

“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 (ISO 9001: 2015, ISO 13485: 2016) 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 Hyeon Koon Myeong (CEO)

Contents

Q Real-Time PCR C Conventional PCR

| | |
|------------------------|----|
| Overview | 7 |
| SolGent Overview | 8 |
| SolGent PCR Technology | 12 |

Molecular Diagnostics

| | |
|---------------------------|----|
| Pathogen Detection | 15 |
|---------------------------|----|

Tuberculosis

| | |
|--|----|
| C <i>DiaPlexC</i> TM MTC/NTM Detection Kit | 16 |
| Q <i>DiaPlexQ</i> TM MTC/NTM Detection Kit | 18 |
| C <i>DiaPlexC</i> TM MTB/M.Bovis Detection Kit | 20 |
| C <i>DiaPlexC</i> TM M.Avium/M.Intracellulare Detection Kit | 22 |

Respiratory Disease

| | |
|---|----|
| Q <i>DiaPlexQ</i> TM RV16 Detection Kit | 24 |
| C <i>DiaPlexC</i> TM RV13 Detection Kit | 26 |
| Q <i>DiaPlexQ</i> TM MERS Virus Detection Kit | 28 |
| Q <i>DiaPlexQ</i> TM Influenza Virus A/B & A Subtype Detection Kit | 30 |
| Q <i>DiaPlexQ</i> TM Influenza Virus A/B Detection Kit | 32 |
| C <i>DiaPlexC</i> TM Influenza Virus A/B Detection Kit | 32 |
| Q <i>DiaPlexQ</i> TM Influenza Virus A Subtype Detection Kit | 34 |
| C <i>DiaPlexC</i> TM Influenza Virus A Subtype Detection Kit | 34 |
| Q <i>DiaPlexQ</i> TM Entero Virus Detection Kit | 36 |

Sexually Transmitted Infection

| | |
|--|----|
| Q <i>DiaPlexQ</i> TM STI 12 Detection Kit | 38 |
| Q <i>DiaPlexQ</i> TM STI 6 Detection Kit | 38 |

Others

| | |
|---|----|
| Q <i>DiaPlexQ</i> TM PneumoPatho 13 Detection Kit | 40 |
| Q <i>DiaPlexQ</i> TM ZCD Detection Kit (ZIKV, CHIKV, DENV) | 42 |
| Q <i>DiaPlexQ</i> TM Dengue Virus Detection Kit | 44 |
| C <i>DiaPlexC</i> TM Malaria Detection Kit | 46 |
| C <i>DiaPlexC</i> TM CRE Detection Kit | 48 |
| Q <i>DiaPlexQ</i> TM Ebola Virus Detection Kit - Zaire | 50 |

Molecular Diagnostics

| | |
|-------------------------|----|
| Human Genotyping | 53 |
|-------------------------|----|

Corneal Dystrophy

| | |
|---|----|
| Q <i>DiaPlexQ</i> TM Avellino Corneal Dystrophy (ACD) Real-Time PCR Genotyping Kit | 54 |
| C <i>DiaPlexC</i> TM Avellino Corneal Dystrophy (ACD) Genotyping Kit | 54 |
| Q <i>DiaPlexQ</i> TM 5 Types Corneal Dystrophy Detection Kit (ACD, RBCD, LCD, TBCD, GCD) | 56 |

Alzheimer's Disease

| | |
|--|----|
| Q <i>DiaPlexQ</i> TM ApoE Genotyping Kit | 58 |
| C <i>DiaPlexC</i> TM Apolipoprotein E (ApoE) Genotyping Kit | 58 |

Hyperhomocysteinemia

| | |
|--|----|
| Q <i>DiaPlexQ</i> TM MTHFR Genotyping Kit | 60 |
| C <i>DiaPlexC</i> TM MTHFR Genotyping Kit | 60 |

G6PD Deficiency

| | |
|--|----|
| C <i>DiaPlexC</i> TM G6PD Genotyping Kit (Asian type) | 62 |
| C <i>DiaPlexC</i> TM G6PD Genotyping Kit (African type) | 62 |

| | |
|---------------------------------------|----|
| SolGent Customized Development | 65 |
|---------------------------------------|----|

| | |
|--|----|
| SolGent Molecular Diagnostic Kits | 66 |
|--|----|



Overview

| | |
|------------------------|----|
| SolGent Overview | 8 |
| SolGent PCR Technology | 12 |

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. All products including the molecular diagnostic kits are manufactured in-house and adhere to global standards ISO9001:2015 and ISO13485:2016. Many of our diagnostic kits have received CE-IVD certification with additional products launching in late 2015 currently processing certification.



ISO13485:2016



ISO9001:2015



Conformite European (CE-IVD)



Headquarters and R&D (Daejeon in Korea)

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**

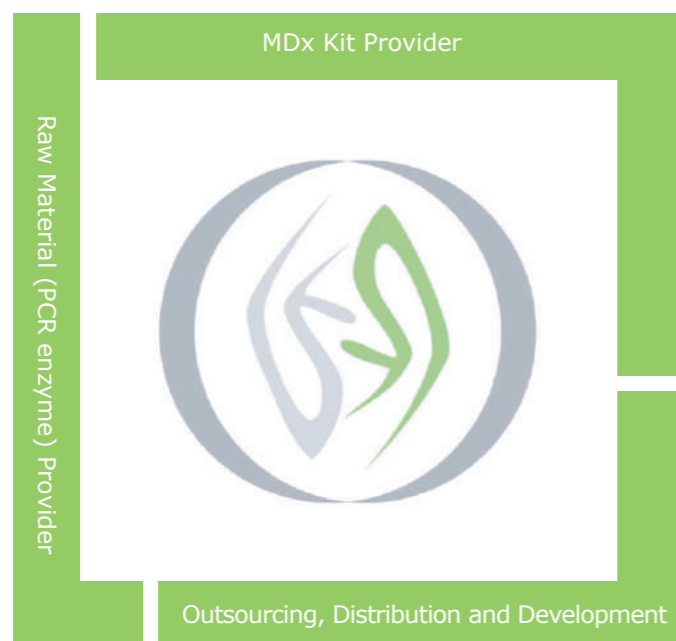
We provide molecular diagnostic kits both to detect highly prevalent pathogens that cause serious diseases like tuberculosis, pneumonia or dengue fever and to reveal genetic abnormalities to prevent exacerbation of existing conditions like ACD (Avellino Corneal Dystrophy). We are looking to establish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



Molecular Diagnostic

The molecular diagnostic business has introduced more than 40 kinds of products to diagnose human genotyping, respiratory virus detection, tuberculosis, sexually transmitted infection and mosquito-related diseases detection kits for a healthy life since 2009.



Partnership

We have a trusted B2C area through CRS(Customer Research Service) and Open System for CDSMD (Customized Development System for MDx). We are listening to the needs of the market by maintaining B2B, and we maintain strategic alliances with several companies, such as OEM and ODM.
· OEM · ODM · Bulk package · Genotyping · PCR set up · Full sequencing



OEM, ODM, LDT

SolGent have supplied products as contents providers for molecular diagnostic kits to pharmaceutical companies and government organizations. We are pleased to provided our technological items and raw materials for your current and developing products. Also, we are able to supply our end-products or customized products as OEM for your business. We operate at a competitive price and our products are based on our possession of the original technologies and our expert knowledge.



B2B

SolGent have a variety of forms of strategic alliances including collaborations, technological alliances and investment partnership. We are looking for partnerships to advance our cost, time and labor saving models to lead the global molecular biological and diagnostic market.

SolGent Customer Service

SolGent Co., Ltd. (Overseas Business Department)

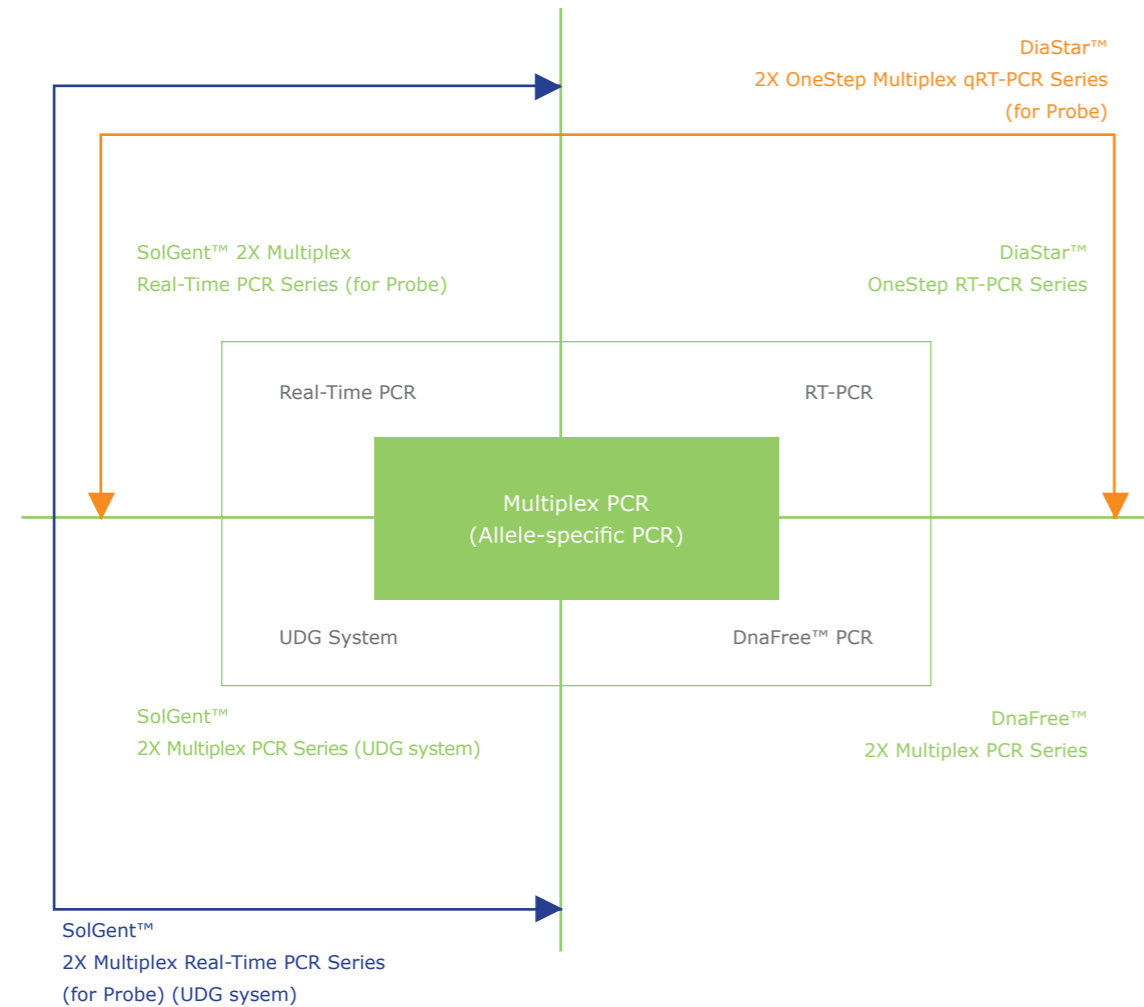
Tel : +82-70-7805-7396 | Fax : +82-42-864-5690

E-mail : global@solgent.com | Website : www.solgent.com

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.

