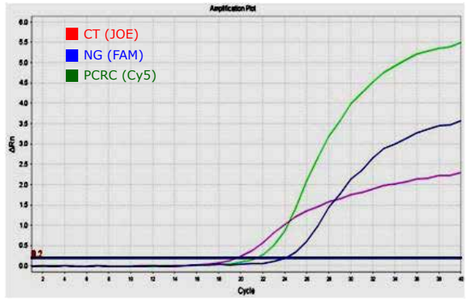


Fig. 1. Amplification Plot information (ABI7500 FAST)

Sample type	JOE	FAM	Cy5	Result
Positive Control	+	+	+	Valid
Negative Control	-	-	+	Valid
NTC (Non-Template Control)	-	-	+	Valid
Sample case 1	+	+	+/-	CT, NG (Co-infection)
Sample case 2	+	-	+/-	CT
Sample case 3	-	+	+/-	NG
Sample case 4	-	-	+	Negative
Sample case 5	-	-	-	Required re-experiment

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQD93-K020 (20 reaction)	*DiaPlexQ*™ CT/NG Detection Kit	2X Multiplex Real-Time PCR Smart mix (with UDG) (CT/NG) Primer & Probe Mixture (CT/NG) Control Template (CT/NG) Nuclease free Water
	SQD93-K100 (100 reaction)		

DiaPlexC

HPV Screening System

Conventional

Multiplex PCR based assay system for detection of human papillomavirus

Pathogen Information

Human papillomavirus (HPV) is the most common sexually transmitted infection. Reaching 0.4 millions patients every year for HPV infection and unfortunately 0.2 millions are death caused by this disease. As a health science sight, the HPV is on of important disease to control healthful and happy human life. HPV is family of Papovaviridae and circular DNA virus which own about 7,900 base pare. Normally 120 species of genotypes are confirmed by the sequence of capsid (L1). There are 3 parts of genotypes. Firstly high risk group (oncogenic HPV genotypes : 16, 18, 31, 35, 39, 45, 51, 58,59, 68, 73, 82), Low risk group (non-oncogenic HPV genotypes : 6, 11, 40, 42, 43, 44, 54, 61, 70,72, 81) and borderline risk group (intermediate HPV genotypes : 26, 53, 66), Especially HPV 16, 18 genotype is main factor virus of HPV, so infection rate and death rate is also highest from that groups. Now commercial medicine for HPV are developed from Merck (Gardasil) and GSK (Cervarix).

Product Specification

Detection target	HPV common (39 types)
Detection technology	Conventional (End-point) Multiplex PCR
Specimen type	Cervical swab specimen, Liquid based cytology specimen (ThinPrep®, SurePath™)
Analytical sensitivity	10 - 10^2 copies
Compatible instruments*	ABI Veriti thermal Cycler (Applied Biosystems) recommended
PCR running time	~ 2 hrs

* Please inquire us for compatible instrument information before use.

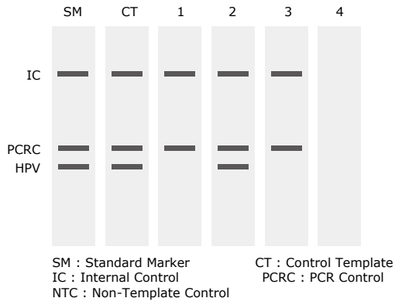
Product Features

- HotStart PCR system : Ultra high specific and sensitive result
- UDG system : No carryover contamination
- Multiplex PCR system : Multiple targets in a single reaction
- Reliable system : Automatic PCR control & Internal control
- Positive control included
- Easy-to-use master mix

Reference

1. Depuydt, C.E., Boulet, G.A.V., Horvath, C.A.J., Benoy, I.H., Verrchen, A.J. and Bogers, J.J. 2007. Comparison of MY09/11 consensus PCR and type-specific PCRs in the detection of oncogenic HPV types. J.Cell.Mol.Med. 11(4) 881-891.
2. Sarma, U., Mahanta, J., Borkakoty, B. and Talukdar K.L. 2013. Detection of Human Papilloma Virus DNA from Dry Paper Cervical Smear- a Hospital Based Study. IJLSR. 3(2) 83-88.
3. Raji, N., Sadeghizadeh, M., Tafreshi, K.N. and Jahanzad, E. 2011 . Detection of human Papillomavirus 18 in cervical cancer samples using PCR-ELISA (DIAPOPS). IRAN. J. MICROBIOL, 3(4) 177-182

Result & Data interpretation



Lane	Interpretation (detection)
1	Negative
2	Positive
3	NTC
4	Required re-experiment

Ordering Information

Technology	Cat. No.	Product	Contents
Conventional (End-point) PCR	SHG40-K100 (100 reaction)	*DiaPlexC*™ HPV Screening System	2X Multiplex PCR Smart mix (HPV SC) Primer Mixture (HPV SC) Standard Marker (HPV SC) Control Template (HPV SC) Nuclease free Water
	SHG40-K300 (300 reaction)		

DiaPlexC

HPV Genotyping System

Conventional

Multiplex PCR based assay system for identification of 35 human papillomavirus genotypes

Pathogen Information

Human papillomavirus (HPV) is the most common sexually transmitted infection. Reaching 0.4 millions patients every year for HPV infection and unfortunately 0.2 millions are death caused by this disease. As a health science sight, the HPV is on of important disease to control healthful and happy human life. HPV is family of Papovaviridae and circular DNA virus which own about 7,900 base pare. Normally 120 species of genotypes are confirmed by the sequence of capsid (L1). There are 3 parts of genotypes. Firstly high risk group (oncogenic HPV genotypes : 16, 18, 31, 35, 39, 45, 51, 58,59, 68, 73, 82), Low risk group (non-oncogenic HPV genotypes : 6, 11, 40, 42, 43, 44, 54, 61, 70,72, 81) and borderline risk group (intermediate HPV genotypes : 26, 53, 66), Especially HPV 16, 18 genotype is main factor virus of HPV, so infection rate and death rate is also highest from that groups. Now commercial medicine for HPV are developed from Merck (Gardasil) and GSK (Cervarix).

Product Specification

Detection target	Set 1 : HPV 18, HPV 35, HPV 40, HPV 44, HPV 6, HPV 43, HPV 11 Set 2 : HPV 34, HPV 58, HPV 68, HPV 61, HPV 30, HPV 32, HPV 51 Set 3 : HPV 69, HPV 56, HPV 53, HPV 31, HPV 67, HPV 70, HPV 33 Set 4 : HPV 73, HPV 52, HPV 59, HPV 39, HPV 26, HPV 45, HPV 16 Set 5 : HPV 83, HPV 62, HPV 54, HPV 82, HPV 81, HPV 66, HPV 90
Detection technology	Conventional (End-point) Multiplex PCR
Specimen type*	*DiaPlexC*™ HPV Screening System (PCR product from Positive sample through diagnostic result)
Analytical sensitivity	1 - 10 copies
Compatible instruments**	ABI Veriti thermal Cycler (Applied Biosystems) recommended
PCR running time	~ 1 hr 30 min

* Firstly, screening the HPV infection using *DiaPlexC*™ HPV Screening System [Cat. No. SHG40-K100] . Secondly, confirm HPV infection with pre-screened sample using *DiaPlexC*™ HPV Genotyping System [Cat. No. SHG41-K100].
** Please inquire us for compatible instrument information before use.

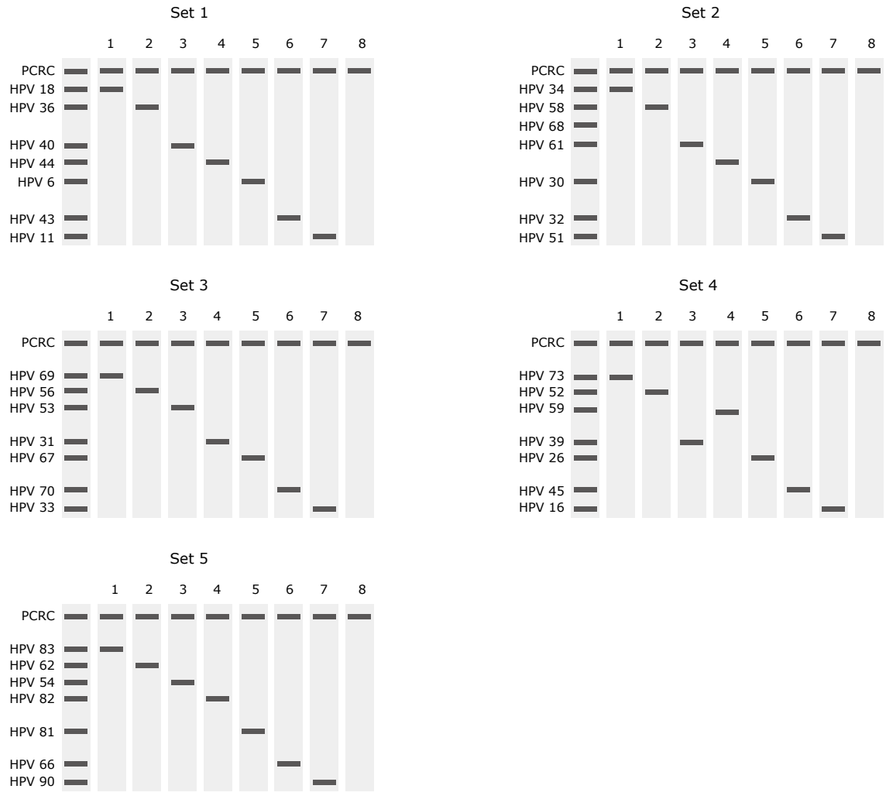
Product Features

- HotStart PCR system : Ultra high specific and sensitive result
- Multiplex PCR system : Multiple targets in a single reaction
- Reliable system : Automatic PCR control
- Easy-to-use master mix

Reference

1. Depuydt, C.E., Boulet, G.A.V., Horvath, C.A.J., Benoy, I.H., Verrchen, A.J. and Bogers, J.J. 2007. Comparison of MY09 /11 consensus PCR and type-specific PCRs in the detection of oncogenic HPV types. J.Cell.Mol.Med. 11(4) 881-891.
2. Franciso, R. P., 2012. Detection and Typing of Human Papilloma Virus by Multiplex PCR with Type-Specific Primer. IRAN. J. MICROBIOL, doi: 10.5402/2012/186915.
3. Sotlar, K., Diemer, D., Dethleffs, A., Hack, Y., Stubner, A., Vollmer, N., Menton, S., Menton, M., Dietz, K., Wallwiener, D., Kandolf. R., and Bultmann, B. 2004. Detection and Typing of Human Papillomavirus by E6 Nested Multiplex PCR. JCM. 3176-3184.

