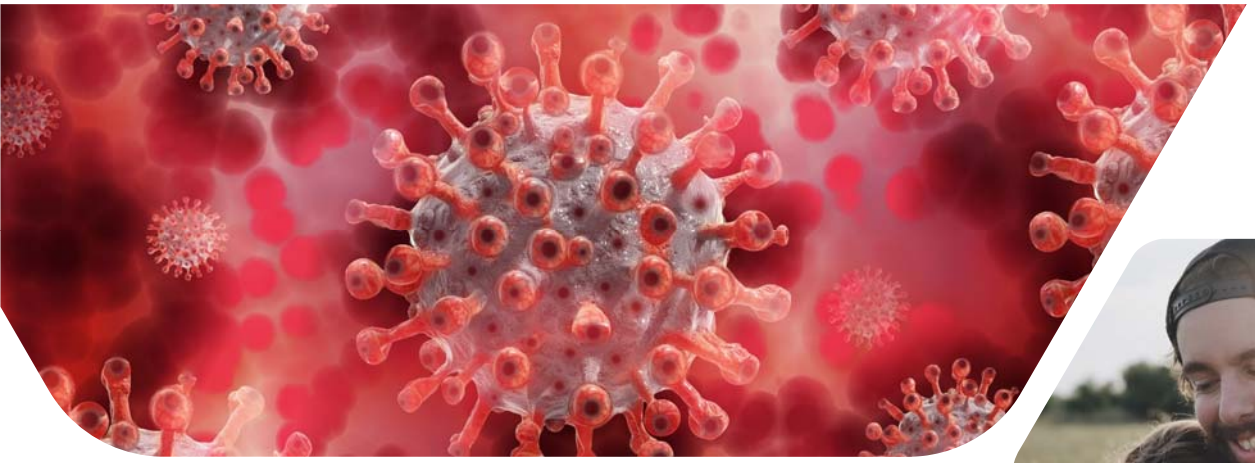
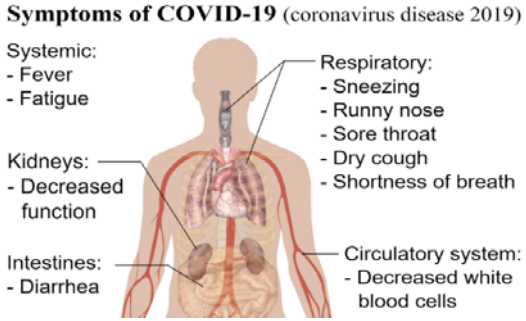


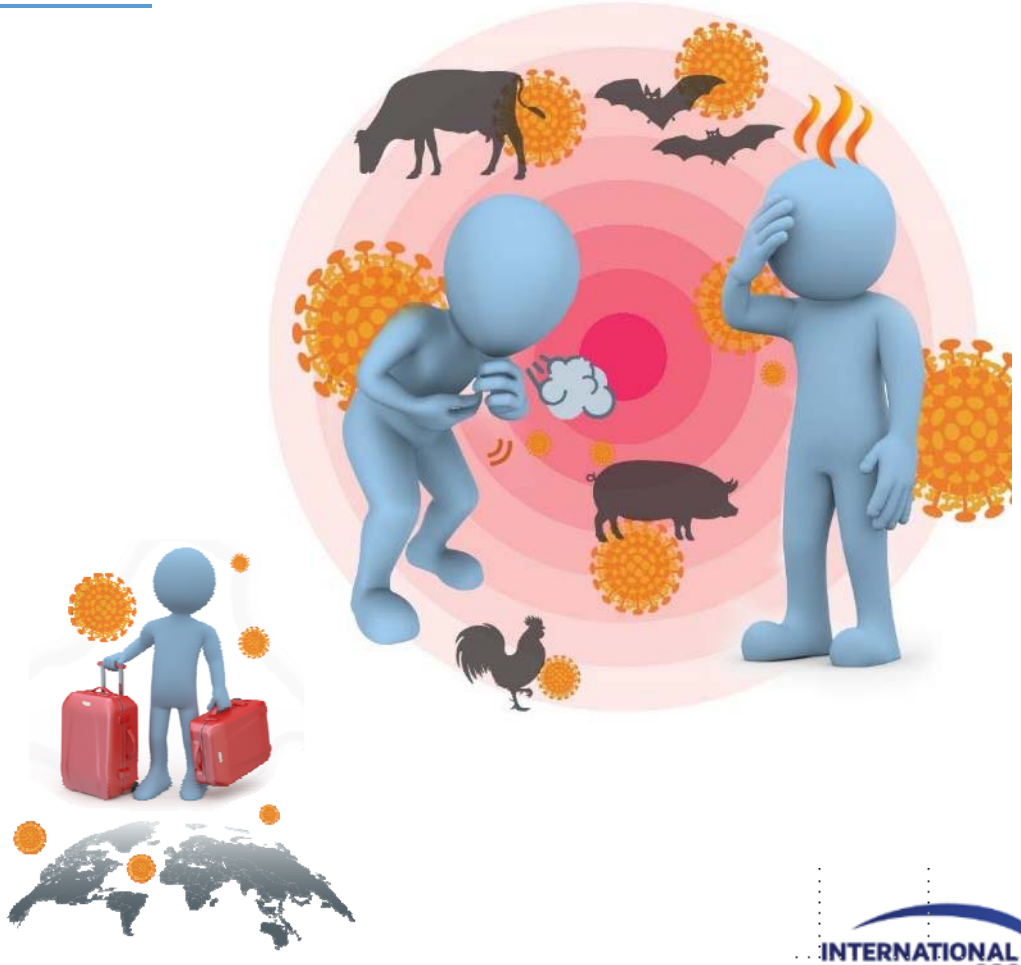
Rapid COVID-19 PoaCheck™

Real-time OneStep LAMP detection kit for COVID-19

SARS-CoV-2 and COVID-19

- **Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causes COVID-19.**
  - SARS-CoV-2 is a new virus.
  - The first cases were identified in people with **pneumonia** in Wuhan, China, in late December 2019.
  - It probably started in animals but is now spreading between people.
  - As this virus is new, we are learning more all the time, and what we know now may change.