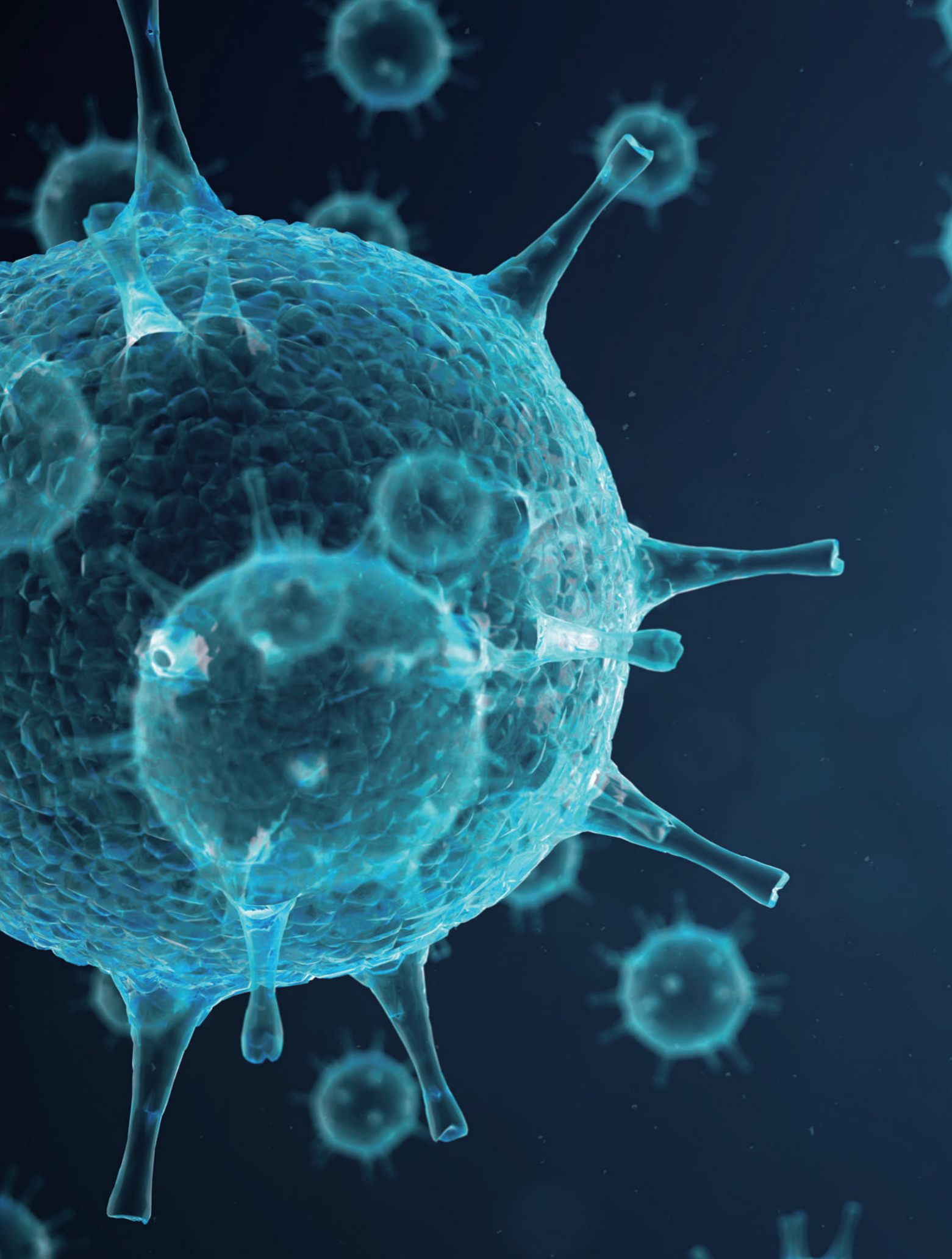
| Technology | Cat. No. | Product | Size |
|---------------|------------|---|---------------|
| Real-Time PCR | SRH22-M25h | SolGent™ 2X Multiplex Real-Time PCR Smart mix (for Probe) | 0.5 ml x 5 ea |
| | SRQ11-K050 | DiaStar™ OneStep Multiplex qRT-PCR Kit (for Probe) | 50 reaction |
| | SRQ11-M10h |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

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™ <i>h-Taq</i> DNA Polymerase | 250 U |
| | MDF01-M25h | DnaFree™ 2X Multiplex PCR Smart mix, with dye | 0.5 ml 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 ml x 5 ea |



Molecular Diagnostics

Pathogen Detection

Tuberculosis

| | |
|---|----|
| <i>DiaPlexC</i> [™] MTC/NTM Detection Kit | 16 |
| <i>DiaPlexQ</i> [™] MTC/NTM Detection Kit | 18 |
| <i>DiaPlexC</i> [™] MTB/M.Bovis Detection Kit | 20 |
| <i>DiaPlexC</i> [™] M.Avium/M.Intracellulare Detection Kit | 22 |

Respiratory Disease

| | |
|--|----|
| <i>DiaPlexQ</i> [™] RV16 Detection Kit | 24 |
| <i>DiaPlexC</i> [™] RV13 Detection Kit | 26 |
| <i>DiaPlexQ</i> [™] MERS Virus Detection Kit | 28 |
| <i>DiaPlexQ</i> [™] Influenza Virus A/B & A Subtype Detection Kit | 30 |
| <i>DiaPlexQ</i> [™] Influenza Virus A/B Detection Kit | 32 |
| <i>DiaPlexC</i> [™] Influenza Virus A/B Detection Kit | 32 |
| <i>DiaPlexQ</i> [™] Influenza Virus A Subtype Detection Kit | 34 |
| <i>DiaPlexC</i> [™] Influenza Virus A Subtype Detection Kit | 34 |
| <i>DiaPlexQ</i> [™] Entero Virus Detection Kit | 36 |

Sexually Transmitted Infection

| | |
|---|----|
| <i>DiaPlexQ</i> [™] STI 12 Detection Kit | 38 |
| <i>DiaPlexQ</i> [™] STI 6 Detection Kit | 38 |

Others

| | |
|--|----|
| <i>DiaPlexQ</i> [™] PneumoPatho 13 Detection Kit | 40 |
| <i>DiaPlexQ</i> [™] ZCD Detection Kit (ZIKV, CHIKV, DENV) | 42 |
| <i>DiaPlexQ</i> [™] Dengue Virus Detection Kit | 44 |
| <i>DiaPlexC</i> [™] Malaria Detection Kit | 46 |
| <i>DiaPlexC</i> [™] CRE Detection Kit | 48 |
| <i>DiaPlexQ</i> [™] Ebola Virus Detection Kit - Zaire | 50 |

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, 2 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

| | |
|--------------------------------|--|
| Detection target | MTC (2 species), NTM (10 species) |
| Registration | CE-IVD |
| 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 - 10 ⁵ 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.

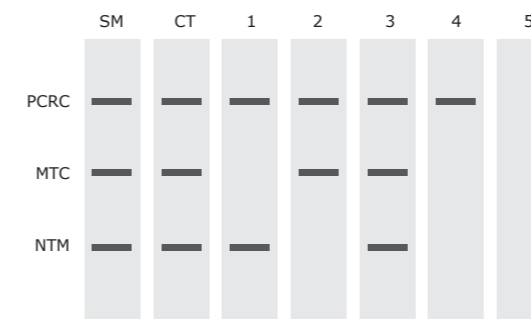
Product Features

- HotStart PCR system : Ultra high specific and sensitive result
- DnaFree™ system : No host genomic DNA contamination (*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.

Result & Data interpretation



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 |
|------------------------------|---------------------------|--|---|
| Conventional (End-point) PCR | SMD21-K020 (20 reaction) | <i>DiaPlexC™</i> 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.

Real-Time 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 | DiaPlexQ™ MTC/NTM Detection Kit ver 3.0 | DiaPlexQ™ MTC/NTM Detection Kit ver 4.0 |
|--------------------------------|---|--|---|
| Detection target | MTC (2 species): IS6110 NTM (13 species): 16s rRNA | MTC (2 species): IS6110, MPB64 NTM (15 species): 16s rRNA | MTC (2 species): IS6110, MPB64 NTM (6 species): 16s rRNA |
| Registration | KFDA, CE-IVD | CE-IVD | CE-IVD |
| Detection technology | Real-Time PCR | | |
| Specimen type | Nasopharyngeal swab, Nasopharyngeal aspirate, Bronchoalveolar lavage (BAL) | | |
| Analytical sensitivity | 10 copies | 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

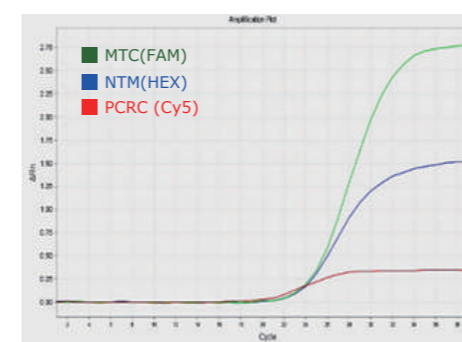
- HotStart PCR system : Ultra high specific and sensitive result
- UDG system : No carryover contamination
- Multiplex PCR system : Multiple targets in a single reaction
- Reliable system : Automatic PCR control
- Positive control included
- DNA extraction solution included (Cat. No. SQD21-K100, SQD26-K100, SQD28-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.

Result & Data interpretation

DiaPlexQ™ MTC/NTM Detection Kit



| Sample type | FAM | 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 |

DiaPlexQ™ MTC/NTM Detection Kit- Ver.3.0

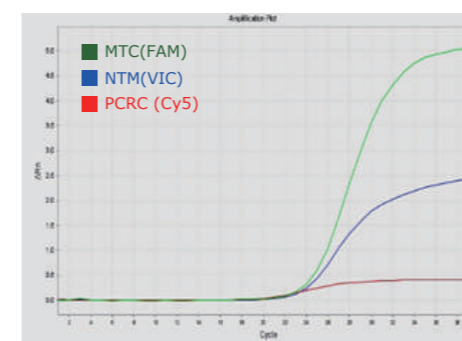


Fig. 2. Amplification Plot information (ABI7500 FAST)

DiaPlexQ™ MTC/NTM Detection Kit- Ver.4.0

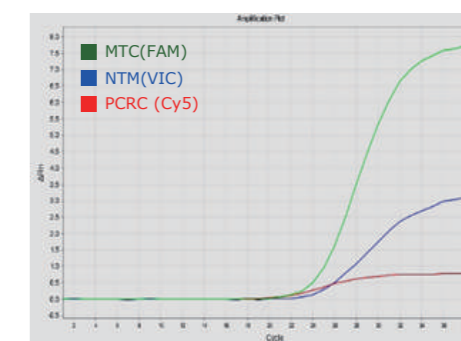


Fig. 3. Amplification Plot information (ABI7500 FAST)

Ordering Information

| Technology | Cat. No. | Product |
|---------------|-------------------------|---|
| Real-time PCR | SQD21-K100 ¹ | DiaPlexQ™ MTC/NTM Detection Kit (w/Ext.) |
| | SQD20-K100 ² | DiaPlexQ™ MTC/NTM Detection Kit |
| | SQD26-K100 ¹ | DiaPlexQ™ MTC/NTM Detection Kit (w/Ext.)- Ver.3.0 |
| | SQD25-K100 ² | DiaPlexQ™ MTC/NTM Detection Kit- Ver.3.0 |
| | SQD28-K100 ¹ | DiaPlexQ™ MTC/NTM Detection Kit (w/Ext.)- Ver.4.0 |
| | SQD27-K100 ² | DiaPlexQ™ MTC/NTM Detection Kit- Ver.4.0 |

¹ SQD21-K100, SQD26-K100, SQD28-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 SQD20-K100, SQD25-K100, SQD27-K100, is composed only of the Real-Time Detection Kit for the diagnosis of MTC/NTM.

