http://paxgenbio.com/

CE IVD

Smart Diagnostics with Universal Array Technology

PaxView® COVID-19 real-time **RT-PCR Kit**

Innovative and Chimeric Technologies
Leading to a New World of Healthcare

PaxGenBio

PaxView® COVID-19 real-time RT-PCR Kit

Intended Use

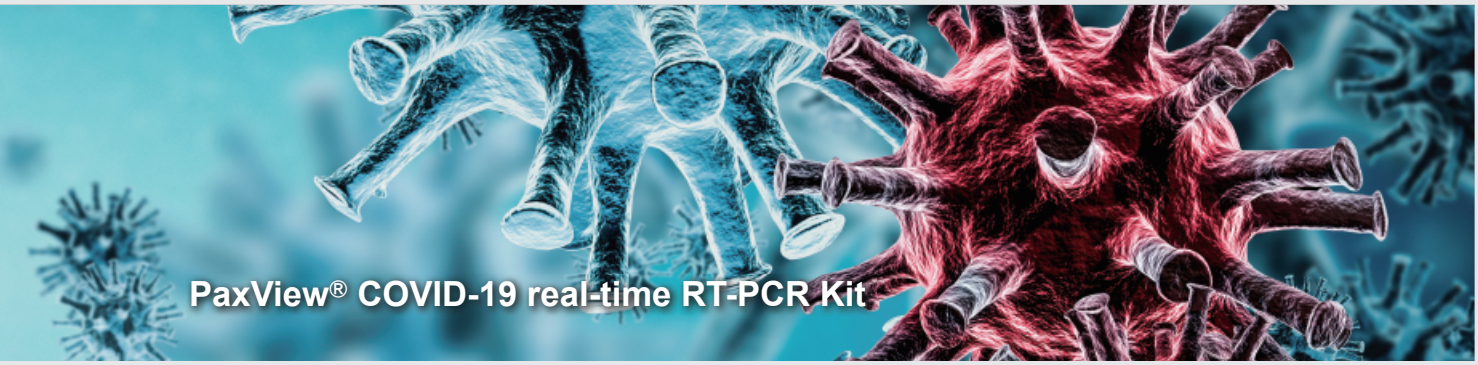
- In vitro diagnostics(IVD) Kits
- Designed for the qualitative detection of COVID-19 viral RNA
- Oropharyngeal swab, nasopharyngeal swab, sputum and bronchoalveolar lavage (BAL)

Introduction

- COVID-19 (Corona Virus disease 2019) is the respiratory infectious disease caused by a novel coronavirus that has not been previously identified in humans.
- The outbreak began in December 2019.
- Reported illness have ranged from mild respiratory symptoms with fever, cough, and shortness of breath to severe illness and death.
- Most estimates of the incubation period for COVID-19 range from 1-14 days.
- The case fatality rate is around 2%.
- The novel coronavirus (nCoV) named as SARS-CoV-2
- beta-coronavirus like MERS-CoV and SARS-CoV.
- All three of these viruses have their origins in bats.
- Sequencing analysis of multiple viral strains from COVID-19 patients suggested that wild animal acted as the natural reservoir for the virus.
- The virus can spread from person to person. The virus is mainly transmitted through contact with respiratory droplets.

Kit Components

Components	4X RT-PCR PREMIX	PRIMER/PROBE MIX	POSITIVE CONTROL
Image			
Volume	240 µl/tube	240 µl/tube	50 µl/tube
Tubes	2 tubes	2 tubes	1 tube



Product description

- Detects the novel coronavirus.
- COVID-19 using one-step real-time RT-PCR in a single tube.
- The target genes for the detection of the virus are Orf1ab and N gene.
- The sequence of primers and probes for the amplification were adapted from sources published by China CDC and WHO.
- The kit includes primers and probe for the amplification of the human RNase P gene that serves as an internal positive control for the real-time RT-PCR.