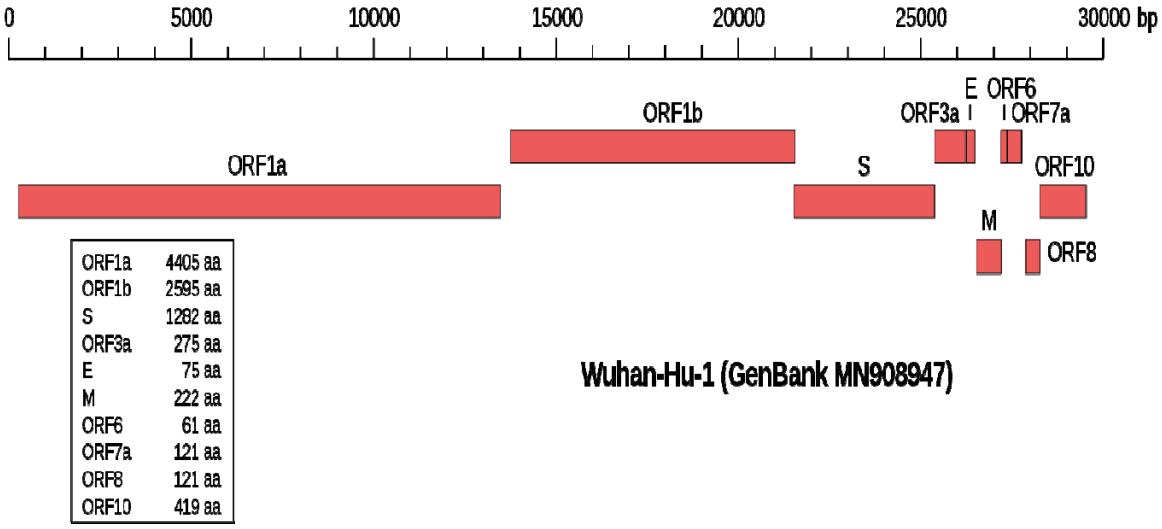


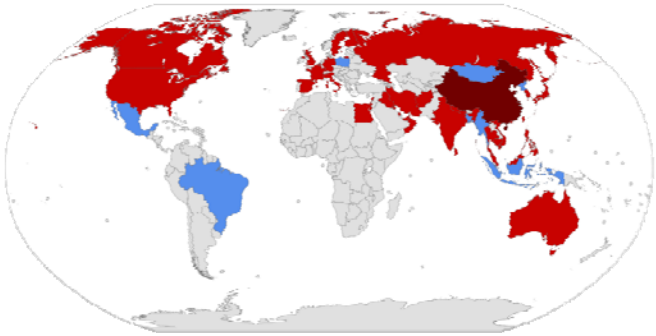


[© 2020 International SOS, https://pandemic.internationalsos.com/2019-ncov/ncov-education-and-communication]

Rapid COVID-19 PoaCheck ™

Rapid Real-time OneStep LAMP detection kit for COVID-19 in 30 min





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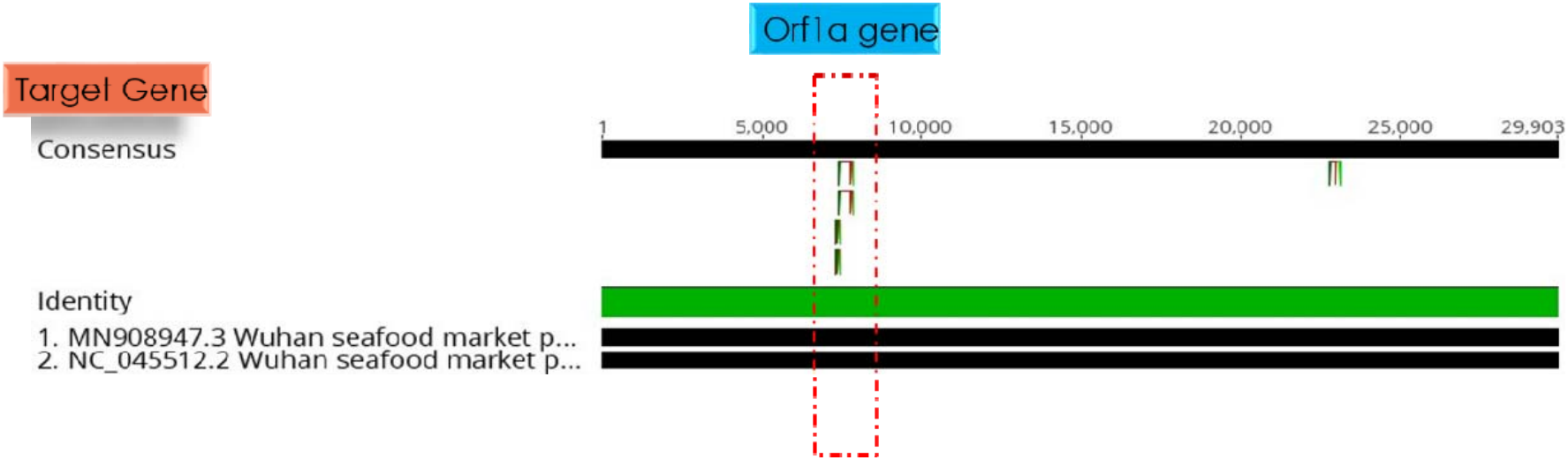
TARGET GENE

Rapid COVID-19 PoaCheck™

Rapid COVID-19 PoaCheck (Orf1a gene) kit was designed to amplify the Orf1a target gene of COVID-19 (2019-nCoV) in the isothermal reaction condition. LAMP (Loop-Mediated Isothermal Amplification) is consist of *Bst* polymerase which has the strand displacement DNA synthesis and 3 primer sets. First, the inner primer binds to the DNA and elongates, causing strand displacement, and the first strand is released. The loop structure is formed from the 5'-end of the separated single strand, and the same process is repeated at the 3'-end and the loop structure is extended. To perform LAMP, four different primers designed specifically to recognize the six distinct positions of the gene to be amplified are used. An additional pair of "loop primers" can further accelerate the reaction. Compared to the general PCR recognition of two positions, LAMP has a very high specificity for the target DNA. The primers used in this product are designed to amplify the Orf1a gene of COVID-19.



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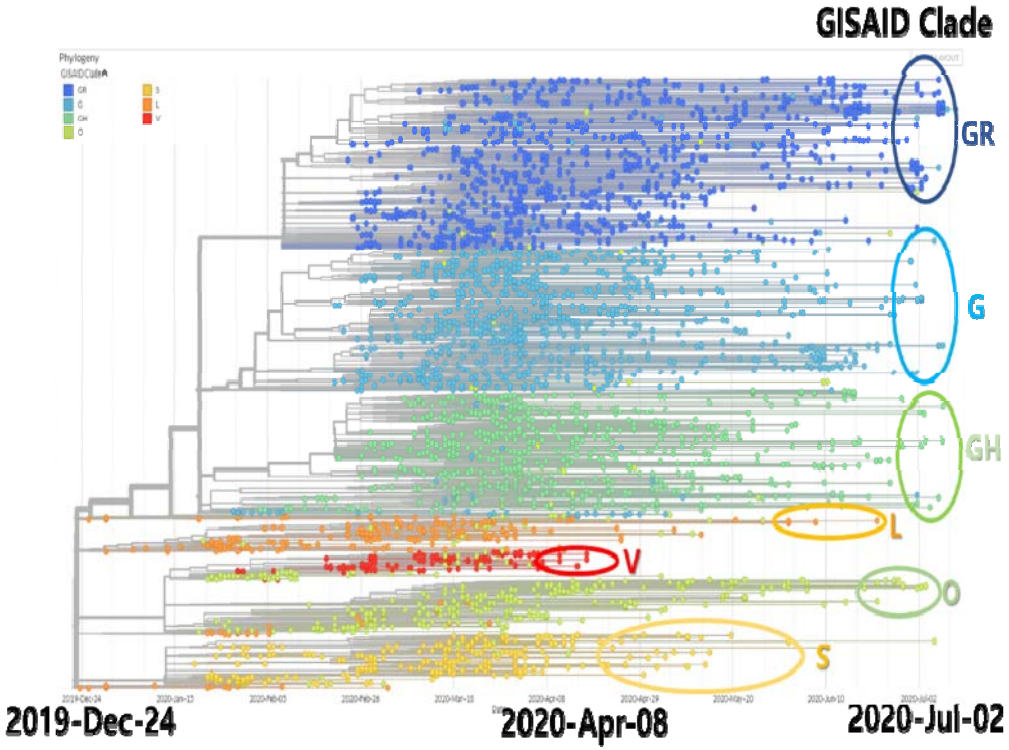
HIGHLY CONSERVED REGION

