

## 4.) iLAMP Novel-CoV19 Detection Kit

Our partners In-vitro diagnostic test kit enables precise and efficient detection of the Coronavirus(2019-nCoV). Their testing kit is based on Real-time RT LAMP PCR (Real-time Reverse Transcription Loop-mediated Isothermal Amplification PCR) method and is intended for use with upper and lower respiratory specimen collected from nasal swab.

### Product Composition

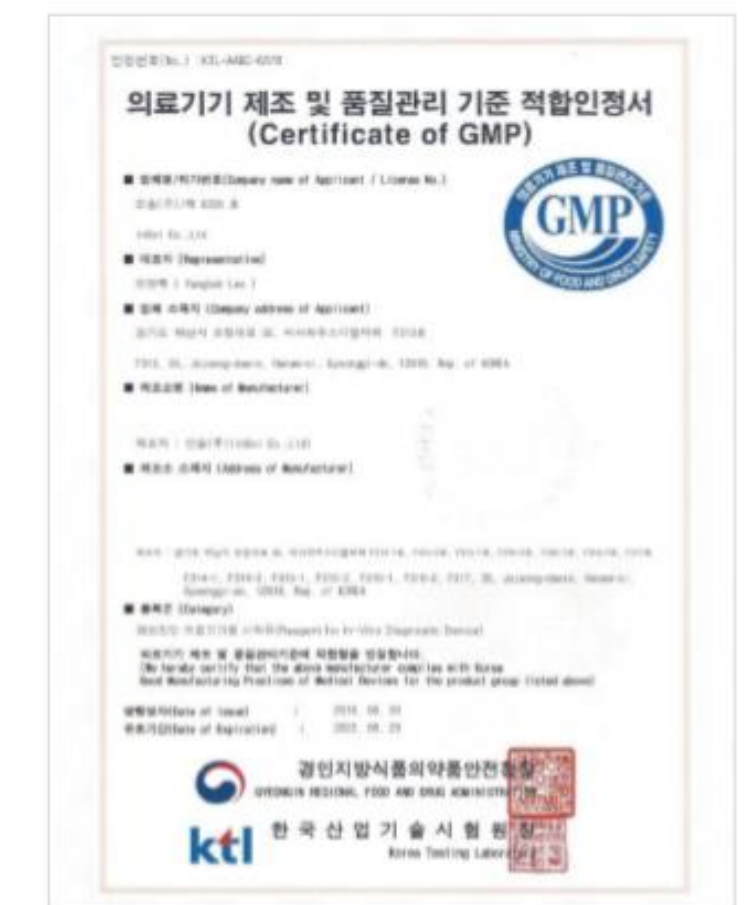
Reagent	Standard Type	PCR Plate Type
Real-time LAMP Premix	1ml x 2 (100tests per kit)	20 $\mu$ l x 96 (96tests per kit)
Positive Control	200 $\mu$ l x 1	200 $\mu$ l x 1



\*2000 tests per box



\*50 tests per tube



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### Key Characteristics

- Rapid Detection System : LAMP(a single temperature method) – enables for 20 min test time yet guarantees 100% accuracy.
- SYBR green : fluorometric determination of nucleic acids– high specificity & sensitivity
- One step qRT-PCR system : en-bloc analysis without separate reverse-transcription process
- User-Friendly protocol: testing only with the RNA specimen
- Inclusion of Positive Control (Plasmid form)

