AMBASSADE AU JAPON

N° 020-304/ABF/TKY

BURKINA FASO

Unité-Progrès-Justice

Tokyo, le 16 avril 2020

L'AMBASSADEUR

A

Madame le Ministre de la Santé

S/C

de Monsieur le Ministre des Affaires Etrangères et de la Coopération

OUAGADOUGOU

Objet : *proposition de vente de Kits de détection Covid-19 sud-coréens*

Madame le Ministre,

J'ai l'honneur de vous faire parvenir, ci-joint pour information, la lettre N° AKEDA-218-10265 du 03 avril 2020 ensemble ses annexes, émanant de M. Chung Si WOO, Secrétaire Général de l'Association pour le Développement Economique Afrique-Corée(AKEDA), basée à Séoul, en République de Corée, relative à une proposition de vente de kits de détection du COVID-19, sous l'appellation commerciale de DiaPlexQ™ Novel Coronavirus (2019-nCoV), par la firme sud-coréenne SolGent Co., Ltd.

SolGent est une compagnie membre d'AKEDA et est spécialisée dans les projets de diagnostics moléculaires humains. Elle a obtenu la certification sud-coréenne pour le développement et la production de réactifs biologiques moléculaires.

Le Kit de détection DiaPlexQ™ Novel Coronavirus (2019-nCoV), selon SolGent, a été développé conformément au guide technique de l'Organisation Mondiale

de la Santé et homologué par le Ministère en charge de la Sûreté du Médicament de la République de Corée.

NB : La compagnie SolGent voudrait mettre les kits de détection à la disposition du Gouvernement burkinabè, à raison de **17 dollars américains par kit.**

OBSERVATIONS

Au regard de ce qui précède et de l'urgence de la situation actuelle du coronavirus dans notre pays, il serait souhaitable que Madame le Ministre de la Santé prenne attache avec l'Ambassade de la République de Corée à Abidjan via le Ministère des Affaires Etrangères et de la Coopération, pour solliciter l'assistance du Gouvernement sud-coréen dans l'acquisition de ces kits de détection.

Elle pourrait également saisir l'opportunité pour solliciter des équipements médicaux tels des lits, des respirateurs, des tenues de protections, des masques et des gels hydro-alcooliques etc.

La soumission d'une requête officielle à l'Ambassade de la République de Corée à Abidjan est souhaitable.

Je vous prie d'agréer **Madame le Ministre,** l'expression de ma haute considération.

Ampliation: Monsieur le Directeur de Cabinet
de SEM le Président du Faso

Pascal BATJOBO
Chevalier de l'Ordre National

Ministère des Affaires Etrangères
et de la Coopération
Service Valise Diplomatique
Arrivée, le: 16 AVR 2020
Sous le N°: 472

AKEDA

Africa - Korea Economic Development Association

Document No.	AKEDA-218-10265
DATE	03/APR/2020
TO	H. E. Mr. Pascal Batjobo, Ambassador of the Republic of Burkina Faso
Subject	Coronavirus(2019-nCoV) Detection Kit

Excellency,

It is a pleasure to present our cordial compliments and inform Your Excellency that following the statement by the World Health Organization (WHO) on March 11th, which considers COVID-19 a pandemic, due to the high mortality rate and its negative social and economic impact worldwide, **SolGent Co., Ltd.**, a corporation duly stablished and existing under the laws of the Republic of Korea, has a genuine corporate intent to provide **DiaPlexQ™ Novel Coronavirus(2019-nCoV) Detection Kit** (see attachments).

We hereby confirm that **SolGent**, a company member of the Africa-Korea Economic Development Association (AKEDA), is specialized in human molecular diagnostics projects and has been assessed and certified as meeting the requirements of ISO 13485:2016 for the design, development and manufacture of molecular biological reagents

The **DiaPlexQ™ Novel Coronavirus(2019-nCoV) Detection Kit** was developed by **SolGent** in accordance with the WHO technical guidance and it received the approval of the Medical Device Policy Division at the Ministry of Food and Drug Safety of the Republic of Korea, on February 27th, 2020.

It would be much appreciated if Your Excellency could kindly recommend the **DiaPlexQ™ Novel Coronavirus(2019-nCoV) Detection Kit (USD $17.00/Kit)**, to the Government of Burkina Faso so that **SolGent** could submit a specific proposal for your country.

We look forward to work with your Excellency meeting the new challenges before us, in that same warm spirit of friendship and cooperation which has been increasingly enhancing the relations between our two countries.

Yours faithfully,

CHUNG SI WOO
Secretary-General
AKEDA

Africa-Korea Economic Development Association
AKEDA

06180 14, Teheran-ro 92-gil, Gangnam-gu, Seoul, Republic of Korea/ www.akeda.co.kr
TEL (02)2052-8677 / FAX (02)2052-8678 / akedakorea@gmail.com

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

KCDC

Recipient: SolGent Co. Ltd
(Via)
Title: Result Announcement of Emergency Use Authorization Request of Medical Devices for In-Vitro Diagnosis

1. Subject:

A. SolGent Co.Ltd, Nr. SG20200204-001 (04.02.2020)

B. Ministry of Food and Drug Safety, Medical Device Policy Division –Nr. 1636 (27.02.2020)

C. Ministry of Food and Drug Safety, Medical Device Policy Division –Nr. 1642 (27.02.2020)

2. In accordance with your request in connection with the paragraph above, we review the suitability of the products for emergency use (permission of exemption) for medical devices and request Authorization for emergency use from the Ministry of Food and Drug Safety in accordance with Article 13-2 (1) and 2 of the Enforcement Decree of the Medical Device Act, and hereby inform you of the result as below.

A. Company Name (Product Name): SolGent Co. Ltd (DiaPlexQ™ Novel Corona Virus Detection Kit)

B. Purpose: In vitro diagnostic medical device that qualitatively detects the gene (Orf1a gene, N gene) of the Corona 19 virus (2019-nCoV) in a sample of suspected respiratory infection patients(sputum, oropharyngeal and nasopharyngeal specimens)

C. Emergency request result: Approved

* Complementary: Improve detailed manual prior sale and supplement the basis for later cutoff.