Highly conserved primer-binding sites



No mutation

hCoV-19; 67,000 gene analysis

1. GISAID EpiCoV Data base(Jul 21, 2020)
2. ClustalW gene alignment
3. 100% coincidence in primer binding region

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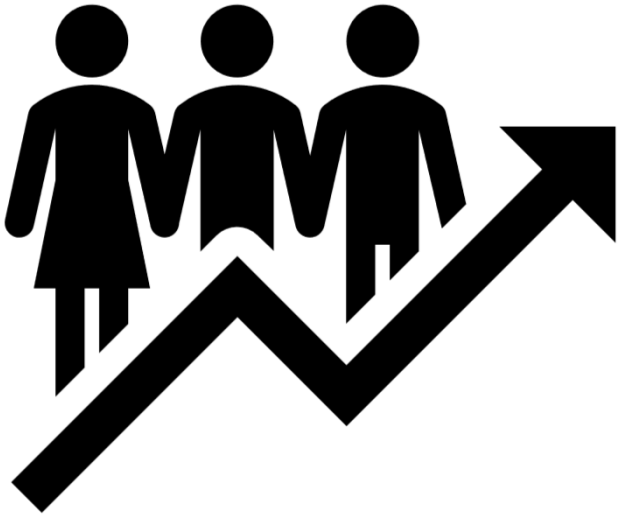
MAIN FEATURES

1) **High specificity test**: Compared to the general PCR method to recognize two positions, LAMP has high specificity because the primers are designed to recognize six gene positions.

2) **Economic test**: Due to the characteristic of isothermal amplification, there is no loss or damage of DNA due to temperature change. The amplification efficiency is very high and the temperature control is unnecessary, it makes the response time becomes short (65℃, 20-30 min).

3) **Easy-to-use master mix**: just adding template and Primer Mix/Dye.

4) **Positive control included (Plasmid)**



BioPOA Co. Ltd.

is the leading company in **biopharmaceutical research and development**.
We provide **the best solutions** in related fields through various disease diagnosis, vaccine R&D, the related services, and commercialization of developed technologies.

New technology for the healthy life of animals and human beings!
BioPOA is leading the research and development
of state-of-the-art new technology for the future.

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VIRUS RELATED RESEARCH ACTIVITIES

COVID-19 PoaCheck ™

LOCAL PATENTS LIST (KOREA)

No	RESEARCH NAME	Remark
1	HN EPITOPE RECOGNIZED BY AVIAN IMMUNE SYSTEM AND ANTIGENIC VARIANT NEWCASTLE DISEASE VIRUSES CARRYING CHANGES IN THE EPITOP	
2	ATTENUATED RECOMBINANT NEWCASTLE DISEASE VIRUS AND VACCINE CONTAINING THE SAME	
3	AVIRULENT INFECTIOUS BURSAL DISEASE VARIANT VIRUS AND USE AS A VACCINE	
4	HN EPITOPE RECOGNIZED BY AVIAN IMMUNE SYSTEM AND ANTIGENIC VARIANT NEWCASTLE DISEASE VIRUSES CARRYING CHANGES IN THE EPITOPE	
5	CHIMERIC VIRUS OF PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME VIRUS, AND VACCINE USING SAME	
6	VARIANT NEWCASTLE DISEASE VIRUS AND VACCINE CONTAINING THE SAME	
7	LOW PATHOGENIC AVIAN INFLUENZA H9N2 SUBTYPE VIRUS HIGHLY PRODUCTIVE IN CHICKEN EMBRYO	
8	MANUFACTURING METHOD OF EUROPEAN TYPE PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME VIRUS AND USE	
9	VARIANT STRAIN OF EUROPEAN TYPE PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME VIRUS AND VACCINE COMPOSITION CONTAINING THE SAME	

VIRUS RELATED RESEARCH ACTIVITIES

COVID-19 PoaCheck ™

LOCAL PATENTS LIST (KOREA)

No	RESEARCH NAME	Remark
10	**PHARMACEUTICAL COMPOSITION FOR TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS**	★★ Application to the development of coronavirus treatment
11	**DETECTION KIT OF COVID-19 AND USES THEREOF**	**LAMP METHOD**
12	DIAGNOSTIC RPA KIT OF SEVERE FEVER WITH THROMBOCYTOPENIA SYNDROME (SFTS) VIRUS	RPA METHOD
13	DIAGNOSTIC RPA KIT OF TSUTSUGAMUSHI INFECTION	RPA METHOD
14	DIAGNOSTIC KIT OF TERTIAN MALARIA	ELISA MEHTOD
15	RPA PRIMER SET FOR DETECTION OF FMD VIRUS PAN TYPE	RPA METHOD
16	RPA PRIMER SET FOR DETECTION OF FMD VIRUS A TYPE	RPA METHOD
17	RECOMBINASE-POLYMERIZATION EFFICIENCY AMPLIFICATION PRIMER PROBE SET FOR RAPID DETECTION OF PINE NEMATODES	RPA METHOD
18	AFRICAN SWINE FEVER VIRUS INFECTIOUS DISEASE DIAGNOSTIC KIT	RPA METHOD
19	SHRIMP WHITE SPOT VIRUS INFECTIOUS DISEASE DIAGNOSIS KIT	RPA METHOD

BIOPOA

RESEARCH CAPACITY for COVID-19

COVID-19 PoaCheck™

Project underway with KCDC

(Korea Centers for Disease Control and Prevention)

Biopoa Co., Ltd. is the **only research company in Korea**
that simultaneously conducts **COVID-19 related diagnostics and vaccine development** projects.