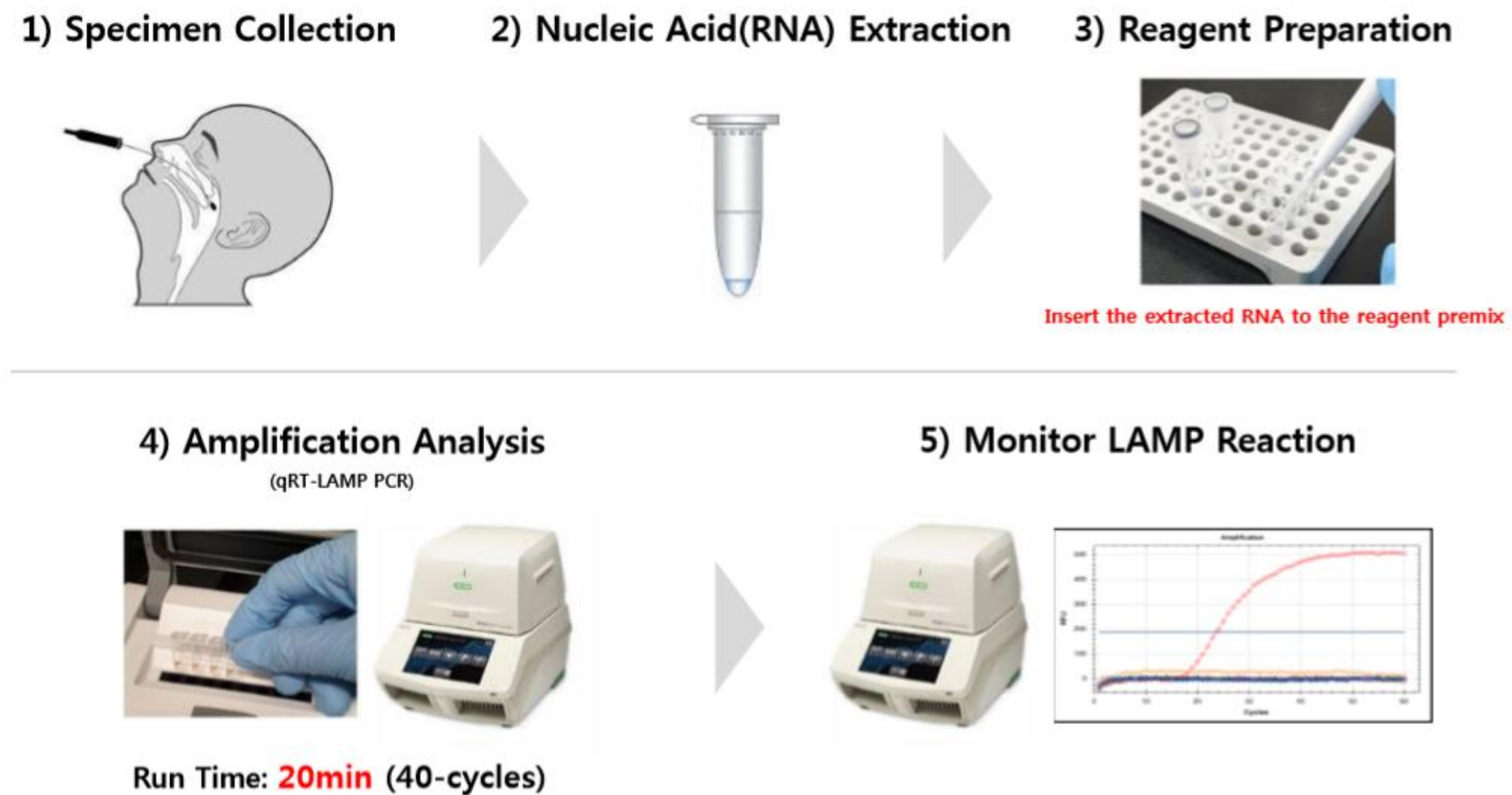
### Specification

Item	Specification
Detection target	2019-nCoV ( COVID-19 )
Target region	N gene
Detection technology	Real-Time RT -LAMP PCR (with One step)
Specimen type	Nasal swab or Throat swab
PCR run time	20 mins
Compatible PCR Device	CFX96™ Real-Time PCR System (Bio-Rad)



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### Testing Procedure



### Testing Condition

#### Reagent Composition

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

#### LAMP PCR Setting

Step	Temperature	Time	Cycle
1	50°C	5min	1 cycle
2	72°C	30sec	30 cycle

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### Result Interpretation

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

Item	SYBR green	PC	NC	Interpretation
Sample 1	-	+	-	COVID-19 Negative
Sample 2	+	+	-	COVID-19 Positive
Sample 3	+	-	+	Invalid result/ Retest
Sample 4	-	-	+	Invalid result/ Retest



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### Technological Comparison

Category	Korea	Competitor A	Competitor 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