D. Emergency Use Approval Period:

From 27.02.2020 ~ Until the end of coronavirus infection-19 epidemic

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

Date : February 27th , 2020

www.solgent.com

Jay You Andrew Seok

Certificate KR11/01709

The management system of

Solgent Co., Ltd.

Head Office: 3F, 32, Techno 6-ro, Yuseong-gu, Daejeon, 34014, Korea

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 6 December 2018 until 7 October 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 28 September 2020
Issue 8. Certified since 7 October 2011

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

UKAS MANAGEMENT SYSTEMS
0005

Solgent Co., Ltd.

ISO 13485:2016
EN ISO 13485:2016

Issue 8

Detailed scope

Design, Development and Manufacture of Molecular biological reagents.

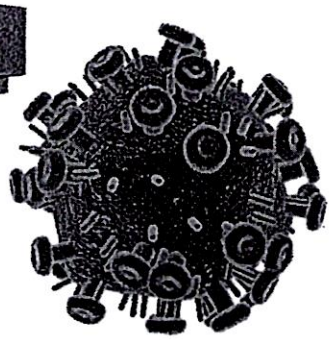
Additional facilities

Factory: 1F, 2F, 43-10, Techno 5-ro, Yuseong-gu, Daejeon, 34014, Korea

UKAS MANAGEMENT SYSTEMS
0005

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

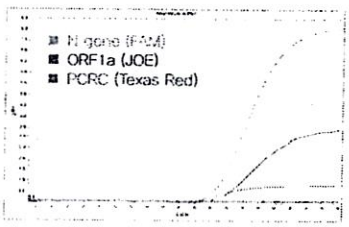
Sample collection
- Sample collection according to sample type

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. +82-70-7805-7206 Fax. +82-42-864-5600

GMP

About 2019 Novel Coronavirus (2019-nCoV)

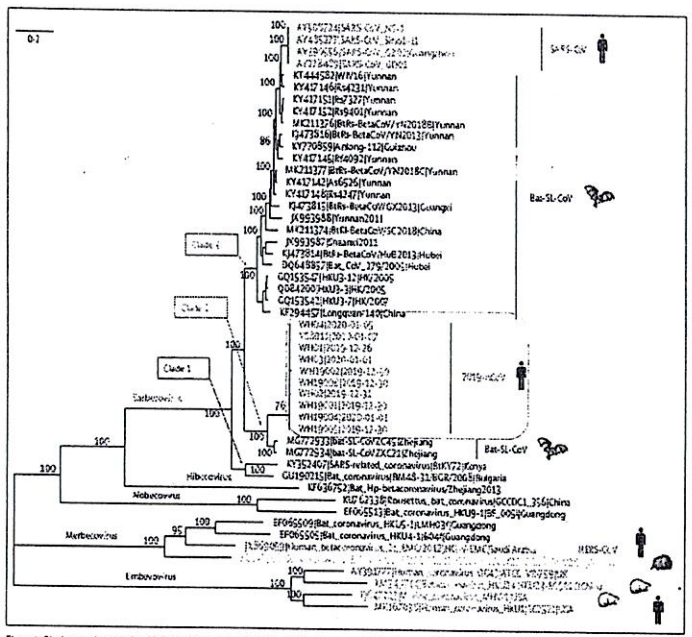


Figure 3: Phylogenetic analysis of full-length genomes of 2019-nCoV and representative viruses of the genus Betacoronavirus
2019-nCoV=2019 novel coronavirus. MERS-CoV=Middle East respiratory syndrome coronavirus. SARS-CoV=severe acute respiratory syndrome coronavirus.

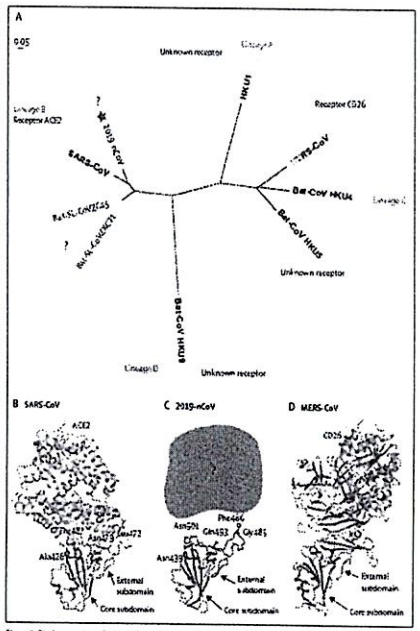


Figure 5: Phylogenetic analysis and homology modelling of the receptor-binding domain of the 2019-nCoV, SARS-CoV, and MERS-CoV

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 characterisation 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)

