

AbaGen® SARS-nCoV-19 Colorimetric LAMP Detection Kit

INSTRUCTIONS FOR USE (IFU)

1. PRODUCT INFO

Name : AbaGen® SARS-nCoV-19 Colorimetric LAMP Detection Kit
Cat No : ABA2021-LAMP-C
Size : 50 or 100 reactions
Manufacturer : Aba Ankara Biyoteknoloji Araştırma Sanayi ve Ticaret Ltd. Şti.

2. INTENDED USE

ViroLAMP Isothermal COVID Detection Kit is a qualitative in vitro diagnostic test for the detection of nucleic acids from SARS-CoV-2 in nasopharyngeal, oropharyngeal swab samples and saliva samples from patients of COVID-19. This product has been designed to target N gene of SARS-CoV-2. FDA and US CDC recommend the use of N gene for Nucleic Acid Amplification-based Tests (NAAT) of SARS-CoV-2.

3. KIT CONTENT

Content	50 rxn	100 rxn
ViroLAMP RT-Mastermix	900 µl	1800 µl
Primer Mix	125 µl	250 µl
Positive Control	25 µl	50 µl
Negative Control	25 µl	50 µl

4. STORAGE CONDITIONS

Store at -20±5°C away from light for 12 months.

5. SPECIMEN PREPARATION AND STORAGE

- > Nasopharyngeal and Oropharyngeal swab specimens shall be used for the test.
- > It is recommended that swab specimens shall be used immediately after collection. However, the specimens can be stored maximum 4 days at 2-8°C in a fridge or maximum 2 months at -20°C in a freezer if immediate use is not achievable.
- > Specimens shall be divided into amounts required for one testing and stored at -20°C in a freezer so as to avoid from thawing repeatedly.
- > Specimens that are no longer needed shall be put in a container for liquids and disposed as liquid medical waste.

6. PRE-TEST PREPARATIONS

- > Reagents shall be stored at -20°C and be avoided from repeated freezing and thawing.
- > Reagents shall be used after completely thawed and well mixed.
- > Since the positive control RNA can be degraded, it is recommended to be aliquoted into small volumes.

7. SPECIMEN PRETREATMENT

While it is possible to use various ways and kits adopted in laboratories to extract RNA and apply on this product, it is recommended that ZR Viral RNA Kit (ZymoResearch, USA) shall be used for RNA extraction and users shall follow the protocol included in the Kit Handbook. After being extracted, RNA shall be stored at -20 ± 2°C in a freezer and shall be divided into amounts required for 1-2 tests since RNA can be degraded.

8. ISOTHERMAL LAMP PCR

8.1. Isothermal LAMP PCR Solution Preparation (on ice)

- Thaw kit components at room temperature.
- Mix thoroughly to ensure homogeneity, centrifuge briefly and then put on the ice.
- Prepare the reaction mix based on the table below.
- It is recommended to use positive and negative controls for each test.
- Spin down all reaction mixture and move to the incubator or thermal cycler.

	Sample RNA	Positive Control	Negative Control
ViroLAMP RT-Mastermix	17.5 µl	17.5 µl	17.5 µl
Primer Mix	2.5 µl	2.5 µl	2.5 µl
Sample RNA	5 µl	-	-
Positive Control	-	5 µl	-
Negative Control	-	-	5 µl
TOTAL Volume	25 µl	25 µl	25 µl

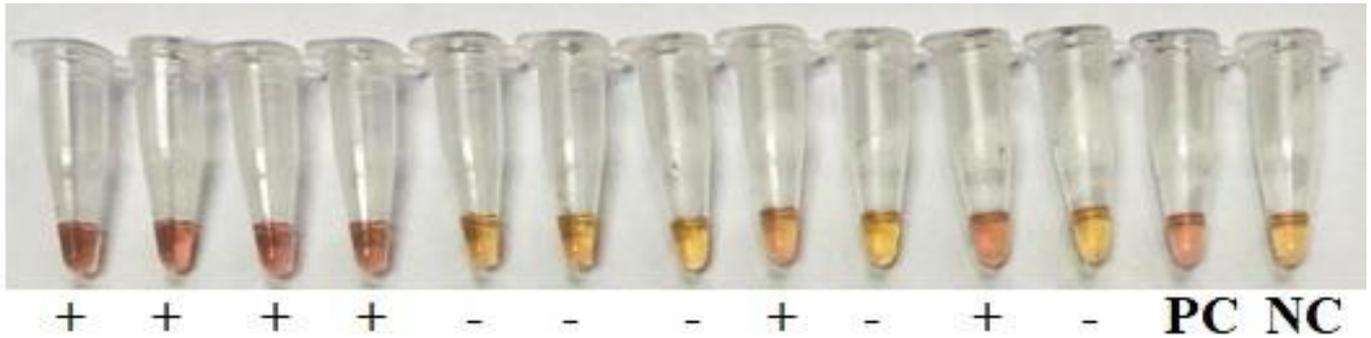
8.2. Reaction Set Up Conditions

- > Set incubator temperature at 70 °C.
- > Load the reaction tubes, and then start the amplification reaction for 35 minutes at 70 °C.
- > 35 minutes later, inactivate the polymerase using the heating block for 5 minutes at 90 °C.

9. EVALUATIONS of RESULTS

Colorimetric detection is available by as pink-red for positive samples and yellow for negative results (Figure 1).

Figure 1. Colorimetric detection of SARS-CoV-2 by ViroLamp. Positive control and positive samples appear red-pink. Negative control and negative samples appear yellow.



10. PRODUCT SPECIFICITY

1. Minimum detection limit is 50 viral genomes equivalent per test.
2. Negative Sample (concentration: 0 genome/test)
3. Positive Sample contains equivalent to 1000 genomes/test

11. LIMITATIONS

1. Test result is for the reference only in clinical practice, it cannot be the sole evidence for diagnosis.
2. Negative results can be caused by low quality of RNA extraction, improper storage conditions and storage period, and inhibitors in the specimen, nucleic acid degradation, etc.
3. False negative or false positive results are likely to be caused by inappropriate collecting, transportation and handling of specimens, or unsuitable experiment operation and environment.
4. False negative results may occur by sequence changes of target sequence of 2019-nCoV due to mutations or other reasons.