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 | <i>Mycobacterium tuberculosis</i> (MTB), <i>Mycobacterium bovis</i> (<i>M. bovis</i>) |
| Registration | CE-IVD |
| 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.

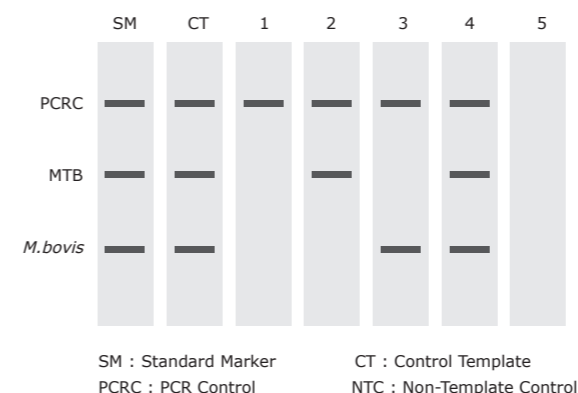
Product Features

- 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.

Result & Data interpretation



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

Ordering Information

| Technology | Cat. No. | Product | Contents |
|------------------------------|---------------------------|---|---|
| Conventional (End-point) PCR | SMD22-K020 (20 reaction) | <i>DiaPlexC™</i> 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) | | |

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 | <i>Mycobacterium avium</i> , <i>Mycobacterium intracellulare</i> |
| Registration | CE-IVD |
| 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 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.

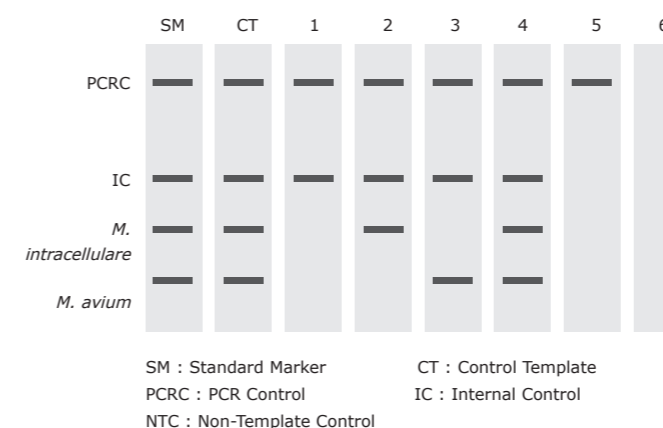
Product Features

- HotStart PCR system : Ultra high specific and sensitive result
- DnaFree™ system : No host genomic DNA contamination
- UDG system : No carryover contamination
- Multiplex PCR 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: comparison of radiological appearances with pulmonary tuberculosis. Thorax. 1996;51:1243-1247.

Result & Data interpretation



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

Ordering Information

| Technology | Cat. No. | Product | Contents |
|------------------------------|---------------------------|--|--|
| Conventional (End-point) PCR | SMD23-K020 (20 reaction) | DiaPlex™ 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) | | |

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 IV : Enterovirus (EntV) Bocavirus (BoV) Metapneumovirus (MPV) |
| | Set II : Influenza virus A (Inf A) Parainfluenza-IV (PIV-IV) Influenza virus B (Inf B) | Set V : Beta Coronavirus OC43 (CoV OC43) Alpha Coronavirus 229E/NL63 (CoV 229E/NL63) MERS-CoV |
| Registration | CE-IVD | |
| Detection technology | Real-Time OneStep RT-PCR | |
| Specimen type | Nasopharyngeal swab, sputum(corona MERS) | |
| 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

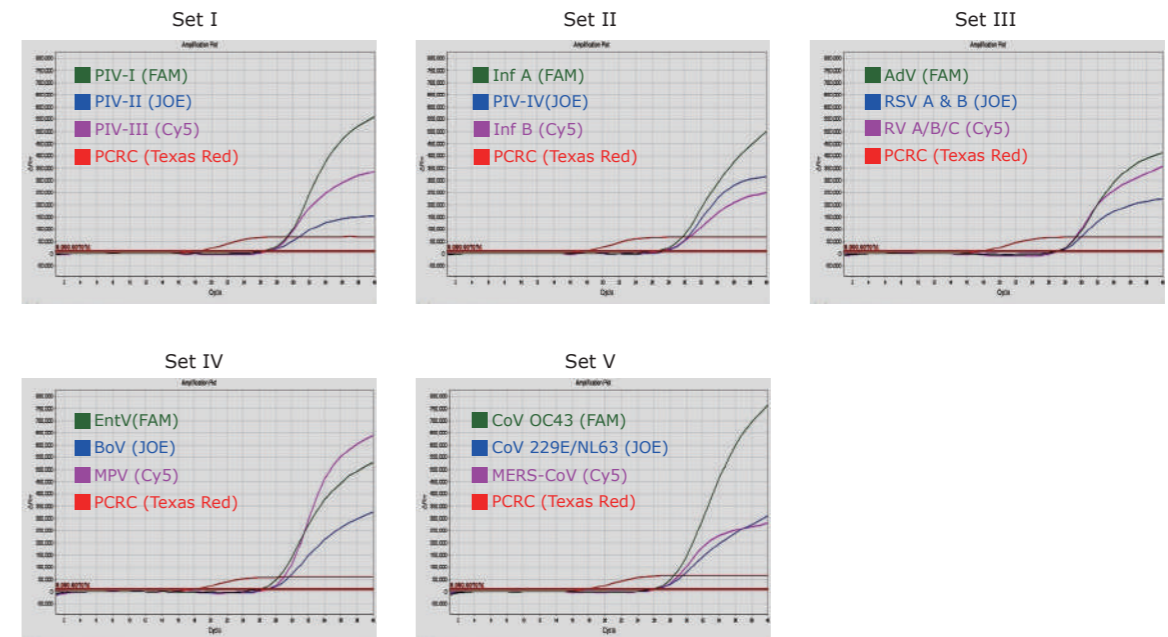


Fig. 1. Amplification Plot information (ABI7500 FAST)

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) | | |

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- II) 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) |
| Registration | KFDA, CE-IVD | |
| 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.

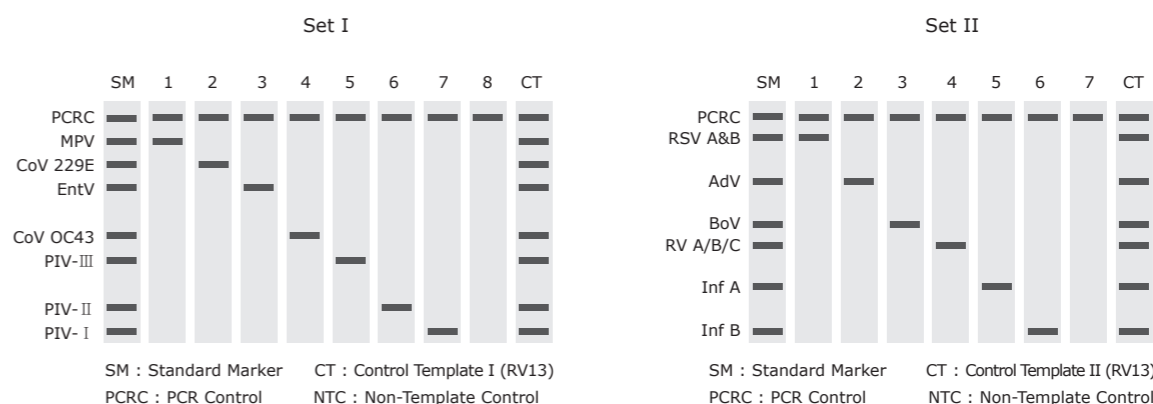
Product Features

- 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



| 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) |

| 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) | DiaPlexC™ RV13 Detection Kit | OneStep RT-PCR Enzyme mix (RV13) |
| | SMD50-K100 (100 reaction) | | 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 |

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 II (upE/ORF1a/ORF1b) | |
|---|--|
| Detection target | <i>upE, ORF1a, ORF1b</i> |
| Registration | RUO |
| 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 |
| Compatible instruments** | ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad) |
| PCR running time | ~ 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 II (upE/ORF1a/ORF1b)

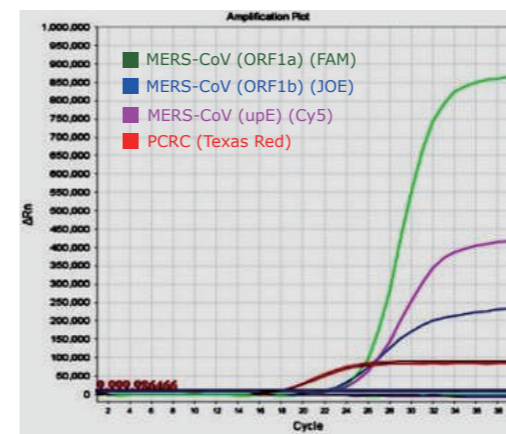


Fig. 1. Amplification Plot information (ABI7500 FAST)

Ordering Information

| Technology | Cat. No. | Product | Contents |
|---------------|---------------------------|---|---|
| Real-Time PCR | 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) | | |

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 and 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 |
| Registration | RUO |
| 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

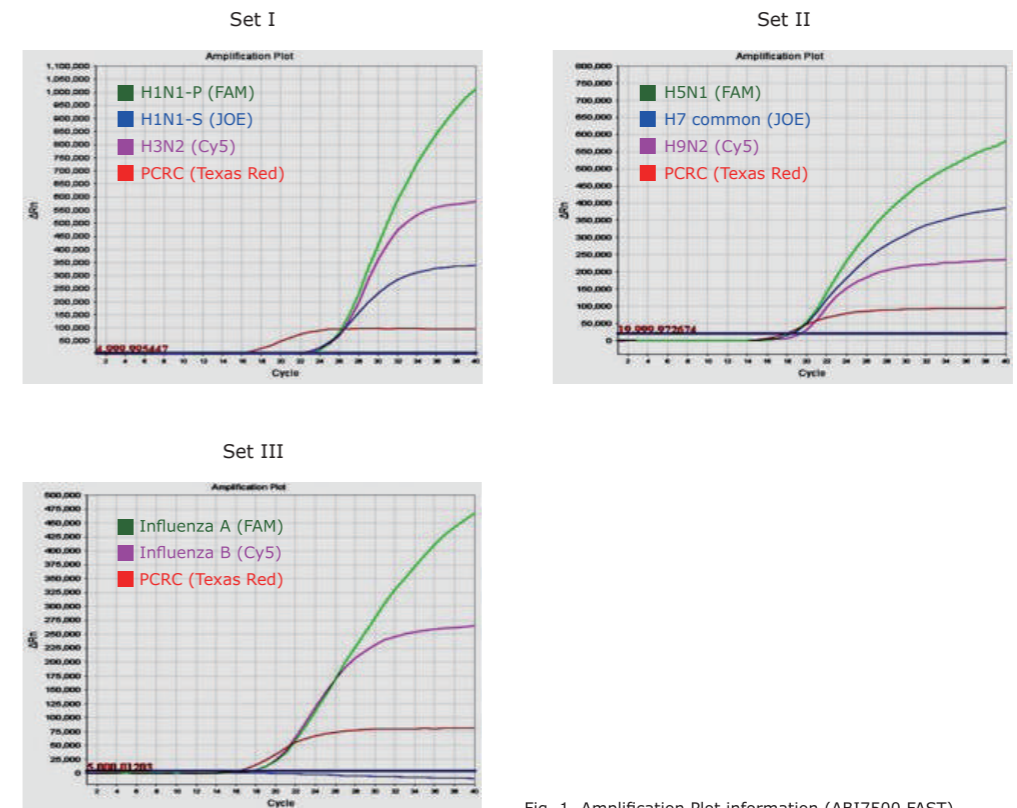


Fig. 1. Amplification Plot information (ABI7500 FAST)

Ordering Information

| Technology | Cat. No. | Product | Contents |
|---------------|------------------------------|---|---|
| Real-Time PCR | 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) | | |

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 and 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 | |
| Registration | CE-IVD | |
| 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 | ~ 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.

