Solution for Genetic Technology

# SolGent Molecular Diagnostics

## Real-Time RT-PCR for Detection 2019-Novel Coronavirus

***Approved at third by KCDC-EUA***

***CE-IVD***

**SolGent**
www.SolGent.com



Revision 11-Mar-2020

# About 2019 Novel Coronavirus (2019-nCoV)

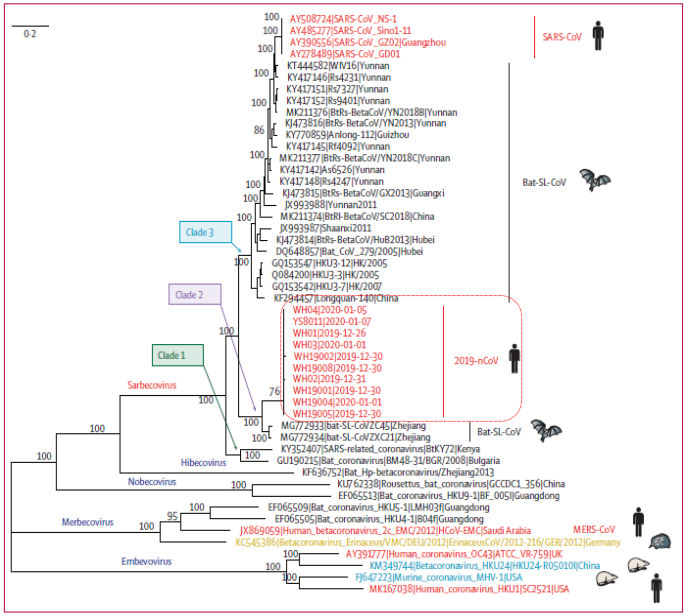



Figure 3: Phylogenetic analysis of full-length genomes of 2019-nCoV and representative viruses of the genus Betacoronavirus
2019-nCoV=2019 novel coronavirus. MERS-CoV=Middle East respiratory syndrome coronavirus. SARS-CoV=severe acute respiratory syndrome coronavirus.

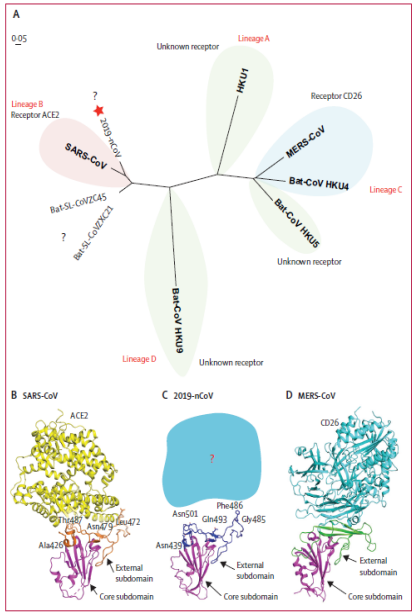



Figure 5: Phylogenetic analysis and homology modelling of the receptor-binding domain of the 2019-nCoV, SARS-CoV, and MERS-CoV

**2019-nCoV was closely related with 88% identity to two bat-derived SARS-like coronaviruses, bat-SL-CoVZC45 and bat-SL-CoVZXC21. 2019-nCoV was closely related with SARS-CoV (about 79 %) and MERS-CoV (about 50 %).**

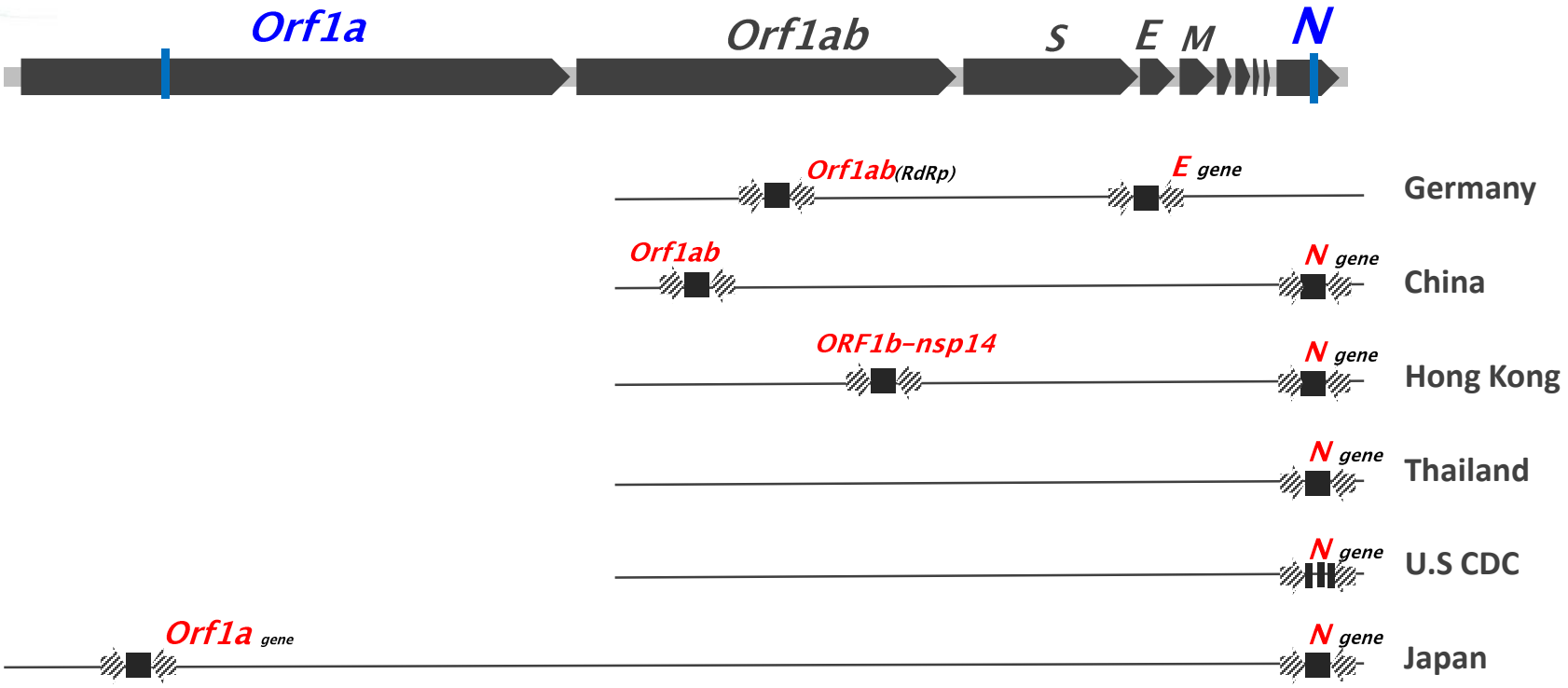
Ref: Genomic characterization and epidemiology of 2019 novel coronavirus: implications for virus origins and receptor binding. Published Online January 29, 2020 https://doi.org/10.1016/S0140-6736(20)30251-8

2019 Novel Coronavirus (2019-nCoV) is a virus (more specifically, a coronavirus) identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. Early on, many of the patients in the outbreak in Wuhan, China reportedly had some link to a large seafood and animal market, suggesting animal-to-person spread. However, a growing number of patients reportedly have not had exposure to animal markets, indicating person-to-person spread is occurring. At this time, it's unclear how easily or sustainably this virus is spreading between people. The latest situation summary updates are available on CDC's web page 2019 Novel Coronavirus, Wuhan, China. (Ref: https://www.cdc.gov/coronavirus/2019-ncov/about/index.html)

# WHO COVID-19(2019-nCoV) technical guidance
# Laboratory testing for 2019-nCoV in humans

| Country | Institute | Gene targets |
|---|---|---|
| China | China CDC | ORF1ab and N |
| Germany | Charité | RdRP, E |
| Hong Kong | HKU | ORF1b-nsp14, N |
| Japan | National Institute of Infectious Diseases | ORF1a |
| Thailand | National Institute of Health | N |
| US | US CDC | Three N primers, Rnase P |
| KOREA | KCDC | RdRp, E |