Result



Ordering Information

Technology	Cat. No.	Product	Contents
Conventional (End-point) PCR	SHG41-K100 (100 reaction)	*DiaPlexC*™ HPV Genotyping System	2X Multiplex PCR Smart mix (HPV GS) Primer Mixture I (HPV GS I) Primer Mixture II (HPV GS II) Primer Mixture III (HPV GS III) Primer Mixture IV (HPV GS IV) Primer Mixture V (HPV GS V) Nuclease free Water

DiaPlexQ

PneumoPatho 13 Detection Kit

Real-Time

Real-Time PCR based assay system for simultaneous detection of pneumonia species

Pathogen Information

Pneumonia is usually caused by infection with viruses or bacteria, and less commonly by other microorganisms, certain drugs and other conditions such as autoimmune diseases. Pneumonia affects approximately 450 million people globally per year, seven percent of the global population, and results in about 4 million deaths per year, mostly in third world countries.

Product Specification

Detection target	Set I : *M. pneumoniae* (MP) *K. pneumoniae* (KP) *C. pneumoniae* (CP) Set II : *S. pneumoniae* (SP) *S. aureus* (SA) *L. pneumophila* (LP) Set III : *P. aeruginosa* (PA) *M. catarrhalis* (MC) *B. pertussis* (BP) Set IV : *H. influenzae* (HI) *A. baumannii* (AB) *M. tuberculosis/ M. avium* (TB/AV)
Detection technology	Real-Time PCR
Specimen type	Nasopharyngeal swab, Nasopharyngeal aspirate, Bronchoalveolar lavage (BAL), Nasal swab, Oropharyngeal swab, Sputum
Analytical sensitivity	10 - 10^2 copies
Compatible instruments*	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)
PCR running time	~ 2 hrs

* Please inquire us for compatible instrument information before use.

Product Features

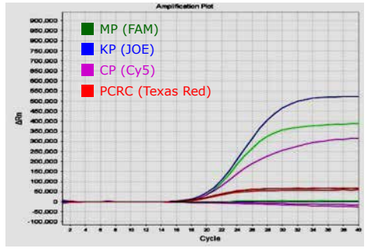
- HotStart PCR system : Ultra high specific and sensitive result
- UDG system : No carryover contamination
- Multiplex PCR system : Multiple targets in a single reaction
- Reliable system : Automatic PCR control
- Positive control included
- Easy-to-use master mix

Reference

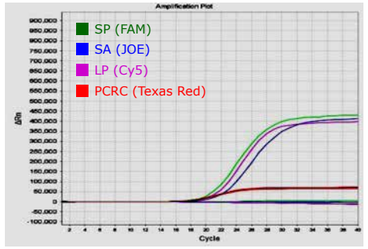
1. Micheal J McConnell et al. Quantitative Real-Time PCR for Detection of Acinetobacter baumannii Colonization in the Hospital Environment. Journal of Clinical Microbiology p. 1412-1414.
2. Ko WC, Paterson DL, Sagnimeni AJ, et al. Community-acquired Klebsiella pneumonia bacteremia: global differences in clinical patterns. Emerg Infect Dis 2002; 8:160-6.
3. Gierczynski R, Jagielski M, Rastswicki W, Klauzewski S (2007) Multiplex-PCR assay for identification of Klebsiella pneumonia isolates carrying the chain loci for K1 and K2 capsule biosynthesis. Pol J Microbiol 56: 153-156.

Result

Set I



Set II



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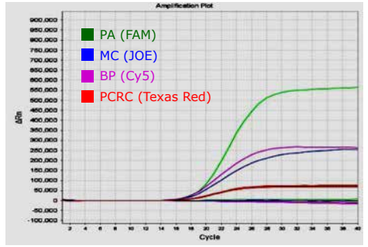


Set IV

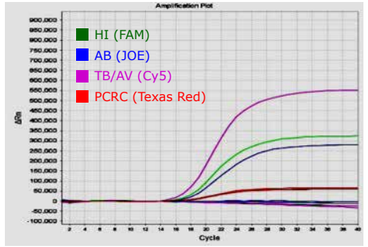


Fig. 1. Amplification Plot information (ABI7500 FAST)

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQD81-K020 (20 reaction)	*DiaPlexQ*™ PneumoPatho 13 Detection Kit	2X Multiplex Real-Time PCR Smart mix (with UDG) (PneumoPatho 13) Primer & Probe Mixture I (PneumoPatho 13) Primer & Probe Mixture II (PneumoPatho 13) Primer & Probe Mixture III (PneumoPatho 13) Primer & Probe Mixture IV (PneumoPatho 13) Control Template I (PneumoPatho 13) Control Template II (PneumoPatho 13) Control Template III (PneumoPatho 13) Control Template IV (PneumoPatho 13) Nuclease free Water
	SQD81-K100 (100 reaction)		

DiaPlexQ

PneumoPatho 6 Detection Kit

Real-Time

Real-Time PCR based assay system for simultaneous detection of pneumonia species

Pathogen Information

Pneumonia is usually caused by infection with viruses or bacteria, and less commonly by other microorganisms, certain drugs and other conditions such as autoimmune diseases. Pneumonia affects approximately 450 million people globally per year, seven percent of the global population, and results in about 4 million deaths per year, mostly in third world countries.

Product Specification

Detection target	Set I : *M. pneumoniae* (MP), *B. pertussis* (BP), *C. pneumoniae* (CP) Set II : *S. pneumoniae* (SP), *H. influenzae* (HI), *L. pneumophila* (LP)
Detection technology	Real-Time PCR
Specimen type	Nasopharyngeal swab, Nasopharyngeal aspirate, Bronchoalveolar lavage (BAL), Nasal swab, Oropharyngeal swab, Sputum
Analytical sensitivity	10 - 10^2 copies
Compatible instruments*	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)
PCR running time	~ 2 hrs

* Please inquire us for compatible instrument information before use.

Product Features

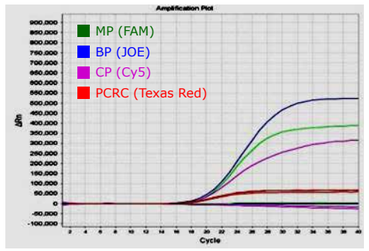
- HotStart PCR system : Ultra high specific and sensitive result
- UDG system : No carryover contamination
- Multiplex PCR system : Multiple targets in a single reaction
- Reliable system : Automatic PCR control
- Positive control included
- Easy-to-use master mix

Reference

1. Micheal J McConnell et al. Quantitative Real-Time PCR for Detection of Acinetobacter baumannii Colonization in the Hospital Environment. Journal of Clinical Microbiology p. 1412-1414.
2. Ko WC, Paterson DL, Sagnimeni AJ, et al. Community-acquired Klebsiella pneumonia bacteremia: global differences in clinical patterns. Emerg Infect Dis 2002; 8:160-6.
3. Gierczynski R, Jagielski M, Rastswicki W, Klauzewski S (2007) Multiplex-PCR assay for identification of Klebsiella pneumonia isolates carrying the chain loci for K1 and K2 capsule biosynthesis. Pol J Microbiol 56: 153-156.

Result

Set I



Set II

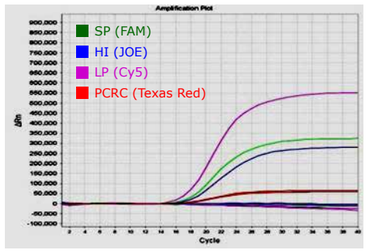


Fig. 1. Amplification Plot information (ABI7500 FAST)

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQD82-K020 (20 reaction)	*DiaPlexQ*™ PneumoPatho 6 Detection Kit	2X Multiplex Real-Time PCR Smart mix (with UDG) (PneumoPatho 6) Primer & Probe Mixture I (PneumoPatho 6) Primer & Probe Mixture II (PneumoPatho 6) Control Template I (PneumoPatho 6) Control Template II (PneumoPatho 6) Nuclease free Water
	SQD82-K100 (100 reaction)		

DiaPlexQ

Dengue Virus Detection Kit

Real-Time

Real-Time OneStep RT-PCR based assay system for detection of dengue virus

Pathogen Information

Dengue Fever and Dengue hemorrhagic fever are caused by an RNA flavi virus that is spread by the bites of mosquitoes, most commonly Aedes aegypti, which is found in tropic and sub-tropic regions. As many as 100 million people are infected yearly. There are four known serotypes of the flavi virus that cause Dengue Fever: DEN-1, DEN-2, DEN-3 and DEN-4. Infection from one serotype of Dengue Fever provides lifelong immunity from that serotype, but not from the other serotypes. There is no vaccines developed yet for Dengue Fever virus, it is essential to identify the strain of the infecting virus and the immunity status of the patient as early as possible.

Product Specification

Detection target	Dengue Fever Virus (Serotype 1/2/3/4)
Detection technology	Real-Time OneStep RT-PCR
Specimen type	Blood
Analytical sensitivity	10 - 10^2 copies
Compatible instruments*	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)
PCR running time	~ 3 hrs

* Please inquire us for compatible instrument information before use.

Product Features

- Simple & Rapid detection system : OneStep Multiplex qRT-PCR based detection
- HotStart PCR system : Ultra high specific and sensitive result
- Reliable system : Automatic PCR control
- Positive control included
- CE certification

Reference

1. Grist NR, Bell EJ, Assaad F. Enteroviruses in human disease. Prog Med Virol. 1978;24:114-57
2. Muir P, Nicholson F, Illavia SJ, et al. Serological and molecular evidence of enterovirus infection in patients with end-stage dilated cardiomyopathy. Heart. 1996;76(3):243-9.
3. Tebruegge M, Curtis N. Enterovirus infections in neonates. Semin Fetal Neonatal Med. 2009;14(4):222-7.
4. Imamura T1, Fuji N, Suzuki A, et al. Enterovirus 68 among children with severe acute respiratory infection, the Philippines. Emerg Infect Dis. 2011;17(8):1430-5.