[References]
1. National institute for viral disease control and prevention (China); http://ivdc.chinacdc.cn/kyjz/202001/t20200121_211337.html
2. Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases Interim guidance (WHO)
3. Real-Time RT-PCR Panel for Detection 2019-Novel Coronavirus (CDC)
4. CDC protocol of real time RT-PCR for influenza A(H1N1) (WHO)

► **Compatible real-time PCR machines:** CFX96(Bio-Rad), ABI 7500/7500Fast(Thermo Fisher Scientific), SLAN-96S(Hongshi), Rotor-Gene Q(QIAGEN)

Performance Characteristics

Analytical Sensitivity (Limit of Detection)

- Serial dilution of in vitro transcription RNA from 10^5 to 0.1 copies/µl was tested.
- The limit of detection (LoD) is 10 copies/µl (100 copies/reaction).

Analytical Specificity (Cross-reactivity)

- Genes of 12 respiratory viruses and 14 bacterial strains were tested.
- The microorganisms tested were not detected.

Key Features and Benefits

- **User friendly & Simple method**
- **One tube & One step RT-PCR**
- **Use internal control with Rnase P gene from RNA extraction**
  → monitor the entire process including the sample collection, RNA extraction, and RT-PCR

Company	Sample Collection	Nucleic acid extraction	Nucleic acid amplification	Remarks
PaxGenBio	**O**	**O**	**O**	Rnase P gene
A Company	X	O[1)]	O	
B Company	X	X	O[2)]	

1) Internal control is added to the extraction reagent
2) Internal control is added to the PCR reaction

Procedure

PCR protocol

Before start, thaw the reagents of the Kit on ice for 10~15 minutes.

↓ Briefly mix & spin

Prepare the Master mixture on the test.

Components	Volume
4X RT-PCR	5µl
Primer/Probe Mix	5µl
Total volume	10µl

↓ Vortex & Spin

Put 10 µl of prepared master mixture into a PCR tube.

↓

Add 10 µl of extracted RNA samples, positive control or negative control to each tube.

↓

Close the cap, and briefly centrifuge the PCR tubes.

↓

Place the tube into real-time thermal cycler and start amplification.

Result analysis

After the test, the [Data Analysis] opens automatically.

↓

Specify the threshold by selecting each fluorescence under the graph.

→ Settings → Baseline Threshold

Single Threshold - User Defined	
FAM	350
HEX	150
Cy5	200

↓

Check the result for each well.

- Graph and Ct value

↓

Refer to Cut-off table.

Target	Fluorescence	Ct value
Orf1ab	FAM	≤40
N	HEX	≤40
IC	Cy5	≤40

↓

For the save, Export → Export All Data Sheets → Save File → Analysis

Results Interpretation

1. Parameter setting

Fluore-scence	Parameter	Level		
		7500/ 7500Fast	CFX96-DX	SLAN96S
FAM	Threshold	30,000	350	100
	Baseline	Auto	Auto	Auto
HEX	Threshold	5,000	150	50
	Baseline	Auto	Auto	Auto
Cy5	Threshold	25,000	200	50
	Baseline	Auto	Auto	Auto

2. Ct. value for controls

Control	FAM (Orf1ab)	HEX (N)	Cy5 (IC)
Positive control	≤35	≤35	≤35
Negative control	No Ct.	No Ct.	No Ct.

3. Interpretation

Case	FAM (Orf1ab)	HEX (N)	Cy5 (IC)	Determination
1	+	+	+	Positive
2	+	+	-	Positive*
3	+	-	+/-	Inconclusive**
4	-	+	+/-	
5	-	-	+	Negative
6	-	-	-	Invalid***

* When the amount of PCR products (FAM or HEX) is substantial on positive result data, the signal of internal control (Cy5) may or may not be observed.

** 1) Recommended to retest by increasing the sample concentration.
2) Recommended to proceed with sequencing.

*** Invalid case

- Sample collection fail
- RNA extraction fail

https://youtu.be/E0p_l03cQn4

Clinical Evaluation

■ Malaysia - Institute For Medical Research

INSTITUT PENYELIDIKAN PERUBATAN
(Institute For Medical Research)
Jalan Pahang
50588 KUALA LUMPUR
MALAYSIA

Telefon : 03-2616 2666
Faks : 03-2693 9335
http ://www.imr.gov.my

Ruj.kami: IMR/P/15/1501/0046/03 (11)
Tarik : 24 April 2020

Performance Analysis

Test		Tested Kit Assay		Interpretation
		Detected	Not Detected	
IMR In-house Panel	SARS-CoV2 Positive (COVID-19)	15	0	Sensitivity= 100%
	SARS-CoV2 Negative (COVID-19)	0	12	Specificity = 100%