# Comparison of COVID-19 Detection region by country



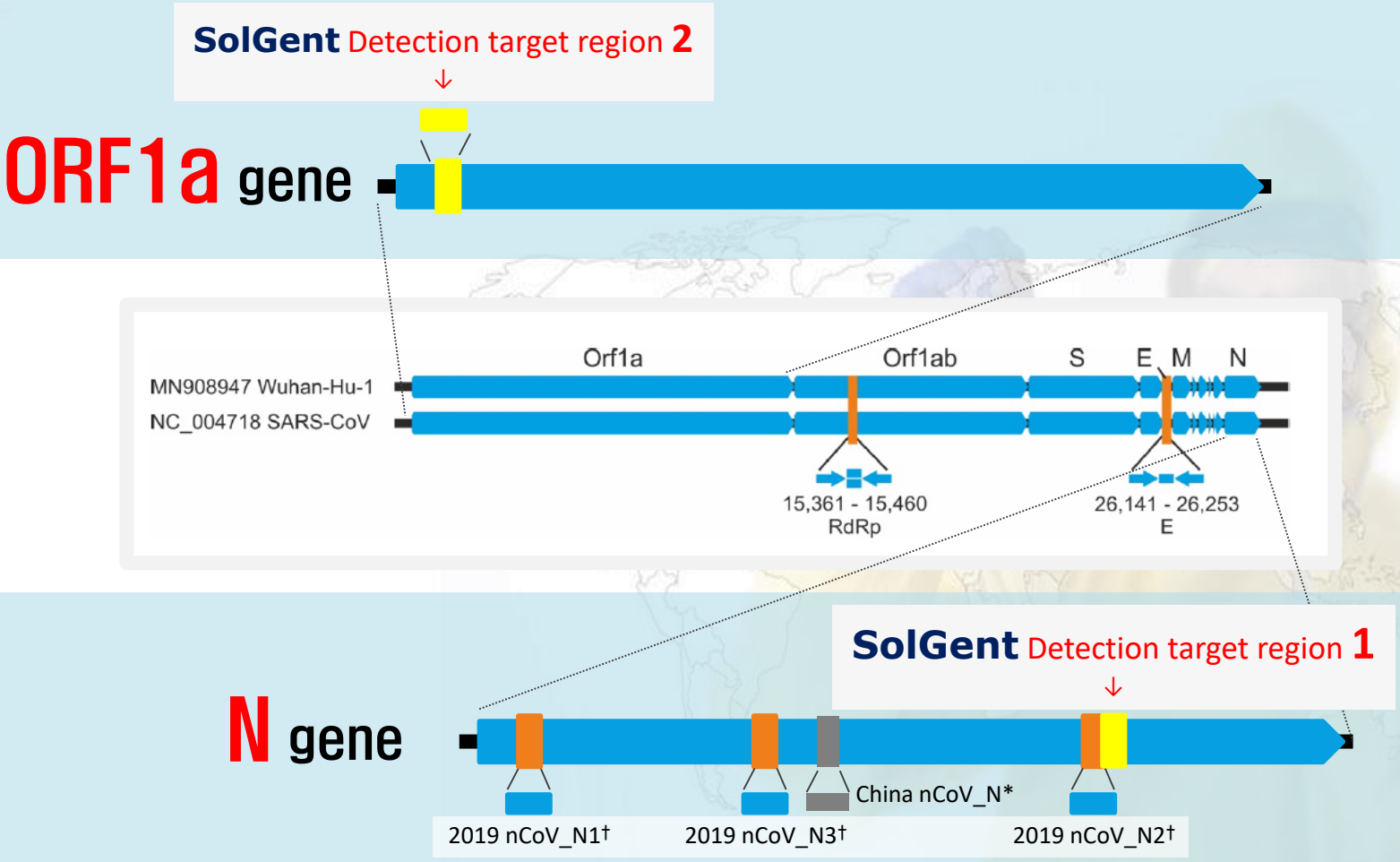
# SolGent

## 2019 Novel Coronavirus Detection system

# *DiaPlexQ*™ 2019 Novel Coronavirus (2019-nCoV) Detection kit

# DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

## Specific Target region




† 2019-Novel Coronavirus (2019-nCoV) Real-time qRT-PCR Panel Primers and Probes by CDC
* National Institute for Viral Disease Control and Prevention

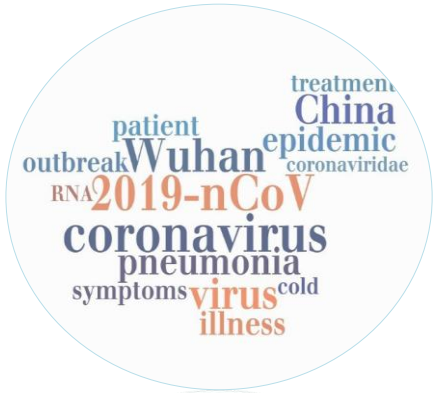
# DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

► Contents

| Components | SQD52-K020 | SQD52-K100 |
|---|---|---|
| 2X OneStep qRT-PCR Buffer (2019-nCoV) | 200 µℓ x 1 ea | 1.0 mL x 1ea |
| OneStep qRT-PCR Enzyme mix (2019-nCoV) | 40 µℓ x 1 ea | 200 µℓ x 1 ea |
| Primer & Probe Mixture (2019-nCoV) | 60 µℓ x 1 ea | 300 µℓ x 1 ea |
| Control Template (2019-nCoV) | 20 µℓ x 1 ea | 100 µℓ x 1 ea |
| RNase Free Water | 200 µℓ x 1 ea | 1.0 mL x 1 ea |

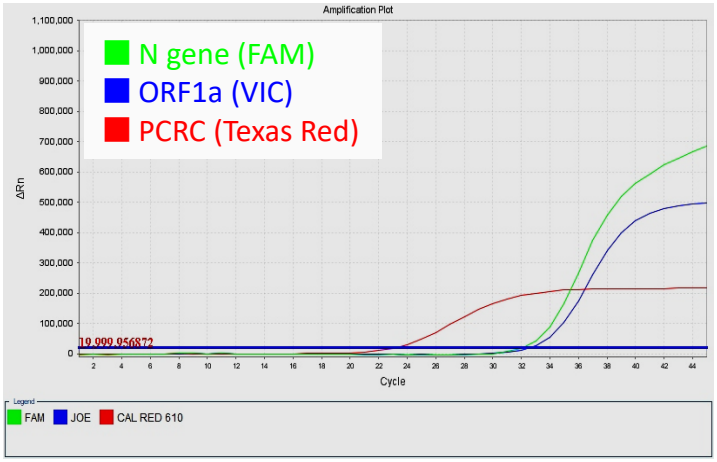
►Specimens
- Nasopharyngeal swab
- Oropharyngeal swab
- Sputum

►Instrument
- Applied Biosystems™ 7500, 7500 Fast Instrument System
- Bio-Rad CFX96™ System



# DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

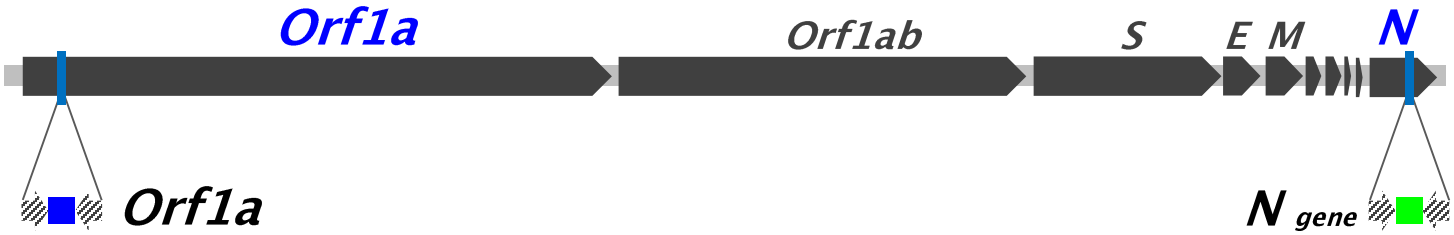
## Amplification Plot information




## Fluorescence information

| Target | 5` Fluorophore | 3` Quencher |
|---|---|---|
| ***N gene*** | ***FAM*** | ***BHQ1*** |
| ***ORF1a*** | ***VIC / JOE**** | ***BHQ1*** |
| ***PCR control*** | ***Texas Red/ Cal Fluor Red 610**** | ***BHQ2*** |