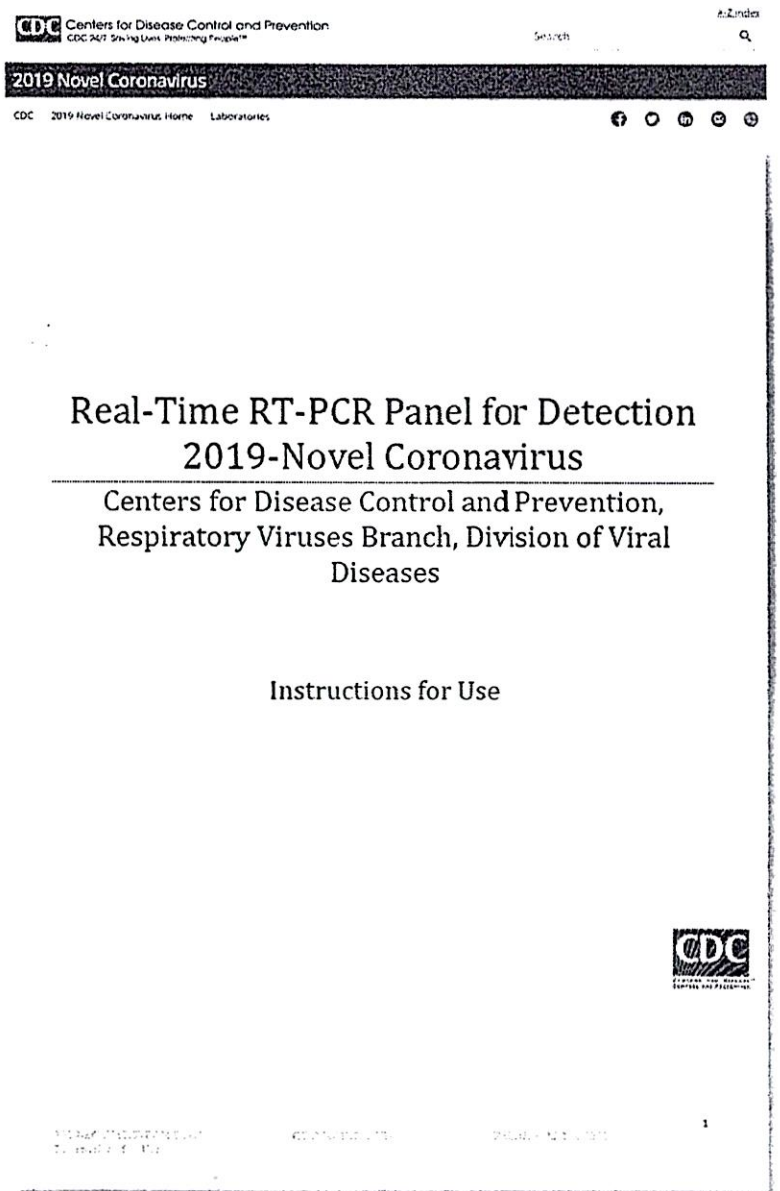
Your Solution for Genetic Technology

SolGent Molecular Diagnostics

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

CDC Novel Coronavirus (2019-nCoV) technical guidance

Laboratory testing for 2019-nCoV in humans


Centers for Disease Control and Prevention

2019 Novel Coronavirus

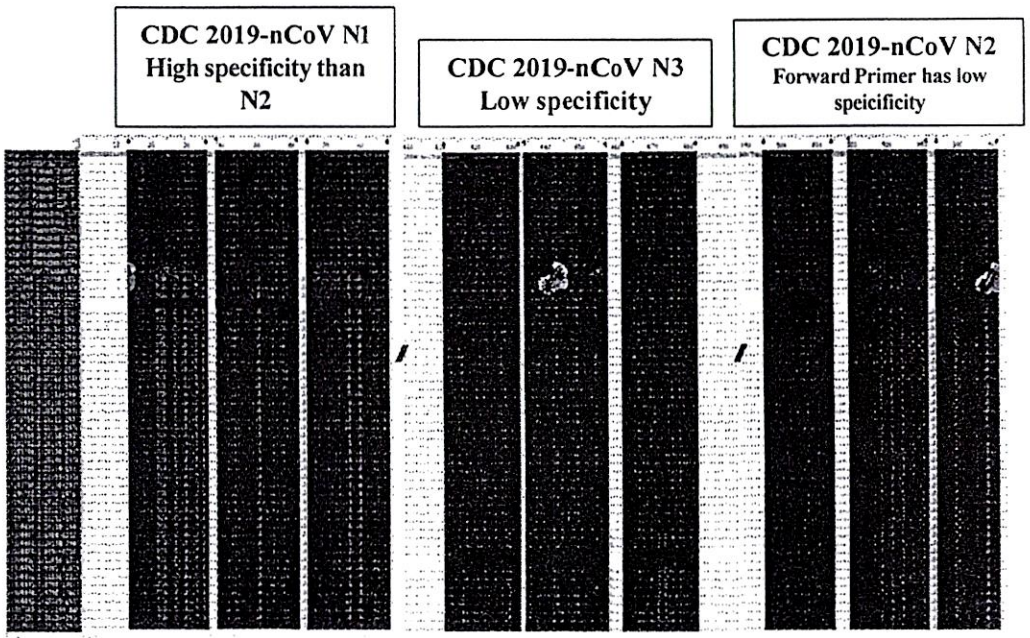
CDC 2019 Novel Coronavirus Home Laboratories

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

Centers for Disease Control and Prevention, Respiratory Viruses Branch, Division of Viral Diseases

Instructions for Use

1



2019-nCoV rRT-PCR Diagnostic Panel Results Interpretation

2019 nCoV_N1	2019 nCoV_N2	2019 nCoV_N3	RP	Result Interpretation[3]
+	+	+	±	2019-nCoV detected
If only one, or two, of three targets is positive			±	Inconclusive Result
-	-	-	+	2019-nCoV not detected
-	-	-	-	Invalid Result

WHO Novel Coronavirus (2019-nCoV) technical guidance

Laboratory testing for 2019-nCoV in humans

World Health Organization

Novel Coronavirus (2019-nCoV) technical guidance: Laboratory testing for 2019-nCoV in humans

‹ Novel Coronavirus 2019

‹ Technical guidance

Laboratory guidance

Early investigations

Overview

On this page you will find information about:

1. The current version of the "Interim guidance for laboratory testing for 2019 novel coronavirus (2019-nCoV) in humans".
2. Molecular testing of 2019-nCoV.
3. WHO appointed 2019-nCoV referral laboratories and procedures.
4. Diagnostic knowledge gaps.

lext page→ China CDC Primers and probes for detection 2019-nCoV (24 January 2020)

Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR – Charité, Berlin Germany (17 January 2020)

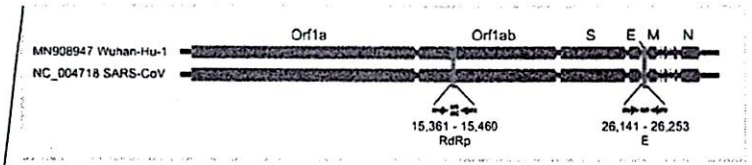
lext page→ Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR – Hong Kong University (23 January 2020)