Comments
Use 10ul of extracted RNA while in house assay use 5 ul of extracted RNA

Disclaimer:
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■ Kazakhstan – National Public Health Center

ҚАЗАҚСТАН РЕСПУБЛИКАСЫ ДЕНСАУЛЫҚ САҚТАУ МИНИСТРЛІГІНІҢ «ҚОҒАМДЫҚ ДЕНСАУЛЫҚ САҚТАУ ҰЛТТЫҚ ОРТАЛЫҒЫ» ШАРУАШЫЛЫҚ ЖҮРГІЗУ ҚҰҚЫҒЫНДАҒЫ РЕСПУБЛИКАЛЫҚ МЕМЛЕКЕТТІК ҚАЗЫНАРЫНЫҢ «САНИТАРИЯЛЫҚ-ЭПИДЕМИОЛОГИЯЛЫҚ САРАПТАМА ЖӘНЕ МОНИТОРИНГ ҒЫЛЫМИ-ПРАКТИКАЛЫҚ ОРТАЛЫҒЫ» ФИЛИАЛЫ

ФИЛИАЛ «НАУЧНО-ПРАКТИЧЕСКИЙ ЦЕНТР САНИТАРНО-ЭПИДЕМИОЛОГИЧЕСКОЙ ЭКСПЕРТИЗЫ И МОНИТОРИНГА» РЕСПУБЛИКАНСКОГО ГОСУДАРСТВЕННОГО ПРЕДПРИЯТИЯ НА ПРАВЕ ХОЗЯЙСТВЕННОГО ВЕДЕНИЯ «НАЦИОНАЛЬНЫЙ ЦЕНТР ОБЩЕСТВЕННОГО ЗДРАВООХРАНЕНИЯ» МИНИСТЕРСТВА ЗДРАВООХРАНЕНИЯ РЕСПУБЛИКИ КАЗАХСТАН

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15-37/4802

14.05.2020г.

Результаты верификационных исследований тест – набора «PaxView COVID-19 real-time RT-PCR Kit»

Лаб. №	Результаты 3 серий испытаний тест – набора «PaxView COVID-19 real-time RT-PCR Kit» (Корея)									Тест-система «BGI Biotechnology», Китай		Референсная методика тест-система «TIB MOLBIOL», (Германия)	
	1 серия (08.05.2020)			2 серия (11.05.2020)			3 серия (11.05.2020)			Ct	Результат	Ct	Результат
	Ct (Green)	Ct (Yellow)	Результат	Ct (Green)	Ct (Yellow)	Результат	Ct (Green)	Ct (Yellow)	Результат				
6329	23,35	21,06	пол	25,42	23,29	пол	24,39	21,82	пол	17,92	пол	27,73	пол
6204	36,35	32,83	пол	36,57	33,94	пол	36,19	33,17	пол	20,77	пол	32,25	пол
6210	27,07	23,90	пол	27,14	24,53	пол	27,56	24,53	пол	18,82	пол	21,43	пол
2179	27,33	24,83	пол	28,75	26,73	пол	28,54	25,68	пол	23,67	пол	25,28	пол
2182	19,82	17,35	пол	21,33	19,46	пол	20,50	18,26	пол	16,40	пол	19,16	пол
6696	-	-	отр	-	-	отр	-	-	отр	-	отр	-	отр
6895	-	-	отр	-	-	отр	-	-	отр	-	отр	-	отр
7165	-	-	отр	-	-	отр	-	-	отр	-	отр	-	отр
7252	-	-	отр	-	-	отр	-	-	отр	-	отр	-	отр
7244	-	-	отр	-	-	отр	-	-	отр	-	отр	-	отр
КЭ	-	-	отр	-	-	отр	-	-	отр	-	отр	-	отр
К-	-	-	отр	-	-	отр	-	-	отр	-	отр	-	отр
К+	31,37	30,46	пол	32,05	31,23	пол	30,95	30,19	пол	27,97	пол	29,46	пол