*ABI 7500 / 7500 Fast: JOE, Texas Red | Bio Rad CFX96™: VIC, Cal Fluor Red 610




2019-nCoV Detection region **2** of **SolGent**

2019-nCoV Detection region **1** of **SolGent**

# DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

| Sample collection | Nucleic acid isolation | Multiplex OneStep RT-qPCR | Data analysis |
|---|---|---|---|
| Sample collection according to sample type | • Manual Method<br>• Auto extraction Method | ***DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit*** | Use of software for each instrument |

- HotStart PCR: high-specificity
- OneStep PCR : multiple targets in a single reaction
- Reliable system: automatic PCR control
- Easy-to-use master mix: just adding template and Primer/Probe Mix
- Rapid detection: OneStep RT-qPCR

**PCR Reaction Time: 2 hour**

# DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

| Sample collection | Nucleic acid isolation | Multiplex OneStep RT-qPCR | Data analysis |
|---|---|---|---|
| Sample collection according to sample type | • Manual Method<br>• Auto extraction Method | DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit | Use of software for each instrument |


| Cap color | Reaction Mixture | Vol. |
|---|---|---|
| Red ● | 2X OneStep RT-qPCR Buffer | 10 ㎕ |
| Blue ● | OneStep RT-qPCR Enzyme mix | 2 ㎕ |
| Violet ● | Primer/Probe Mixture | 3 ㎕ |
| | Sample template | 5 ㎕ |
| | **Total** | **20 ㎕** |

| PCR Condition | | | | |
|---|---|---|---|---|
| | Reverse Transcription | 50 ℃ | 15 min | X 1 |
| | Initial PCR activation | 95 ℃ | 15 min | X 1 |
| | Denaturation | 95 ℃ | 20 sec | X 45 |
| | Annealing / Extension | 60 ℃ | 40 sec | |

# DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

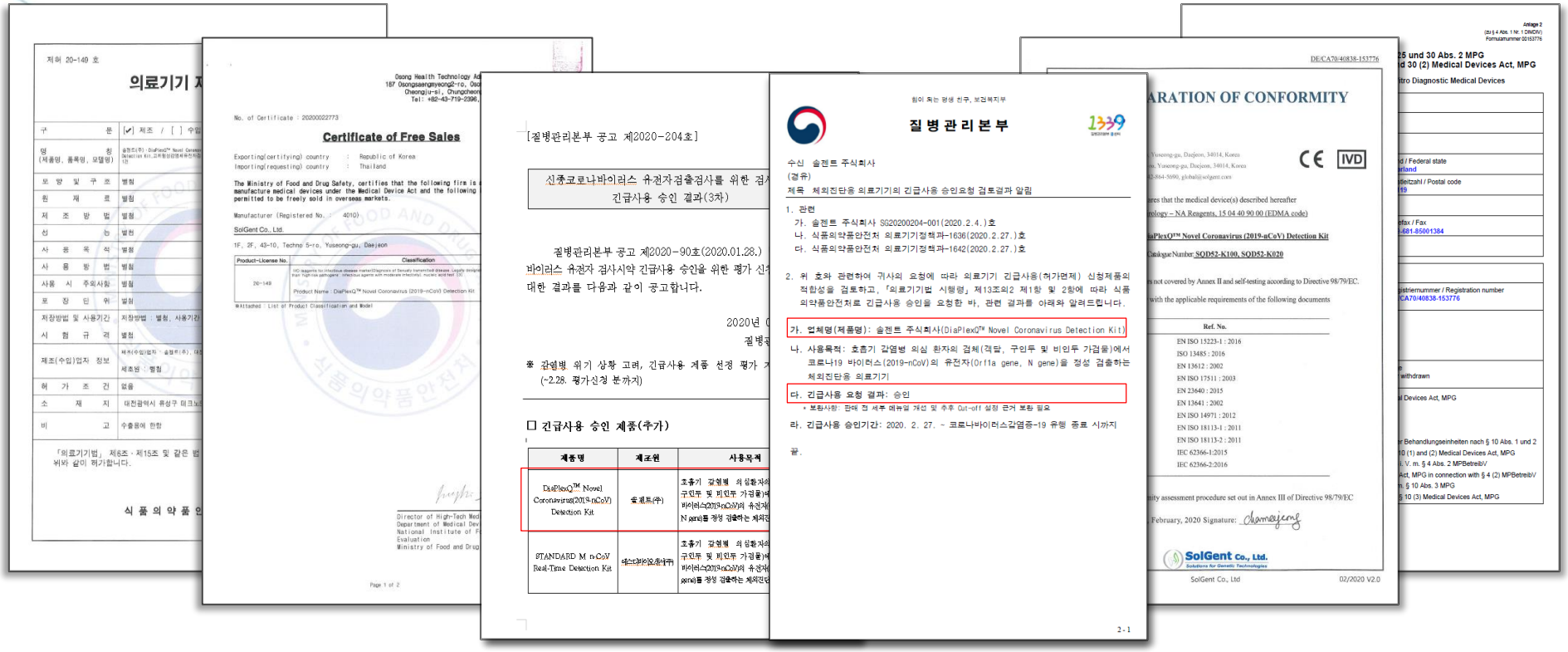
## Interpretation of Results

| Type | FAM | JOE / VIC | Texas Red/ Cal Fluor Red 610 | Result Interpretation |
|---|---|---|---|---|
| | N gene | Orf1a | PCRC | |
| PC(Positive Control) | + | + | + | Valid |
| NTC (Non-Template Control) | - | - | + | Valid |
| Sample case 1 | + | - | +/- | *2019-nCoV detected* |
| Sample case 2 | - | + | +/- | *2019-nCoV detected* |
| Sample case 3 | + | + | +/- | *2019-nCoV detected* |
| Sample case 4 | - | - | + | *2019-nCoV not detected* |
| Sample case 5 | - | - | - | Invalid Result* |

- PC should be **positive** and with CT values within 35 cycles. If PC are *negative*, the testing results for that plate are invalid. Repeat qRT-PCR test.
- NTC should be **negative.** If NTCs are *positive*, the testing results for that plate are invalid.
- Detection of the PCR Control(PCRC) in the Texas Red(or Cal Fluor Red 610) detection channel is not required for positive results in the FAM or JOE(VIC) detection channel. A high Virus RNA load in the sample can lead to reduced or absent PCR Control signal.
- If the results show $40<Ct \leq 45$, perform the experiment again.

* RT-PCR inhibition or reagent failure. Repeat testing from original sample or collect and test a new sample.