	Name	Job Title	R&D Project name	Period
1	S. H. Cho	CEO	COVID-19 vaccine candidate development using virus delivery system	2020. 04 - 2020. 12
2	H. W. Lee	Executive director	Development of high-sensitivity rapid diagnosis material for COVID-19 using immune response	2020. 05 - 2020. 12

질병관리본부 KCDC

BIOPOA

REGISTRATION CERTIFICATES

COVID-19 PoaCheck™

체외 제허 20-668 호

체외진단의료기기 제조 허가증

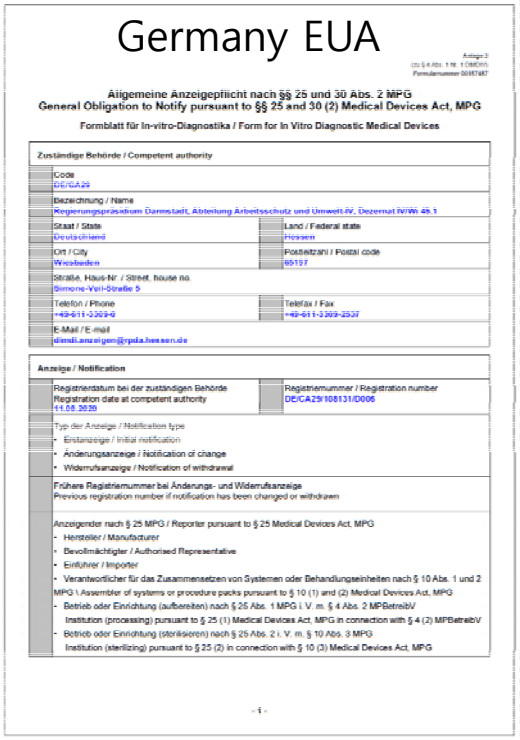
(업 허가번호 : 체외 제 6967 호)

구 분	[✔] 제조 / [ ] 수입	[✔] 품목 / [ ] 품목류	
명 칭 (제품명, 품목명, 모델명)	Rapid COVID-19 PoaCheck,고위험성감염체유전자검사시약,Rapid COVID-19 PoaCheck	분류번호(등급)	N05030.01 (3)
모 양 및 구 조	별첨		
원 재 료	별첨		
제 조 방 법	별첨		
성 능	별첨		
사 용 목 적	별첨		
사 용 방 법	별첨		
사용 시 주의사항	별첨		
포 장 단 위	별첨		
저장방법 및 사용기간	저장방법 : 별첨, 사용기간 : 별첨		
시 험 규 격	별첨		
제조(수입)업자 정보	제조(수입)업자 : 주식회사 바이오포아, 경기도 화성시 동탄기흥로 660-26 제조원 : 별첨		
허 가 조 건	없음		
소 재 지	별첨		
비 고	수출용에 한함		

「체외진단의료기기법」 제5조·제11조 및 같은 법 시행규칙 제6조·제26조에 따라 위와 같이 허가합니다.

2020 년 08 월 14 일

식 품 의 약 품 안 전 처 장 (인)



Germany EUA

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: DE/CA29

Bezeichnung / Name: Regierungspräsidium Darmstadt, Abteilung Arbeitsschutz und Umwelt-IV, Dezernat IV/W 45.1

Staat / State: Deutschland | Land / Federal state: Hessen

Ort / City: Wiesbaden | Postleitzahl / Postal code: 65197

Straße, Haus-Nr. / Street, house no.: Simone-Veil-Straße 5

Telefon / Phone: +49-611-2309-0 | Telefax / Fax: +49-611-2309-2537

E-Mail / E-mail: dindi.anzeigen@rpda.hessen.de

Anzeige / Notification

Registrierdatum bei der zuständigen Behörde / Registration date at competent authority: 44.05.2020

Registriernummer / Registration number: DE/CA29/108131/D006

Typ der Anzeige / Notification type
- Erstanzeige / Initial notification
- Änderungsanzeige / Notification of change
- Widerrufsanzeige / Notification of withdrawal

Frühere Registriernummer bei Änderungs- und Widerrufsanzeige
Previous registration number if notification has been changed or withdrawn

Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG
- Hersteller / Manufacturer
- Bevollmächtigter / Authorised Representative
- Einführer / Importer
- 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
- Betrieb oder Einrichtung (aufbereiten) nach § 26 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV
  Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV
- Betrieb oder Einrichtung (sterilisieren) nach § 26 Abs. 2 i. V. m. § 10 Abs. 3 MPG
  Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG

BIOPOA

DECLARATION OF CONFORMITY

CE

Legal Manufacturer: BioPOA Co., Ltd.
Address: 593-26, Dongtangiheung-ro, Hwaseong-si, Gyeonggi-do, 18469, Republic of Korea
Tel: +82-31-375-8304 Fax: +82-31-375-8305
Web: www.biopoa.com

European Representative: KTR Europe GmbH
Address: Mergenthalerallee 77, Eschborn, 65760, Germany

Product: In vitro polymerase chain reaction (PCR) assay for COVID-19 For Professional Use Only
Rapid COVID-19 PoaCheck™

EDMA code/Term: 15.04.40.90.00 Other Virology-NA reagents

Classification Under IVDD: Others of Annex II, IVDD 98/79/EC

Conformity assessment Route: Annex III

General Applicable Directive
In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Standards we are implementing

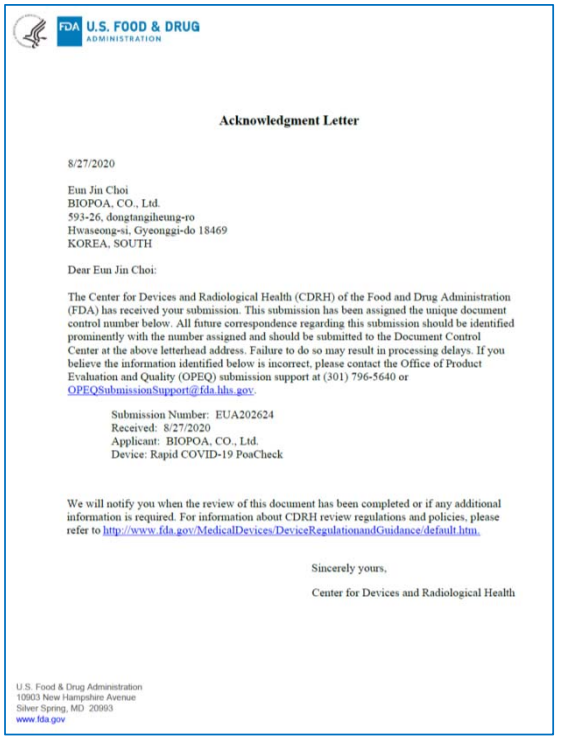
EN ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
GMP	Manufacturer complies with Korea Good Manufacturing Practices of Medical Devices for the Reagent for in vitro Diagnostic Medical Devices.