CE IVD

Result & Data interpretation

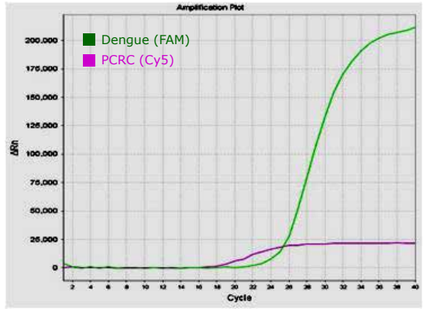


Fig. 1. Amplification Plot information (ABI7500 FAST)

Sample type	FAM	Cy5	Result
Positive Control	+	+	Valid
Negative Control	-	+	Valid
NTC (Non-Template Control)	-	+	Valid
Sample case 1	+	+/-	Positive
Sample case 2	-	+	Negative
Sample case 3	-	-	Required re-experiment

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQD01-K020 (20 reaction)	*DiaPlexQ*™ Dengue Virus Detection Kit	OneStep qRT-PCR Enzyme mix (Dengue) 5X OneStep qRT-PCR Buffer (Dengue) Primer & Probe Mixture (Dengue) Control Template (Dengue) RNase free Water
	SQD01-K100 (100 reaction)		

DiaPlexC

Malaria Detection Kit

Conventional

CE IVD

Multiplex PCR based assay system for identification of malaria species

Pathogen Information

Malaria is an infectious disease caused by four types of *Plasmodium* species, namely *P. falciparum, P. vivax, P. malariae* and *P. ovale*. These parasites are only transmitted via the bites of infected female Anopheles mosquitoes. Malaria is endemic in 106 countries. Global death due to the malaria infection is estimated at 1 million individuals per year. *P. falciparum* is a major cause of severe malaria and approximately 10-20% of the patients with *falciparum* malaria require urgent detection and intensive medical care. *P. vivax* is the second most harmful parasite of human malaria that cause more than 390 million clinical cases per year and is a chief risk factor for severe anemia among young children in most vivax-endemic areas. In general, the distribution of *P. malariae* coincides with that of *P. falciparum* in malaria-endemic areas in Africa. Although going undiagnosed in most cases of asymptomatic subclinical conditions, *P. ovale* is a cause of morbidity in many areas of tropical Africa.

Product Specification

Detection target	*Plasmodium falciparum, Plasmodium vivax, Plasmodium malariae, Plasmodium ovale*
Detection technology	Conventional (End-point) Multiplex PCR
Specimen type	Blood
Analytical sensitivity	10 - 10^2 copies
Compatible instruments*	ABI Veriti thermal Cycler (Applied Biosystems) recommended
PCR running time	~ 2 hrs

* Please inquire us for compatible instrument information before use.

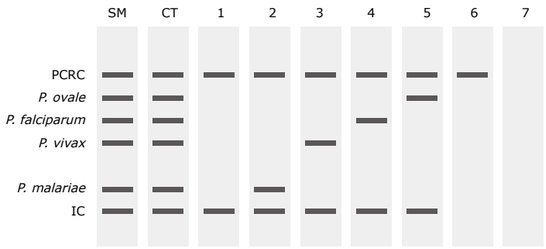
Product Features

- HotStart PCR system : Ultra high specific and sensitive result
- UDG system : No carryover contamination
- Multiplex PCR system : Multiple targets in a single reaction
- Reliable system : Automatic PCR control & Internal control
- Positive control included
- Easy-to-use master mix
- CE certification

Reference

1. JY Kim, YK Goo, et al. (August 2014). "Development and Efficacy of Real-Time PCR in the Diagnosis of Vivax Malaria Using Field Samples in the Republic of Korea". PLOS ONE. 9 (8) : e105871
2. Sutherland CJ, Tanomsing N, Nolder D, et al. (May 2010). "Two non-recombining sympatric forms of the human malaria parasite *Plasmodium* ovale occur globally". J. Infect. Dis. 201 (10) : 1544-50
3. Kilama W, Ntoumi F (October 2009). "Malaria: a research agenda for the eradication era". Lancet 374 (9700) : 1480-2.
4. Dondorp AM, Day NP (July 2007). "The treatment of severe malaria". Trans. R. Soc. Trop. Med. Hyg. 101 (7) : 633-4.
5. "Global Malaria Mortality Between 1980 and 2010: A Systematic Analysis". journalistsresource.org

Result & Data interpretation



SM : Standard Marker
PCRC : PCR Control
NTC : Non-Template Control

CT : Control Template
IC : Internal Control

Lane	Interpretation (detection)
1	Negative
2	P. malariae
3	*P. vivax*
4	*P. falciparum*
5	*P. ovale*
6	NTC
7	Required re-experiment

Ordering Information

Technology	Cat. No.	Product	Contents
Conventional (End-point) PCR	SMD35-K020 (20 reaction)	*DiaPlexC*™ Malaria Detection Kit	2X Multiplex PCR Smart mix (with UDG) (Malaria) Primer Mixture (Malaria) Standard Marker (Malaria) Control Template (Malaria) Nuclease free Water
	SMD35-K100 (100 reaction)		

DiaPlexC

CRE Detection Kit

Conventional

Multiplex PCR based assay system for simultaneous detection of CRE genes: *VIM*, *IMP*, *NDM* and *KPC*

Pathogen Information

Carbapenem-Resistant *Enterobacteriaceae* (CRE) is a type of gram-negative bacteria that is resistant to the antibiotics related to the Carbapenem. Unguided or prolong use of antibiotics leads some bacteria to become insensitive due to the generation of Metallo-β-lactamase. The carbapenemase gene is known to include the *KPC*, *NDM*, *VIM*, *IMP*, *SIM*, *GES*, *SPM* and *OXA* gene families. Its severity came to the forth as the first reported infected patient from *NDM*-1 (New Delhi Metallo-β-lactamase-1) and quickly spread worldwide. In particular, the *NDM*-1 and *KPC-2* gene exists in a plasmid of some strains that can be propagated easily into heterogeneity by conjunction.
The European Union (EU) and the World Health Organization recognize the emergence of antibiotic-resistant strains as a serious situation, and try to prevent its spread by strict management through ongoing monitoring and research development. CRE is now a global challenge and has been associated with high rates of morbidity and mortality. Therefore, the accurate and fast detection of the carbapenem family of antibiotic-resistant genes is very important.

Product Specification

Detection target	*VIM (Verona ingetron-encoded Metallo-β -lactamase-1)* *IMP (Imipenem-resistant P.aeruginosa)* *NDM (New Delhi Metallo β -lactamase)* *KPC (Klebsiella pneumonia carbapenemase)*
Detection technology	Conventional (End-point) Multiplex PCR
Specimen type	Urine, Bile acid, Sputum, Blood, gastric juice, Stool
Analytical sensitivity	10 - 10^2 copies
Compatible instruments*	ABI Veriti thermal Cycler (Applied Biosystems) recommended
PCR running time	~ 1 hr 30 min

* Please inquire us for compatible instrument information before use.

Product Features

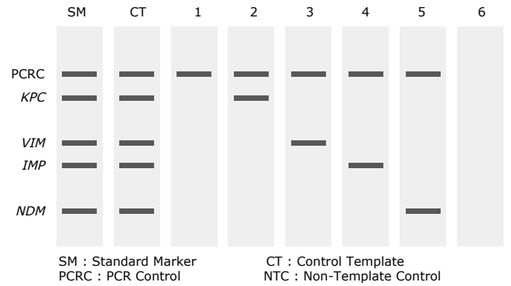
- HotStart PCR system : Ultra high specific and sensitive result
- DnaFree™ system : No host genomic DNA contamination
- UDG system : No carryover contamination
- Multiplex PCR system : Multiple targets in a single reaction
- Reliable system : Automatic PCR control
- Positive control included
- Easy-to-use master mix
- CE certification

Reference

1. Schwaber MJ, Carmeli Y. Carbapenem-resistant *Enterobacteriaceae*: a potential threat. JAMA 2008;300:2911—3.
2. CDC, Healthcare Infection Control Practices Advisory Committee. Management of multidrug-resistant organisms in healthcare settings, 2006. Atlanta, GA: US Department of Health and Human Services, CDC, Healthcare Infection Control Practices Advisory Committee.
3. Srinivasan A, Patel JB. Klebsiella pneumonia carbapenemase-producing organisms: an ounce of prevention really is worth a pound of cure. Infect Control Hosp Epidemiol 2008;29:1107—9.

CE IVD

Result & Data interpretation



Lane	Interpretation (detection)
1	Negative (or NTC)
2	*KPC*
3	*VIM*
4	*IMP*
5	*NDM*
6	Required re-experiment

Ordering Information

Technology	Cat. No.	Product	Contents
Conventional (End-point) PCR	SMD71-K020 (20 reaction)	*DiaPlexC*™ CRE Detection Kit	2X Multiplex PCR Smart mix (with UDG) (CRE) Primer Mixture (CRE) Standard Marker (CRE) Control Template (CRE) Nuclease free Water
	SMD71-K100 (100 reaction)		

DiaPlexQ

Entero Virus (Stool) Detection Kit

Real-Time

Real-Time OneStep RT-PCR based assay system for detection of enterovirus

Pathogen Information

Enterovirus EV is positive sense single-strand RNA (+ssRNA) virus of icosahedral symmetry. Poliovirus, coxsackie A, B virus and Eco virus and Enterovirus are group of them. The virus firstly multiply in the mucosal cells from gastrointestinal tract, GI tract. And then show the pathogenic reaction through the central nervous system reaction and extend the infection. Additionally multiplied virus expose as a stool and being the one of infection factor. The symptom of Enterovirus is normally shows similar as influenza or general repiratory illness, however, part of virus can be the cause of herpangina, aseptic meningitis, hand-foot- and mouth disease, myocarditis, acute hemorrhagic conjunctivitis virus. Rarely the virus infect to central nervous system and being the factor of encephalitis or encephalomeningitis. In a serious case it remains after effects or death of factor.

Product Specification

Detection target	Entero Virus (A/B/C/D type)
Detection technology	Real-Time OneStep RT-PCR
Specimen type	Stool
Analytical sensitivity	10 - 10^2 copies
Compatible instruments*	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)
PCR running time	~ 2 hrs

* Please inquire us for compatible instrument information before use.

