

Product Introduction

Novel-CoV19 RT-LAMP PCR Kit



Overview

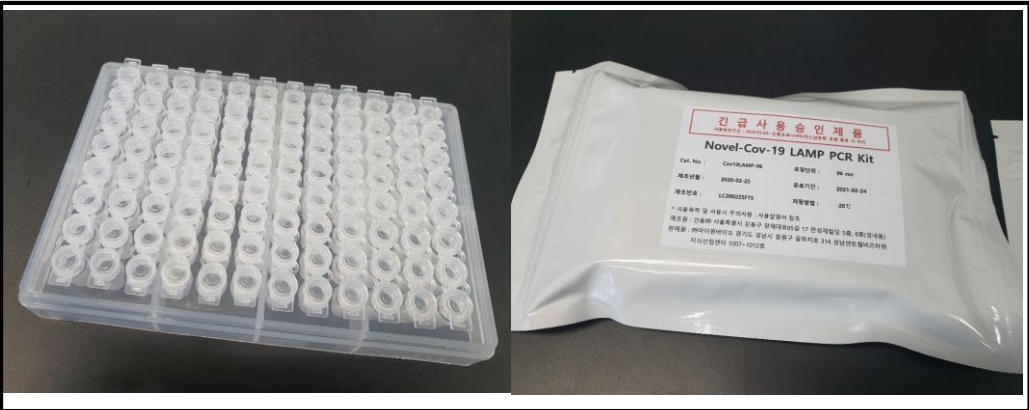
Our In-vitro Diagnostic product enables precise and efficient detection of the Coronavirus disease (2019-nCoV), utilizing Real-time RT LAMP PCR – Real-time Reverse-Transcription Loop-mediated isothermal Amplification PCR method on nasopharyngeal swab specimen of a suspected patient.

Product Composition

Reagent	IONEDE96	IONED100
Real-time LAMP Premix	20μl x 96 (96test/kit)	1ml x 2 (100test/2tube)
Positive Control	200μl x 1	200μl x 1



[IONED100]



[IONEDE96]

Product Introduction

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Novel-CoV19 RT-LAMP PCR Kit



Specification

Item	Specification
Detection target	2019-nCoV (COVID-19)
Target region	N gene
Detection technology	Real-Time RT -LAMP PCR (with OneStep)
Specimen type	Nasopharyngeal swab, Oropharyngeal swab, etc
PCR running time	20 mins
Compatible PCR Device	CFX96™ Real-Time PCR System (Bio-Rad)

Key Characteristics

- **Rapid Detection System : Implementation of isothermal reaction method – enables for 20-min test time**
- SYBR green Application : Fluorometric Detection – enables for High Specificity
- One step qRT-PCR system : en-bloc analysis without separate reverse-transcription process
- User-Friendly Diagnostic System: Analysis possible only with the RNA specimen
- Inclusion of Positive Control (Plasmid form)

Product Introduction

Diagnostics Procedure

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1) Specimen Collection



2) Nucleic Acid Extraction



3) Reagent Preparation



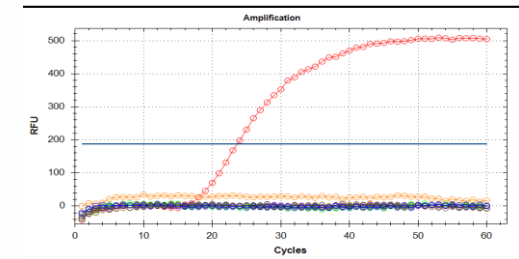
Novel-CoV19 RT-LAMP PCR Kit Usage

4) Amplification Analysis

(qRT-LAMP PCR)



5) Monitor LAMP Reaction



Run Time: **20min** (40-cycles)



Reagent Composition

Component	Volume ($\mu\ell$)
Real-time LAMP Premix	20 $\mu\ell$
Template RNA (or cDNA)	5 $\mu\ell$
Total volume	25 $\mu\ell$

