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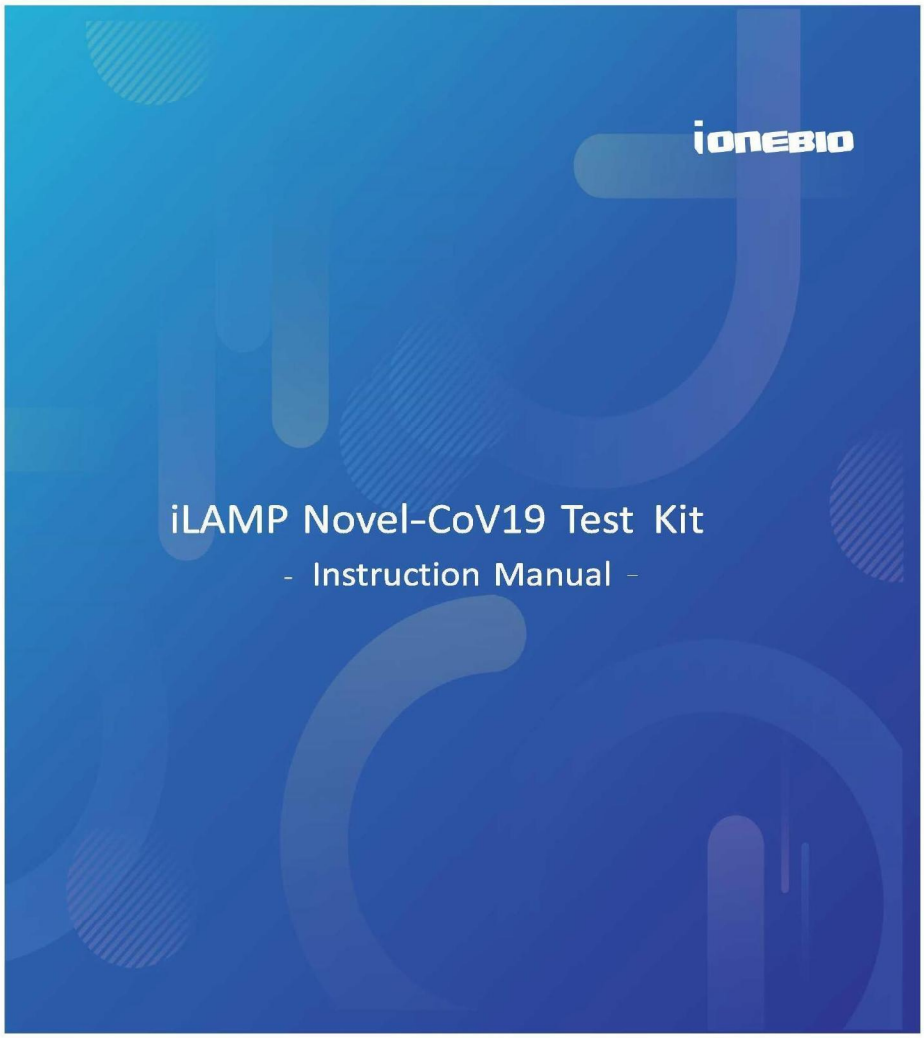
IVD

REF

CoV19-iLAMP



Real-time Reverse transcription LAMP-PCR assay system

CONTENTS

1. Specimen collection, storage and shipping

1) Use a sterile swab and collect specimen from nasopharyngeal swab, oropharyngeal swab or sputum from patients with signs and symptoms of infection who are suspected of COVID-19.

2) Store the specimen in a virus transport medium(VTM) or a sterile container at 4℃ and transport to the laboratory within 48 hours.

3) If specimens can't be transported within 48 hours, store them on ice at -70℃ and use cold insulation material when transported.

4) Avoid repeated freezing and thawing.

2. RNA isolation

1) Use a RNA extraction kit or an automated nucleic acid purification instrument to isolate RNA from specimens.

RNA extraction kit example

RNA extraction instrument example

2) Extraction methods may affect the amount of RNA extracted, purity and the results of Real- time RT-LAMP PCR. We recommend commercialized RNA extraction kits recommended by WHO or the U.S. CDC

3. Test kit Components

(Product name: iLAMP Novel-CoV19 Detection kit)

No.	Reagent	Volume(for 50tests)
1	Real-time LAMP Premix (Green cap)	1 ㎖ x 1
2	Positive control (Red cap)	50μl x 1

4. Supplies not provided with the test kit

- vortexer
- microcentrifuge or centrifuge

- sterile pipettes/ pipette filter tips
- RNase-free water: Disposable latax gloves
- cooling device
- tube or plates: Real-time PCR tube strip (0.1 ㎖)
- RNA extraction kit or RNA extraction instrument
- sterile swab

5. Reagent preparation

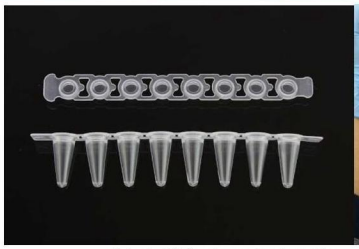
1) Preparation before test: Thaw all reagents at 4°C and keep on ice or cold rack.
The testing personnel must wear poly-gloves to avoid contamination.

2) Master mix preparation

Component	Volume (㎕)
Real-time LAMP Premix	20
Template RNA (or cDNA)	5
Total volume per test	25

* Must vortex and spin down
* Positive control: use the positive control provided with the test kit (red cap) *
Negative control: use RNase-free water

3) Carefully pipette out 20 ㎕ of LAMP PCR premix(Green cap) into a 0.1ml qPCR tube strip (ex. Tube strip compatible for the instrument CFX96)



0.1ml qPCR tube strip example

Pipetting out into a tube stirp

4) Add 5 ㎕ of the extracted template RNA into the premix tube strip
Add 5 ㎕ of Positive Control(red cap, provided with the test kit) into a separate tube strip
Add 5 ㎕ of Negative Control(RNase-free water, not provided with the test kit) into a separate tube strip.