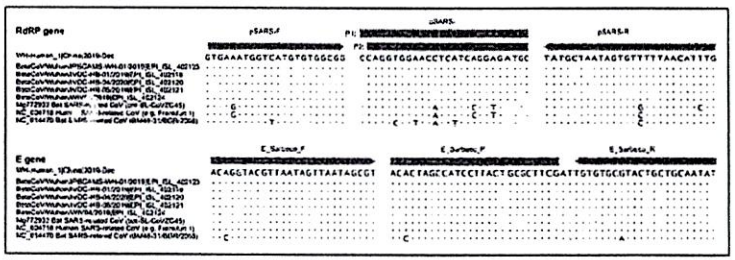
PCR and sequencing protocol for 2019-nCoV - Department of Medical Sciences, Ministry of Public Health, Thailand (Updated 28 January 2020)

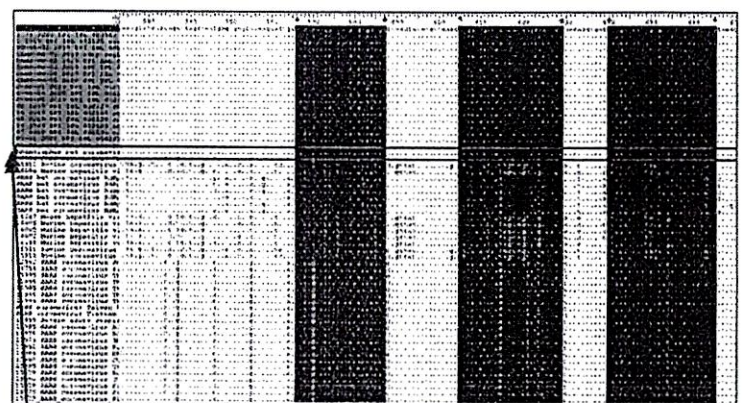
PCR and sequencing protocols for 2019-nCoV- National Institute of Infectious Diseases Japan (24 January 2020)

US CDC panel primer and probes– U.S. CDC, USAV – U.S. CDC, USA (28 January 2020)

US CDC panel primer and probes– U.S. CDC, USA (28 January 2020)





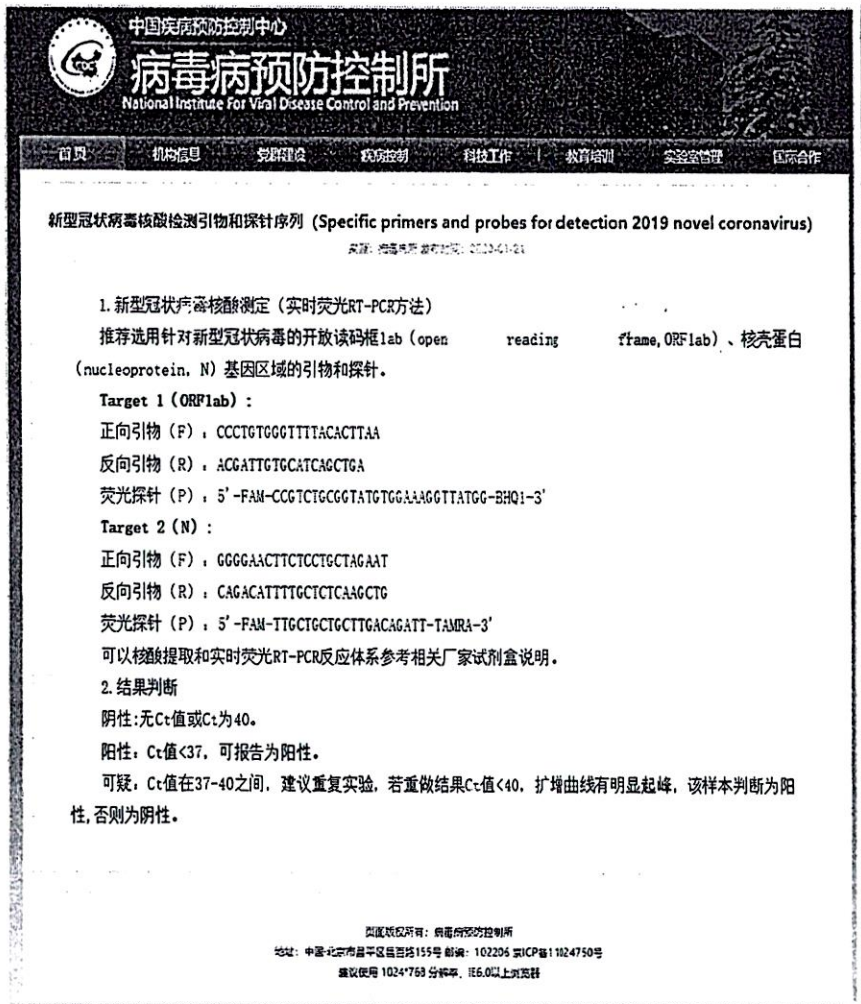


99% homologies KP876546_1_1-370_ Rhinolophus_bat_coronavirus_BtCoV_4991_RNA-depende

KCDC announced the Same guidance: Laboratory testing for 2019-nCoV in humans

WHO Novel Coronavirus (2019-nCoV) technical guidance

Laboratory testing for 2019-nCoV in humans



中国疾病预防控制中心

病毒病预防控制所

National Institute For Viral Disease Control and Prevention

首页 | 机构信息 | 党群建设 | 病防控制 | 科技工作 | 教育培训 | 实验室管理 | 国际合作

新型冠状病毒核酸检测引物和探针序列 (Specific primers and probes for detection 2019 novel coronavirus)

1. 新型冠状病毒核酸测定（实时荧光RT-PCR方法）

推荐选用针对新型冠状病毒的开放读码框1ab（open reading frame, ORF1ab）、核壳蛋白（nucleoprotein, N）基因区域的引物和探针。

Target 1（ORF1ab）：

正向引物（F）：CCCTGTGGGTTTTACACTTAA

反向引物（R）：ACGATTGTGCATCAGCTGA

荧光探针（P）：5'-FAM-CCGTCTGCGGTATGTGGAAAGGTTATGG-BHQ1-3'