- Comparison kit :TIB MOLBIOL(Germany), BGI Technology(China)
- Equipment used: Rotor-Gene Q(Qiagen)
- Sample used: Positive 5, Negative 5
- Test results: 100% match

Certificate

TÜVRheinland

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

PaxGenBio Co., Ltd.
#803~807, 361, Simin-daero, Dongan-gu,
Anyang-si, Gyeonggi-do 14057
Republic of Korea

has established and applies a quality management system for medical devices for the following scope:

In accordance with EN ISO 13485:2016 Medical devices -Quality management systems-Requirements for regulatory purposes (ISO 13485:2016)
See attachment(s) for the scope

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-02-05
Certificate Registration No.: SX 60146677 0001
An audit was performed. Report No.: 12031532 001
This Certificate is valid until: 2020-10-29

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-14369-01-03

Date 2020-02-06

Masahiro Asami

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

www.mt-procons.com

promedt CONSULTING

Certificate
of EU product notification

Herewith we confirm that

MT Promedt Consulting GmbH
Altenhofstraße 80
66386 St. Ingbert
Germany

has taken over the function of an European Authorized Representative according to the requirements of Article 10 of the IVDD 98/79/EC for

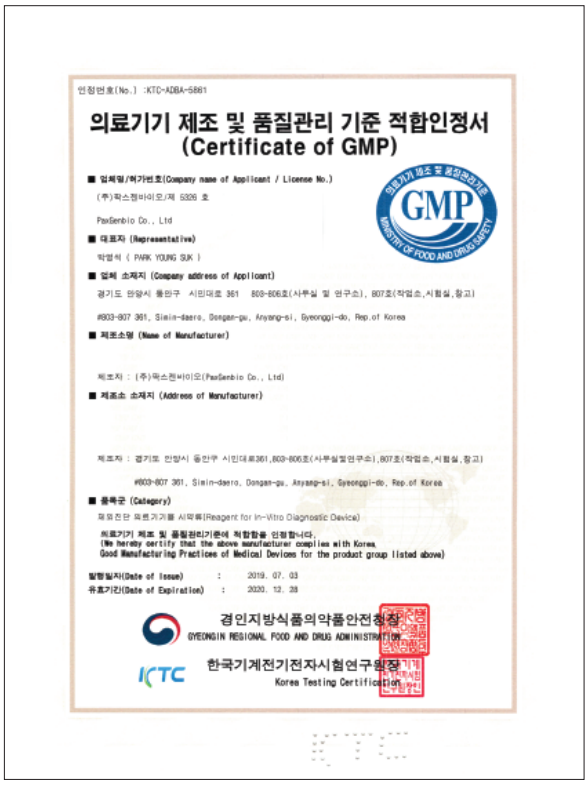
PaxGenBio Co., Ltd.
#803~807, 361, Simin-daero,
Dongan-gu, Anyang-si
Gyeonggi-do, 14057
Republic of Korea

MT Promedt Consulting GmbH has made the product notification at the relevant competent authority according to Article 10(3).
The in vitro diagnostic medical devices of the manufacturer, covered by the notification, are listed in Annex I of this certificate.
This certificate does not attest the conformity of the medical devices with the above mentioned directive. The conformity is stated in the respective product-related Declarations of Conformity signed under the sole responsibility of the manufacturer.