We hereby declare that the product mentioned above meets the provisions of the European Directive 98/79/EC for In vitro Diagnostic Medical Devices. All supporting documentations are retained at the premises of the manufacturer and manufacturer is exclusively responsible for the declaration of conformity.

Place: Hwaseong-si, Republic of Korea
Date of Issue: August 3rd, 2020
Valid From: August 3rd, 2020

Signature

SUN HEE, Cho
CEO of BioPOA Co., Ltd.



FDA U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

8/27/2020

Eun Jin Choi
BIOPOA, CO., Ltd.
593-26, dongtangiheung-ro
Hwaseong-si, Gyeonggi-do 18469
KOREA, SOUTH

Dear Eun Jin Choi:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: EUA202624
Received: 8/27/2020
Applicant: BIOPOA, CO., Ltd.
Device: Rapid COVID-19 PoaCheck

We will notify you when the review of this document has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

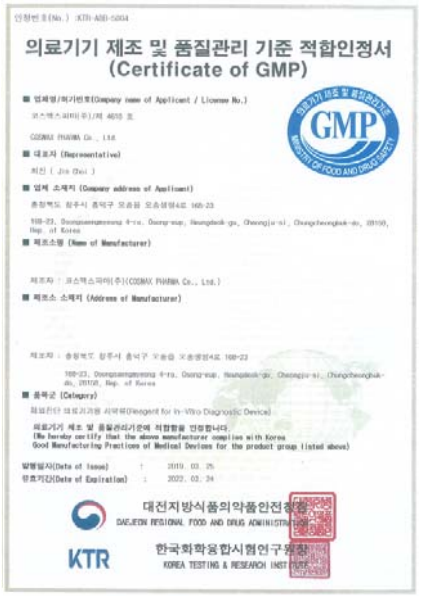
Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

- KFDA permission of manufacturing COVID-19 PoaCheck for export only

BIOPOA

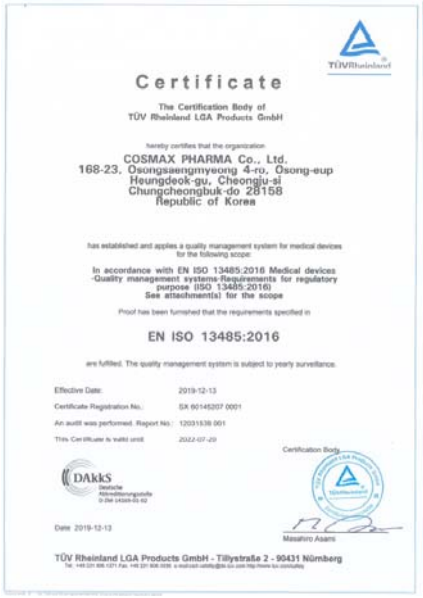
MANUFACTURING SITE (OEM SITE) COVID-19 PoaCheck™


의료기기 제조 및 품질관리 기준 적합인정서
(Certificate of GMP)

GMP

KTR

ISO13485
(approved in 2016)


Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

COSMAX PHARMA Co., Ltd.
168-23, Osongsaengmyeong 4-ro, Osong-eup
Heungdeok-gu, Cheongju-si
Chungcheongbuk-do 28158
Republic of Korea

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

EN ISO 13485:2016

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

KGMP for Medical Appliances
(approved in 2016)

Major activities
- medical appliances,
- functional cosmetics,
- diagnostic kits

Rapid COVID-19 PoaCheck™ is produced under the **approved facility** controlled by the experts. Also it has been **processed in the cleanest environment in order to prevent cross contamination** from air, the whole processing take place in each clean rooms divided.

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KIT COMPONENTS

ONE TEST KIT CONTAINS

No	Name	Cap	Q'ty / 100 rxn
1	COVID-19 Orf1a gene primer mixture	Orf	300 µL, 1 ea
2	LAMP reaction mixture	Mix	1 mL, 1 ea
3	Positive control (Orf1a)	OC	30 µL, 1 ea
4	Molecular grade water	DW	1 mL, 1ea
5	LAMP dye (FAM)	Dye	40 µL, 1 ea

This kit contains all necessary contents for real time LAMP reaction.

Therefore examiners do not need to purchase additional reagent.

COVID-19 PoaCheck^{Tm} contents are progressively apply for one tube reverse transcription reaction and LAMP amplification process.

It can be monitoring the nucleic acid amplification result based on real time manner through the amplification plot.

It is also provided as positive control to assist the comparison analysis with the clinical patient sample data.

Simple contents **Easy to use and convenient**

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KIT SPECIFICATION Rapid COVID-19 PoaCheck™ COVID-19 PoaCheck™

Item	Specification
Detection target	2019-nCoV (COVID-19)
Target gene	Orf1a
Detection technology	Real-Time OneStep LAMP
Specimen type	Nasopharyngeal swab, Oropharyngeal swab, Sputum
Compatible instruments	CFX96™ Real-Time PCR System (BioRad) ABi7500/7500 Fast Real Time PCR system (Applied Biosystems)
Running Time	20-30 mins
KIT Unit	100 Tests/KIT

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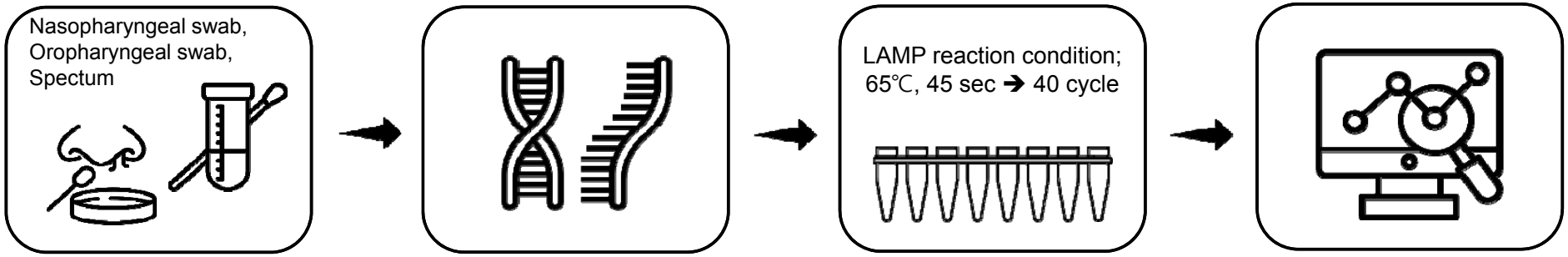
SIMPLE TESTING PROCESS