Target 2（N）：

正向引物（F）：GGGGAACTTCTCCTGCTAGAAT

反向引物（R）：CAGACATTTTGCTCTCAAGCTG

荧光探针（P）：5'-FAM-TTGCTGCTGCTTGACAGATT-TAMRA-3'

可以核酸提取和实时荧光RT-PCR反应体系参考相关厂家试剂盒说明。

2. 结果判断

阴性：无Ct值或Ct为40。

阳性：Ct值<37，可报告为阳性。

可疑：Ct值在37-40之间，建议重复实验，若重做结果Ct值<40，扩增曲线有明显起峰，该样本判断为阳性，否则为阴性。

ORF1ab, N gene

HKU Med LKS Faculty of Medicine School of Public Health 香港大學公共衞生學院

Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by RT-PCR

This protocol is designed to detect 2019-nCoV in human clinical specimens. The two monoplex assays described here are reactive with coronaviruses under the subgenus *Sarbecovirus* that includes 2019-nCoV, SARS-CoV and bat SARS-like coronaviruses. The rationales for using this detection approach are: 1) the genetic diversity of 2019-nCoV in humans and animals is yet to be fully determined and 2) many laboratories lack positive controls for 2019-nCoV. *Viral RNA extracted from SARS-CoV can be used a positive control in the assays below.* As SARS was eliminated in humans, suspected cases that are positive in these RT-PCR assays should be considered to be infected by the 2019-nCoV. The N gene RT-PCR is recommended as a screening assay and the Orf1b assay as a confirmatory one. In the event of a positive PCR result, sequence analyses of the amplicons will further help to confirm the result and to distinguish between SARS-CoV and 2019-nCoV. An N gene positive/Orf1b negative result should be regarded as indeterminate and the case is recommended to be referred to a WHO reference lab for further testing.

These assays have been evaluated using a panel of controls and only the positive control (SARS-CoV RNA) is tested positive in these assays. NB. Synthetic oligonucleotide positive controls or equivalents for 2019-nCoV is not available at present but will be available shortly.

Suitable biosafety precautions should be taken for handling human clinical specimens suspected to be 2019-nCoV infections (https://www.who.int/health-topics/coronavirus/laboratory-diagnostics-for-novel-coronavirus).

Primer and probe sequences

Assay 1 (Target: ORF1b-nsp14)

Forward primer (HKU-ORF1b-nsp14F): 5'-TGGGGYTTTACRGGTAACCT-3'

Reverse primer (HKU- ORF1b-nsp14R): 5'-AACRCGCTTAACAAAGCACTC-3'

Probe (HKU-ORF1b-nsp141P): 5'-FAM-TAGTTGTGATGCWATCATGACTAG-TAMRA-3'

Assay 2 (Target: N)

Forward primer (HKU-NF): 5'-TAATCAGACAAGGAACTGATTA-3'

Reverse primer (HKU-NR): 5'-CGAAGGTGTGACTTCCATG-3'

Probe (HKU-NP): 5'-FAM-GCAAATTGTGCAATTTGCGG-TAMRA-3'