LAMP PCR Setting

Step	Temperature	Time	Cycles
1	50°C	5min	1 cycle
2	70°C	30sec	30 cycle



Results Interpretation

Result	Cut-off (Unit: Ct value)
Positive	≤25
Negative	> 25

Item	SYBR green	PC	NC	Interpretation
Sample1	-	+	-	No detection (Neg.)
Sample2	+	+	-	COVID-19 Positive
Sample3	+	-	+	Invalid result/ Retest
Sample4	-	-	+	Invalid result/ Retest



Technological Comparison

Category	iONEBIO	Competitor Type A	Competitor Type B
Method	Realtime RT-LAMP PCR	Realtime RT-PCR	IgM/IgG Test (Antibody)
Specimen	Nucleic Acid (RNA)	Nucleic Acid (RNA)	Antigen-Antibody (Finger-prick)
Test Duration	Within 20 min	2 Hours	15 min
Sensitivity (Limit of Detection)	1 Copy (Even 1-copy of virus can be detected)	100 Copies (CANNOT detect positive for specimen with less than 100-copies of virus)	10,000 Copies (CANNOT detect positive for specimen with less than 10,000-copies of virus)
Characteristic	High Speed , High Accuracy	Low Speed, High Accuracy	High Speed , Low Accuracy

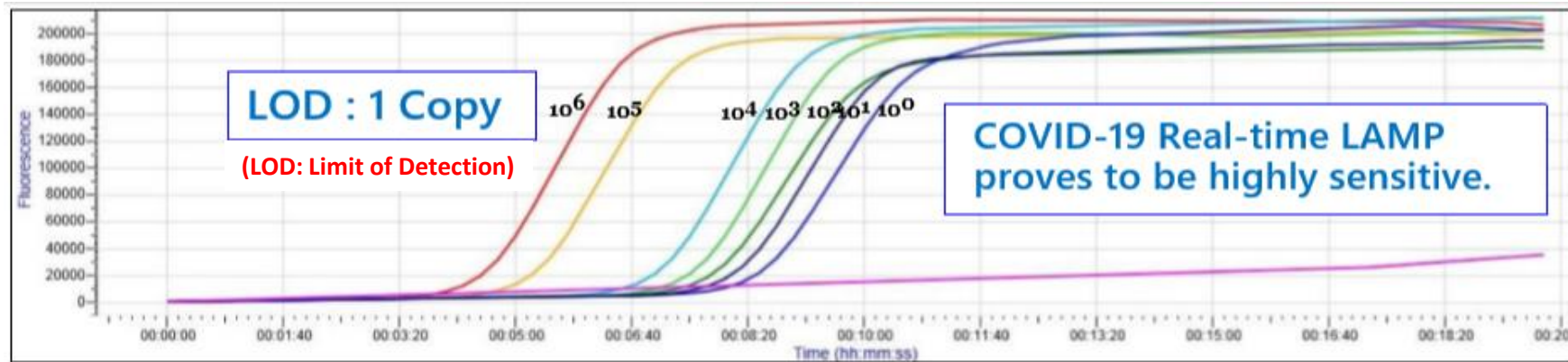
iONEBIO – Technological Advantage

IgM/IgG Diagnostic Kit (Antibody) enables for rapid testing; however, accompanies low-specificity (accuracy) risk of less than 80%. On the other hand, RT-PCR Diagnostic Kits display higher specificity close to 100% range; however takes around 2 hours until a single analysis is complete.

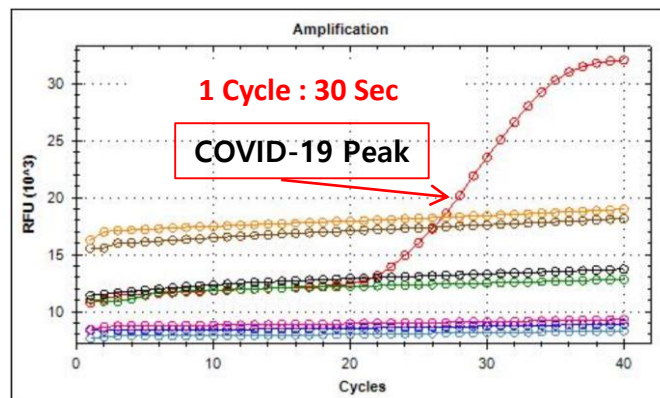
iONEBIO’s RT-LAMP PCR Kit is groundbreakingly rapid and accurate; thus is the most competitive diagnostic kit for COVID-19 available in the global market.