# *Certifications of DiaPlexQ™ Novel Corona Detection kit*

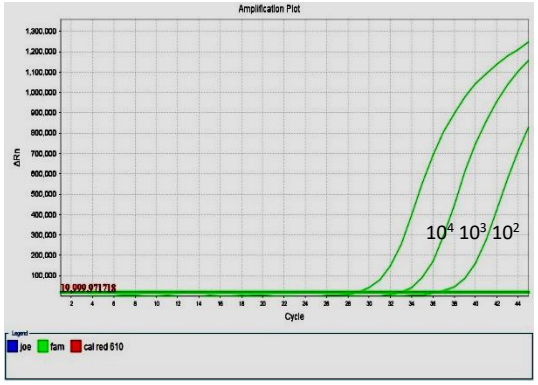



***CFS of KFDA*** ***Approved at third by KCDC-EUA*** ***CE-IVD***

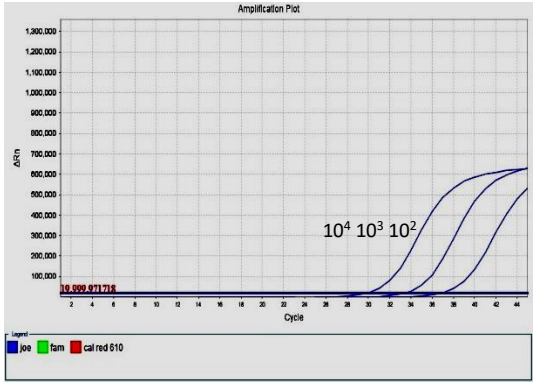
# DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

## The Analytical Sensitivity Test by viral RNA

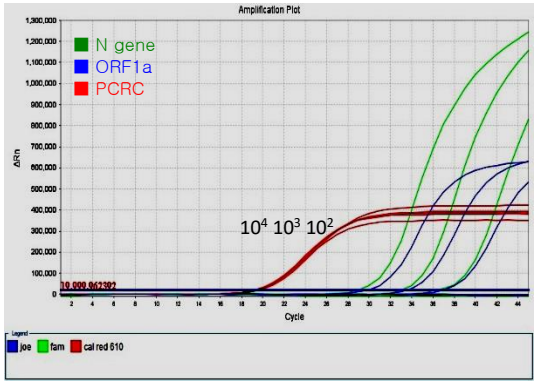
N gene




ORF1a




Merged
ORF1a & N gene




| Viral RNA Concentration | Total Copies / rxn | Hit Rate (%) |
|---|---|---|
| 63 fg/ul | 10,000 | 100 |
| 6.3 fg/ul | 1,000 | 100 |
| 630 ag/ul | 100 | 100 |
| 63 ag/ul | 10 | 95 |

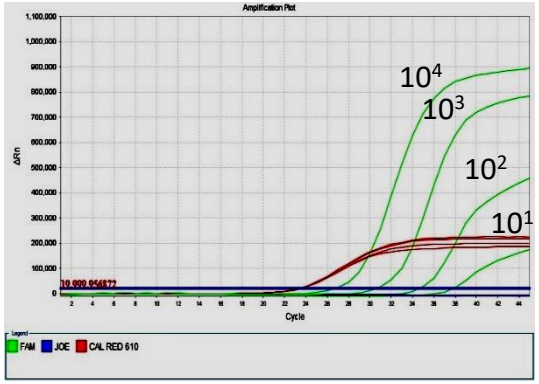
*Viral RNA reference: National Hospital Resource Bank (NCCP No. 43326)

*The analytical sensitivity of the DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit determined by Probit analysis is 100 copies/ul of viral RNA*

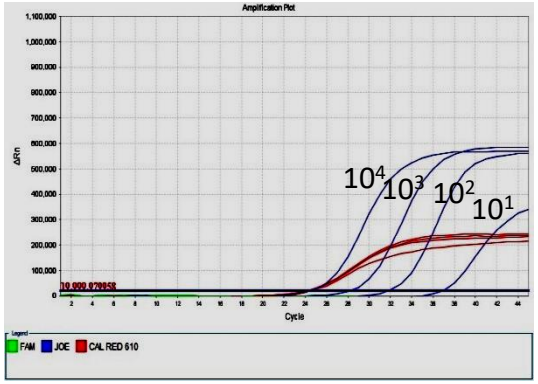
# DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

## *The Analytical Sensitivity Test by In vitro* synthesized Transcripts RNA

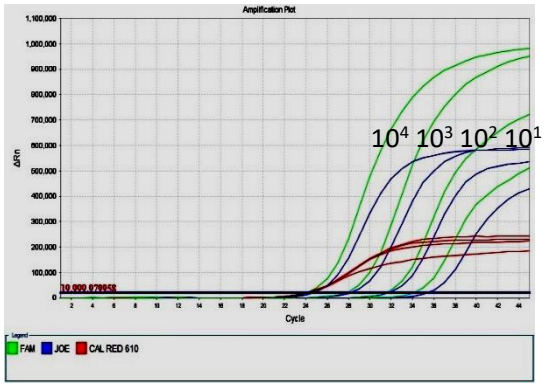
*N gene*
*Single Transcripted RNA*




*ORF1a*
*Single Transcripted RNA*




*ORF1a & N gene*
*Dual Transcripted RNA*



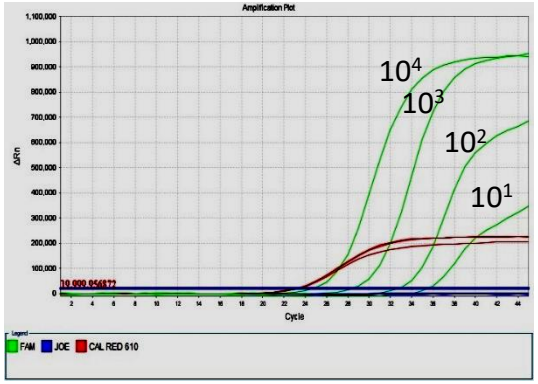

| *Transcripts RNA Conc. of N gene* | *Transcripts RNA Conc. of Orf1a* | *Total Copies / rxn* | *Hit Rate (%)* |
|---|---|---|---|
| 7.5 fg/ul | 1.25 fg/ul | 10,000 | 100 |
| 750 ag/ul | 125 ag/ul | 1,000 | 100 |
| 75 ag/ul | 12.5 ag/ul | 100 | 100 |
| 7.5 ag/ul | 1.25 ag/ul | 10 | 95 |

*The analytical sensitivity of the DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit determined by Probit analysis is 10 copies/ul of in vitro transcripted RNA*

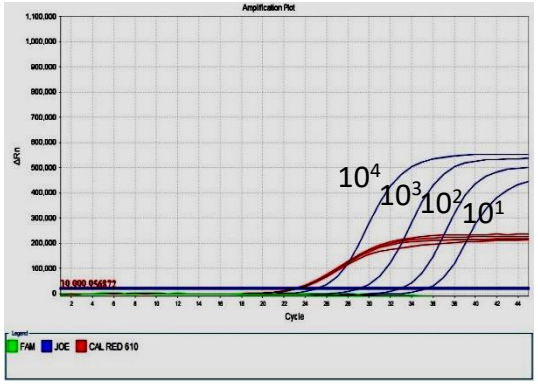
# DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

## The Analytical Sensitivity Test by Target region Plasmid DNA

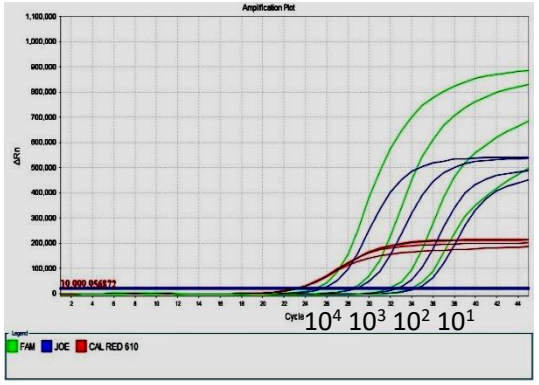
*N gene – Single Plasmid DNA*




*ORF1a – Single Plasmid DNA*




*ORF1a & N gene – Multi Plasmid DNA*



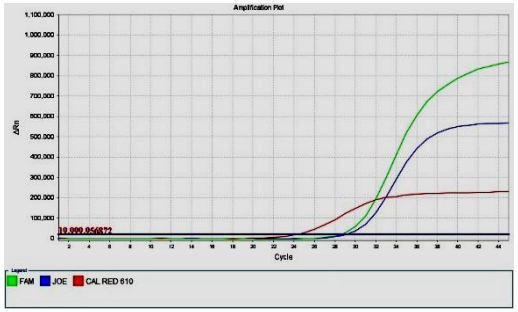

| Plasmid DNA Conc. of N gene | Plasmid DNA Conc. of Orf1a | Total Copies / rxn | Hit Rate (%) |
|---|---|---|---|
| 200 fg/ul | 200 fg/ul | 10,000 | 100 |
| 20 ag/ul | 20 ag/ul | 1,000 | 100 |
| 2 ag/ul | 2 ag/ul | 100 | 100 |
| 0.2 ag/ul | 0.2 ag/ul | 10 | 95 |