ORF1b, N gene

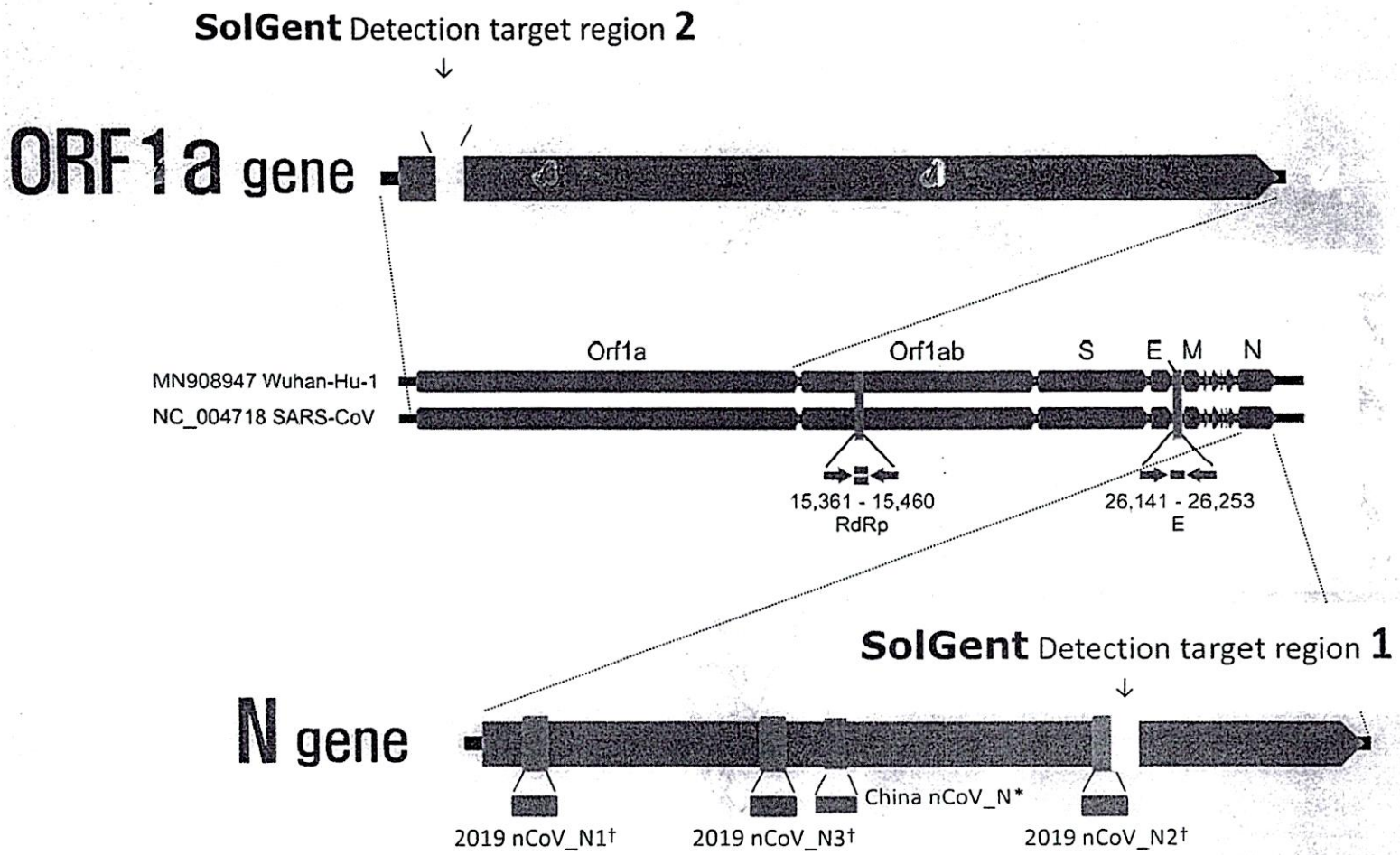
SolGent

2019 Novel Coronavirus Detection system

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

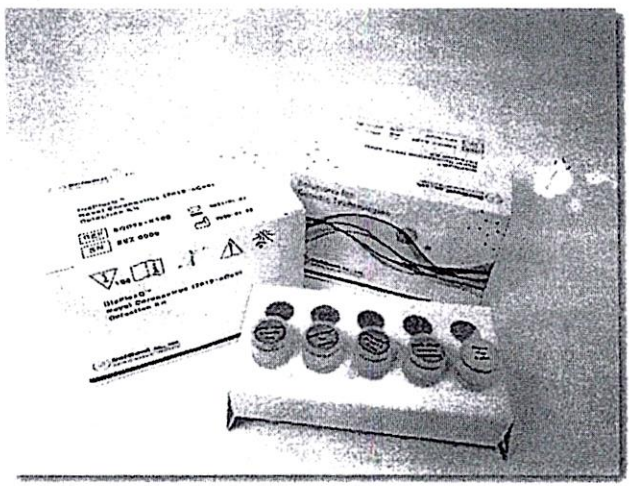
DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

Specific Target region



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

DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

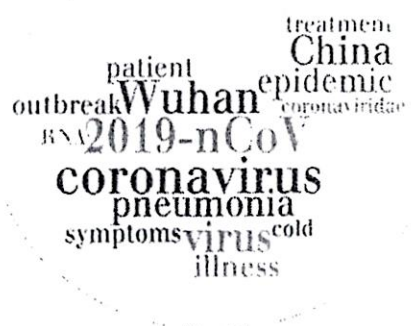


► Contents

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

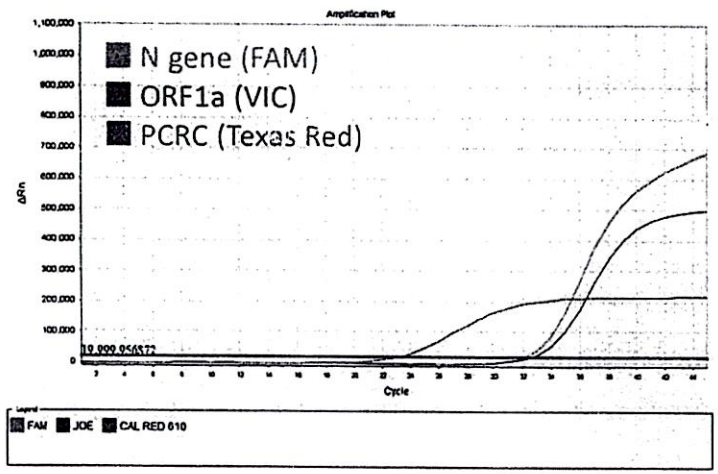
►Specimens
- Nasopharyngeal swab
- Oropharyngeal swab
- Sputum

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



DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

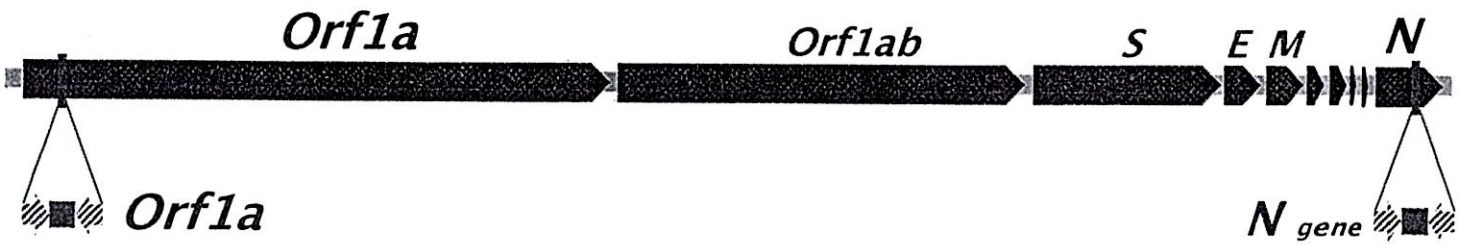
- **Amplification Plot information**



- **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 **SolGnet**

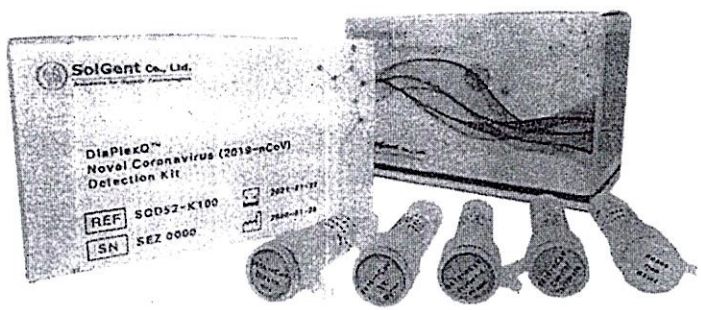
2019-nCoV Detection region **1** of **SolGnet**

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 • 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