5) Vortex gently to make sure the master mix(LAMP premix and the extracted template RNA) is mixed well, and spin down to ensure the master mix is in the bottom of the tube strip.

6. Instrument

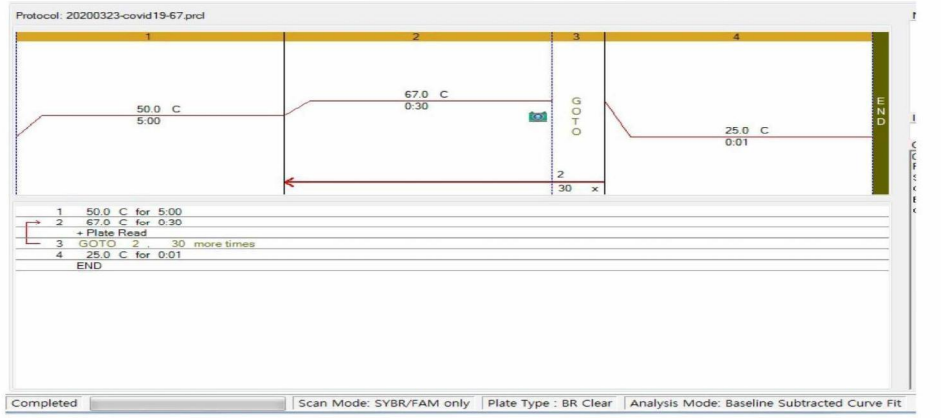
1) Instrument: This test kit should be used with a Bio-Rad CFX96 Touch Real-Time PCR Detection System. Please refer to the instruction manual provided with the instrument.

[Bio-Rad CFX96 Touch Real-Time PCR detection Instrument)

2) Instrument setting: Set the cycler, temperature and time as shown in the table below.

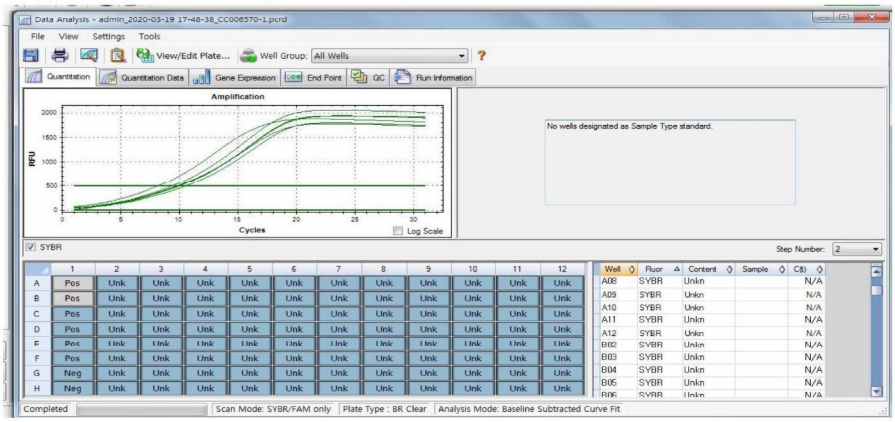
Temperature	Time	Cycles
50 ℃	5 min	1
67 ℃	30 sec	30 (30sec/cycle)

Lid Temp. 100℃



a screenshot of the programming process

7. Result analysis/interpretation



A screenshot of result analysis process.

1) The result is positive when the target peak is showing after 30 cycles.
2) Set threshold as shown in the table below.

Target	Threshold
Novel-Coronavirus 19	1000

3) Check the Ct value for each target. Result interpretation is as defined in the table below.

No.	Cut-off(Ct value)	Interpretation
1	≤ 26	Positive
2	> 26	Negative

4) Check the final result as defined in the table below.

No.	COVID-19	Positive control(PC)	Negative control(NC)	Interpretation
1	-	+	-	Negative
2	+	+	-	Positive
3	+	-	+	Invalid result/ Retest
4	-	-	+	Invalid result/ Retest

5) Quality control

Control RNA Ct value validity is as shown in the table below. If the value is not within the valid number, the test result is invalid and retest is required.

Validity		Test
Positive control	Ct ≤ 25	Test according to the instructions on page 5 (reagent preparation)
Negative control	No detection	

8. Notes on the test procedure

1) Notes on the test kit

- The test kit must be used for In-vitro diagnostic test only.
- The test kit must be used with Bio-Rad CFX96 Touch Real-Time PCR Detection System.
- The test must be conducted by experienced personnel.
- All specimen and reagents must be stored separately.
- Thaw all reagents completely before use, and keep on cold rack

- Always wear gloves and a laboratory coat before experiment to avoid any contamination that can affect the test results. Clean the lab before/after the test
- Any supplemental items used for the test such as extracted RNA, pipette tip and other commodities must be disposed in accordance with the laws of the respective country.

2) Notes on the reagent

- Do not use any expired reagents. The reagents provided with the kit must not be mixed with reagents from different lots.
- Do not mix specimens from different lots.
- Store reagents on ice (-25 ~ -15℃) until the test preparation.

3) Notes on the result interpretation

- Interpret the results after checking the Ct value of each target.
- The test results should be finally confirmed by doctors or experts, not the test kit alone.
- The test kit must be used with a Bio-Rad CFX96 Touch Real-Time PCR Detection System. Using other instruments might affect the results of the test kit.

9. General Information

1) Test kit storage: -25 ~ -15℃
2) Period of use:12 months