Product Features

- Simple & Rapid detection system : OneStep Multiplex qRT-PCR based detection
- HotStart PCR system : Ultra high specific and sensitive result
- Reliable system : Automatic PCR control
- Positive control included

Reference

1. Grist NR, Bell EJ, Assaad F. Enteroviruses in human disease. Prog Med Virol. 1978;24:114-57
2. Muir P, Nicholson F, Illavia SJ, et al. Serological and molecular evidence of enterovirus infection in patients with end-stage dilated cardiomyopathy. Heart. 1996;76(3):243-9.
3. Tebruegge M, Curtis N. Enterovirus infections in neonates. Semin Fetal Neonatal Med. 2009;14(4):222-7.
4. Imamura T1, Fuji N, Suzuki A, et al. Enterovirus 68 among children with severe acute respiratory infection, the Philippines. Emerg Infect Dis. 2011;17(8):1430-5.

Result & Data interpretation

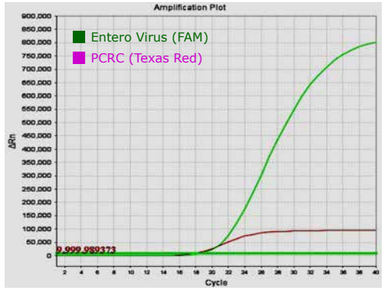
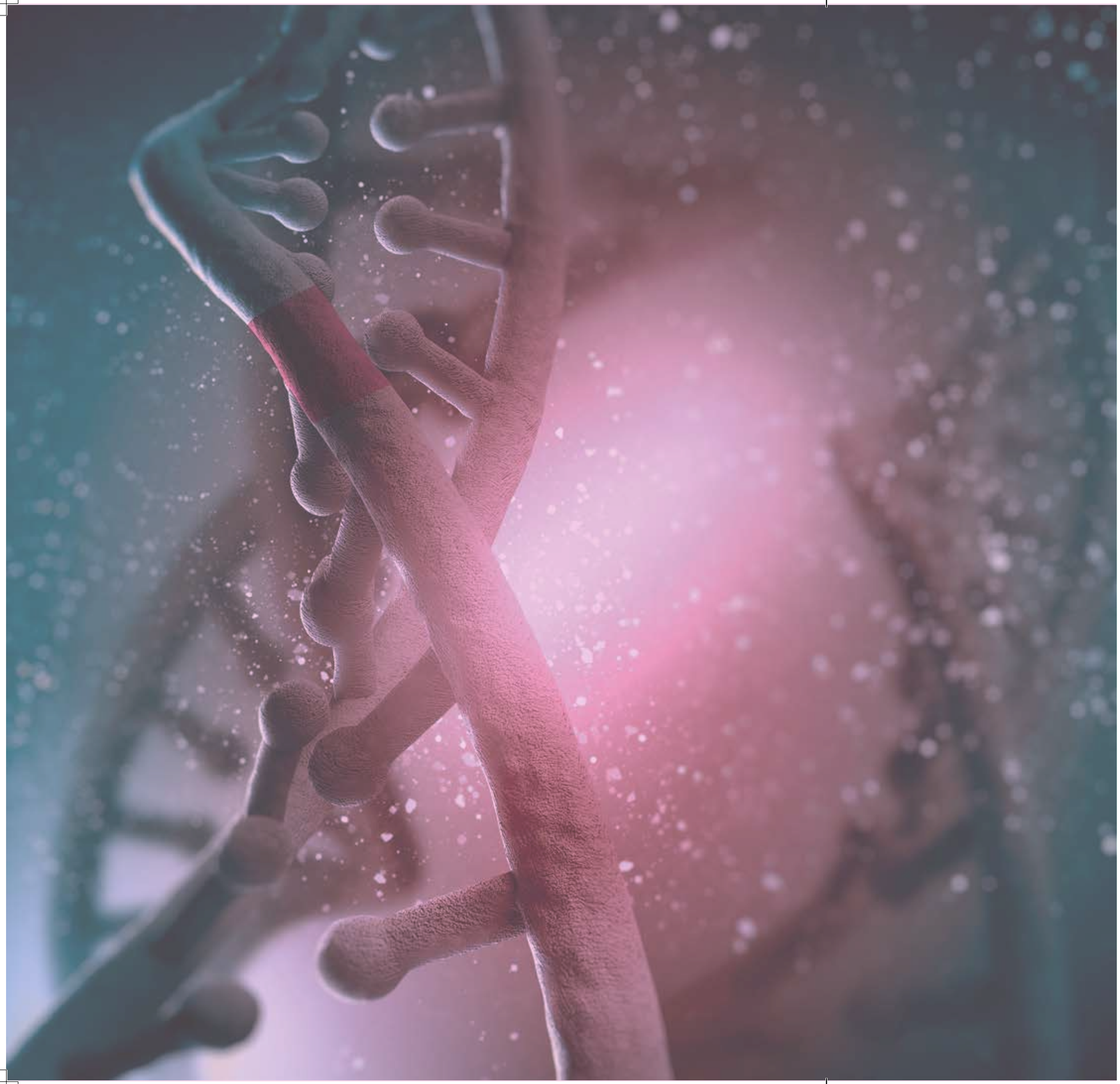


Fig. 1. Amplification Plot information (ABI7500 FAST)

Sample type	FAM	Texas Red / Cal Red 610	Result
Positive Control	+	+	Valid
Negative Control	-	+	Valid
NTC (Non-Template Control)	-	+	Valid
Sample case 1	+	+	Positive
Sample case 2	-	+	Negative
Sample case 3	+	-	Valid (Positive)
Sample case 4	-	-	Required re-experiment

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQD52-K020 (20 reaction)	*DiaPlexQ*™ Entero Virus (Stool) Detection Kit	OneStep qRT-PCR Enzyme mix (Entero-Stool) 2X OneStep qRT-PCR Buffer (Entero-Stool) Primer & Probe Mixture (Entero-Stool) Control Template (Entero-Stool) RNase free Water
	SQD52-K100 (100 reaction)		



Molecular Diagnostics

Human Genotyping

Avellino Corneal Dystrophy

Alzheimer's Disease

Hyperhomocysteinemia

G6PD Deficiency

DiaPlexQ

Avellino Corneal Dystrophy (ACD) Genotyping Kit

Real-Time

DiaPlexC

Avellino Corneal Dystrophy (ACD) Genotyping Kit

Conventional

Real-Time PCR (or Multiplex allele-specific PCR) based assay system for the genotyping of the ACD gene SNP related to avellino corneal dystrophy

Pathogen Information

ACD is a hereditary disease and one of the corneal dystrophies involving the formation of corneal opacities on different layers of the corneal stroma, which leads to significant impairment of the corneal transparency and refraction. ACD is caused by the formation and deposition of abnormal hyaline protein which is generated by the replacement of histidine from arginine due to the mutation of cordon 124 (exon 4) in the βigh 3 gene. The deposited abnormal hyaline protein is usually known as kerato-epithelin and forms a granular, lattice precipitate causing visual impairment and might lead to blindness if it remains undiagnosed. Genetic mutation is highly accelerated after laser eye surgery in those people who have ACD, causing a worsening in vision rather than improvement after surgery. The awareness of ACD has developed across the world, with some opticians now refusing access to LASIK in patients with ACD due to the harmful effects the procedure has on patients.

Product Specification

	***DiaPlexQ*™ Avellino Corneal Dystrophy (ACD) Real-Time PCR Genotyping Kit**	***DiaPlexC*™ Avellino Corneal Dystrophy (ACD) PCR Genotyping Kit**
Detection target	SNP of R124 (βigh3 coding gene codon 124, exon4)	
Detection technology	Real-Time PCR	Conventional (End-point) Multiplex PCR
Specimen type	Blood, Buccal epithelial cell, Hair (root)	
Compatible instruments*	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)	ABI Veriti thermal Cycler (Applied Biosystems) recommended
PCR running time	~ 1hr 30 min	~ 1hr 30 min

* Please inquire us for compatible instrument information before use.

Product Features

- HotStart PCR system : Ultra high specific and sensitive result
- UDG system : No carryover contamination
- Multiplex PCR : Multiple targets in a single reaction
- Reliable system : Automatic Internal control (*DiaPlexC*™)
- Positive control included
- Easy-to-use master mix
- CE certification

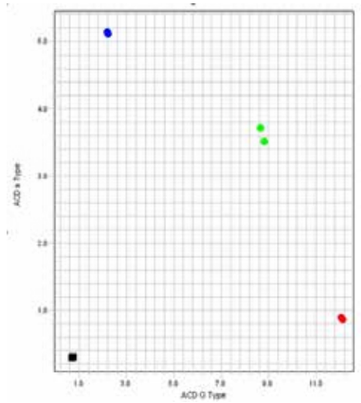
Reference

1. Kocak-Atlintas AG, Kocak-Midillioglu I, Akarsu AN, Duman S. βigh gene analysis in the different diagnosis of corneal dystrophies. Cornea 2001; 20: 64-8.
2. Klintworth GK. Advances in the molecular genetics of corneal dystrophies. Am J Ophthalmol 1999; 128: 747-54.
3. Konishi M, Mashima Y, Nakamura Y, et al. Granular-lattice (Avellino) corneal dystrophy in Japanese patients. Cornea 1997; 16: 635-8.