COVID-19 PoaCheck ™

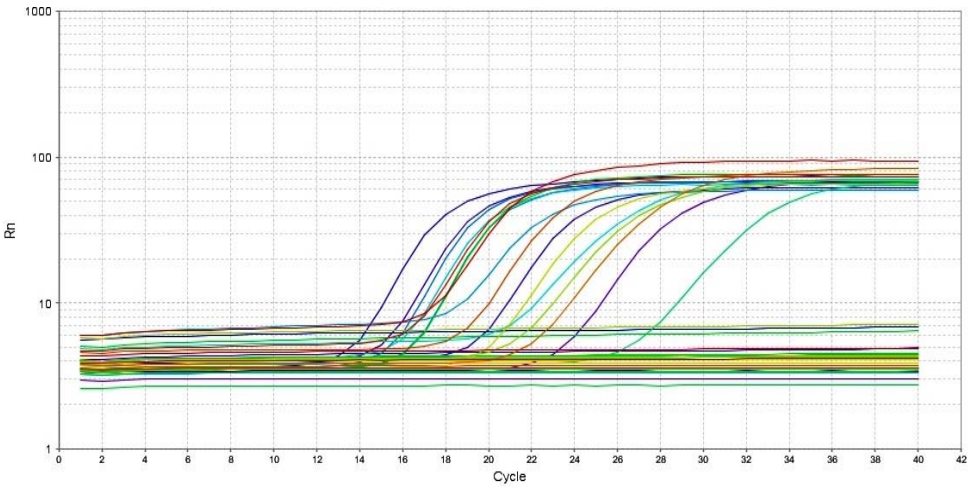


Sample collection from suspected patients

Nucleic acid preparation

OneStep Real Time **LAMP reaction**

Data analysis



◄ Example of **Real Time LAMP reaction** with clinical samples

OneStep Real Time LAMP reaction time

Less than **20 mins** for real positive clinical samples

To confirm the real negative result,
it needs **10 mins** more reaction.

Fast and Quick Process

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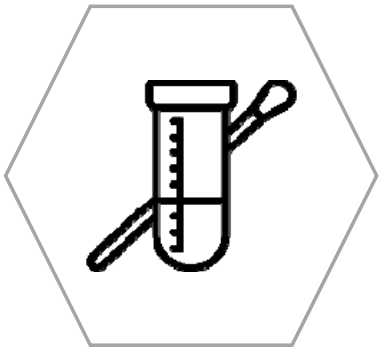
MATERIALS AND METHOD



- **Specimen storage condition**

  1) The specimen can be kept at 4℃ up to 72 hours.

     For keeping it for more time than 72 hours, it is should be kept it under -70℃.

  2) Viral RNA extraction kits are available from various manufactures.

     You can use your own extraction systems or commercial kits.

  3) Extracted RNA should be keep under -70℃.

- **Required Materials and Devices (NOT Provided)**

  Applied Biosystems™ 7500 Fast real-time PCR instrument system (Thermo Fisher Scientific) or CFX96™ real-time PCR detection system (Bio-Rad) / Biological cabinet / Vortex mixer / Micropipets (0.5 – 1000 ㎕) / Sterile filter tips (10, 20, 200, 1000 ㎕) / Sterile microtubes / Refrigerator / Freezer / Tube racks / Microcentrifuge / Biohazard waste container

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MATERIALS AND METHOD

Procedure of Real time RT-LAMP

* Use the reagents which are stored at -20℃ after spin down briefly when those are melted before use.
* Be careful of contamination when you use the positive control for amplification.

1) Please make the reaction mixture on the ice. Mix well the reagents according to the table below.

No. of Reactions (Unit: ㎕)	1	8	16	32
COVID-19 Orf1a gene primer mixture	3.0	24	48	96
LAMP reaction mixture	10	80	160	320
Molecular grade water	4.6-1.6	36.8-12.8	73.6-25.6	147.2-51.2
LAMP dye	0.4	3.2	6.4	12.8
RNA	2.0-5.0	2.0-5.0	2.0-5.0	2.0-5.0
Total	20	160	320	640

2) Mix well by tapping 5 times or vortexing briefly and then spin down.

3) Aliquot 15-18 ㎕ of one-step RT-LAMP master mix to each PCR tube.

4) Add positive and negative control (DW) to each PCR tube.

* It is highly recommended that the mixture for negative control should be made separately to avoid cross contamination.

5) Close the lid of PCR tube and then spin down briefly to remove the bubble.

6) Real time RT-LAMP reaction should be done at least 40 min.

7) Set the program as below table.

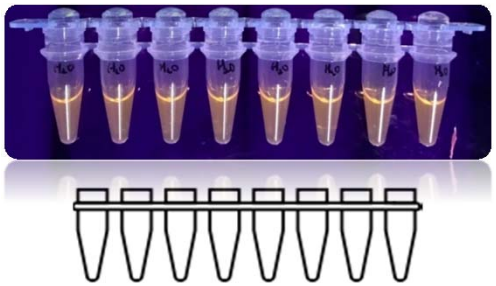
Step	No. of Cycle	Temperature	Duration
1	40	65℃	45 sec

8) Plate setup

- Set the fluorophores with FAM.
- Type the sample names in each tube.

* Unknown: Clinical sample
* Negative control
* Positive control

9) Click Start Run



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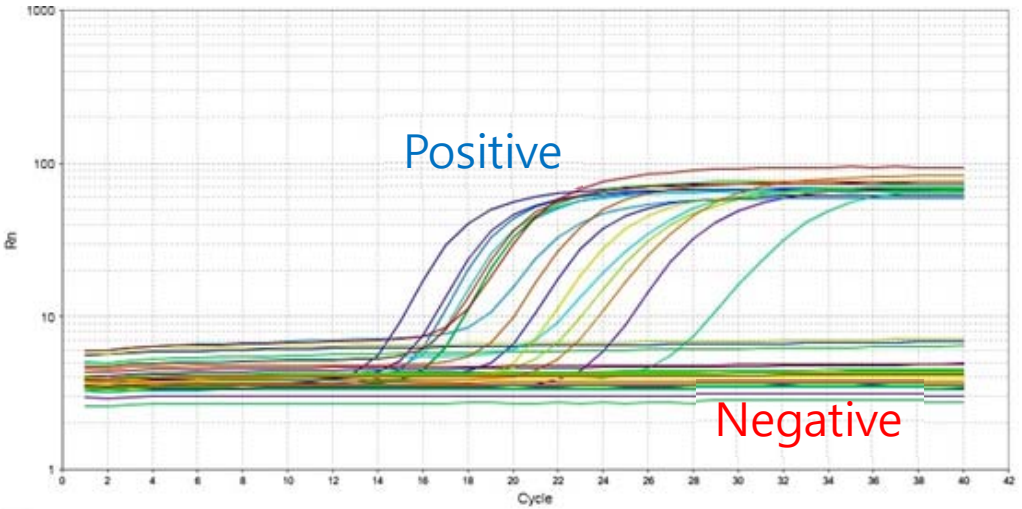
READING THE RESULT

COVID-19 PoaCheck ™



<Example of RT-LAMP reaction with clinical samples>

Case	Positive control	Negative control	Orf1a gene	Interpretation (Ct Value)
1	+	-	+	SARS-CoV-2 Positive (≤30)
2	+	-	-	SARS-CoV-2 Negative (30≥)
3	+	+	+/-	Invalid result / retest
4	-	+	+/-	
5	-	-	+/-	

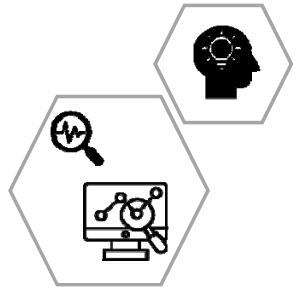
*** Cut-off value**

Analyte	Fluorophore	Threshold Setting	Cut off value for positive
Orf1a gene	FAM	Auto	≤30

1) In case of Cut off value ≤30, The result is regarded as false positive and retested.
2) The negative control is not amplified. If the negative control is amplified, retest is performed.
3) If false positives repeatedly appear even after retesting, wipe the experiment space including the pipette with RNase away and/or 70% alcohol, and test with a new tip.