Result & Data interpretation

DiaPlexQ™ Influenza Virus A/B Detection Kit

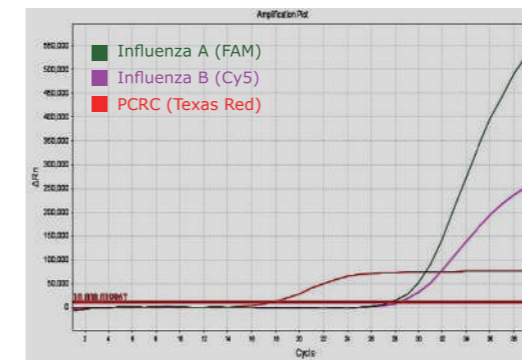
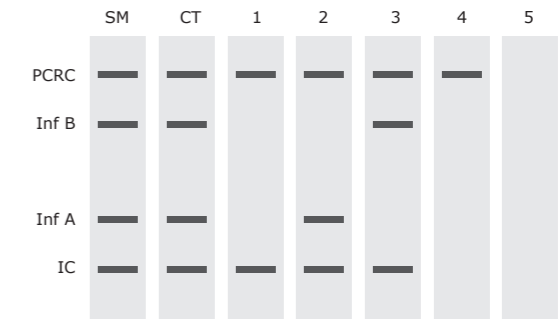


Fig. 1. Amplification Plot information (ABI7500 FAST)

| 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 CT : Control Template
 PCRC : PCR Control IC : Internal Control
 NTC : Non-Template 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) | <i>DiaPlexQ™</i> 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) | <i>DiaPlexC™</i> 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) | | |

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 |
| Registration | CE-IVD | |
| 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 | ~ 2 hrs 30 min |

* 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

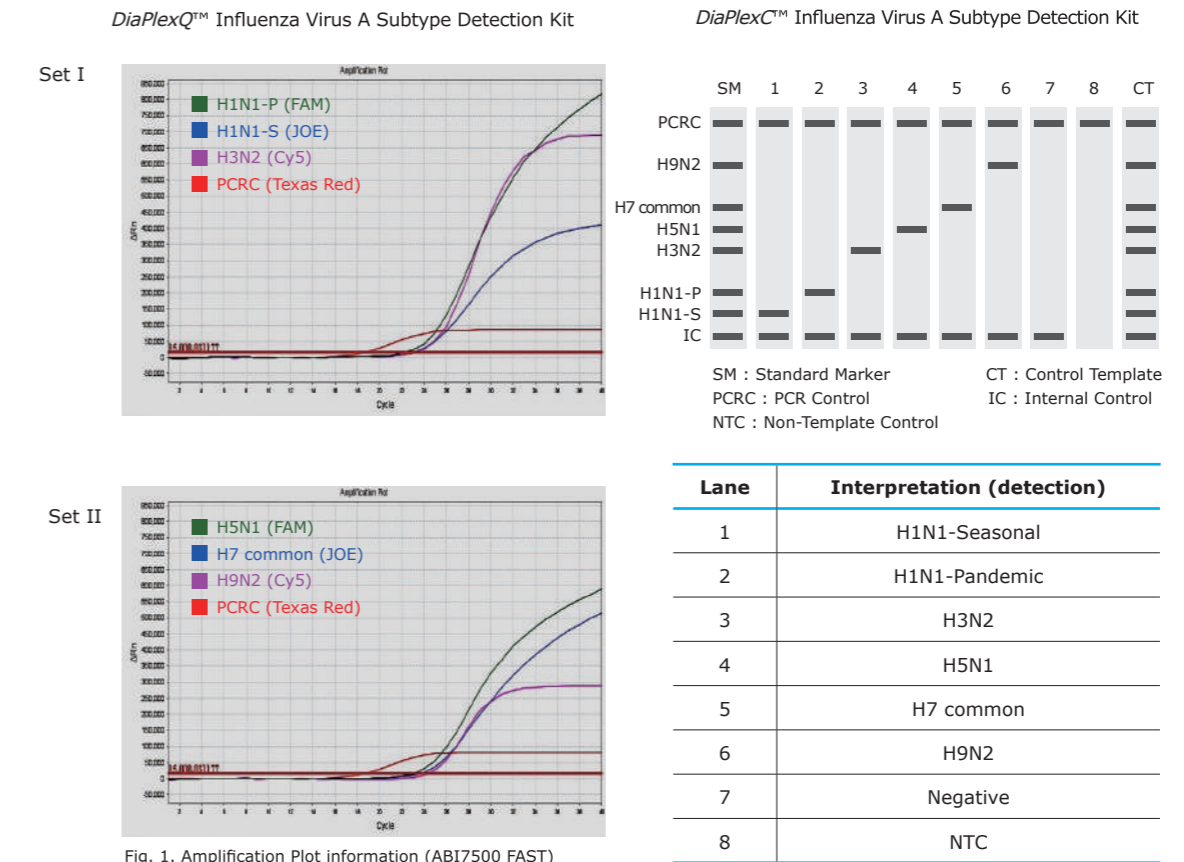


Fig. 1. Amplification Plot information (ABI7500 FAST)

Ordering Information

| Technology | Cat. No. | Product | Contents |
|------------------------------|---------------------------|--|---|
| Real-Time PCR | SQD41-K020 (20 reaction) | <i>DiaPlexQ™</i> 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) | <i>DiaPlexC™</i> 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) | | |

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 respiratory 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 | Enterovirus (A/B/C/D type) |
| Registration | CE-IVD |
| 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

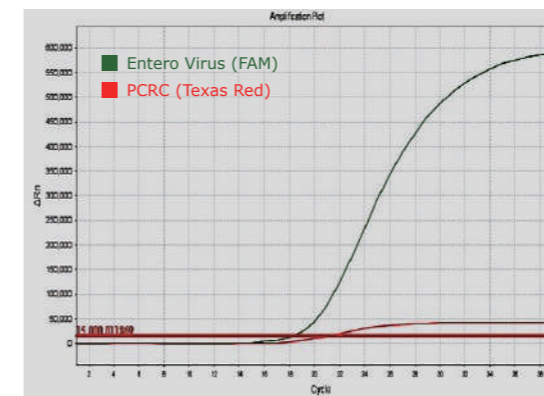


Fig. 1. Amplification Plot information (ABI7500 FAST)

| 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™ Enterovirus Detection Kit | OneStep qRT-PCR Enzyme mix (Enterovirus) 2X OneStep qRT-PCR Buffer (Enterovirus) Primer & Probe Mixture (Enterovirus) Control Template (Enterovirus) RNase free Water |
| | SQD51-K100 (100 reaction) | | |

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

| | <i>DiaPlexQ™</i> STI 12 Detection Kit | <i>DiaPlexQ™</i> STI 6 Detection Kit |
|--------------------------------|--|--|
| Detection target | Set I : <i>N. gonorrhoeae</i> (NG) <i>C. trachomatis</i> (CT) <i>M. hominis</i> (MH) Set II : <i>T. vaginalis</i> (TV) <i>U. urealyticum</i> (UU) <i>M. genitalium</i> (MG) | Set III : Herpes simplex virus 1 (HSV-1) Herpes simplex virus 2 (HSV-2) <i>G. vaginalis</i> (GV) Set IV : <i>T. pallidum</i> (TP) <i>C. albicans</i> (CA) <i>U. parvum</i> (UP) |
| | <i>DiaPlexQ™</i> STI 12 Detection Kit : All set (Set I ~ Set IV) | |
| | <i>DiaPlexQ™</i> STI 6 Detection Kit : Only major group (Set I and Set II) | |
| Registration | RUO | |
| 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

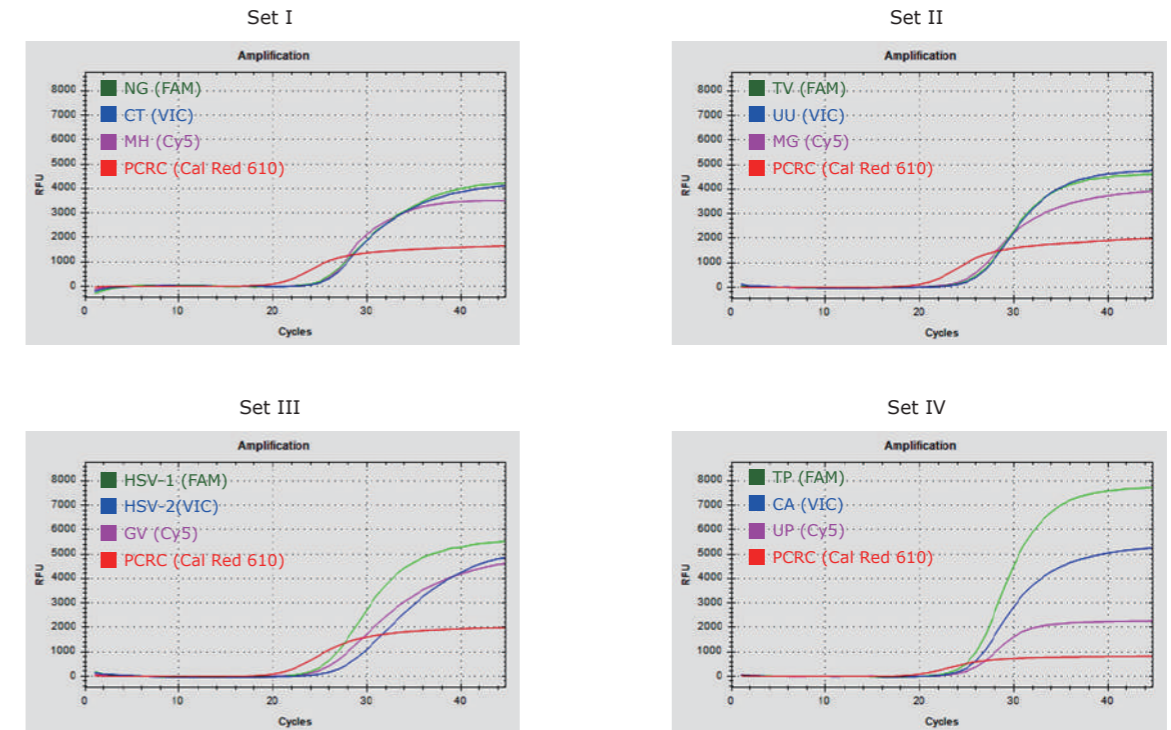


Fig. 1. Amplification Plot information (CFX96 Real-Time PCR System(Bio-Rad))

Ordering Information

| Technology | Cat. No. | Product | Contents |
|---------------|---------------------------|--|---|
| Real-Time PCR | SQD99-K020 (20 reaction) | <i>DiaPlexQ™</i> STI 12 Detection Kit (Ver. 2) | 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 I (STI 12) Control Template II (STI 12) Control Template III (STI 12) Control Template IV (STI 12) Nuclease free Water |
| | SQD99-K100 (100 reaction) | | |
| | SQD94-K020 (20 reaction) | <i>DiaPlexQ™</i> 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) | | |