CE IVD

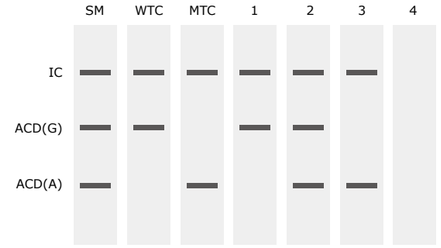
Result & Data interpretation

DiaPlexQ™ Avellino Corneal Dystrophy (ACD) Real-Time PCR Genotyping Kit



Color	Genotyping
Red	ACD G/G type
Blue	ACD A/A type
Green	ACD G/A type
Black	Non-Template Control

DiaPlexC™ Avellino Corneal Dystrophy (ACD) Genotyping Kit



SM : Standard Marker
IC : Internal Control
WTC : Wild Type Control
MTC : Mutant Type Control

Lane	Interpretation (detection)
1	ACD (G/G homozygote, normal)
2	ACD (G/A heterozygote, mutant)
3	ACD (A/A homozygote, mutant)
4	Required re-experiment

Fig. 1. Allelic Discrimination Plot information (ABI7500 FAST)

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQH26-K020 (20 reaction)	*DiaPlexQ*™ Avellino Corneal Dystrophy (ACD) Real-Time PCR Genotyping Kit	2X Multiplex Real-Time PCR Smart mix (ACD) Primer & Probe Mixture (ACD) A/A type Control DNA (ACD) G/A type Control DNA (ACD) G/G type Control DNA (ACD) Nuclease free Water
	SQH26-K100 (100 reaction)		
Conventional (End-point) PCR	SHG06-K020 (20 reaction)	*DiaPlexC*™ Avellino Corneal Dystrophy (ACD) Genotyping Kit	2X Multiplex PCR Smart mix (with UDG) (ACD) Primer Mixture (ACD) Standard Marker (ACD) Wild type Control (ACD) Mutant type Control (ACD) Nuclease free Water
	SHG06-K100 (100 reaction)		

DiaPlexQ

Apolipoprotein E (ApoE) Genotyping Kit

Real-Time

DiaPlexC

Apolipoprotein E (ApoE) Genotyping Kit

Conventional

Real-Time PCR (or Multiplex allele-specific PCR) based assay system for the genotyping of the ApoE gene SNP related to alzheimer's disease

Pathogen Information

Apolipoprotein E (ApoE) consists of three isoforms: E2, E3 and E4. These three isoforms make six genotypes, (homozygous genotypes: E2/E2, E3/E3 E4/E4 and heterozygous genotypes: E2/E3, E2/E4, E3/E4). Isoform E2 is usually known as a protective isoform whereas isoform E4 is generally responsible for diseases. The predominant abnormalities are due to a single nucleotide polymorphism (SNP) of codon 112 (Cys/Arg) and codon 158 (Arg/Cys). The polymorphism has functional effects on the lipoprotein metabolism. ApoE is the primary ligand for two receptors, LDL receptors found in the liver and other tissues and ApoE specific receptors found in the liver. The co-ordinate interaction of these lipoprotein complexes with their receptors forms the basis for the metabolic regulation of cholesterol. ApoE has been found to be associated with elevated cholesterol levels or lipid derangements that lead to various clinical problems like coronary heart diseases, strokes, periphery artery diseases, and diabetes mellitus. In addition to the genotype-phenotype associations with the cardiovascular disease, the alleles and isoforms of ApoE have been related to dementias, most commonly Alzheimer's disease. Determining the genotype of ApoE is thus considered to be an important test for patients with the disease, as well as a precautionary test for healthy people.

Product Specification

	***DiaPlexQ*™ ApoE Genotyping Kit**	***DiaPlexC*™ Apolipoprotein E (ApoE) Genotyping Kit**
Detection target	ApoE genotype (Mutation T112C and T158C of ApoE gene) E2/E2, E3/E3, E4/E4, E2/E3, E2/E4, E3/E4	
Detection technology	Real-Time PCR	Conventional (End-point) Multiplex PCR
Specimen type	Blood	
Compatible instruments*	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)	ABI Veriti thermal Cycler (Applied Biosystems) recommended
PCR running time	~ 1 hr 30 min	~ 1 hr 30 min

* Please inquire us for compatible instrument information before use.

Product Features

- HotStart PCR system : Ultra high specific and sensitive result
- UDG system : No carryover contamination (*DiaPlexQ*™)
- Multiplex PCR : Multiple targets in a single reaction
- Reliable system : Automatic Internal control (*DiaPlexC*™)
- Positive control included
- Easy-to-use master mix
- CE certification

Reference

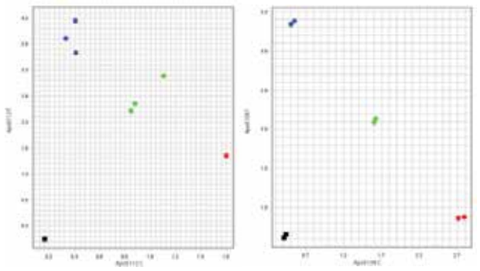
1. Lepara O, Valjevac A, Alajbegovic A, Zaciragic A, Nakas-Icindic E (August 2009). "Decreased serum lipids in patients with probable Alzheimer's disease". Bosn J Basic Med Sci 9 (3): 215-20.
2. Golomb BA, Evans MA (2008). "Statin adverse effects : a review of the literature and evidence for a mitochondrial mechanism". Am J Cardiovasc Drugs 8 (6): 373-418

CE IVD

Result & Data interpretation

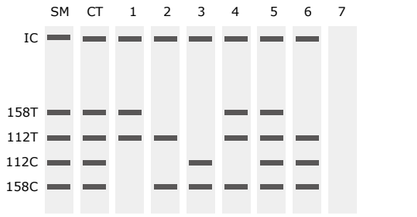
DiaPlexQ™ ApoE Genotyping Kit

<ApoE 112 site> <ApoE 158 site>



ApoE genotype	SNP	112 site	158 site
E2/E2	TT/TT	● T/T type	● T/T type
E2/E3	TT/TC	● T/T type	● T/C type
E2/E4	TC/TC	● T/C type	● T/C type
E3/E3	TT/CC	● T/T type	● C/C type
E3/E4	TC/CC	● T/C type	● C/C type
E4/E4	CC/CC	● C/C type	● C/C type
		■ Non-Template Control	

DiaPlexC™ Apolipoprotein E (ApoE) Genotyping Kit



SM : Standard Marker
IC : Internal Control
CT : Control Template

Lane	Interpretation (detection)	
	SNP	ApoE genotype
1	112 TT/158 TT	E2/E2
2	112 TT/158 CC	E3/E3
3	112 CC/158 CC	E4/E4
4	112 TT/158 TC	E2/E3
5	112 TC/158 TC	E2/E4
6	112 TC/158 CC	E3/E4
7	Required re-experiment	

Fig. 1. Allelic Discrimination Plot information (ABI7500 FAST)

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQH01-K020 (20 reaction)	*DiaPlexQ*™ ApoE Genotyping Kit	2X Multiplex Real-Time PCR Smart mix (ApoE) Primer & Probe Mixture (ApoE 112) Primer & Probe Mixture (ApoE 158) T/T type Control DNA (ApoE 112) T/C type Control DNA (ApoE 112) C/C type Control DNA (ApoE 112) T/T type Control DNA (ApoE 158) T/C type Control DNA (ApoE 158) C/C type Control DNA (ApoE 158) Nuclease free Water
	SQH01-K100 (100 reaction)		
Conventional (End-point) PCR	SHG01-K020 (20 reaction)	*DiaPlexC*™ Apolipoprotein E (ApoE) Genotyping Kit	2X Multiplex PCR Smart mix (ApoE) Primer Mixture (ApoE) Standard Marker (ApoE) Control Template (ApoE) Nuclease free Water
	SHG01-K100 (100 reaction)		

DiaPlexQ

MTHFR Genotyping Kit

Real-Time

DiaPlexC

MTHFR Genotyping Kit

Conventional

Real-Time PCR (or Multiplex allele-specific PCR) based assay system for the genotyping of the MTHFR gene C677T and A1298C SNP related to hyperhomocysteinemia

Pathogen Information

The MTHFR gene provides instructions to make an enzyme called methylenetetrahydrofolate reductase. This enzyme is responsible for converting one form of folate (5, 10-methylentetrahyfrofolate) into the unstable but most active folate (5-methyltetrahydrofolate or methylfolate) in every single cell of the human body. Methylfolate has two critical tasks, it helps make neurotransmitters in our brain and it allows for making a critical compound called s-adenosylmethionine (SAMe), which helps regulate more than 200 enzymes in the human body. This enzyme catalyzes the conversion of homocysteine to another amino acid, methionine. The polymorphism of the MTHFR gene generally occurs through the mutation of C677T and A1298C that reduces the functional ability of the MTHFR enzyme and causes an increase in levels of homocysteine in the blood as well as dysregulation of various important enzymes responsible to maintain the homeostasis in the body. So, MTHFR polymorphism can cause cerebrovascular disease, cardiovascular disease, peripheralvascular disease and a variety of venous thrombosis risks, cancer, depression etc. In addition, it is reported to cause birth defects, especially neural tube defects and premature birth of the fetus. So, it is important to screen the MTHFR to reduce risk factors in general and to prevent health from worsening in people who have already noticed the above mentioned diseases in their family health.

Product Specification

	***DiaPlexQ*™ MTHFR Genotyping Kit**	***DiaPlexC*™ MTHFR Genotyping Kit**
Detection target	Mutation C677T and A1298C of MTHFR gene	
Detection technology	Real-Time PCR	Conventional (End-point) Multiplex PCR
Specimen type	Blood	
Compatible instruments*	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)	ABI Veriti thermal Cycler (Applied Biosystems) recommended
PCR running time	~ 1 hr 30 min	~ 1 hr 30 min

* Please inquire us for compatible instrument information before use.

Product Features

- HotStart PCR system : Ultra high specific and sensitive result
- UDG system : No carryover contamination (*DiaPlexQ*™)
- Multiplex PCR : Multiple targets in a single reaction
- Reliable system : Automatic Internal control (*DiaPlexC*™)
- Positive control included
- Easy-to-use master mix
- CE certification

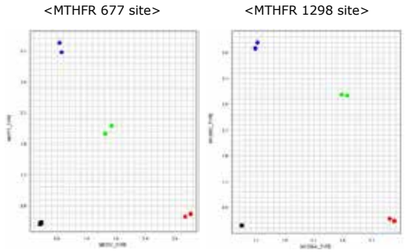
Reference

1. Fodinger M, Horl WH, Sunder-Plassmann G (2000). "Molecular biology of 5,10 methylenetetrahydrofolate reductase". J Nephrol 13 (1): 20-33
2. Schneider JA, Rees DC, Lui YT, Clegg JB (May 1998). "Worldwide distribution of a common methylenetetrahydrofolate reductase mutation". Am. J. Hum. Genet, 62 (5): 1258-60
3. Frosst P, Blom HJ, Milos R, Goyette P, Sheppard CA, Matthews RG, Boers GJ, den Heijer M, Kluijtmans LA, van den Heuval LP et al. (May 1995). "A candidate genetic risk factor for vascular disease: a common mutation in methylene-tetrahydrofolate reductase". Nat. Genet. 10 (1): 111-3.

