SUGENOMICS Biotechnology

Viro-LAMP Isothermal COVID Detection Kit (Fluorometric)

Catalog No	Size
• DL01B100	100 Reaction

INSTRUCTIONS FOR USE

1. PRODUCT NAME:
Viro-LAMP Isothermal COVID Detection Kit (Fluorometric)
Cat No : DL01B100
Size : 100 reactions

2. MANUFACTURER:
SuGenomik Biyoteknoloji, METU Technopolis, Yenimahalle, Ankara.

3. 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.

4. KIT CONTENT

Content	100 Reaction
ViroLAMP RT-Mastermix	1800 µl
Primer Mix	250 µl
Positive Control	50 µl
Negative Control	50 µl

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

6. 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℃ in a fridge or maximum 2 months at −20℃ in a freezer if immediate use is not achievable.
- Specimens shall be divided into amounts required for one testing and stored at −20℃ 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.

7. PRE-TEST PREPARATIONS
- Reagents shall be stored at −20℃ 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.
- This kit was validated on ABI StepOne Plus system and compatible with standard RT-PCR machines such as ABI 7000, 7300,7500, Roche 480, MX3000P, MX3005P, Rotorgene TM6000, Icycler IQTM4/5, Bio-Rad CFX96 and LongGene Q2000B.

8. 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℃ in a freezer and shall be divided into amounts required for 1-2 tests since RNA can be degraded.

9. ISOTHERMAL LAMP PCR
9.1) Isothermal LAMP PCR Solution Preparation (on ice)
a) Thaw kit components at room temperature.
b) Mix thoroughly to ensure homogeneity, centrifuge briefly and then put on the ice.
c) Prepare the reaction mix based on the table below.
d) It is recommended to use positive and negative controls for each test.
e) Spin down all reaction mixture and move to the LAMP PCR step.

Components	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

9.2) Reaction Set Up Conditions
- Set up the channels of the real-time PCR device according to the table below.

Genes	Channels (Dyes)
SARS-CoV-2, N gene	FAM or SYBRGreen

- For Applied Biosystems ABI (QS5, 7500 and StepOne etc) real-time PCR instruments, set to "passive reference" dye as "none".
- Set up isothermal LAMP PCR temperature, time, and cycling conditions according to the table below.

Steps	Temp.	Time	Cycles
Amplification	70 ℃	30 sec (Reading at the end of each cycle)	70*

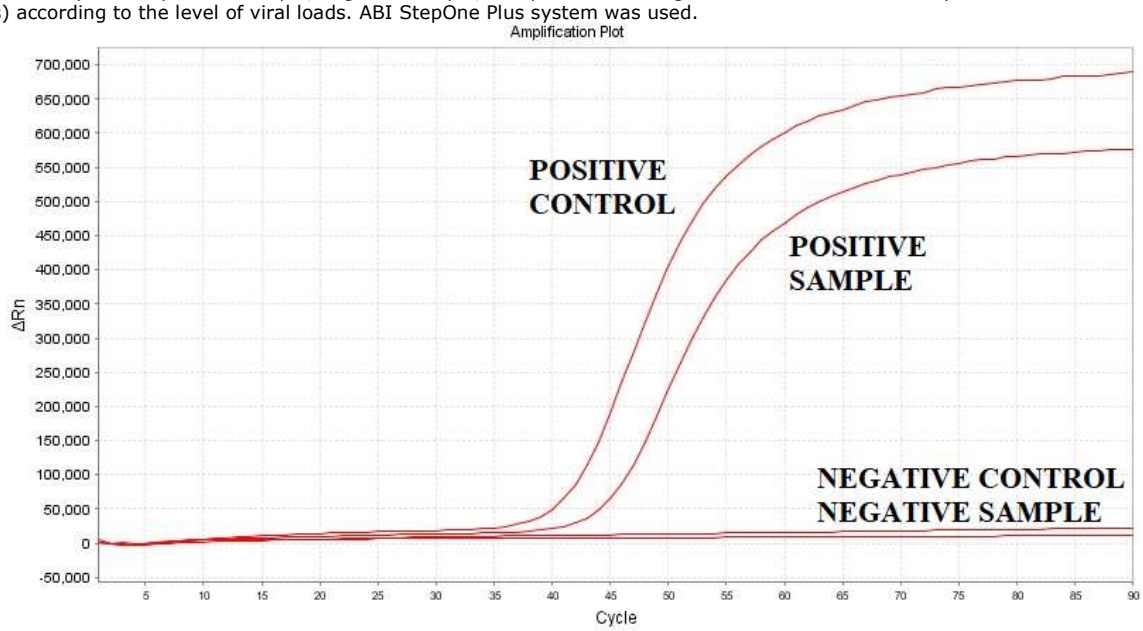
***70 cycles takes for 35 minutes. According to viral load, Ct values can be detected as 28-40th cycles (14-20 minutes).**

SuGenomik Biyoteknoloji Ltd Şti
Address: METU Technopolis, Yenimahalle, Ankara.
Web: www.sugenomik.com
Mail: info@sugenomik.com
Tel: +90(312)385 85 89

10. EVALUATIONS of RESULTS

Analyze the amplification of the samples, positive and negative controls for any increase. If the fluorescence increases in Positive Control but doesn't in Negative Control, amplification reaction is proceeding properly (Fig 1). If any other situation occurs, however, amplification reaction may be proceeding in a wrong way. In such a case, re-test affected samples from reagent preparation.

Figure1. Amplification plots for positive sample, negative sample, and positive and negative controls. Positive samples were detected at 28-42th cycles (14-21 minutes) according to the level of viral loads. ABI StepOne Plus system was used.



11. 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

12. 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.

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