*The analytical sensitivity of the DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit determined by Probit analysis is 10 copies/ul of in vitro trasncripted RNA*

# DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

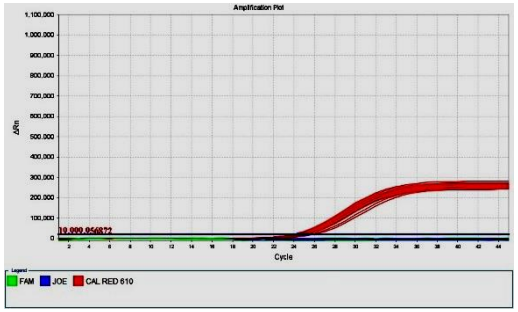
*Organisms tested to demonstrate the analytical Specificity*
*(Respiratory virus associated, Human RNA)*

**Control Template (2019-nCoV)**




N gene (FAM)
ORF1a (JOE)
PCRC (Texas Red)

**38 negative strains**




N gene (FAM)
ORF1a (JOE)
PCRC (Texas Red)

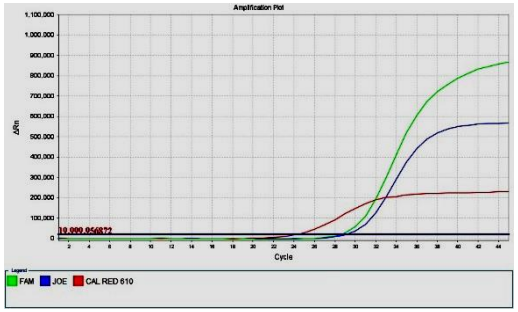
| *Organisms* | *FAM or JOE ( N or Orf1a)* | *Texas Red (PCRC)* |
|---|---|---|
| *Parainfluenza I* | N/D | ≤ 26 |
| *Parainfluenza II* | N/D | ≤ 26 |
| *Parainfluenza III* | N/D | ≤ 26 |
| *Parainfluenza IV* | N/D | ≤ 26 |
| *Influenza A* | N/D | ≤ 26 |
| *Influenza B* | N/D | ≤ 26 |
| *Adenovirus* | N/D | ≤ 26 |
| *Respiratory syncytial virus A* | N/D | ≤ 26 |
| *Respiratory syncytial virus B* | N/D | ≤ 26 |
| *Rhino 8, A* | N/D | ≤ 26 |
| *Bocavirus* | N/D | ≤ 26 |
| *Metapneumovirus* | N/D | ≤ 26 |
| *Beta Coronavirus OC43* | N/D | ≤ 26 |
| *Alpha Coronavirus 229E* | N/D | ≤ 26 |
| *Enterovirus* | N/D | ≤ 26 |
| Human total RNA (10ng/μl) | N/D | ≤ 26 |
| Control Template (2019-nCoV) | N/D | ≤ 26 |

*DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit did not Cross-react with any of specified organisms*

# DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

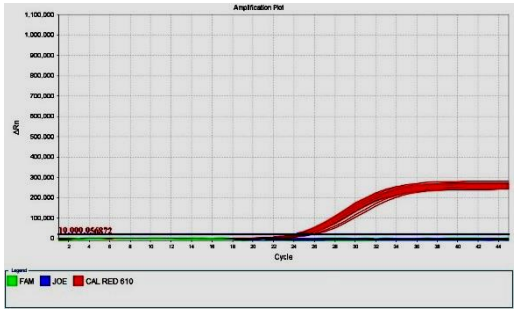
*Organisms tested to demonstrate the analytical Specificity*
*(Pneumonia and Tuberculosis associated)*

***Control Template (2019-nCoV)***




N gene (FAM)
ORF1a (JOE)
PCRC (Texas Red)

***38 negative strains***




N gene (FAM)
ORF1a (JOE)
PCRC (Texas Red)

| *Organisms* | *FAM or JOE ( N or Orf1a)* | *Texas Red (PCRC)* |
|---|---|---|
| *Acinetobacter baumannii* | N/D | ≤ 26 |
| *Bordetella parapertussis* | N/D | ≤ 26 |
| *Bordetella pertussis* | N/D | ≤ 26 |
| *Chlamydophila pneumoniae* | N/D | ≤ 26 |
| *Haemophilus influenza* | N/D | ≤ 26 |
| *Klebsiella pneumoniae* | N/D | ≤ 26 |
| *Legionella pneumophila* | N/D | ≤ 26 |
| *Moraxella catarrhalis* | N/D | ≤ 26 |
| *Mycoplasma pnemoniae* | N/D | ≤ 26 |
| *Pseudomonas aeruginosa* | N/D | ≤ 26 |
| *Serratia marcescens* | N/D | ≤ 26 |
| *Staphylococcus aureus* | N/D | ≤ 26 |
| *Stenotrophomonas maltophilia* | N/D | ≤ 26 |
| *Streptococcus pneumoniae* | N/D | ≤ 26 |
| *Mycobacterium abscessus* | N/D | ≤ 26 |
| *Mycobacterium avium* | N/D | ≤ 26 |
| *Mycobacterium bovis* | N/D | ≤ 26 |
| *Mycobacterium chelonae* | N/D | ≤ 26 |
| *Mycobacterium intracellulare* | N/D | ≤ 26 |
| *Mycobacterium kansasii* | N/D | ≤ 26 |
| *Mycobacterium scrofulaceum* | N/D | ≤ 26 |
| *Mycobacterium tuberculosis* | N/D | ≤ 26 |

*DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit did not Cross-react with any of specified organisms*

- Ordering information for relative Products

| Name of kits | Cat. No. | Detection Method |
|---|---|---|
| *DiaPlexQ™* Novel Coronavirus (2019-nCoV) Detection Kit | SQD52-K100<br>SQD52-K020 | Real-Time PCR |
| *DiaPlexQ™* 2019-nCoV (RdRp, E, N) Detection Kit | SQD55-K100<br>SQD55-K020 | |
| *DiaPlexQ™* RV16 Detection Kit | SQD50-K100<br>SQD50-K020 | |
| *DiaPlexQ™* PneumoPatho16 Detection Kit | SQD80-K100<br>SQD80-K020 | |
| *DiaPlexQ™* MTC/NTM detection Kit-Ver. 3.0 | SQD25-K100<br>SQD25-K020 | |

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E-mail global@solgent.com
website www.solgent.com

## *DiaPlexQ™* RV16 Detection Kit

► Target Organisms

| | |
|---|---|
| SET/01 | *Parainfluenza virus I*<br>*Parainfluenza virus II*<br>*Parainfluenza virus III* |
| SET/02 | *Parainfluenza virus IV*<br>*Influenza A virus*<br>*Influenza B virus* |
| SET/03 | *Adenovirus*<br>*Respiratory syncitial virus A/B*<br>*Rhinovirus* |
| SET/04 | *Enterovirus*<br>*Bocavirus*<br>*Metapneumovirus* |
| SET/05 | *Alpha Corona virus 229E/NL63*<br>*Beta Corona virus OC43*<br>*MERS Corona virus* |

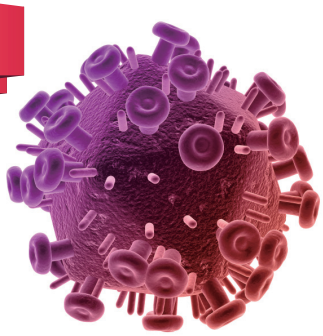
## *DiaPlexQ™* PP16 Detection Kit

► Target Organisms

| | |
|---|---|
| SET/01 | *Mycoplasma pnemoniae (MP)*<br>*Klebsiella pneumoniae (KP)*<br>*Legionella pneumophila (LP)* |
| SET/02 | *Streptococcus pneumoniae (SP)*<br>*Staphylococcus aureus (SA)*<br>*Chlamydophila pneumoniae (CP)* |
| SET/03 | *Pseudomonas aeruginosa (PA)*<br>*Moraxella catarrhalis (MC)*<br>*Bordetella pertussis (BP)* |
| SET/04 | *Haemophilus influenza (HI)*<br>*Acinetobacter baumannii (AB)*<br>*M. tuberculosis (TB) / M. avium (AV)* |
| SET/05 | *Serratia marcescens (SMar)*<br>*Bordetella parapertussis (BPara)*<br>*Stenotrophomonas maltophilia (SMalt)* |