CE IVD

Result & Data interpretation

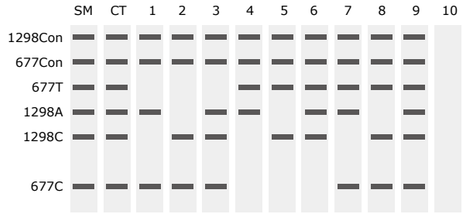
DiaPlexQ™ MTHFR Genotyping Kit



Color	677 site	1298 site
Red	C/C type	A/A type
Blue	T/T type	C/C type
Green	C/T type	A/C type
Black	Non-Template Control	

Fig. 1. Allelic Discrimination Plot information (ABI7500 FAST)

DiaPlexC™ MTHFR Genotyping Kit



SM : Standard Marker
1298Con : 1298 Control

CT : Control Template
677Con : 677 Control

Lane	Interpretation (detection)	Lane	Interpretation (detection)
1	677CC, 1298AA (Normal)	6	677TT, 1298AC
2	677CC, 1298CC	7	677CT, 1298AA
3	677CC, 1298AC	8	677CT, 1298CC
4	677TT, 1298AA	9	677CT, 1298AC
5	677TT, 1298CC	10	Required re-experiment

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQH31-K020 (20 reaction)	*DiaPlexQ*™ MTHFR Genotyping Kit	2X Multiplex Real-Time PCR Smart mix (MTHFR) Primer & Probe Mixture (MTHFR 677) Primer & Probe Mixture (MTHFR 1298) C/C type Control DNA (MTHFR 677) C/T type Control DNA (MTHFR 677) T/T type Control DNA (MTHFR 677) A/A type Control DNA (MTHFR 1298) A/C type Control DNA (MTHFR 1298) C/C type Control DNA (MTHFR 1298) Nuclease free Water
	SQH31-K100 (100 reaction)		
Conventional (End-point) PCR	SHG31-K020 (20 reaction)	*DiaPlexC*™ MTHFR Genotyping Kit	2X Multiplex PCR Smart mix (MTHFR) Primer Mixture (MTHFR) Standard Marker (MTHFR) Control Template (MTHFR) Nuclease free Water
	SHG31-K100 (100 reaction)		

DiaPlexC

G6PD Genotyping Kit (African type)
G6PD Genotyping Kit (Asian type)

Conventional

CE IVD

Multiplex allele-specific PCR based assay system for screen of G6PD deficiency

Pathogen Information

G6PD, glucose-6-phosphate dehydrogenase is an enzyme found in the red blood cells (RBCs, erythrocytes). Its role is to protect RBCs from molecules called reactive oxygen that is usually formed in oxidative stress or after taking certain medication like antimalarial drugs. People with a G6PD deficiency can tolerate small amounts of these exposures, depending on the specific defect present in the gene. The G6PD deficiency is an X-linked recessive hereditary disease that is due to the single nucleotide polymorphism in certain target genes as mentioned below. In a G6PD deficiency condition, RBCs undergo a process called hemolysis that leads to anemia, even jaundice and kidney failure if untreated. A blood test may show as normal in a person with G6PD deficiency if it is done during or immediately following an acute episode of hemolysis. Genotyping of the G6PD gene is therefore important for taking early steps to maintain the health.

Product Specification

	***DiaPlexC*™ G6PD Genotyping Kit (African type)**	***DiaPlexC*™ G6PD Genotyping Kit (Asian type)**
Detection target	202 G → A 376 A → G 542 A → T 563 C → T (Mediterranean) 680 G → T 968 T → C	383 T → C (Vanua Lava) 487 G → A (Mahidol) 563 C → T (Mediterranean) 592 C → T (Coimbra) 871 G → A (Viangchan) 1360 C → T (Union) 1376 G → T (Canton) 1388 G → A (Kaiping)
Detection technology	Conventional (End-point) Multiplex PCR	
Specimen type	Blood	
Compatible instruments*	ABI Veriti thermal Cycler (Applied Biosystems) recommended	
PCR running time	~ 1 hr 30 min	~ 1 hr 30 min

* Please inquire us for compatible instrument information before use.

Product Features

- HotStart PCR system : Ultra high specific and sensitive result
- Multiplex PCR : Multiple targets in a single reaction
- Reliable system : Automatic Internal control
- Positive control included
- Easy-to-use master mix
- CE certification

Reference

1. YK Goo, SY Ji, et al. (May 2014). "First Evaluation of Glucose-6-Phosphate Dehydrogenase (G6PD) Deficiency in Vivax Malaria Endemic Regions in the Republic of Korea". PLOS ONE. 9 (5) : e97390
2. Mehta, A, Mason, P.J., and Vulliamy, T.J. (2000) Glucose-6-phosphate dehydrogenase deficiency. Baillieres Best Prat. Res. Clin. Haematol 13, 21-38
3. Beutler, E., Kuhl, W., Vives-Corrons, J.L., and Prchal, J.T. (1989) Molecular heterogeneity of glucose-6-phosphate dehydrogenase deficiency A-. Blood 74, 2550-2555.

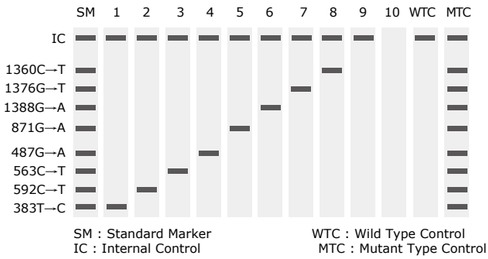
Result & Data interpretation

DiaPlexC™ G6PD Genotyping Kit (African type)

SM : Standard Marker
IC : Internal Control
WTC : Wild Type Control
MTC : Mutant Type Control

Lane	Interpretation (detection)	Lane	Interpretation (detection)
1	Negative	5	542 A → T
2	376 A → G	6	680 G → T
3	202 G → A	7	968 T → C
4	563 C → T (Mediterranean)	8	Required re-experiment

DiaPlexC™ G6PD Genotyping Kit (Asian type)



SM : Standard Marker
IC : Internal Control
WTC : Wild Type Control
MTC : Mutant Type Control

Lane	Interpretation (detection)	Lane	Interpretation (detection)
1	383 T → C (Vanua Lava)	6	1388 G → A (Kaiping)
2	592 C → T (Coimbra)	7	1376 G → T (Canton)
3	563 C → T (Mediterranean)	8	1360 C → T (Union)
4	487 G → A (Mahidol)	9	Negative
5	871 G → A (Viangchan)	10	Required re-experiment

Ordering Information

Technology	Cat. No.	Product	Contents
Conventional (End-point) PCR	SHG11-K020 (20 reaction)	*DiaPlexC*™ G6PD Genotyping Kit (African type)	2X Multiplex PCR Smart mix (G6PD-African type) Primer Mixture (G6PD-African type) Standard Marker (G6PD-African type) Mutant type Control (G6PD-African type) Wild type Control (G6PD-African type) Nuclease free Water
	SHG11-K100 (100 reaction)		
	SHG16-K020 (20 reaction)	*DiaPlexC*™ G6PD Genotyping Kit (Asian type)	2X Multiplex PCR Smart mix (G6PD-Asian type) Primer Mixture (G6PD-Asian type) Standard Marker (G6PD-Asian type) Mutant type Control (G6PD-Asian type) Wild type Control (G6PD-Asian type) Nuclease free Water
	SHG16-K100 (100 reaction)		

Molecular Diagnostics

Microbial Contamination Screening

Mycoplasma

Bacteria

Fungi

DiaPlexQ

Mycoplasma Detection Kit
Mycoplasma 9 Detection Kit

Real-Time

DiaPlexC

Mycoplasma Detection Kit

Conventional

Real-Time PCR (or Multiplex PCR) based assay system for detection of mycoplasma species in cell culture contaminants

Pathogen Information

Mycoplasma infections have been relatively common in cell culture: (5 - 35% of all cell cultures are infected and much higher in some countries that do not practice systematic detection and elimination). Biomedical product Mycoplasma infections which are typically difficult to detect during routine cell culture work can cause physiological and morphological distortions that affect experimental results. Furthermore, a Mycoplasma infection in one cell culture has the potential to spread to yet uninfected laboratory cell cultures.

Product Specification

	***DiaPlexQ*™ Mycoplasma Detetcion Kit**	***DiaPlexQ*™ Mycoplasma 9 Detetcion Kit**	***DiaPlexC*™ Mycoplasma Detection Kit**
Detection target	Mycoplasma of 65 species 54 *Mycoplasma sp.* 3 *Acholeplasma sp.* 6 *Spiroplasma sp.* 2 *Ureaplasma sp.*	Mycoplasma of 9 species *Acholeplasma laidlawii* *Mycoplasma synoviae* *Mycoplasma fermentans* *Mycoplasma hyorhinis* *Mycoplasma gallisepticum* *Mycoplasma orale* *Mycoplasma arginini* *Mycoplasma pnuemoniae* *Spiroplasma citri*	Mycoplasma of 65 species 54 *Mycoplasma sp.* 3 *Acholeplasma sp.* 6 *Spiroplasma sp.* 2 *Ureaplasma sp.*
Detection technology	Real-Time PCR		Conventional (End-point) Multiplex PCR
Specimen type	Culture media, Suspension media, Raw material and final material of Biopharmaceuticals		
Analytical sensitivity	10 - 10^2 copies	10 - 10^2 copies	10 - 10^2 copies
Compatible instruments*	ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad)		ABI Veriti thermal Cycler (Applied Biosystems) recommended
PCR running time	~ 2 hrs	~ 2 hrs	~ 2 hrs

* Please inquire us for compatible instrument information before use.