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 : <i>M. pneumoniae</i> (MP) <i>K. pneumoniae</i> (KP) <i>L. pneumophila</i> (LP) Set II : <i>S. pneumoniae</i> (SP) <i>S. aureus</i> (SA) <i>C. pneumoniae</i> (CP) | Set III : <i>P. aeruginosa</i> (PA) <i>M. catarrhalis</i> (MC) <i>B. pertussis</i> (BP) Set IV : <i>H. influenzae</i> (HI) <i>A. baumannii</i> (AB) <i>M. tuberculosis/ M. avium</i> (TB/AV) |
| Registration | RUO | |
| 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

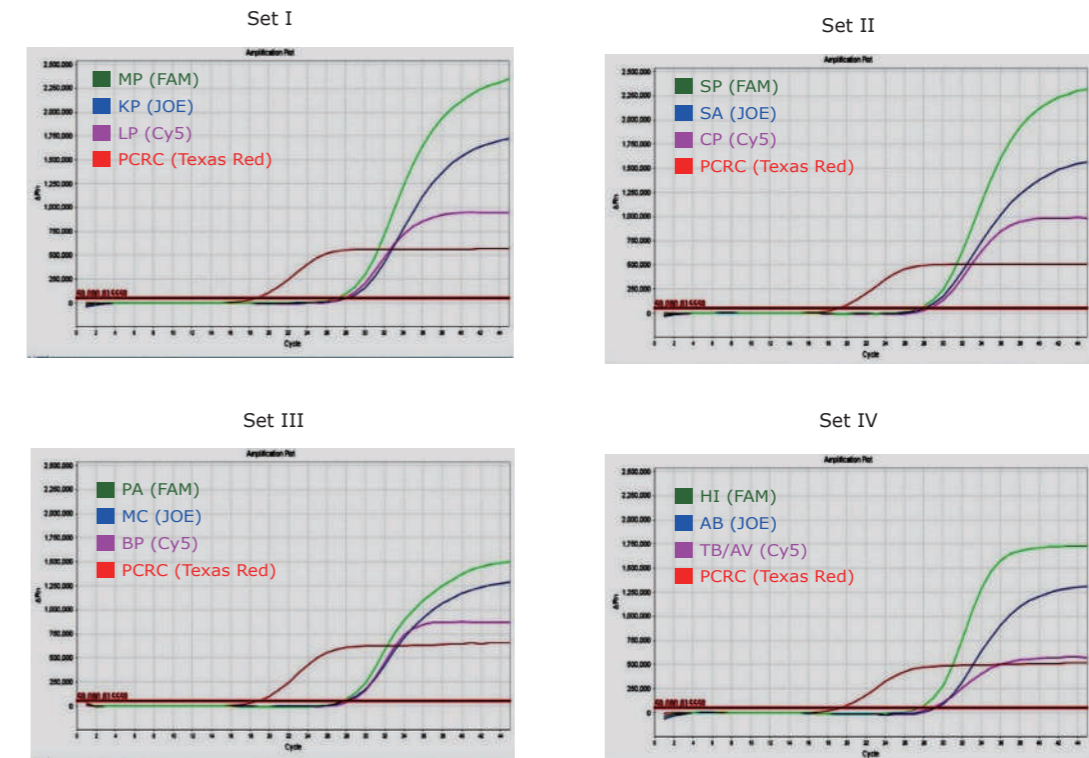


Fig. 1. Amplification Plot information (ABI7500 FAST)

Ordering Information

| Technology | Cat. No. | Product | Contents |
|---------------|------------------------------|--|--|
| Real-Time PCR | SQD82-K020 (20 reaction) | DiaPlexQ™ PneumoPatho 13 Detection Kit (Ver. 2) | 2X Multiplex Real-Time PCR Smart mix (with UDG) (PP 13) Primer & Probe Mixture I (PP 13) Primer & Probe Mixture II (PP 13) Primer & Probe Mixture III (PP 13) Primer & Probe Mixture IV (PP 13) Control Template I (PP 13) Control Template II (PP 13) Control Template III (PP 13) Control Template IV (PP 13) Nuclease free Water |
| | SQD82-K100 (100 reaction) | | |

Real-Time OneStep RT-PCR based assay system for detection of Zika virus, Chikungunya virus and Dengue virus

Pathogen Information

ZIKA virus, like Dengue, Yellow fever, West-Nile, and Japanese encephalitis viruses, is a member of the virus family Flavivirus, which is known as a virus causing mosquito-borne infectious diseases including Dengue fever, yellow fever, and Japanese encephalitis. It has been known that body infection by Zika virus often causes only mild symptoms compared with other mosquito-borne infectious diseases and not been recognized as a serious disease. In particular, as Dengue virus and Chikungunya virus occur in the same area as Zika virus occur, it is essential to distinguish them from Zika virus and detect. Therefore, supply of kit capable of rapidly distinguishing, detecting and dragonizing infection with Zika virus, Dengue virus and Chikungunya virus is judged to be able to contribute to alleviate the currently rampant incidence of Zika virus

Product Specification

| | |
|--------------------------------|---|
| Detection target | Zika virus, Chikungunya virus and Dengue virus |
| Registration | CE-IVD |
| Detection technology | Real-Time OneStep RT-PCR |
| Specimen type | Blood, plasma, serum |
| 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. First report of autochthonous transmission of Zika virus in Brazil. Zanluca C, de Melo VC, Mosimann AL, Dos Santos GI, Dos Santos CN, Luz K. Mem Inst Oswaldo Cruz. 2015 Jun;110(4):569-72. doi: 10.1590/0074-02760150192. Epub 2015 Jun 9. PMID: 26061233
2. Zika virus: following the path of dengue and chikungunya. Musso D, Cao-Lormeau VM, Gubler DJ. Lancet. 2015 Jul 18;386(9990):243-4. doi: 10.1016/S0140-6736(15)61273-9. No abstract available. PMID: 26194519
3. Outbreak of Exanthematous Illness Associated with Zika, Chikungunya, and Dengue Viruses, Salvador, Brazil. Cardoso CW, Paploski IA, Kikuti M, Rodrigues MS, Silva MM, Campos GS, Sardi SI, Kitron U, Reis MG, Ribeiro GS. Emerg Infect Dis. 2015 Dec;21(12):2274-6. doi: 10.3201/eid2112.151167. No abstract available. PMID: 26584464
4. Possible Association Between Zika Virus Infection and Microcephaly - Brazil, 2015. Schuler-Faccini L, Ribeiro EM, Feitosa IM, Horovitz DD, Cavalcanti DP, Pessoa A, Doriqui MJ, Neri JI, Neto JM, Wanderley HY, Cernach M, El-Husny AS, Pone MV, Seroa CL, Sanseverino MT; Brazilian Medical Genetics Society-Zika Embryopathy Task Force. MMWR Morb Mortal Wkly Rep. 2016 Jan 29;65(3):59-62. doi: 10.15585/mmwr.mm6503e2.

Result & Data interpretation

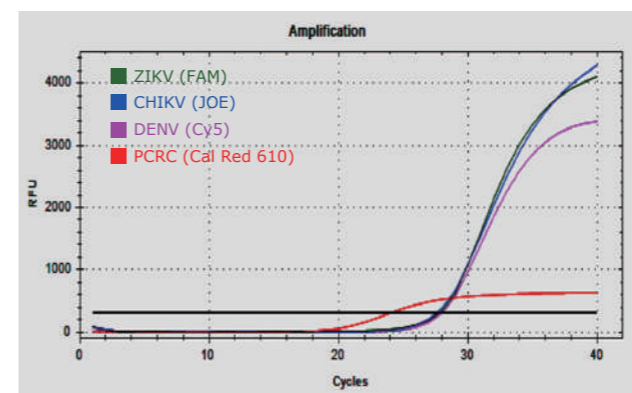


Fig. 1. Amplification Plot information (CFX96 Real-Time PCR System(Bio-Rad))

| Sample type | FAM | JOE/VIC* | CY5 | Texas Red / Cal Red 610 | Result |
|----------------------------|-----|----------|-----|-------------------------|------------------------------|
| Positive Control | + | + | + | + | Valid |
| Negative Control | - | - | - | + | Valid |
| NTC (Non-Template Control) | - | - | - | + | Valid |
| Sample case 1 | + | - | - | +/- | ZIKV positive |
| Sample case 2 | - | + | - | +/- | CHIKV positive |
| Sample case 3 | - | - | + | +/- | DENV positive |
| Sample case 4 | + | + | - | +/- | Positive (ZIKV, CHIKV) |
| Sample case 5 | + | - | + | +/- | Positive (ZIKV, DENV) |
| Sample case 6 | + | + | + | +/- | Positive (ZIKV, CHIKV, DENV) |
| Sample case 7 | - | - | - | - | Required re-experiment |

Ordering Information

| Technology | Cat. No. | Product | Contents |
|---------------|---------------------------|---|---|
| Real-Time PCR | SQD06-K020 (20 reaction) | DiaPlexQ™ ZCD Detection Kit (ZIKV, CHIKV, DENV) | OneStep qRT-PCR Enzyme mix (ZCD) 2X OneStep qRT-PCR Buffer (ZCD) Primer & Probe Mixture (ZCD) Control Template (ZCD) RNase free Water |
| | SQD06-K100 (100 reaction) | | |

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) |
| Registration | CE-IVD |
| 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.

Result & Data interpretation

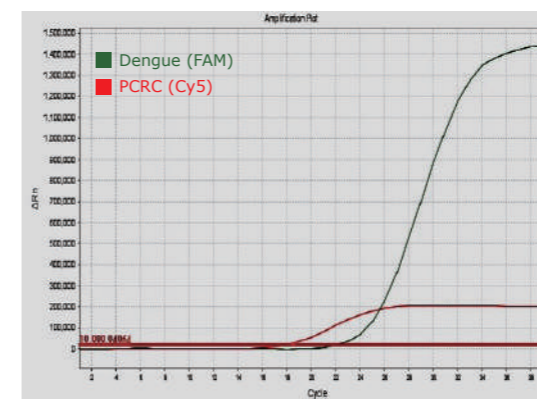


Fig. 1. Amplification Plot information (ABI7500 FAST)

| 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) | <i>DiaPlexQ</i> TM Dengue Virus Detection Kit | OneStep qRT-PCR Enzyme mix (Dengue) 2X OneStep qRT-PCR Buffer (Dengue) Primer & Probe Mixture (Dengue) Control Template (Dengue) RNase free Water |
| | SQD01-K100 (100 reaction) | | |

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 | <i>Plasmodium falciparum</i> , <i>Plasmodium vivax</i> , <i>Plasmodium malariae</i> , <i>Plasmodium ovale</i> |
| Registration | CE-IVD |
| 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.

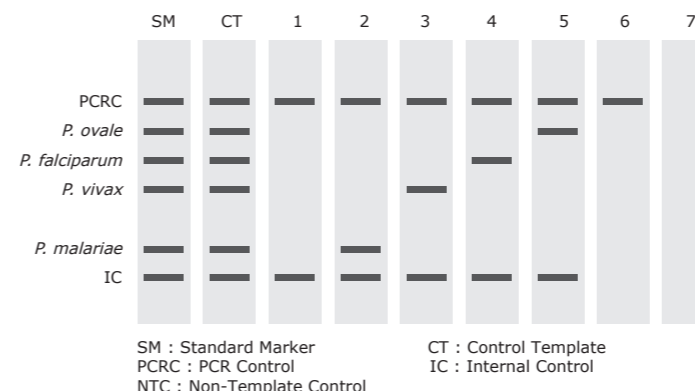
Product Features

- 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



| Lane | Interpretation (detection) |
|------|----------------------------|
| 1 | Negative |
| 2 | <i>P. malariae</i> |
| 3 | <i>P. vivax</i> |
| 4 | <i>P. falciparum</i> |
| 5 | <i>P. ovale</i> |
| 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) | | |

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 | <i>VIM</i> (Verona integron-encoded Metallo-β-lactamase-1) <i>IMP</i> (Imipenem-resistant <i>P.aeruginosa</i>) <i>NDM</i> (New Delhi Metallo β-lactamase) <i>KPC</i> (<i>Klebsiella pneumonia carbapenemase</i>) |
| Registration | CE-IVD |
| 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.