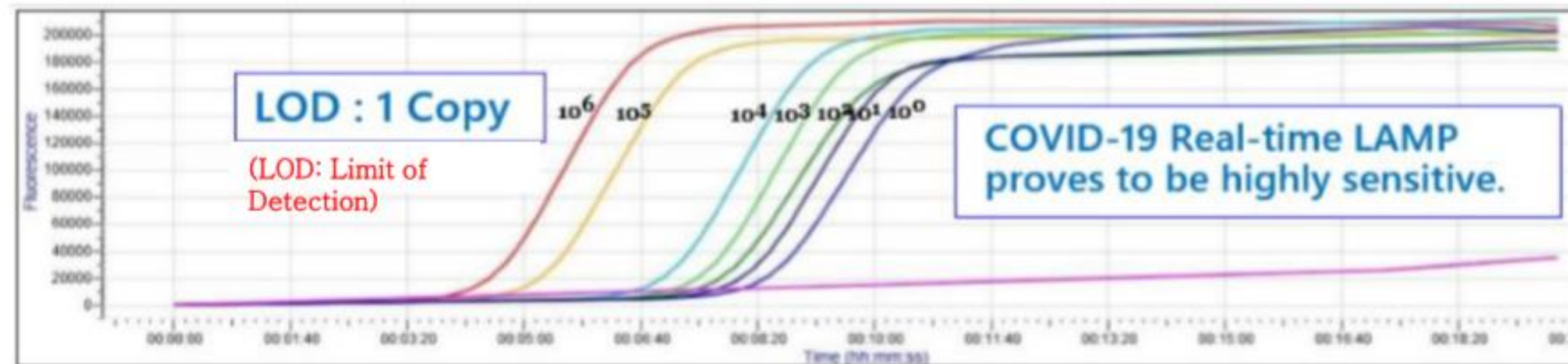
### Technological Advantage

IgM/IgG test kit(Antibody) can be rapid, however, accompanies **low accuracy rate of 80%**.

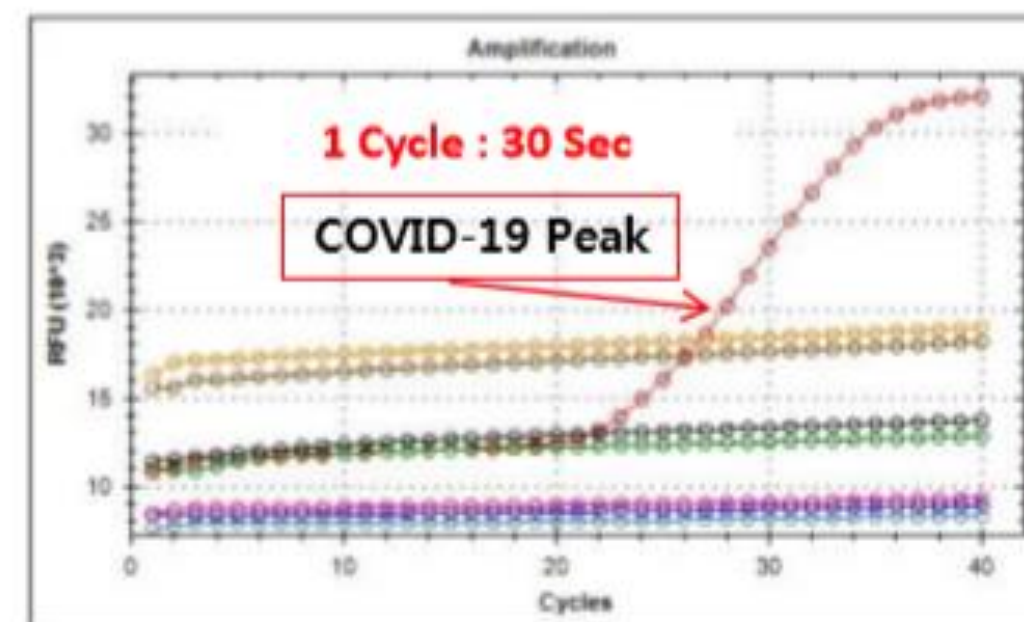
Real-time RT PCR test Kit can be higher accuracy close to 100% range, however, accompanies **low testing speed of 2~6 hours** iONEBIO's RT-LAMP PCR Kit is **groundbreakingly rapid(20min) and accurate(100%)**; thus is the most **competitive diagnostic kit for COVID-19** available on the global market. **With just 1 equipment, 288 tests can be done in an hour while competitors can take none.**

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- 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