Product Features

- HotStart PCR system: Ultra high specific and sensitive result
- DnaFree™ system : No host genomic DNA contamination
- UDG system: No carryover contamination
- Multiplex PCR: Multiple targets in a single reaction
- Reliable system: Automatic PCR control (*DiaPlexC*™)
- Positive control included
- Easy-to-use master mix

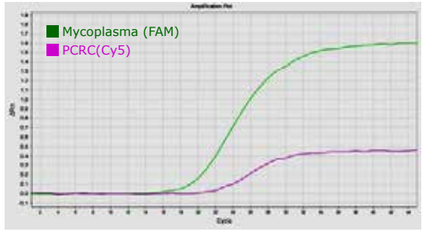
Reference

1. McGarrity G.J., Steiner, T. and Vanaman, V. Detection of Mycoplasmal Infection of Cell Cultures by DNA Fluorochrome Staining. In Methods in Mycoplasmology, Vol. 2, J. G. Tully and S. Razin, eds. (Academic Press, New York, 1983) p. 183-190.
2. McGarrity G.J., Vanaman V, Sarama J. Cytogenetic effects of mycoplasmal infection of cell cultures: a review. In Vitro 20: 1-18, 1984

- Easy-to-use master mix

Result & Data interpretation

DiaPlexQ™ Mycoplasma Detection Kit



DiaPlexQ™ Mycoplasma 9 Detection Kit

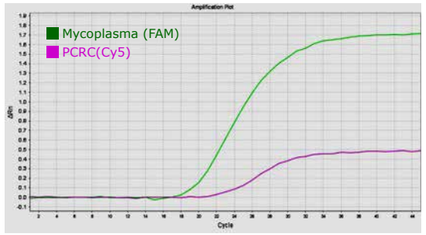
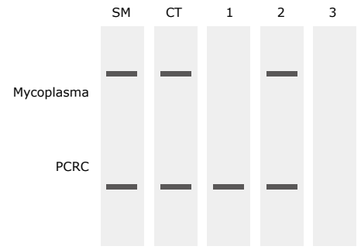


Fig. 1. Amplification Plot information (ABI7500 FAST)

DiaPlexC™ Mycoplasma Detection Kit



SM : Standard Marker
PCRC : PCR Control
CT : Control Template
NTC : Non-Template Control

Lane	Interpretation (detection)
1	Negative (or NTC)
2	Mycoplasma
3	Required re-experiment

Ordering Information

Technology	Cat. No.	Product	Contents
Real-Time PCR	SQD61-K020 (20 reaction)	*DiaPlexQ*™ Mycoplasma Detection Kit	2X Multiplex Real-Time PCR Smart mix (with UDG) (Mycoplasma) Primer & Probe Mixture (Mycoplasma) Control Template (Mycoplasma) Nuclease free Water
	SQD61-K100 (100 reaction)		
	SQD64-K020 (20 reaction)	*DiaPlexQ*™ Mycoplasma 9 Detection Kit	2X Multiplex Real-Time PCR Smart mix (with UDG) (Mycoplasma 9) Primer & Probe Mixture (Mycoplasma 9) Control Template (Mycoplasma 9) Nuclease free Water
	SQD64-K100 (100 reaction)		
Conventional (End-point) PCR	SMD61-K020 (20 reaction)	*DiaPlexC*™ Mycoplasma Detection Kit	2X Multiplex PCR Smart mix (with UDG) (Mycoplasma) Primer Mixture (Mycoplasma) Standard Marker (Mycoplasma) Control Template (Mycoplasma) Nuclease free Water
	SMD61-K100 (100 reaction)		

DiaPlexC

Bacteria Detection Kit

Conventional

Multiplex PCR based assay system for detection of 85 species of Bacteria in cell culture contaminants

Pathogen Information

Bacteria is a widespread cell culture contaminant, usually introduced through poor aseptic technique. Sources of contamination include the cells themselves, the media or serum, and airborne contamination. Even when excellent aseptic technique is applied, it is essential to monitor and test for contamination.

Product Specification

Detection target	Bacteria of 85 species
Detection technology	Conventional (End-point) Multiplex PCR
Specimen type	Culture media, Suspension media, Raw material and final material of Biopharmaceuticals
Analytical sensitivity	10 - 10^3 copies
Compatible instruments*	ABI Veriti thermal Cycler (Applied Biosystems) recommended
PCR running time	~ 2 hrs

* Please inquire us for compatible instrument information before use.

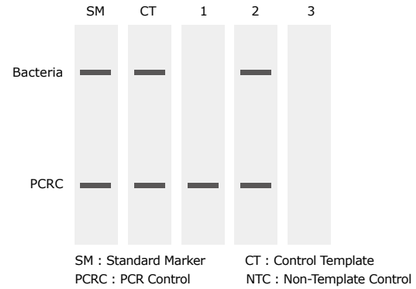
Product Features

- HotStart PCR system: Ultra high specific and sensitive result
- DnaFree™ system : No host genomic DNA contamination
- UDG system: No carryover contamination
- Multiplex PCR: Multiple targets in a single reaction
- Reliable system: Automatic PCR control
- Positive control included
- Easy-to-use master mix

Reference

1. Park SH, Kim HJ, Kim JH, Kim TW, Kim HY. Simultaneous detection and identification of Bacillus cereus group bacteria using multiplex PCR. J Microbiol Biotechnol. 2007 Jul;17(7):1177-82.
2. Aksu G, Ruhi MZ, Akan H, Bengisun S, Ustün C, Arslan O, Ozenci H. Aerobic bacteria and fungal infections in peripheral blood stem cell transplants. Bone Marrow Transplant. 2001 Jan;27(2):201-5.
3. Warwick S, Wilks M, Hennessy E, Powell-Tuck J, Small M, Sharp J, Millar MR. Use of quantitative 16S ribosomal DNA detection for diagnosis of central vascular catheter associated bacteria infection. J Clin Microbiol. 2004 Apr;42(4):1402-8.

Result & Data interpretation



SM : Standard Marker
PCRC : PCR Control
CT : Control Template
NTC : Non-Template Control

Lane	Interpretation (detection)
1	Negative (or NTC)
2	Bacteria
3	Required re-experiment

Ordering Information

Technology	Cat. No.	Product	Contents
Conventional (End-point) PCR	SMD62-K020 (20 reaction)	*DiaPlexC*™ Bacteria Detection Kit	2X Multiplex PCR Smart mix (with UDG) (Bacteria) Primer Mixture (Bacteria) Standard Marker (Bacteria) Control Template (Bacteria) Nuclease free Water
	SMD62-K100 (100 reaction)		

DiaPlexC

Fungi Detection Kit

Conventional

Multiplex PCR based assay system for detection of 16 species of Fungi in cell culture contaminants

Pathogen Information

Fungi is one of the major ubiquitously found contaminants in the laboratory. It can contaminate any kind of biological related materials and spoil them. In the laboratory, cell cultures, culture media, broth, serum and plasma are all highly susceptible to the fungal contamination unless strict aseptic measures are applied. Even when excellent aseptic technique is applied, it is essential to monitor and test to confirm results are free from contamination. In the absence of antibiotics they will grow rapidly; however, if antibiotics are routinely used low levels of fungal infections may develop that might be more difficult to observe.

Product Specification

Detection target	Fungi of 16 species *Aspergillus niger*, *Candida albicans*, *Candida parapsilosis*, *Malassezia furfur*, *Rhodotorula mucilaginosa*, *Pneumocystis jirovecii*, *Paecilomyces sp.*, *Penicillium sp.*, *Saccharomyces cerevisiae*, *Trichosporon asahii*, *Trichosporon Pullulans*, *Candida krusei*, *Candida glabrata*, *Candida tropicalis*, *Cryptococcus neoformans*, *Aspergillus fumigatus*
Detection technology	Conventional (End-point) Multiplex PCR
Specimen type	Culture media, Suspension media, Raw material and final material of Biopharmaceuticals
Analytical sensitivity	10 - 10^3 copies
Compatible instruments*	ABI Veriti thermal Cycler (Applied Biosystems) recommended
PCR running time	~ 2 hrs

* Please inquire us for compatible instrument before use.

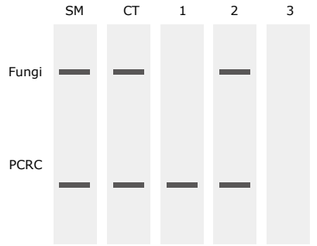
Product Features

- HotStart PCR system: Ultra high specific and sensitive result
- DnaFree™ system : No host genomic DNA contamination
- UDG system: No carryover contamination
- Multiplex PCR: Multiple targets in a single reaction
- Reliable system: Automatic PCR control
- Positive control included
- Easy-to-use master mix

Reference

1. Judith Behnsen, Andrea Hartmann, Jeannette Schmaler, Alexander Gehrke, Axe A. Brakhage, and Peter F. Zipfe. (2008) The Opportunistic Human Fungus Aspergillus fumigatus Evades the Host Complement System. Infect. Immun. 2008. Vol. 76 no. 2, 820-827.
2. Mahmoud A. Ghannoum, Richard J. Jurevic, Pranab K. Mukherjee, Fan Cui, Masoumeh Sikaroodi, Ammar Naqvi, Patrick M. Gillevet. Characterization of the Oral Fungal Microbiome (Mycobiome) in Healthy Individuals. 2010. Vol 6.

Result & Data interpretation

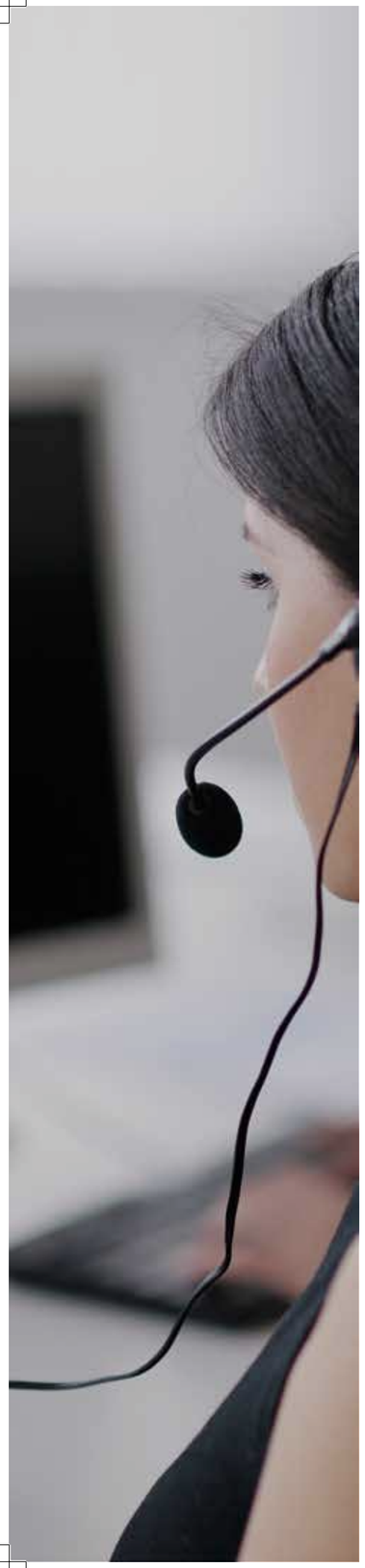


SM : Standard Marker
PCRC : PCR Control
CT : Control Template
NTC : Non-Template Control

Lane	Interpretation (detection)
1	Negative (or NTC)
2	Fungi
3	Required re-experiment

Ordering Information

Technology	Cat. No.	Product	Contents
Conventional (End-point) PCR	SMD63-K020 (20 reaction)	*DiaPlexC*™ Fungi Detection Kit	2X Multiplex PCR Smart mix (with UDG) (Fungi) Primer Mixture (Fungi) Standard Marker (Fungi) Control Template (Fungi) Nuclease free Water
	SMD63-K100 (100 reaction)		



SolGent Customized Development

SolGent provides a PCR-based customized development service in molecular diagnostics matching the needs for each customer's research or business. The platform for SolGent's customized development service is a powerful genetic analysis technology including sequencing and bioinformatics, and high-efficiency SolGent PCR relative products. Molecular diagnostic kits are in high demands for research and diagnostic purposes with great potential for detection and amplification of target genes. SolGent's customized development service is an one-stop, in-house system with high fidelity in diagnosis.