24. March 2020

Dr. Michael Rinck
- Managing Director -

Enclosure
Annex I



인정번호(No.) :KTC-ADBA-5881

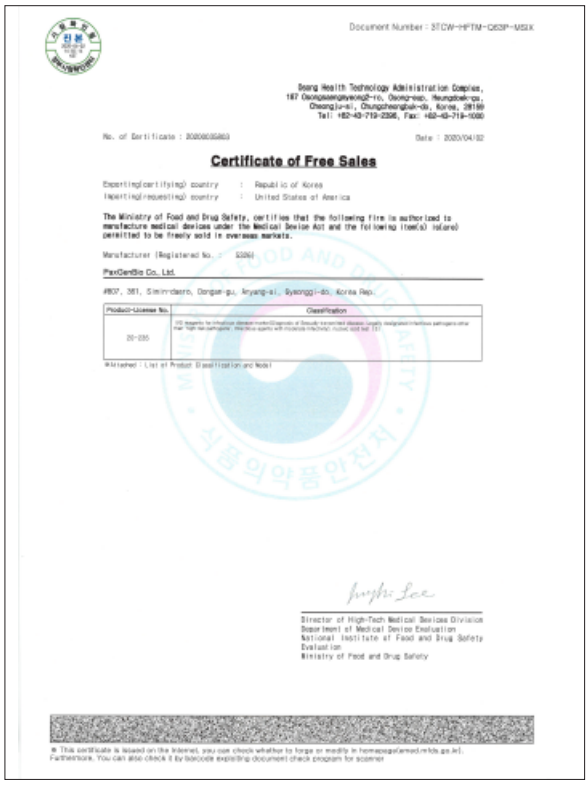
의료기기 제조 및 품질관리 기준 적합인정서
(Certificate of GMP)

■ 업체명/허가번호(Company name of Applicant / License No.)
(주)팍스젠바이오/제 5326 호
PaxGenbio Co., Ltd
■ 대표자 (Representative)
박영석 (PARK YOUNG SUK)
■ 업체 소재지 (Company address of Applicant)
경기도 안양시 동안구 시민대로 361 803-806호(사무실 및 연구소), 807호(작업소,시험실,창고)
#803-807 361, Simin-daero, Dongan-gu, Anyang-si, Gyeonggi-do, Rep.of Korea
■ 제조소명 (Name of Manufacturer)
제조자 : (주)팍스젠바이오(PaxGenbio Co., Ltd)
■ 제조소 소재지 (Address of Manufacturer)
제조자 : 경기도 안양시 동안구 시민대로361,803-806호(사무실및연구소),807호(작업소,시험실,창고)
#803-807 361, Simin-daero, Dongan-gu, Anyang-si, Gyeonggi-do, Rep.of Korea
■ 품목군 (Category)
체외진단 목적기기를 사약류(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. 07. 03
유효기간(Date of Expiration) : 2020. 12. 28

GMP MINISTRY OF FOOD AND DRUG SAFETY

경인지방식품의약품안전청장
GYEONGIN REGIONAL FOOD AND DRUG ADMINISTRATOR

KTC 한국기계전기전자시험연구원장
Korea Testing Certification



Document Number : STCW-HFTM-C63P-MSIX

Bong Health Technology Administration Complex,
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No. of Certificate : 20200035803 Date : 2020/04/02

Certificate of Free Sales

Exporting(certifying) country : Republic of Korea
Importing(requesting) country : United States of America

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following item(s) is(are) permitted to be freely sold in overseas markets.

Manufacturer (Registered No. : 5326)
PaxGenBio Co., Ltd.
#807, 361, Simin-daero, Dongan-gu, Anyang-si, Gyeonggi-do, Korea Rep.

Product-License No.	Classification
20-235	

※Attached : List of Product Classification and Model

Director of High-Tech Medical Devices Division
Department of Medical Device Evaluation
National Institute of Food and Drug Safety Evaluation
Ministry of Food and Drug Safety

※ This certificate is issued on the Internet, you can check whether to forge or modify in homepage(emed.mfds.go.kr). Furthermore, You can also check it by barcode exploiting document check program for scanner

Kit Package layout

Shipping Packing Box

■ Thermal Insulation Container

- EPS (Expanded Polystyrene, **Neopor**®)

* **Neopor**: A new material with high thermal insulation performance by mixing graphite, an inorganic material with existing EPS

■ Cold Chain System: PCM(Phase Change Material)

* PCM is a phase change material (liquid->solid, solid->gas, etc.), A substance that absorbs heat when the surrounding temperature rises, and when the temperature decreases, it crystallizes and releases heat.

■ Carton Dimension

- Measurement: 45.5(H) x 45.5(D) x 50.0(H) Cm
- Total Weight: 21 Kg
- 40 Kits per Carton
- Shipping Stability for 7 days

Ordering Information

Product Name	Cat. No.	Package	Storage	Expiration date
PaxView® COVID-19 real-time RT-PCR Kit	R0501N	96tests/Kit	-25 ℃ ~ -15 ℃	12 months

Innovative and Chimeric Technologies
Leading to a New World of Healthcare

PaxGenBio

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