SolGent

NEW



긴급사용승인(KCDC EUAL), CE-IVD

# DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

(Cat.no. SQD52-K100, SQD52-K020)

Multiplex OneStep qRT-PCR based assay system
Qualitative Detection of 2019-nCoV
Control Template (2019-nCoV) included

## Detection Target Region

- ORF1a
- N gene

## Specimen type

- Nasopharyngeal swab
- Oropharyngeal swab
- Sputum

## Instruments

- Applied Biosystems™ 7500 Real-Time PCR Instrument System
- Applied Biosystems™ 7500 Fast Real-Time PCR Instrument System
- Bio-Rad CFX96™ System

## Process

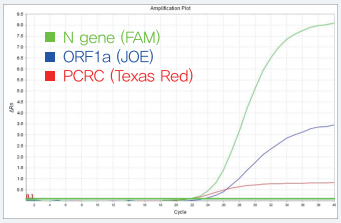
**Sample collection**
- Sample collection according to sample type

**Nucleic acid isolation**
- Manual Method
- Auto extraction Method

**Multiplex qPCR**
DiaPlexQ ™ Novel Coronavirus (2019-nCoV) Detection Kit

**Data analysis**
- Use of software For each instrument

## Result Analysis




Amplification Plot information

| Target | 5` Fluorophore | 3` Quencher |
|---|---|---|
| N gene | FAM | BHQ1 |
| ORF1a | VIC / JOE* | BHQ1 |
| PCR control | *Texas Red/ Cal Fluor Red 610 | BHQ2 |

*ABI 7500 / 7500 Fast: JOE, Texas Red
Bio Rad CFX96™ : VIC, Cal Fluor Red 610

## Ordering Information for Relative Products

| Name of Kits | Cat. No. | Approval | Detection Method |
|---|---|---|---|
| DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit | SQD52-K100 | KCDC EUAL, CE-IVD | Real-Time PCR |
| DiaPlexQ™ 2019-nCoV (RdRp, E, N) Detection Kit | SQD55-K100 | CE-IVD | |
| DiaPlexQ™ RV16 Detection Kit | SQD50-K100 | CE-IVD | |
| DiaPlexQ™ PneumoPatho 16 Detection Kit | SQD80-K100 | RUO | |
| DiaPlexQ™ MTC/NTM Detection Kit - Ver 3.0 | SQD25-K100 | CE-IVD | |

SolGent Co., Ltd (In South Korea)
1, 2F, 43-10 Techno 5-ro, Yuseong-gu, Daejeon, 34014, Korea
**Tel** +82-70-7805-7396 **Fax** +82-42-864-5690
**E-mail** global@solgent.com **website** www.solgent.com

# SolGent Co.,Ltd.

## DiaPlexQ™ Novel Coronavirus Detection Kit

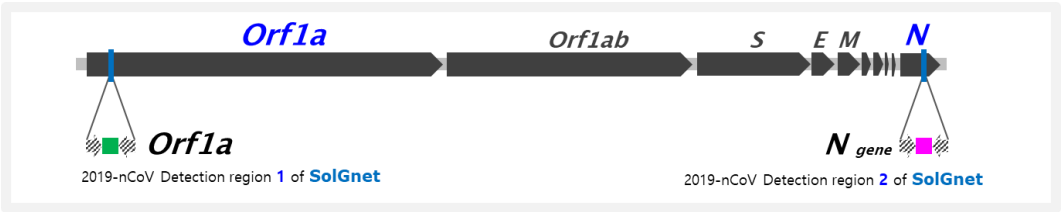
## Features

1. Multiplex OneStep qRT-PCR
2. Hot Start PCR system by using optimized Hot Start polymerase
3. Commercial Real-time PCR Instrument available
4. High specificity: simultaneous detection of ORF1a and N gene.

| Components | SQD52-K020 | SQD52-K100 |
|---|---|---|
| 2X OneStep qRT-PCR Buffer (2019-nCoV) | 200 ㎕ x 1 ea | 1.0 mL x 1ea |
| OneStep qRT-PCR Enzyme mix (2019-nCoV) | 40 ㎕ x 1 ea | 200 ㎕ x 1 ea |
| Primer & Probe Mixture (2019-nCoV) | 60 ㎕ x 1 ea | 300 ㎕ x 1 ea |
| Control Template (2019-nCoV) | 20 ㎕ x 1 ea | 100 ㎕ x 1 ea |

## Detection Targents

■ Simultaneous Detection of ORF1a / N gene




- CDC 2019-Novel Coronavirus (2019-nCoV) Real-time rRT-PCR Panel Primers and Probes
- High specific targets were selected based on the Chinese CDC and US CDC.

## Performance

- Analytical sensitivity is ~10 copies. Sensitivity is measured using the RNA(In vitro transcript) with the target gene region of Novel Coronavirus (2019-nCoV) as a template.

- It showed high specificity and not detected on other viruses and bacteria other than new coronavirus as a result of specificity test for respiratory virus, pneumonia, and 38 species of tuberculosis.

## Related Products (16 species of respiratory virus detection kit including like-coronavirus)

1. The Kit consists of 5 SETs, Including MERS-CoV, which detects various respiratory viruses.
2. Coronavirus OC43/229E/NL63 vs. MERS-CoV(simultaneous detection of upE/ORF1a)

| *SET I* | *SET II* | *SET III* | *SET IV* | *SET V* |
|---|---|---|---|---|
| *Parainfluenza virus I* | *Influenza virus A* | *Adenovirus* | *Enterovirus* | *Coronavirus OC43* |
| *Parainfluenza virus II* | *Influenza virus B* | *Respiratory Syncytial virus A/B* | *Bocavirus* | *Coronavirus 229E/NL63* |
| *Parainfluenza virus III* | *Parainfluenza virus IV* | *Rhinovirus A/B/C* | *Metapneumovirus* | *Coronavirus MERS* |

Product Marketing Manager
Business support team: Junho Park (C.P : 010-7541-1525, Tel : 070-7893-7847, E.mail : junho.park@solgent.com)
**SolGent Co.,Ltd.**
Tel. +82-1544-5695 l Address: 43-10, Techno 5ro, Yuseong-gu, Daejeon, 34014, Korea

# EC DECLARATION OF CONFORMITY

**SolGent Co., Ltd.**
Head Office : 3F, 32, Techno 6-ro, Yuseong-gu, Daejeon, 34014, Korea
Factory : 1F, 2F, 43-10, Techno 5-ro, Yuseong-gu, Daejeon, 34014, Korea
Tel : +82-42-864-5695, Fax: +82-42-864-5690, global@solgent.com

CE IVD

Declares that the medical device(s) described hereafter

Other Virology – NA Reagents, 15 04 40 90 00 (EDMA code)

Model Name:**DiaPlexQ™ 2019-nCoV (RdRp, E, N) Detection Kit**

Catalogue Number: **SQD55-K100, SQD55-K020**

Has been classified as Others not covered by Annex II and self-testing according to Directive 98/79/EC.