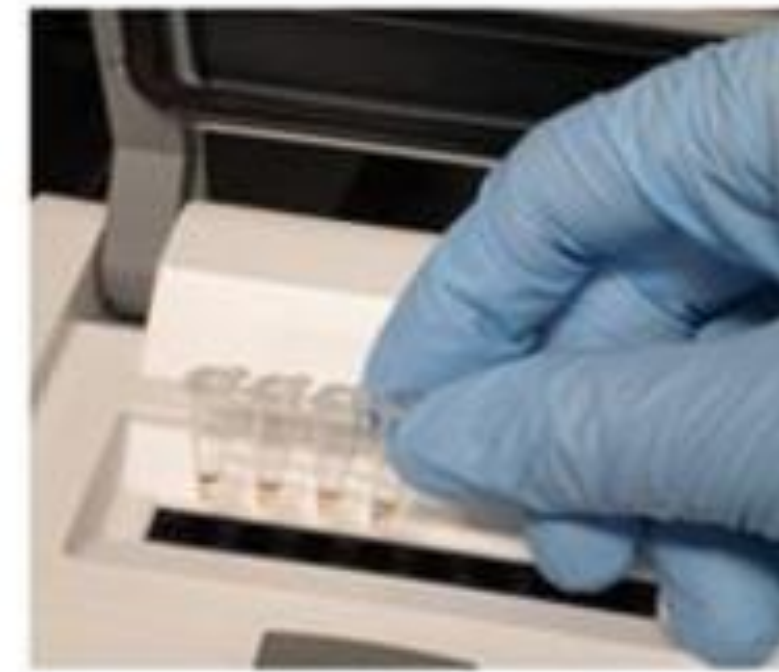


#### **4.) iLAMP Novel-CoV19 Detection Kit**

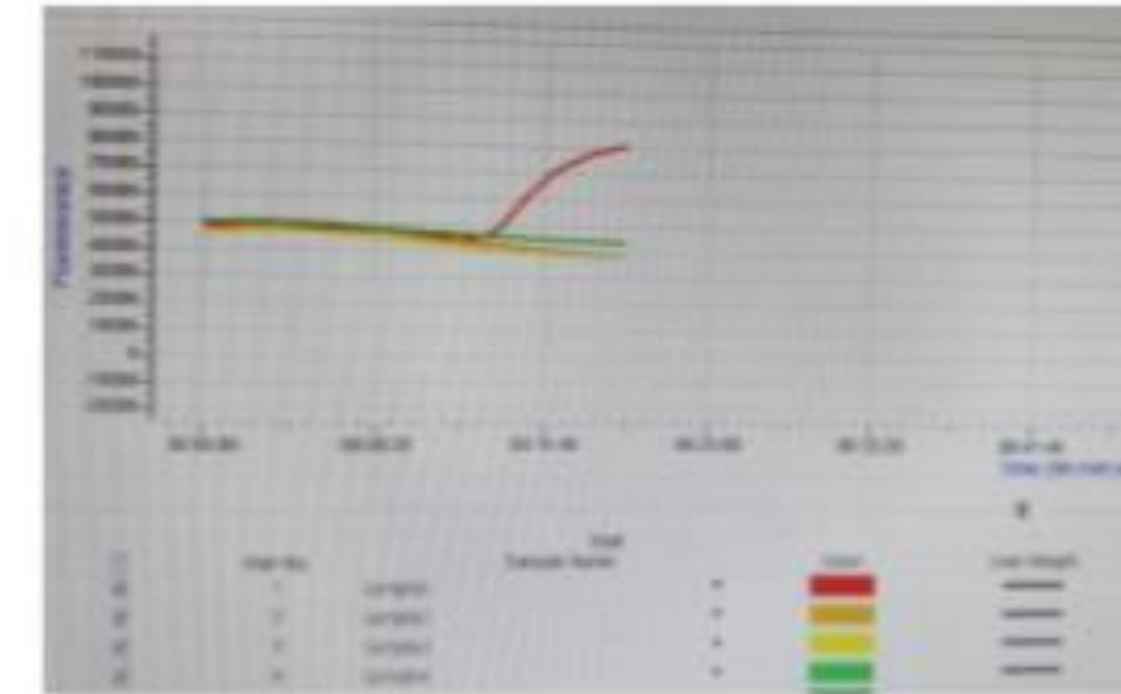
##### **Simple User-Friendly Protocol**



(1) Mix COVID-19 Real-time LAMP Reagent with RNA(2 $\mu$ 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.