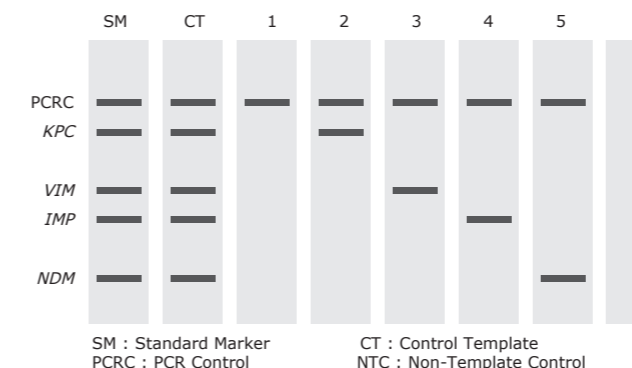
Product Features

- 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.

Result & Data interpretation



| Lane | Interpretation (detection) |
|------|----------------------------|
| 1 | Negative (or NTC) |
| 2 | <i>KPC</i> |
| 3 | <i>VIM</i> |
| 4 | <i>IMP</i> |
| 5 | <i>NDM</i> |
| 6 | Required re-experiment |

Ordering Information

| Technology | Cat. No. | Product | Contents |
|------------------------------|---------------------------|------------------------------------|---|
| Conventional (End-point) PCR | SMD71-K020 (20 reaction) | <i>DiaPlexC™</i> 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) | | |

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) |
| Registration | CE-IVD |
| 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

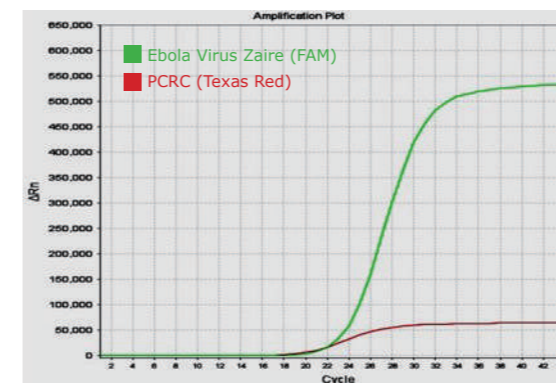
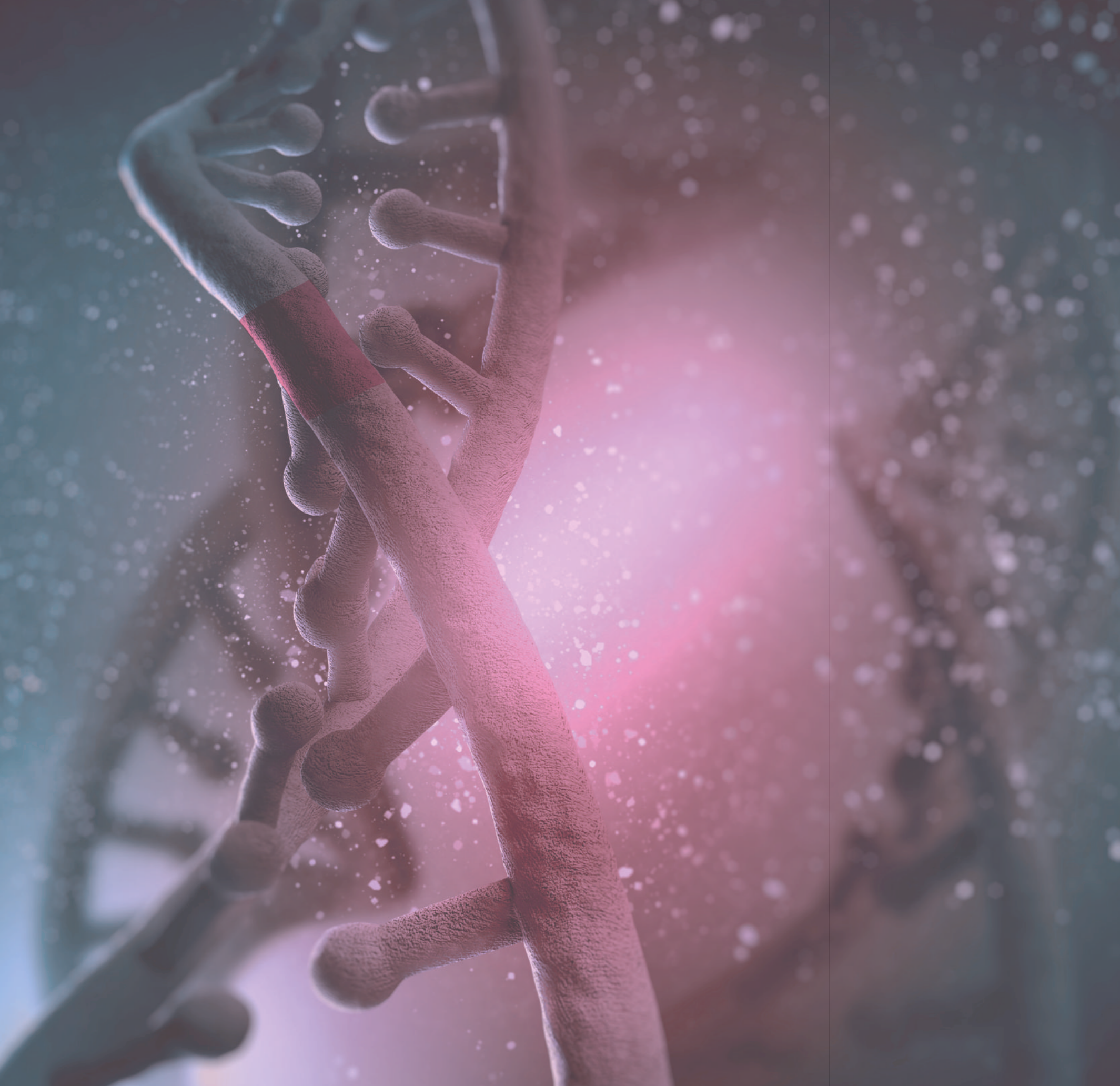


Fig. 1. Amplification Plot information (ABI7500 FAST)

| 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) | | |



Molecular Diagnostics

Human Genotyping

Corneal Dystrophy

| | |
|--|----|
| <i>DiaPlexQ</i> [™] Avellino Corneal Dystrophy (ACD) Real-Time PCR Genotyping Kit | 54 |
| <i>DiaPlexC</i> [™] Avellino Corneal Dystrophy (ACD) Genotyping Kit | 54 |
| <i>DiaPlexQ</i> [™] 5 Types Corneal Dystrophy Detection Kit (ACD, RBCD, LCD, TBCD, GCD) | 56 |

Alzheimer's Disease

| | |
|---|----|
| <i>DiaPlexQ</i> [™] ApoE Genotyping Kit | 58 |
| <i>DiaPlexC</i> [™] Apolipoprotein E (ApoE) Genotyping Kit | 58 |

Hyperhomocysteinemia

| | |
|---|----|
| <i>DiaPlexQ</i> [™] MTHFR Genotyping Kit | 60 |
| <i>DiaPlexC</i> [™] MTHFR Genotyping Kit | 60 |

G6PD Deficiency

| | |
|---|----|
| <i>DiaPlexC</i> [™] G6PD Genotyping Kit (Asian type) | 62 |
| <i>DiaPlexC</i> [™] G6PD Genotyping Kit (African type) | 62 |

Real-Time PCR (or Multiplex allele-specific PCR) based assay system for the genotyping of the ACD gene SNP related to avellino corneal dystrophy
Genetic 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 codon 124 (exon 4) in the β IGH3 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 (β IGH3 coding gene codon 124, exon4) | |
| Registration | KFDA, CE-IVD | |
| 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. β IGH 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.

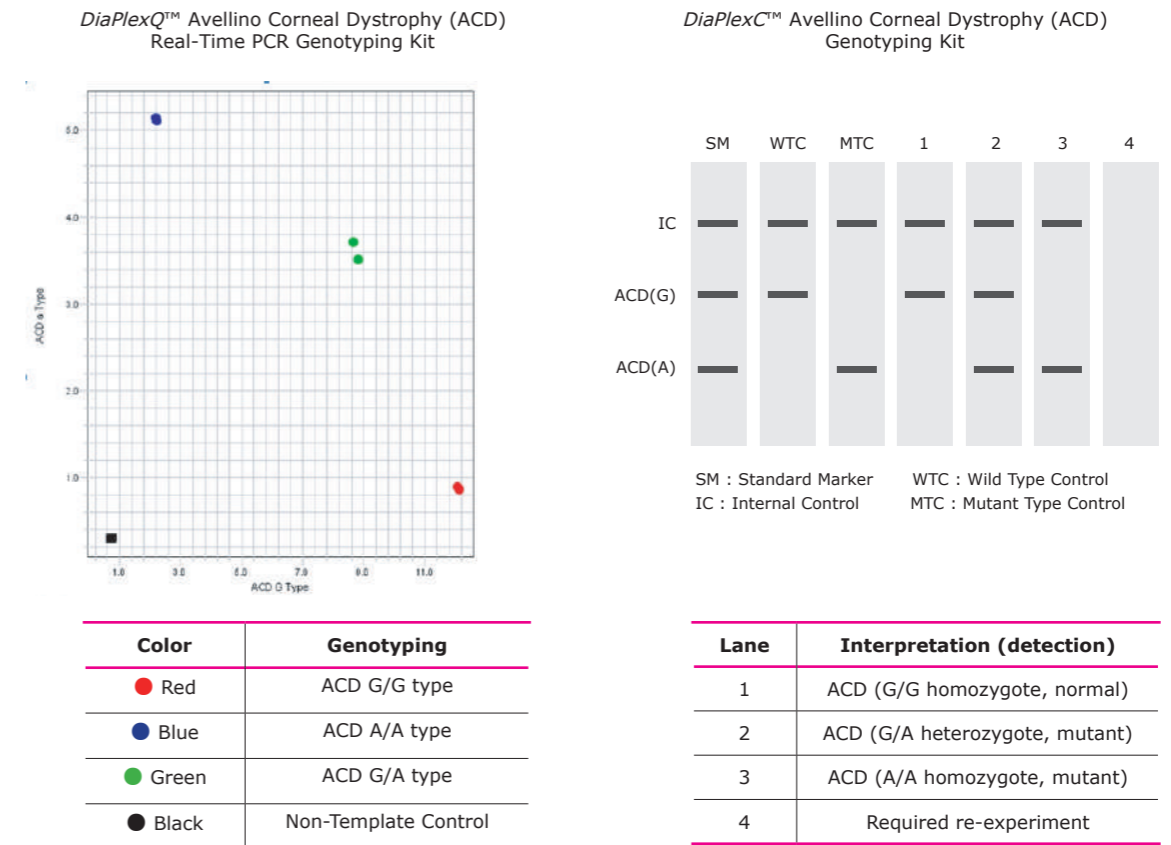
Result & Data interpretation


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

Ordering Information

| Technology | Cat. No. | Product | Contents |
|------------------------------|---------------------------|--|---|
| Real-Time PCR | SQH26-K020 (20 reaction) | <i>DiaPlexQ™</i> 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) | <i>DiaPlexC™</i> 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) | | |