Is in conformity with the applicable requirements of the following documents

| Ref. No. |
|---|
| EN ISO 15223-1 : 2016 |
| ISO 13485 : 2016 |
| EN 13612 : 2002 |
| EN ISO 17511 : 2003 |
| EN 23640 : 2015 |
| EN 13641 : 2002 |
| EN ISO 14971 : 2012 |
| EN ISO 18113-1 : 2011 |
| EN ISO 18113-2 : 2011 |
| IEC 62366-1:2015 |
| IEC 62366-2:2016 |

Is subject to the conformity assessment procedure set out in Annex III of Directive 98/79/EC

26th, February, 2020 Signature: Chameejeong

SolGent Co., Ltd.
Solutions for Genetic Technologies

**Anlage 2**
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00153776

# Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
# General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

## Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

| **Zuständige Behörde / Competent authority** | | | |
|---|---|---|---|
| | Code<br>**DE/CA70** | | |
| | Bezeichnung / Name<br>**Landesamt für Umwelt- und Arbeitsschutz** | | |
| | Staat / State<br>**Deutschland** | | Land / Federal state<br>**Saarland** |
| | Ort / City<br>**Saarbrücken** | | Postleitzahl / Postal code<br>**66119** |
| | Straße, Haus-Nr. / Street, house no.<br>**Don-Bosco-Straße 1** | | |
| | Telefon / Phone<br>**+49-681-85000** | | Telefax / Fax<br>**+49-681-85001384** |
| | E-Mail / E-mail<br>**lua@lua.saarland.de** | | |

| **Anzeige / Notification** | | | |
|---|---|---|---|
| | Registrierdatum bei der zuständigen Behörde<br>Registration date at competent authority<br>**27.02.2020** | | Registriernummer / Registration number<br>**DE/CA70/40838-153776** |
| | Typ der Anzeige / Notification type<br>£ Erstanzeige / Initial notification<br>S Änderungsanzeige / Notification of change<br>£ Widerrufsanzeige / Notification of withdrawal | | |
| | Frühere Registriernummer bei Änderungs- und Widerrufsanzeige<br>Previous registration number if notification has been changed or withdrawn<br>**DE/CA70/40838-143224** | | |
| | Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG<br>£ Hersteller / Manufacturer<br>S Bevollmächtigter / Authorised Representative<br>£ Einführer / Importer<br>£ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG<br>£ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV<br>Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV<br>£ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG<br>Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG | | |

| **Anzeigender / Reporting organisation (person)** | | | |
|---|---|---|---|
| | Code<br>**DE/0000040838** | | |
| | Bezeichnung / Name<br>**Medical Technology Promedt Consulting GmbH** | | |
| | Staat / State<br>**Deutschland** | | Land / Federal state<br>**Saarland** |
| | Ort / City<br>**ST. INGBERT** | | Postleitzahl / Postal code<br>**66386** |
| | Straße, Haus-Nr. / Street, house no.<br>**Altenhofstrasse 80** | | |
| | Telefon / Phone<br>**+49-6894-581020** | | Telefax / Fax<br>**+49-6894-581021** |
| | E-Mail / E-mail<br>**info@mt-procons.com** | | |

| **Hersteller / Manufacturer** | | | |
|---|---|---|---|
| | Bezeichnung / Name<br>**Solgent Co., Ltd.** | | |
| | Staat / State<br>**KR** | | |
| | Ort / City<br>**Daejeon** | | Postleitzahl / Postal code<br>**34014** |
| | Straße, Haus-Nr. / Street, house no.<br>**3F, 32, Techno 6-ro, Yuseong-gu** | | |
| | Telefon / Phone<br>**+82-42-864-5695** | | Telefax / Fax<br>**+82-42-864-5690** |
| | E-Mail / E-mail<br>**global@solgent.com** | | |

| **Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9)**<br>**Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG** | | | |
|---|---|---|---|
| | Bezeichnung / Name<br>**Dr. Michael Rinck** | | |
| | Staat / State<br>**Deutschland** | | Land / Federal state<br>**Saarland** |
| | Ort / City<br>**ST. INGBERT** | | Postleitzahl / Postal code<br>**66386** |
| | Straße, Haus-Nr. / Street, house no.<br>**Altenhofstrasse 80** | | |
| | Telefon / Phone<br>**+49-6894-581020** | | Telefax / Fax<br>**+49-6894-581021** |
| | E-Mail / E-mail<br>**info@mt-procons.com** | | |

| **Vertreter / Deputy (optional)** | | | |
|---|---|---|---|
| | Bezeichnung / Name<br>**Clemens Mohr** | | |
| | Telefon / Phone<br>**+49-6894-581020** | | Telefax / Fax<br>**+49-6894-581021** |
| | E-Mail / E-mail<br>**info@mt-procons.com** | | |
| | £ Erstanzeige / Initial notification<br>S Änderungsanzeige / Notification of change | | |

**In-vitro-Diagnostikum / In vitro diagnostic medical device**

Klassifizierung / Classification

£ Produkt der Liste A, Anhang II / Device of List A, Annex II

£ Produkt der Liste B, Anhang II / Device of List B, Annex II

£ Produkt zur Eigenanwendung / Device for self-testing

S Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)

App (Software auf mobilen Endgeräten) £ ja / yes S nein / no

Anzeige nach § 25 Abs. 3 Nummer 3 MPG

Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG

£ "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"

Handelsname des Produktes / Trade name of the device

**DiaplexC RV13 Detection Kit; DiaPlexQ Ebola Virus Detection Kit; DiaPlexQ RV16 Detection Kit; LytePrime Mplex ZCD RT-PCR Kit 1.0 (ZIKV/CHIKV/DENV); DiaPlexQ ZCD Detection Kit (ZIKV, CHIKV, DENV); DiaPlexQ Novel Corona Virus (2019-nCoV) Detection Kit; DiaPlexQ 2019-nCoV (RdRp, E, N) Detection Kit**

Produktbezeichnung / Name of device

Angabe der benutzten Nomenklatur / Nomenclature used

S EDMS-Klassifikation / EDMS Classification

£ GMDN

Nomenklaturcode / Nomenclature code

**15-04-40-90-00**

Nomenklaturbezeichnung / Nomenclature term

**OTHER VIROLOGY - NA REAGENTS**

Kurzbeschreibung / Short description

In Deutsch / In German

**Das DiaPlexC RV13 Detection Kit wird verwendet zum Nachweis von Metapneumoviren (MPV), Coronaviren (OC43; 229E), Bocaviren, Rhinoviren A/B/C (und anderen separat gemeldet: Enteroviren, Parainfluenza I, II, III, Respiratory-Syncytial-Viren, Adenoviren und Influenzaviren A/B mittels Verwendung einer Multiplex-PCR Technologie. Das DiaPlexQ Ebola Virus Detection Kit wird verwendet zum qualitativen Nachweis von Ebolaviren in Blut oder Serum mittels OneStep qRT-PCR. Das DiaPlexQ RV16 Detection Kit wird verwendet zum qualitativen Nachweis von Rhinovirus (RV A / B / C), Bocavirus (BoV), Metapneumovirus (MPV), Beta Coronavirus OC43 (CoV OC43), Alpha Coronavirus 229E (CoV 229E), Alpha Coronavirus NL63 (CoV NL63), MERS Coronavirus (MERS)(und anderen, separat gemeldet: Parainfluenza-I, Parainfluenza-II, Parainfluenza-III, Parainfluenza-IV, Influenza A (Inf. A), Influenza B (Inf. B), Adenovirus (AdV), Respiratorisches Synzytialvirus (RSV A & B), Enterovirus (EntV)), aus Sputum- oder Nasopharyngeal-Abstrichproben mittels OneStep qRT-PCR. Das LytePrime Mplex ZCD RT-PCR Kit 1.0 (ZIKV/CHIKV/DENV) wird verwendet zum qualitativen Nachweis von Zika Viren (ZIKV), Chikungunya Viren (CHIKV) und Dengue Viren (DENV) im Serum oder Vollblut. Das DiaPlexQ ZCD Detection Kit (ZIKV, CHIKV, DENV) wird verwendet zum Nachweis von Zika Viren, Chikungunya Viren und Dengue Viren. DiaPlexQ Novel Corona Virus (2019-nCoV) Detection Kit ist ein in vitro-diagnostisches Reagenz zum qualitativen Nachweis des ORF1a, N-Gens von COVID-19 durch Multiplex OneStep qRT-PCR. DiaPlexQ 2019-nCoV (RdRp, E, N) Detection Kit ist ein in-vitro-diagnostisches Reagenz zum qualitativen Nachweis von ORF1ab(RdRp), E-Gen, N-Gen von COVID-19 mittels Multiplex OneStep qRT-PCR. Nur von Fachpersonal anzuwenden. Interne Admin.-Nr.: SOL-08, SOL-08-01 bis SOL-08-05.**