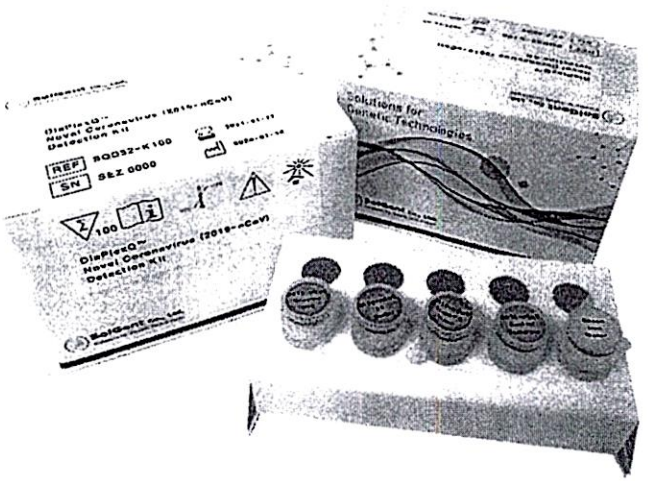
PCR Reaction Time: 2 hour



DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

Sample collection | Nucleic acid isolation | **Multiplex OneStep RT-qPCR** | Data analysis

DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit



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

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*

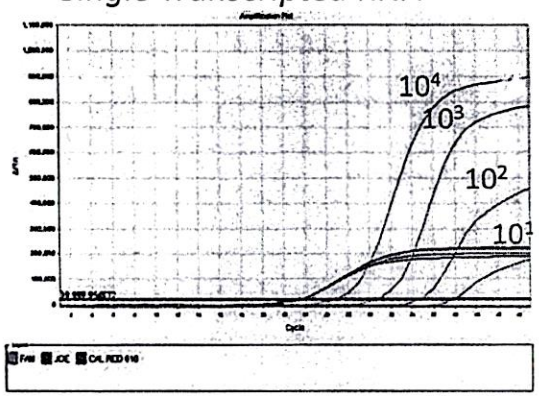
- PC should be **positive** and with CT values within 35 cycles. If PC are *negative*, the testing results for that plate are invalid. Repeat rRT-PCR test.
- NTC should be **negative**. If NTCs are *positive,* the testing results for that plate are invalid.
- Detection of the PCR Control(PCRC) in the 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

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

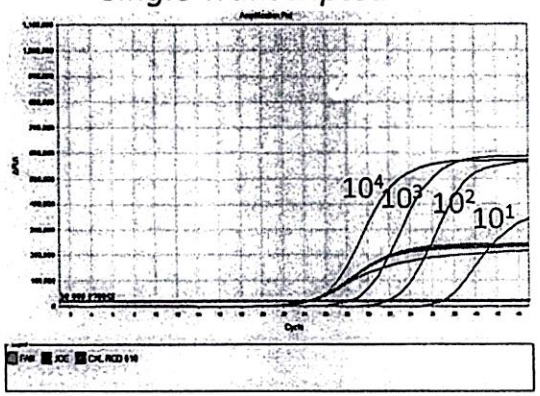
DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

The Analytical Sensitivity Test by In vitro synthesized Transcripts RNA

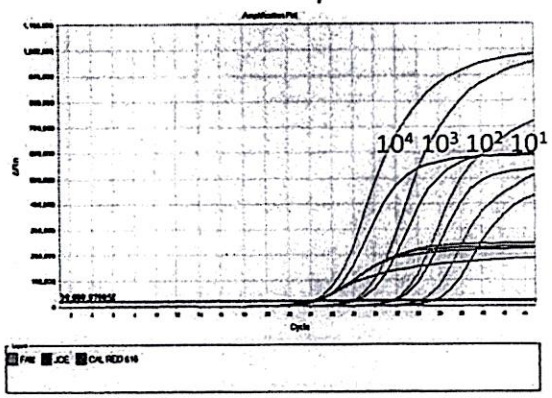
N gene
Single Transcripted RNA



ORF1a
Single Transcripted RNA



ORF1a & N gene
Dual Transcript RNA



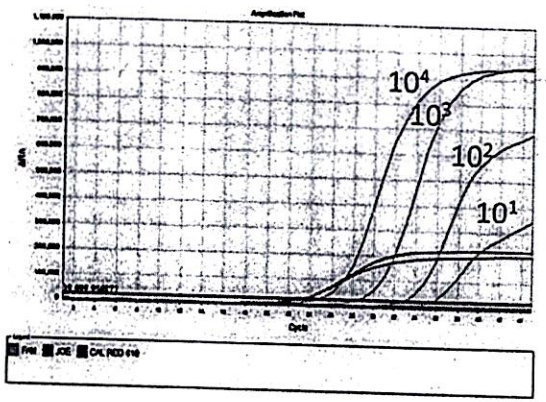
Transcripts RNA Conc. of N gene	Transcripts RNA Conc. of Orf1a	Total Copies / rxn	Hit Rate (%)
7.5 fg/ul	1.25 fg/ul	10,000	100
750 ag/ul	125 ag/ul	1,000	100
75 ag/ul	12.5 ag/ul	100	100
7.5 ag/ul	1.25 ag/ul	10	95

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

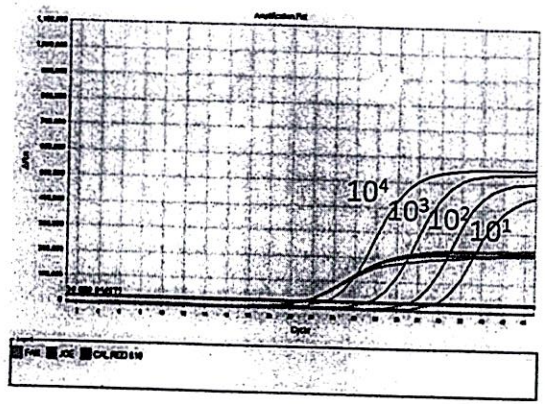
DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