Real-Time PCR (or Multiplex allele-specific PCR) based assay system for the genotyping of the SNP of codon 124, 555(exon4) in TGFβ1 related to avellino corneal dystrophy

Genetic information

The TGFβ1 gene is firstly appear at the 5q31 chromosome related corneal dystrophy on the corneal epithelium. Morbid cover of TGFβ1 is detected from the cornea, so we suppose the cause of disease related on 5q31 chromosome. There are Avellino Corneal Dystrophy(ACD), Reis-Bückler's Corneal dystrophy(RBCD), lattice Corneal dystrophy(LCD), granular Corneal dystrophy(GCD type1), Thiel-Behnke Corneal Dystrophy(TBCD) which are related with chromosome 5q31 and TGFβ1 gene. The IC3D had classified the diseases as category1. Although there are some remedies like sublayer corneal transplantation and penetrating keratoplasty, there are many cases that the disease recur after the operation. In case of heterozygote people perform the laser surgery such as like LASEK or LASIK. There is possibility of lose eye sight caused by corneal opacity. The Corneal Dystrophy genetic diagnosis before LASEK, LASEK surgery is kind of essential clinical test

Product Specification

| | |
|--------------------------------|---|
| Detection target | SNP of codon 124, 555 in TGFβ1 (R124H, R124L, R124C, R555Q, R555W) |
| Registration | CE-IVD |
| Detection technology | Real-Time PCR |
| Specimen type | Blood, Buccal epithelial cell |
| Compatible instruments* | ABI 7500 / 7500 Fast Real-Time PCR System (Applied Biosystems) CFX96™ Real-Time PCR System (Bio-Rad) |
| PCR running time | ~ 3hrs |

* Please inquire us for compatible instrument information before use.

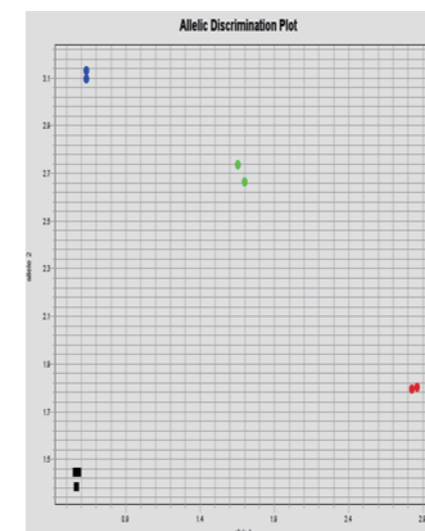
Product Features

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

Reference

1. Ridgway AEA, Moller HU (1992) Genetics of granular dystrophy. Ophthalmology 99:175
2. Rogers C, Cohen P, Lawless M (1993) Phototherapeutic keratectomy for Reis-Bucklers'corneal dystrophy. Aust N Z J Ophthalmol 21:247-25
3. Munier FL, Korvatska E, Djemaï A, Le Paslier D, Zografos L, Pescia G, Schorderet DF(1997) Kerato-epithelin mutations in four 5q31-linked corneal dystrophies. Nat Genet 15:247-25
4. Garner A. Histochemistry of corneal granular dystrophy. Br J Ophthalmol 1969;53:799 805.
5. Akiya S, Brown SI. Granular dystrophy of the cornea: characteristic electron microscopic lesion. Arch Ophthalmol 1970 ;84:179-92.
6. Owens SL, Sugar J. Edward DP. Superficial granular corneal dystrophy with amyloid deposit. Arch Ophthalmol 1992; 110:175-6.
7. Holland EJ, Daya SM, Stone EM, et al. Avellino corneal dystrophy: clinical manifestations and natural history. Ophthalmology 1992;99:1564-8.

Result & Data interpretation



| Color | Genotyping |
|-------|---|
| Red | Wild-type |
| Blue | Mutant type (ACD, RBCD, LCD, TBCD, GCD) |
| Green | CD Hetero type |
| Black | Non-Template Control |

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

SNP Information

| 5 Type Corneal Dystrophy(CD) | Gene | Genotype |
|--|---------------|----------|
| Avellino Corneal Dystrophy, ACD | TGFβ1 (βIGH3) | R124H |
| Reis-Bückler's Corneal Dystrophy, RBCD | TGFβ1 (βIGH3) | R124L |
| Lattice Corneal Dystrophy, LCD | TGFβ1 (βIGH3) | R124C |
| Thiel-Behnke Corneal Dystrophy, TBCD | TGFβ1 (βIGH3) | R555Q |
| Granular Corneal Dstrophy, GCD type1 | TGFβ1 (βIGH3) | R555W |

Ordering Information

| Technology | Cat. No. | Product | Contents |
|---------------|------------------------------|---|--|
| Real-Time PCR | SQH29-K020 (20 reaction) | DiaPlexQ™ 5 Types Corneal Dystrophy Detection Kit (ACD, RBCD, LCD, TBCD, GCD) | 2X Multiplex Real-Time PCR Smart mix (CD) Primer & Probe Mixture (CD) Wild-type Control Template (CD) Hetero-type Control Template (CD) Mutant-type Control Template (CD) Nuclease free Water |
| | SQH29-K100 (100 reaction) | | |

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

Genetic 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

| | <i>DiaPlexQ™</i> ApoE Genotyping Kit | <i>DiaPlexC™</i> 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 | |
| Registration | KFDA, CE-IVD | |
| 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.

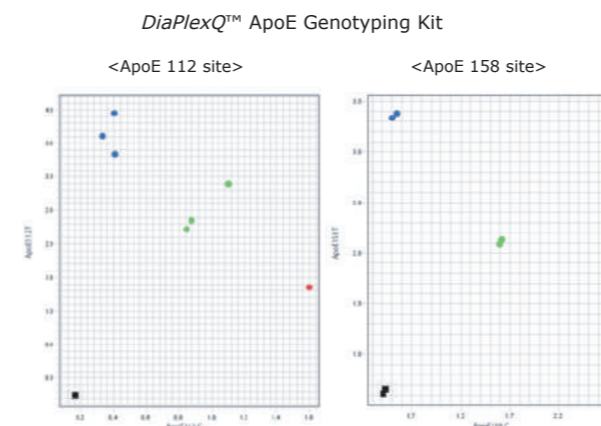
Product Features

- 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

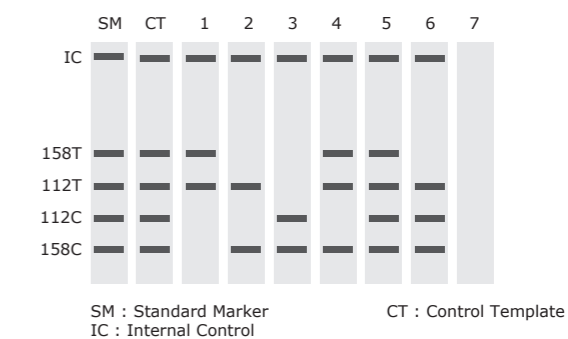
Result & Data interpretation



| 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 | |

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

DiaPlexC™ Apolipoprotein E (ApoE) Genotyping Kit



| 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 | |

Ordering Information

| Technology | Cat. No. | Product | Contents |
|------------------------------|---------------------------|---|--|
| Real-Time PCR | SQH01-K020 (20 reaction) | <i>DiaPlexQ™</i> 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) | <i>DiaPlexC™</i> 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

DiaPlexC™ MTHFR Genotyping Kit

Real-Time

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

Genetic 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-methylenetetrahydrofolate) 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, peripheral vascular 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 | |
| Registration | KFDA, CE-IVD | CE-IVD |
| 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 Cyclor (Applied Biosystems) recommended |
| PCR running time | ~ 1 hr 30 min | ~ 1 hr 30 min |

* Please inquire us for compatible instrument information before use.

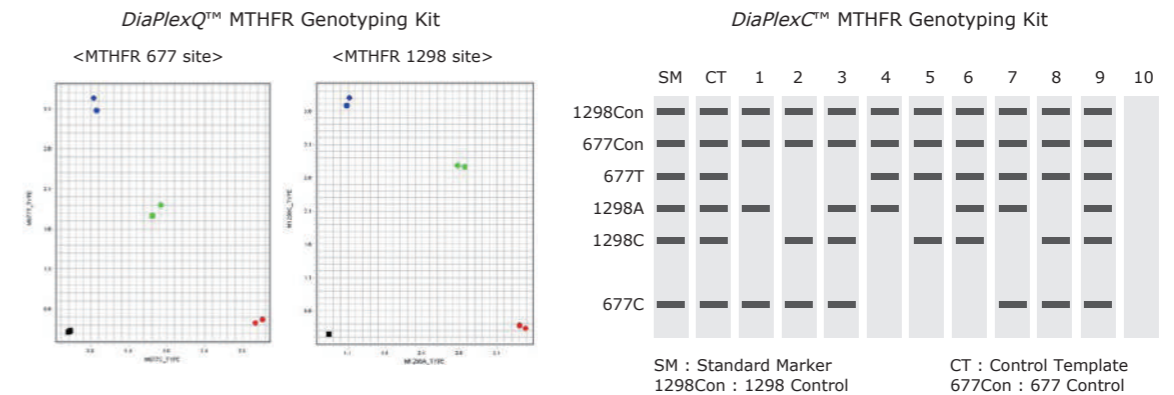
Product Features

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

Reference

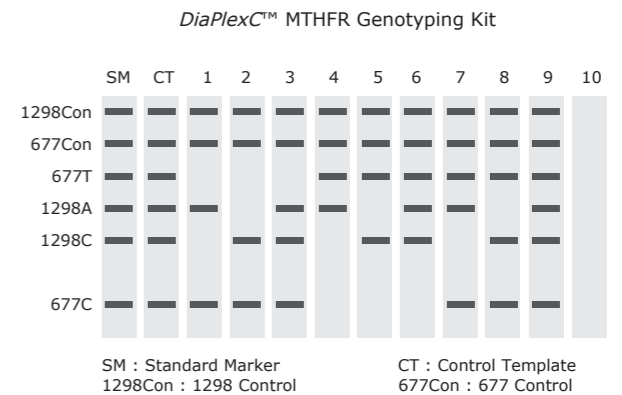
1. Fodinger M, Horl WH, Sunder-Plassmann G (2000). "Molecular biology of 5,10 methylenetetrahydrofolate reductase". J Nephrol 13 (1): 20-33
2. Schneider JA, Rees DC, Lui YT, Clegg JB (May 1998). "Worldwide distribution of a common methylenetetrahydrofolate reductase mutation". Am. J. Hum. Genet. 62 (5):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

Result & Data interpretation



| 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)



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) | | |

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

Genetic 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

| | DiaPlex™ G6PD Genotyping Kit (African type) | DiaPlex™ 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) |
| Registration | CE-IVD | |
| 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

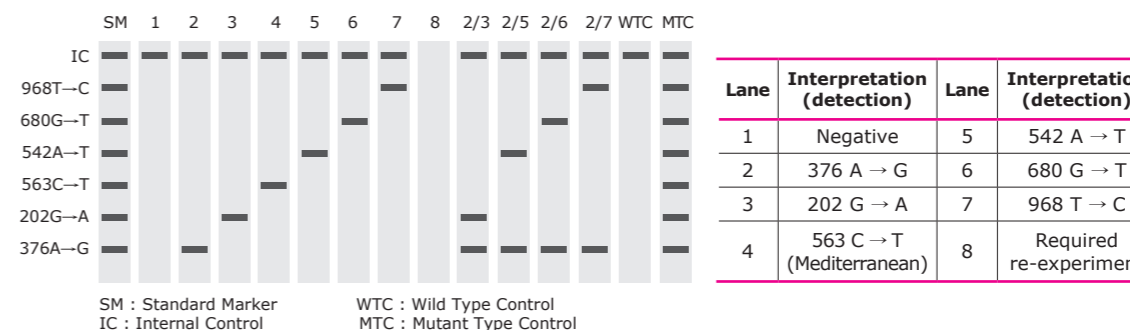
- HotStart PCR system : Ultra high specific and sensitive result
- Multiplex PCR : Multiple targets in a single reaction
- Reliable system : Automatic Internal control
- Positive control included
- Easy-to-use master mix
- CE certification