- 1-Copy Sensitivity



- Test Completion within **20-min** (30sec/cycle * 40-cycles)



- COVID-19 Clinical sample
- Adenovirus type 55
- H. Influenzae
- S. Pneumoniae
- M. Pneumoniae
- SFTS Virus
- Malaria
- Scrub. Typhus



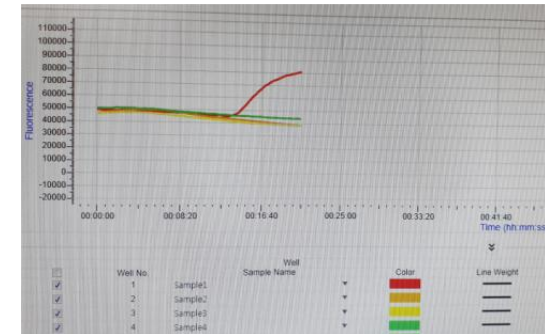
Simple User-Friendly Protocol



(1) Mix COVID-19 Real-time LAMP Reagent with RNA(2 μ l) extract



(2) Place the RNA Premix in PCR Device



(3) Identify the computed Peak

- Only simple knowledge on PCR device operation necessary to conduct test procedures.
- iONEBIO's Diagnostic kits – leaving out the process of synthesizing RNA to cDNA – allow for 20-min rapid diagnosis of COVID-19.



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- **Bio-Rad CFX 96 Real-Time PCR Detection Device** or equivalent
 - The most widely used Realtime PCR Device for molecular diagnosis around the world
 - iONEBIO Diagnostic Kit displays the most accurate result with utilization of the above PCR device.
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Manufacturer Certification

Medical Product Manufacturer License

ionebio



인정번호(No.) : KTL-AABC-6378

의료기기 제조 및 품질관리 기준 적합인정서 (Certificate of GMP)

■ 업체명/허가번호(Company name of Applicant / License No.)
인솔(주) 제 6220 호
InSol Co., Ltd

■ 대표자 (Representative)
이양복 (Yangbok Lee)

■ 업체 소재지 (Company address of Applicant)
경기도 하남시 조경대로 35, 미사하우스티오피타워 F313호
F313, 35, Jojeong-daero, Hanam-si, Gyeonggi-do, 12918, Rep. of KOREA

■ 제조소명 (Name of Manufacturer)
제조사 : 인솔(주) (InSol Co., Ltd)
■ 제조소 소재지 (Address of Manufacturer)
제조자 : 경기도 하남시 조경대로 35, 미사하우스티오피타워 F314-1호, F314-2호, F315-1호, F315-2호, F316-1호, F316-2호, F317호
F314-1, F314-2, F315-1, F315-2, F316-1, F316-2, F317, 35, Jojeong-daero, Hanam-si, Gyeonggi-do, 12918, 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. 08. 30
유효기간(Date of Expiration) : 2022. 08. 29

경인지방식품의약품안전청
GYEONGIN REGIONAL FOOD AND DRUG ADMINISTRATION

ktl 한국 산업 기술 시험원
Korea Testing Laboratory

문서확인번호 : L42P-JDEL-67LK-KJUL

제 6220 호

의료기기 제조업 허가증

1. 업소명 : 인솔(주)

2. 소재지 : 경기도 하남시 조경대로 35 미사하우스티오피타워 F314-2, F315-1, F315-2, F316-1, F316-2호

3. 대표자(생년월일) : 이양복(1953년 07월 20일)

4. 품질책임자(생년월일) : 전봉균(1969년 03월 25일)

5. 허가조건 :

「의료기기법」 제6조·제15조 및 같은 법 시행규칙 제3조·제29조에 따라
위와 같이 허가합니다.