*** Warnings and Precaution**

1) Carefully read this instruction before starting the procedure.
2) Clinical samples should be regarded as potentially infectious materials and prepared the LAMP reaction mixture in a laminar flow hood.
3) Do not use the kit after its expiration date written on box.
4) Avoid repeated thawing and freezing of the reagents, this may cause wrong test result.
5) Once the reagents have been thawed, vortex, and spin down briefly the tubes before use.
6) Prepare quickly the reaction mixture on ice.
7) Use always sterile pipette tips with filters.
8) Wear separate coats and gloves in each area.
9) Collected test samples in sterile tubes.
10) Test samples should extracted immediately or frozen at -20℃ to -80℃.



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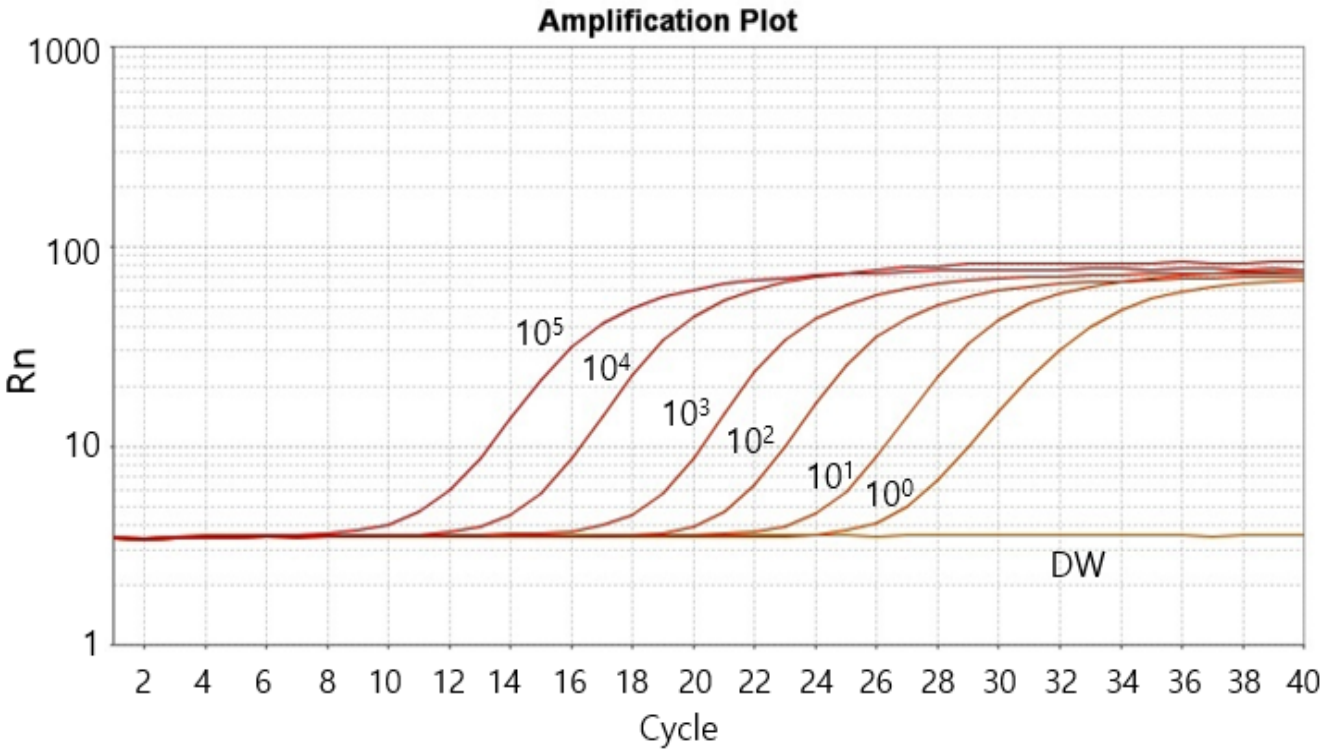
KIT PERFORMANCE (Sensitivity)

COVID-19 PoaCheck ™

Analytical Sensitivity



Reaction condition; 65℃, 45 sec, 40 cycles
1 cycle = 45 sec

Step	No. of Cycle	Temperature	Duration
1	40	65℃	45 sec

Sensitivity - LoD : 1 copies / $\mu\ell$

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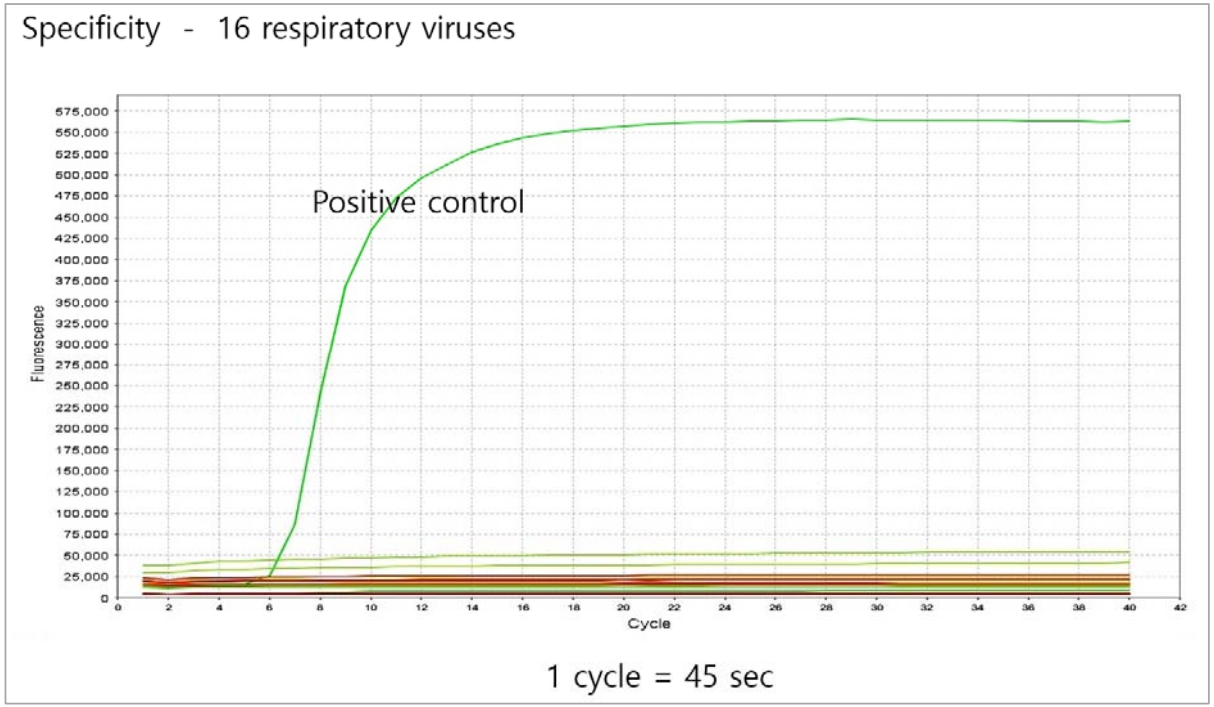
KIT PERFORMANCE (Specificity)