| | |
|---|---|
| | In Englisch / In English<br>**DiaPlexC RV13 Detection Kit is designed to detect Metapneumovirus (MPV), Coronavirus OC43(CoV OC43), Coronavirus 229E (CoV 229E), Enterovirus (EntV), Parainfluenza I, II, III (PIV-I, II, III), Respiratory syncytial virus (RSV), Adenovirus (AdV), Bocavirus (Bov), Rhinovirus A/B/C (RV A/B/C) and Influenza virus A/B (Inf A/B) using multiplex PCR technology. DiaPlexQ Ebola Virus Detection Kit is used for the qualitative detection of Ebola Virus from blood or serum of Ebola Virus infected patients by OneStep qRT-PCR. DiaPlexQ RV16 Detection Kit ualitative detection of Parainfluenza-I, Parainfluenza-II, Parainfluenza-III, Parainfluenza-IV, Influenza A (Inf A), Influenza B (Inf B), Adenovirus (AdV), Respiratory syncytial virus (RSV A & B), Rhinovirus (RV A/B/C), Enterovirus (EntV), Bocavirus (BoV), Metapneumovirus (MPV), Beta Coronavirus OC43 (CoV OC43), Alpha Coronavirus 229E (CoV 229E), Alpha Coronavirus NL63 (CoV NL63), MERS Coronavirus (MERS)) from sputum or Nasopharyngeal smear samples of each Virus infected patients by OneStep qRT-PCR. LytePrime Mplex ZCD RT-PCR Kit 1.0 (ZIKV/CHIKV/DENV) is intended for qualitative detection of Zika virus (ZIKV), Chikungunya virus (CHIKV) and Dengue virus (DENV) from human serum and whole blood. DiaPlexQ ZCD Detection Kit (ZIKV, CHIKV, DENV) is designed to detect Zika virus, Chikungunya virus and Dengue virus rapidly and accurately. DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit is in vitro diagnostic reagent to qualitative detection of ORF1a, N gene of COVID-19 by Multiplex OneStep qRT-PCR. DiaPlexQ 2019-nCoV (RdRp, E, N) Detection Kit is in vitro diagnostic reagent to qualitative detection of ORF1ab(RdRp), E gene, N gene of COVID-19 by Multiplex OneStep qRT-PCR. For professional use only. Internal Admin.-No.: SOL-08, SOL-08-01 to SOL-08-05.** |

| **Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung / Addtional information for Annex II and self-testing in vitro diagnostic medical devices** | |
|---|---|
| | Nummer(n) der Bescheinigung(en) / Certificate number(s) |
| | £ In Übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A) In conformity with Common Technical Specifications (for Annex II List A devices) |
| | Ergebnisse der Leistungsbewertung<br>Outcome of performance evaluation |

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **St. Ingbert**

Datum
Date **2020-02-26**

Name **Sabrina Neumann**

Unterschrift
Signature

| **Bearbeitungsvermerke / Processing notes**<br>Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority | | | |
|---|---|---|---|
| | Bearbeiter / Person responsible<br>**Frau Caroline Bauer** | | Telefon / Phone<br>**0681 8500-1198** |

인정번호(No.) :KTL-ABBAR-6562

# 의료기기 제조 및 품질관리 기준 적합인정서
# (Certificate of GMP)

■ **업체명/허가번호(Company name of Applicant / License No.)**

솔젠트(주)/제 4010 호

SolGent Co.,Ltd.

■ **대표자 (Representative)**

석도수, 유재형 ( Do-su Seok, Jae-hyung, You )

■ **업체 소재지 (Company address of Applicant)**

대전광역시 유성구 테크노6로 32 , 3층(관평동)

3F, 32, Techno 6-ro, Yuseong-gu, Daejeon, 34014, Rep. of KOREA

■ **제조소명 (Name of Manufacturer)**

제조자 : 솔젠트(주)(SolGent Co.,Ltd.)

■ **제조소 소재지 (Address of Manufacturer)**

제조자 : 대전광역시 유성구 테크노5로 43-10, 1층, 2층

1F, 2F, 43-10, Techno 5-ro, Yuseong-gu, Daejeon, 34014, Rep. of KOREA

■ **품목군 (Category)**

체외진단 의료기기용 시약류(Reagent for In-Vitro Diagnostic Device)

**의료기기 제조 및 품질관리기준에 적합함을 인정합니다.**
**(We hereby certify that the above manufacturer complies with Korea Good Manufacturing Practices of Medical Devices for the product group listed above)**

**발행일자(Date of Issue)** : 2019. 09. 24

**유효기간(Date of Expiration)** : 2022. 10. 22

대전지방식품의약품안전청장
DAEJEON REGIONAL FOOD AND DRUG ADMINISTRATION

한 국 산 업 기 술 시 험 원 장
Korea Testing Laboratory

2019년 09월 24일

| 변경 및 처분 사항 등(Changes and Administrative measures) | |
|---|---|
| 년 월 일(Date) | 내 용(Description) |
| 2019-09-24 | 대표자 변경에 따른 재발급 |

인정번호(No.) : KTL-ABBAR-6562

[붙임]

| 순번(NO.) | 품목군(Name of Category) | 비 고(Remarks) |
|---|---|---|
| 1 | 체외진단 의료기기용 시약류<br>Reagent for In-Vitro Diagnostic Device | |

SolGent Co., Ltd.
Solutions for Genetic Technologies

SOLGENT CO., LTD.
3F, 32, Techno 6-ro, Yuseong-gu,
Daejeon, 34014, South Korea
Tel.:+82-70-7805-7396 /Fax.:+82-42-936-5695

# PRECAUTION FOR TREATMENT AND STORAGE IN DELIVERY

2020 March 06th

I. This diagnostic kit will be shipped with an ice pack for the product quality on the stability

※ For custom clearance, packing the kit in dry ice for transport is not possible.

II. Multiple freeze and thaw may effect performance of product, please refrain freeze-thaw.

III. The retention period of the product quality is 5 days, if keeps under refrigeration.

IV. The shipping box should be avoided exposure to direct sunlight and heat on its way.

IV. The shipping box should be required refrigeration(-20℃) before the customer receive.

※ We have no obligation regarding any claim based on failure to comply with the above requirement.

Yours Sincerely,

Jae Hyung You & Du-su Seock / CEO of SolGent Co., Ltd.

Date : March 06th , 2020

www.solgent.com


SolGent Co., Ltd.
Solutions for Genetic Technologies
DiaPlexQ™
Novel Coronavirus (2019-nCoV)
Detection Kit
REF SQD52-K020
SN SEZ 0116
2021-02-08
2020-02-07
IVD
SolGent Co., Ltd.
Head Office : 3F, 32, Techno 6-ro, Yuseong-gu, Daejeon, 34014, Korea
Factory : 1F, 2F, 43-10, Techno 5-ro, Yuseong-gu, Daejeon, 34014, Korea
EC REP
MT Promedt Consulting GmbH
Altenhofstrasse 80, D-66386 St. Ingbert, Germany
DiaPlexQ™
Novel Coronavirus (2019-nCoV)
Detection Kit
REF SQD52-K100
SN SEZ 0116
2021-02-08
2020-02-07
IVD
SolGent Co., Ltd.
Head Office : 3F, 32, Techno 6-ro, Yuseong-gu, Daejeon, 34014, Korea
Factory : 1F, 2F, 43-10, Techno 5-ro, Yuseong-gu, Daejeon, 34014, Korea
EC REP
MT Promedt Consulting GmbH
Altenhofstrasse 80, D-66386 St. Ingbert, Germany
Solgent Co., Ltd.
Solutions for Genetic Technologies
Solutions for
Genetic Technologies
SolGent Co., Ltd.
Solutions for Genetic Technologies
RNase free Water
2019-nCoV Control Template
2019-nCoV Primer & Probe
2019-nCoV Enzyme Mix
2019-nCoV 2X Buffer

# THANK YOU

**SolGent** | www.SolGent.com