2018 년 09 월 12 일

경인지방식품의약품안전청

본 증명서는 인터넷으로 발급되었으며, 홈페이지(amed.mfds.go.kr)의 발급문서전북확인 메뉴를 통해 위변조 여부를 확인할 수 있습니다.
또한, 문서확인과 비교도도 전북확인(스캐너용 문서확인프로그램)을 이용하실 수 있습니다.

All Manufacturing Process
Outsourced to INSOL Co.,Ltd.



Purchase Order & Leadtime

No.	Category	Description
1	Sample MOQ:	100 T (100 Tests Amount)
2	Sample Shipment Leadtime:	3 weeks upon Sample Order Issuance
3	Purchase Order MOQ:	Minimum Order Quantity 10,000 T (10,000 Tests Amount)
4	Production Leadtime :	4 weeks upon issuance of initial order, 3 weeks for subsequent orders
5	Production Capacity:	1-million T per-month

Purchase Order Premises

Minimum Order Quantity of samples specifically for licensing purposes is 100T, the lead-time of which takes 3 weeks upon issuance of Purchase Order.

Minimum Order Quantity of a main order is 10,000T (10,000 test amount)

Monthly Production Capacity is 1,000,000 Tests.



► Payment Terms

- 100% (T/T) Full Down Payment upon Purchase Order. (For orders less than 100,000 kits)
- 50% Down Payment upon order, 50% Balance Payment before Lading (For orders more than 100,000 kits)

► Delivery Terms

- FOB Incheon, Korea / Transportation fee, applicable tax, and other expenses to be covered by importer
- HS Code : 3822.00.2019 (Diagnostics Reagent)

► Transportation Means

- Transportation : Air freight, FedEx, or other designated carrier
- Additional Cost : Door-to-Door Transportation Cost, Packing Cost, Premium Service Option
- Delivery Request Due : 1-Business day before shipment date (by 3pm KST)
- Expected Date of Delivery : Cargo Pickup at 3/16, Delivery on 3/17 6pm (Considering no customs delay)
- For countries that forbid the usage of dry-ice, PCM shall be used for cargo refrigeration.

Company Introduction

iONEBIO

iONEBIO



iONEBIO is a research & development company based on the optics design capabilities, engaging into Dental, Medical Equipment, Genetic Tests, and Healthcare Devices. With our top-notch optics design technology, we have secured distinctive competitiveness, and have a vision to lead the New Growth Industry through extensive development of 3D systems.

Company / iONEBIO Co., Ltd.

Est. / Jan. 2018

President & CEO / Minbae Kim, Yeongbok Jung

Manpower / 21 employees (2020)

HQ / Gyeonggi, Seongnam-city, Jungwongu

Galmachiro 314, Seongnam Central Biz Tower

1008~1012

Business Reg. / 681-86-00934

덴탈 기기 연구개발

**Dental
Device**

유전자분석 I 분자진단

**DNA
Testing**

바디 기기 개발

Healthcare

2018 iONEBIO Co.,Ltd Establishment

3D Oral Scanner Module Development

Disease Prediction Genetic Test Development

Periodontal Disease Diagnosis

2019 Venture Business Certification

Stylex Healthcare Business Acquisition

3D intra oral scanner Prototype development

Dr.Perioe Dental Genetic Test Initiation

Oral Cancer Diagnostic Kit Innovative Tech Task Designation

(Seoul National University & KTFC Affiliation)

2020 Seongnam HQ Relocation

Intl' Sales of Genetic Test & Posture Healthcare Devices

(Mongolia, Vietnam, USA)



iONEBIO is making headway in the future New Growth Industry that is to lead the 4th Industrial Revolution Era, via development of optics medical equipment, bio-diagnostic products, and genetic analysis. Our optics technology and bioindustry technology possess potentially infinite possibilities to nimbly accommodate the quick-trended industry's needs.

[R&D / Product Development]

Oral Cancer Diagnostic Kit

3D Intra-Oral Scanner Device

3D Urinary Assay System

Cache Brush Platform

Dr.Perio Oral-bacteria Genetic Test

Virus Genetic Test

Stylex-Q Posture-Therapy Device