COVID-19 PoaCheck™

Analytical Specificity



NO.	Name	Result
1	human coronavirus HKU1	Negative (-)
2	human coronavirus OC43	Negative (-)
3	human coronavirus NL63	Negative (-)
4	Human parainfluenza virus 2	Negative (-)
5	Adenovirus	Negative (-)
6	Human Metapneumovirus (MPV)	Negative (-)
7	human respiratory syncytial virus B	Negative (-)
8	Human rhinovirus A/B	Negative (-)
9	Brevibacterium casei	Negative (-)
10	Micrococcus luteus	Negative (-)
11	Streptococcus pyogenes	Negative (-)
12	Streptococcus mitis/oralis	Negative (-)
13	Serratia marcescens	Negative (-)
14	Entrobacter aerogenes	Negative (-)
15	Klebsiella oxytoca	Negative (-)
16	Staphylococcus warneri	Negative (-)
17	Proteus mirabilis	Negative (-)
18	Citrobacter freundii	Negative (-)
19	Enterococcus faecalis	Negative (-)
20	Streptococcus agalactiae	Negative (-)
21	Staphylococcus epidermidis	Negative (-)
22	Enterobacter cloacae ssp cloacae	Negative (-)
23	Propionibacterium acnes	Negative (-)
24	Dermabacter hominis	Negative (-)
25	Stenotrophomonas maltophilia	Negative (-)
26	Acinetobacter baumanii	Negative (-)
27	Pseudomonas aeruginosa	Negative (-)
28	Streptococcus equi	Negative (-)
29	Escherichia coli	Negative (-)
30	Corynebacterium striatum	Negative (-)
31	Klebsiella pneumoniae	Negative (-)
32	COVID-19 (Positive control)	Positive (+)

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ASSAY PERFORMANCE

Performance test		Comparison reagent (AOO™ 2019-nCoV Assay)		Total
		Positive	Negative	
Test reagent (COVID-19 PoaCheck™)	Positive	73	0	73
	Negative	1	80	81
Total		74	80	154

Sensitivity	98.6%
Specificity	100%
Concordance ratio	99.4%

INFORMATION

Sales information of **Rapid COVID-19 PoaCheck™**

- Same pricing policy basis on Korea FOB in all countries for export except Africa
- Minimum Order Quantity (MOQ): 500 kits / order
- Storage condition: under -15℃
- Storage expiration duration: upto 6 months
- Production Capacity: 250,000 test (2,500 kits) / week
- Accuracy: Rapid COVID-19 PoaCheckTM detected only coronavirus-19 among 31 other viruses and bacteria.

Please contact your dealer for price, payment term, delivery condition and so on.

REFERENCES

Rapid COVID-19 PoaCheck™ was shown better results than published LAMP primer sets described below the references.

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3. Lu R, et al. 2020. **A Novel Reverse Transcription Loop-Mediated Isothermal Amplification Method for Rapid Detection of SARS-CoV-2.** Int J Mol Sci. 2020 Apr; 21(8): 2826. Published online 2020 Apr 18. doi: 10.3390/ijms21082826.
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5. Mohamed ET, et al. 2020. **A Single and Two-Stage, Closed-Tube, Molecular Test for the 2019 Novel Coronavirus (COVID-19) at Home, Clinic, and Points of Entry. ChemRxiv. 2020 Feb 19. doi: 10.26434/chemrxiv.11860137.**
6. Park GS, et al. 2020. **Development of Reverse Transcription Loop-Mediated Isothermal Amplification Assays Targeting Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2).** J Mol Diagn. 2020 Jun;22(6):729-735. doi: 10.1016/j.jmoldx.2020.03.006. Epub 2020 Apr 7.
7. Rho GT and Lee WS. 2020. **LAMP contents and its usage for detection of 2019 novel coronavirus.** Korea Patent No. 10-2109196.

Rapid COVID-19 PoaCheck - Summary for Selling point

Company	Kogene	Seegene	SDBiosensor	Solgent	Biopoa
Product Name	PowerCheck 2019-nCoV Real-time PCR kit	Allplex 2019-nCoV Assay	Standard MnCoV Real-time Detection kit	DiaPlexQ Novel Coronavirus (2019-nCoV) Detection kit	Rapid COVID-19 PoaCheck
Cat No.	R6900T	RP10243X	M-NCOV-01	SQD52-K100	Poa-nCoV-LAMP-100
Target gene	RdRp, E gene	RdRp, E gene, N gene	RdRp, E gene	Orf1a, N gene	Orf1a
Test/Kit	50	100	100	100	100
Method	RT-PCR	RT-PCR	RT-PCR	RT-PCR	RT-LAMP
Reaction Time	2 hrs	2 hrs	2 hrs	2 hrs	20-30 min
Sensitivity	98.2% >	98.2% >	98.2% >	98.2% >	98.6% (73/74)
Specificity	100%	100%	100%	100%	100% (80/80)
Limitation of Detection (LoD)	RdRp gene: 7.6 copies/㎕ E gene: 5.7 copies/㎕	RdRp gene: 100 copies/㎕ E gene: 100 copies/㎕ N gene: 100 copies/㎕	Orf1ab(RdRp) gene: 0.5 copies/㎕ E gene: 0.5 copies/㎕	Orf1a: 2 copies/㎕ N gene:2 copies/㎕	1 copies/㎕
Amount of RNA for reaction	5 ㎕	5 ㎕	5 ㎕	5 ㎕	2 ㎕
Machine	CFX96 ABI7500	CFX96	CFX96 ABI7500	CFX96 ABI7500	CFX96 ABI7500
Character	Low speed/ High accuracy	Low speed/ High accuracy	Low speed/ High accuracy	Low speed/ High accuracy	High speed/ High accuracy

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