Reference

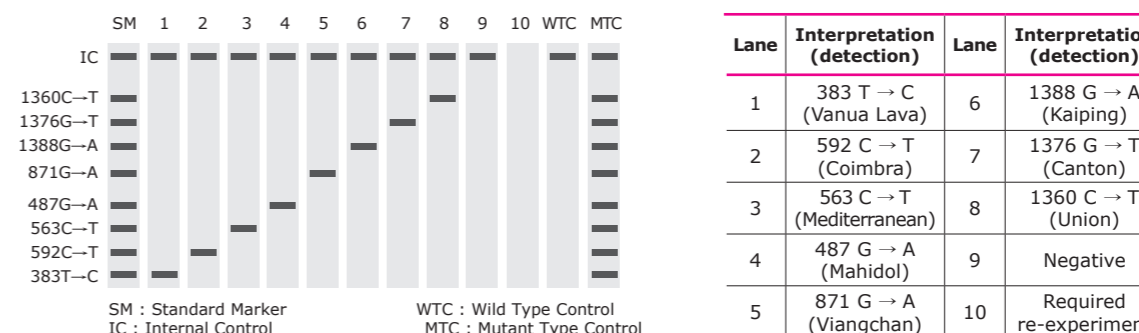
1. YK Goo, SY Ji, et al. (May 2014). "First Evaluation of Glucose-6-Phosphate Dehydrogenase (G6PD) Deficiency in Vivax Malaria Endemic Regions in the Republic of Korea". PLOS ONE. 9 (5) : e97390
2. Mehta, A, Mason, P.J., and Vulliamy, T.J. (2000) Glucose-6-phosphate dehydrogenase deficiency. Baillieres Best Prat. Res. Clin. Haematol 13, 21-38
3. Beutler, E., Kuhl, W., Vives-Corrans, J.L., and Prchal, J.T. (1989) Molecular heterogeneity of glucose-6-phosphate dehydrogenase deficiency A-. Blood 74, 2550-2555.
4. Lee et al. Prevalence of glucose-6-phosphate dehydrogenase (G6PD) deficiency among malaria patients in Upper Myanmar. BMC Infectious Diseases (2018) 18:131

Result & Data interpretation

DiaPlex™ G6PD Genotyping Kit (African type)



DiaPlex™ G6PD Genotyping Kit (Asian type)



Ordering Information

| Technology | Cat. No. | Product | Contents |
|------------------------------|---------------------------|---|--|
| Conventional (End-point) PCR | SHG11-K020 (20 reaction) | DiaPlex™ 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) | DiaPlex™ 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) | | |



SolGent Customized Development _____ 65

SolGent Molecular Diagnostic Kits _____ 66

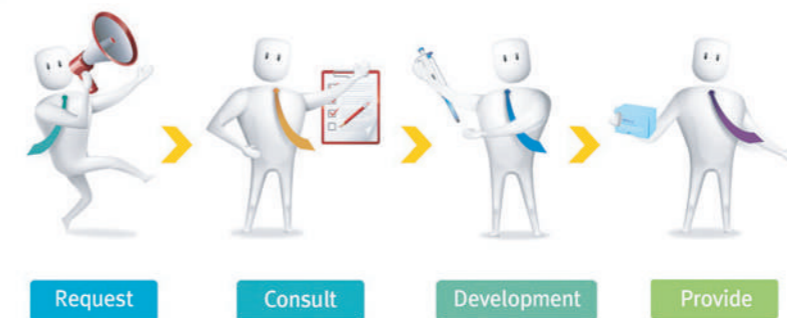
SolGent Customized Development

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

Pathogen Detection Kit

| Category | Technology | Product | Cat. No. | Description | Specimen* | Registration* | Page |
|---|--------------------------------|---|--|--|---|---------------|------|
| Tuberculosis | Real-Time PCR | <i>DiaPlexQ</i> TM MTC/NTM Detection Kit | SQD21 | Simultaneous detection of MTC and NTM complex | S, BAL, C, U, BF, B, T | CE IVD | 18 |
| | Multiplex PCR | <i>DiaPlexC</i> TM MTC/NTM Detection Kit | SMD21 | Simultaneous detection of MTC and NTM complex | NS, NA, BAL, O, S | CE IVD | 16 |
| | | <i>DiaPlexC</i> TM MTB/M. Bovis Detection Kit | SMD22 | Simultaneous detection of MTB and <i>M. bovis</i> | NS, NA, BAL, S | CE IVD | 20 |
| | | <i>DiaPlexC</i> TM M. Avium/M. Intracellulare Detection Kit | SMD23 | Simultaneous detection of <i>M. avium</i> and <i>M. intracellulare</i> | S, BAL, L, G, U, BF, B, T, ST | CE IVD | 22 |
| | Real-Time PCR | <i>DiaPlexQ</i> TM MTC/NTM Detection Kit - Ver.3.0 | SQD27, SQD28 | Simultaneous detection of MTC and NTM complex | S, BAL, C, U, BF, B, T | CE IVD | 18 |
| | | <i>DiaPlexQ</i> TM MTC/NTM Detection Kit - Ver.4.0 | SQD25, SQD26 | Simultaneous detection of MTC and NTM complex | S, BAL, C, U, BF, B, T | CE IVD | 18 |
| Respiratory Disease | Real-Time OneStep RT-PCR | <i>DiaPlexQ</i> TM RV16 Detection Kit | SQD50 | Simultaneous detection of 16 major respiratory viruses | NS, S (MERS only) | CE IVD | 24 |
| | | <i>DiaPlexQ</i> TM MERS Virus Detection Kit | SQD54 | Detection of MERS Virus | NS, NA, BAL, O, S | RUO | 28 |
| | | <i>DiaPlexQ</i> TM 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 |
| | | <i>DiaPlexQ</i> TM Influenza Virus A/B Detection Kit | SQD42 | Simultaneous typing of influenza virus A and B | NS, NA, BAL, O, S | CE IVD | 32 |
| | | <i>DiaPlexQ</i> TM Influenza Virus A Subtype Detection Kit | SQD41 | Simultaneous typing of influenza virus A subtypes | NS, NA, BAL, O, S | CE IVD | 34 |
| | | <i>DiaPlexQ</i> TM Entero Virus Detection Kit | SQD51 | Detection of enterovirus (A/B/D type) | NS, NA, BAL, TS, S | CE IVD | 36 |
| | OneStep Multiplex RT-PCR | <i>DiaPlexC</i> TM RV13 Detection Kit | SMD50 | Simultaneous detection of 13 major respiratory viruses | NS, NA, BAL, O, S | CE IVD | 26 |
| | | <i>DiaPlexC</i> TM Influenza Virus A/B Detection Kit | SMD42 | Simultaneous typing of influenza virus A and B | NS, NA, BAL, O, S | CE IVD | 32 |
| | | <i>DiaPlexC</i> TM 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 | <i>DiaPlexQ</i> TM STI 12 Detection Kit | SQD99 | Simultaneous detection of 12 pathogens causing STIs | US, U | RUO |
| <i>DiaPlexQ</i> TM STI 6 Detection Kit | | | SQD94 | Simultaneous detection of 6 pathogens causing STIs | US, U | RUO | 38 |
| Pneumonia | Real-Time PCR | <i>DiaPlexQ</i> TM PneumoPatho 13 Detection Kit (ver2.) | SQD82 | Simultaneous detection of 13 pathogens causing pneumonia | NS, NA, BAL, O, S | RUO | 40 |
| Mosquito-transmitted infection | Real-Time OneStep RT-PCR | <i>DiaPlexQ</i> TM ZCD Detection Kit (ZIKV, CHIKV, DENV) | SQD06 | Detection of zika virus, chikungunya virus and dengue virus | B, P, S | CE IVD | 42 |
| | | <i>DiaPlexQ</i> TM Dengue Virus Detection Kit | SQD01 | Detection of dengue virus | B | CE IVD | 44 |
| | Multiplex PCR | <i>DiaPlexC</i> TM Malaria Detection Kit | SMD35 | Identification of 4 malaria species | B | CE IVD | 46 |

Pathogen Detection Kit

| Category | Technology | Product | Cat. No. | Description | Specimen* | Registration* | Page |
|---|--------------------------|--|----------|---|-----------------|---------------|------|
| Multidrug resistant Gram-negative Bacterial Infection | Multiplex PCR | <i>DiaPlexC</i> TM CRE Detection Kit | SMD71 | Simultaneous detection of CRE genes (<i>VIM</i> , <i>IMP</i> , <i>NDM</i> , <i>KPC</i>) | U, BA, S, B, ST | CE IVD | 48 |
| Ebola | Real-Time OneStep RT-PCR | <i>DiaPlexQ</i> TM Ebola Virus Detection Kit- Zaire | SQD71 | Detection of Ebola Virus Zaire | B, S, P | CE IVD | 50 |

Human Genotyping Kit

| Category | Technology | Product | Cat. No. | Description | Specimen* | Registration* | Page |
|----------------------|---------------|---|----------|---|-----------|---------------|------|
| Corneal Dystrophy | Real-Time PCR | <i>DiaPlexQ</i> TM Avellino Corneal Dystrophy (ACD) Real-Time PCR Genotyping Kit | SQH26 | ACD genotyping | B, BC, H | CE IVD | 54 |
| | Multiplex PCR | <i>DiaPlexC</i> TM Avellino Corneal Dystrophy (ACD) Genotyping Kit | SHG06 | ACD genotyping | B, BC, H | CE IVD | 54 |
| | Real-Time PCR | <i>DiaPlexQ</i> TM 5 Types Corneal Dystrophy Detection Kit (ACD, RBCD, LCD, TBCD, GCD) | SRH29 | CD genotype screening | B, BC, H | CE IVD | 56 |
| Alzheimer's Disease | Real-Time PCR | <i>DiaPlexQ</i> TM ApoE Genotyping Kit | SQH01 | ApoE mutation (T112C, T158C) detection | B | CE IVD | 58 |
| | Multiplex PCR | <i>DiaPlexC</i> TM Apolipoprotein E (ApoE) Genotyping Kit | SHG01 | ApoE mutation (T112C, T158C) detection | B | CE IVD | 58 |
| Hyperhomocysteinemia | Real-Time PCR | <i>DiaPlexQ</i> TM MTHFR Genotyping Kit | SQH31 | Detection of C677T and A1298C SNP of the MTHFR gene | B | CE IVD | 60 |
| | Multiplex PCR | <i>DiaPlexC</i> TM MTHFR Genotyping Kit | SHG31 | Detection of C677T and A1298C SNP of the MTHFR gene | B | CE IVD | 60 |
| G6PD Deficiency | Multiplex PCR | <i>DiaPlexC</i> TM G6PD Genotyping Kit (African type) | SHG11 | G6PD mutation | B | CE IVD | 62 |
| | | <i>DiaPlexC</i> TM G6PD Genotyping Kit (Asian type) | SHG16 | G6PD mutation | B | CE IVD | 62 |

* 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