The Analytical Sensitivity Test by Target region Plasmid DNA

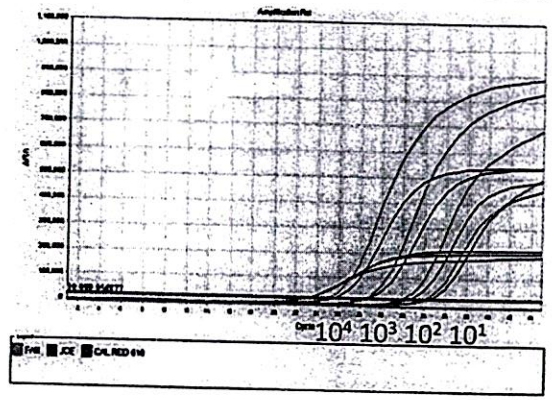
N gene – Single Plasmid DNA



ORF1a – Single Plasmid DNA



ORF1a & N gene – Multi Plasmid DNA



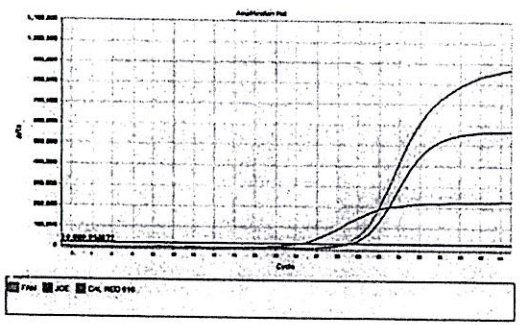
Plasmid DNA Conc. of N gene	Plasmid DNA Conc. of Orf1a	Total Copies / rxn	Hit Rate (%)
200 fg/ul	200 fg/ul	10,000	100
20 ag/ul	20 ag/ul	1,000	100
2 ag/ul	2 ag/ul	100	100
0.2 ag/ul	0.2 ag/ul	10	95

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

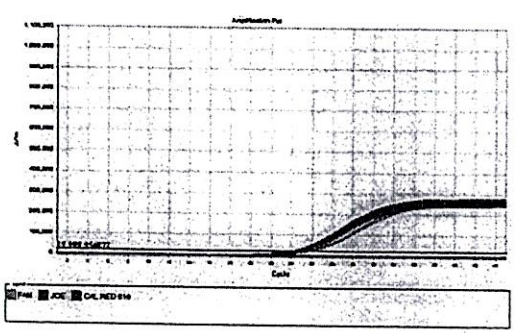
Organisms tested to demonstrate the analytical Specificity
(Respiratory virus associated, Human RNA)

Control Template (2019-nCoV)



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

38 negative strains



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

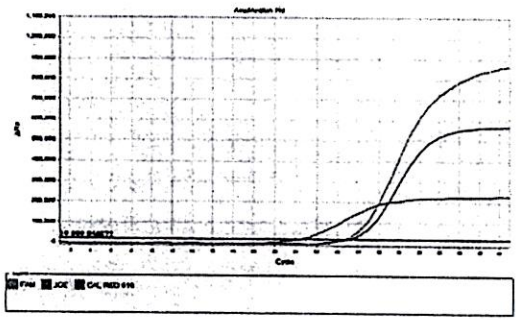
Organisms	FAM or JOE (N or Orf1a)	Texas Red (PCRC)
Parainfluenza I	N/D	≤ 26
Parainfluenza II	N/D	≤ 26
Parainfluenza III	N/D	≤ 26
Parainfluenza IV	N/D	≤ 26
Influenza A	N/D	≤ 26
Influenza B	N/D	≤ 26
Adenovirus	N/D	≤ 26
Respiratory syncytial virus A	N/D	≤ 26
Respiratory syncytial virus B	N/D	≤ 26
Rhino 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

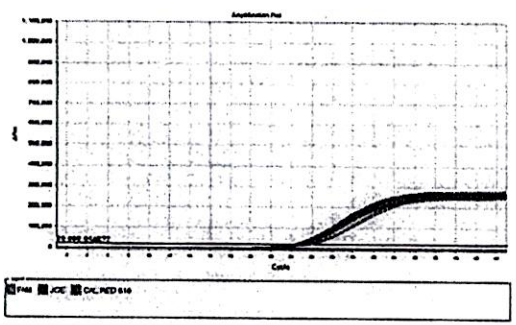
Organisms tested to demonstrate the analytical Specificity
(Pneumonia and Tuberculosis associated)

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 SQD52-K020	Real-Time PCR
DiaPlexQ™ RV16 Detection Kit	SQD50-K100 SQD50-K020	Real-Time PCR
DiaPlexQ™ PneumoPatho16 Detection Kit	SQD80-K100 SQD80-K020	Real-Time PCR

SolGent Co., Ltd (In South Korea)
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

DiaPlexQ™ RV16 Detection Kit

► Target Organisms

SET/01
- *Parainfluenza virus I*
- *Parainfluenza virus II*
- *Parainfluenza virus III*

SET/02
- *Parainfluenza virus IV*
- *Influenza A virus*
- *Influenza B virus*

SET/03
- *Adenovirus*
- *Respiratory syncitial virus A/B*
- *Rhinovirus*

SET/04
- *Enterovirus*
- *Bocavirus*
- *Metapneumovirus*

SET/05
- *Alpha Corona virus 229E/NL63*
- *Beta Corona virus OC43*
- *MERS Corona virus*

DiaPlexQ™ PP16 Detection Kit

► Target Organisms

SET/01
- *Mycoplasma pnemoniae (MP)*
- *Klebsiella pneumoniae (KP)*
- *Legionella pneumophila (LP)*

SET/02
- *Streptococcus pneumoniae (SP)*
- *Staphylococcus aureus (SA)*
- *Chlamydophila pneumoniae (CP)*

SET/03
- *Pseudomonas aeruginosa (PA)*
- *Moraxella catarrhalis (MC)*
- *Bordetella pertussis (BP)*

SET/04
- *Haemophilus influenza (HI)*
- *Acinetobacter baumannii (AB)*
- *M. tuberculosis (TB) / M. avium (AV)*

SET/05
- *Serratia marcescens (SMar)*
- *Bordetella parapertussis (BPara)*
- *Stenotrophomonas maltophilia (SMalt)*

THANK YOU

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