Application

- Viral Pathogen Detection Kit
- Bacterial Pathogen Detection Kit
- Differential Gene Expression
- Therapeutic Drug Monitoring
- SNP Genotyping
- Genetic Disease Analysis
- Food & Environmental Pathogen Detection
- Forensic Studies
- Plant/Animal Species Classification
- GMO Identification

Work Flow

	Step 1	Step 2	Step 3
Milestones	Genetic Analysis	PCR Setup	Product Development
Specification	SNP VNTP MS/SSR/STR	Multiplex PCR Allele Specific PCR OneStep RT-PCR Real-Time PCR OneStep qRT-PCR	Manufacturing QC Guideline
Timeline	2 - 4 Weeks	2 - 4 Weeks	2 - 4 Weeks

SolGent Molecular Diagnostic Kits

Based on July 30 (2015)

Pathogen Detection Kit

Category	Technology	Product	Cat. No.	Description	Specimen*	Registration*	Page
Ebola	Real-Time OneStep RT-PCR	*DiaPlexQ*™ Ebola Virus Detection Kit - Zaire	SQD71	Detection of Ebola Virus Zaire	B, S, P	CE IVD	16
Tuberculosis	Real-Time PCR	*DiaPlexQ*™ MTC/NTM Detection Kit	SQD20, SQD21	Simultaneous detection of MTC and NTM complex	S, BAL, C, U, BF, B, T	CE IVD	18
	Multiplex PCR	*DiaPlexC*™ MTC/NTM Detection Kit	SMD21	Simultaneous detection of MTC and NTM complex	NS, NA, BAL, O, S	CE IVD	18
		DiaPlexC™ MTB/M.Bovis Detection Kit	SMD22	Simultaneous detection of MTB and *M. bovis*	NS, NA, BAL, S	CE IVD	20
		DiaPlexC™ M.Avium/M. Intracellulare Detection Kit	SMD23	Simultaneous detection of *M. avium* and *M. intracellulare*	S, BAL, L, G, U, BF, B, T, ST	CE IVD	22
Respiratory Disease	Real-Time OneStep RT-PCR	*DiaPlexQ*™ RV16 Detection Kit	SQD50	Simultaneous detection of 16 major respiratory viruses	NS, NA, BAL, O, S	RUO	24
		DiaPlexQ™ MERS Virus Detection Kit	SQD53, SQD54	Detection of MERS Virus	NS, NA, BAL, O, S	RUO	28
		DiaPlexQ™ Influenza Virus A/B & A Subtype Detection Kit	SQD43	Simultaneous typing of influenza virus A and B, A subtypes	NS, NA, BAL, O, S	RUO	30
		DiaPlexQ™ Influenza Virus A/B Detection Kit	SQD42	Simultaneous typing of influenza virus A and B	NS, NA, BAL, O, S	CE IVD	32
		DiaPlexQ™ Influenza Virus A Subtype Detection Kit	SQD41	Simultaneous typing of influenza virus A subtypes	NS, NA, BAL, O, S	CE IVD	34
		DiaPlexQ™ Entero Virus (Respiratory) Detection Kit	SQD51	Detection of enterovirus (A/B/D type)	NS, NA, BAL, TS, S	RUO	36
	OneStep Multiplex RT-PCR	*DiaPlexC*™ RV13 Detection Kit	SMD50	Simultaneous detection of 13 major respiratory viruses	NS, NA, BAL, O, S	CE IVD	26
		DiaPlexC™ Influenza Virus A/B Detection Kit	SMD42	Simultaneous typing of influenza virus A and B	NS, NA, BAL, O, S	CE IVD	32
		DiaPlexC™ Influenza Virus A Subtype Detection Kit	SMD41	Simultaneous typing of influenza virus A subtypes	NS, NA, BAL, O, S	CE IVD	34
Sexually Transmitted Infection	Real-Time PCR	*DiaPlexQ*™ STI 12 Detection Kit	SQD95	Simultaneous detection of 12 pathogens causing STIs	US, U	RUO	38
		DiaPlexQ™ STI 6 Detection Kit	SQD94	Simultaneous detection of 6 pathogens causing STIs	US, U	RUO	38
		DiaPlexQ™ CT/NG Detection Kit	SQD93	Simultaneous detection of *C. trachomatis* and *N. gonorrhoeae*	US, U	RUO	40
	Multiplex PCR	*DiaPlexC*™ HPV Screening System	SHG40	HPV screening	CS	RUO	42
		DiaPlexC™ HPV Genotyping System	SHG41	HPV genotyping	CS	RUO	44
Pneumonia	Real-Time PCR	*DiaPlexQ*™ PneumoPatho 13 Detection Kit	SQD81	Simultaneous detection of 13 pathogens causing pneumonia	NS, NA, BAL, O, S	RUO	46
		DiaPlexQ™ PneumoPatho 6 Detection Kit	SQD94	Simultaneous detection of 6 pathogens causing pneumonia	NS, NA, BAL, O, S	RUO	48
Dengue Fever	Real-Time OneStep RT-PCR	*DiaPlexQ*™ Dengue Virus Detection Kit	SQD01	Detection of dengue virus	B	CE IVD	50
Malaria	Multiplex PCR	*DiaPlexC*™ Malaria Detection Kit	SMD35	Identification of 4 malaria species	B	CE IVD	52

Pathogen Detection Kit

Category	Technology	Product	Cat. No.	Description	Specimen*	Registration*	Page
Multidrug resistant Gram-negative Bacterial Infection	Multiplex PCR	*DiaPlexC*™ CRE Detection Kit	SMD71	Simultaneous detection of CRE genes (*VIM, IMP, NDM, KPC*)	U, BA, S, B, ST	CE IVD	54
Gastrointestinal Infection	Real-Time OneStep RT-PCR	*DiaPlexQ*™ Entero Virus (Stool) Detection Kit	SQD52	Detection of enterovirus (A/B/C/D type)	ST	RUO	56

Human Genotyping Kit

Category	Technology	Product	Cat. No.	Description	Specimen*	Registration*	Page
Avellino Corneal Dystrophy	Real-Time PCR	*DiaPlexQ*™ Avellino Corneal Dystrophy (ACD) Real-Time PCR Genotyping Kit	SQH26	ACD genotyping	B, BC, H	CE IVD	60
	Multiplex PCR	*DiaPlexC*™ Avellino Corneal Dystrophy (ACD) Genotyping Kit	SHG06	ACD genotyping	B, BC, H	CE IVD	60
Alzheimer's Disease	Real-Time PCR	*DiaPlexQ*™ ApoE Genotyping Kit	SQH01	ApoE mutation (T112C, T158C) detection	B	CE IVD	62
	Multiplex PCR	*DiaPlexC*™ Apolipoprotein E (ApoE) Genotyping Kit	SHG01	ApoE mutation (T112C, T158C) detection	B	CE IVD	62
Hyperhomocysteinemia	Real-Time PCR	*DiaPlexQ*™ MTHFR Genotyping Kit	SQH31	Detection of C677T and A1298C SNP of the MTHFR gene	B	CE IVD	64
	Multiplex PCR	*DiaPlexC*™ MTHFR Genotyping Kit	SHG31	Detection of C677T and A1298C SNP of the MTHFR gene	B	CE IVD	64
G6PD Deficiency	Multiplex PCR	*DiaPlexC*™ G6PD Genotyping Kit (African type)	SHG11	G6PD mutation	B	CE IVD	66
		DiaPlexC™ G6PD Genotyping Kit (Asian type)	SHG16	G6PD mutation	B	CE IVD	66

Microbial Contamination Screening Kit

Category	Technology	Product	Cat. No.	Description	Specimen*	Registration*	Page
Mycoplasma	Real-Time PCR	*DiaPlexQ*™ Mycoplasma Detection Kit	SQD61	Detection of 65 mycoplasma species	CM, SM, R	NN	70
		DiaPlexQ™ Mycoplasma 9 Detection Kit	SQD64	Detection of 9 major mycoplasma species	CM, SM, R	NN	70
	Multiplex PCR	*DiaPlexC*™ Mycoplasma Detection Kit	SMD61	Detection of 65 mycoplasma species	CM, SM, R	NN	70
Bacteria	Multiplex PCR	*DiaPlexC*™ Bacteria Detection Kit	SMD62	Detection of 85 baterial species	CM, SM, R	NN	72
Fungi	Multiplex PCR	*DiaPlexC*™ Fungi Detection Kit	SMD63	Detection of 16 Fungal species	CM, SM, R	NN	74

* Specimen
B : Blood, BA : Bile acid, BAL : Bronchoalveolar/Bronchial lavage, BC : Buccal epithelial cell, BF : Body fluids, C : Cerebrospinal fluid, CM : Culture media, CS : Cervical swab specimen/Liquid based cytology specimen, G : Gastric lavage, H : Hair root, L : Lung biopsy, NA : Nasopharyngeal/ Nasal aspirate, NS : Nasopharyngeal/Nasal swab, O : Oropharyngeal swab, P : Plasma, R : Raw material and final material of Biopharmaceuticals, S : Serum, SM : Suspension media, ST : Stool, T : Tissue/Tissue biopsy, TS : Throat swab, U : Urine, US : Urogenital swab specimen
* Registration
RUO : Research use only, NN : Not necessary