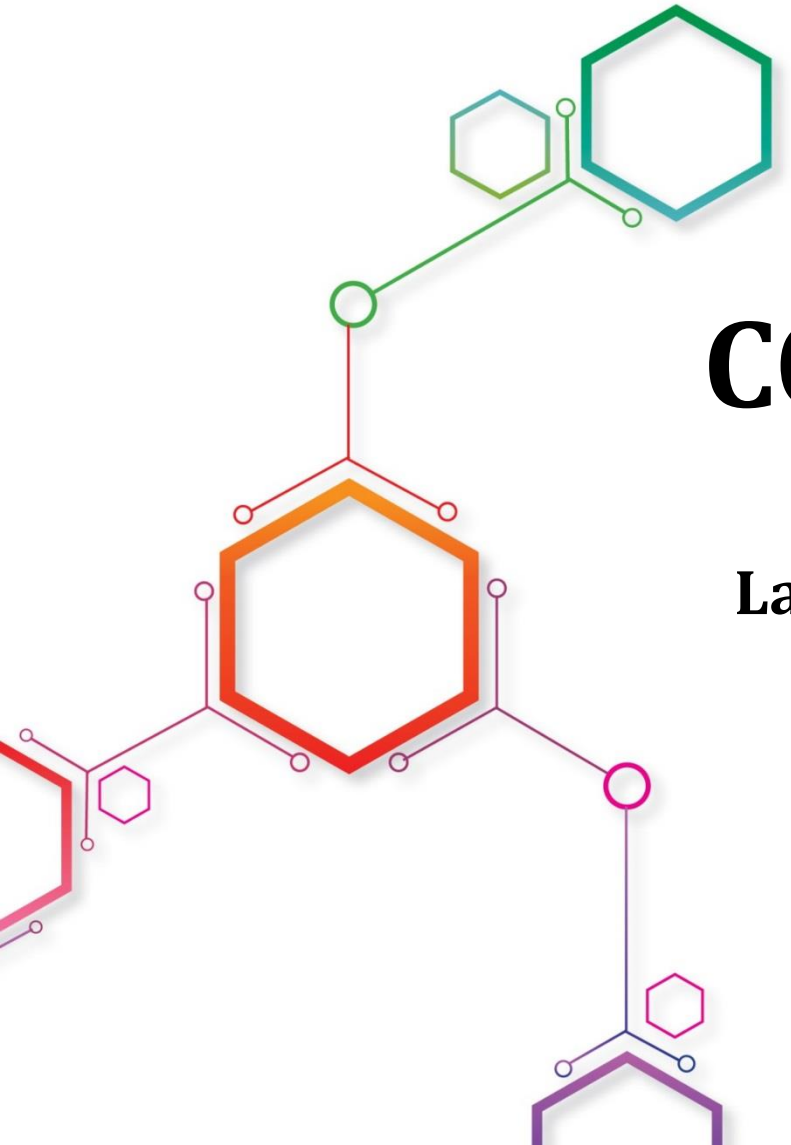
LabGenomics

A leading bio company in molecular diagnostics



COVID-19 Test Kit

LabGun™ COVID-19 Assay PCR Kit

❑ Proposal

1. We can supply 500,000 kits per week.
2. The first shipment can be deliverd to your designated address within a week from your purchase.
3. We can increase the kit quantity up to 5 million per month.
4. Our kits are approved by Korean government and CE certified.
5. The kits are in preparation of FDA EUA (Emergency Use Athorization).
6. We have prven record of the test result accuracy of 99.9%.
7. Results come in as short as 6 hours.
8. The kit is one of the proven products which diagnosed curruntly 20,000 people per day in South Korea.

❑ Intended Use

- SARS-CoV-2 is the virus that causes COVID-19, a contagious disease that causes respiratory infection varying from common cold symptoms to severe pneumonia and occasionally death.

- The LabGun™ COVID-19 Assay PCR Kit is intended for the qualitative detection of Coronavirus disease 2019 (COVID-19) strain SARS-CoV-2, in patients that meet the clinical criteria for COVID-19 (e.g. fever, cough, shortness of breath) in lower respiratory tract or upper respiratory tract.

❑ Kit Specification

Application	Real-time Reverse-transcription PCR test for detection of SARS-CoV-2 coronavirus (COVID-19) gene *RdRp*
Limit of Detection	1 X 10^2 copies/reaction
Sensitivity*	99.9%
Specificity*	99.9%
Types of samples	• Sputum, bronchoalveolar lavage (BAL), tracheal aspirate (lower respiratory tract) • Nasopharyngeal and oropharyngeal fluids, nasal swab (upper respiratory tract)
Thermocyler Run Time	2.5 hours

* Data based on 246 clinical samples test

❑ Thermal Cycler Capability

- Real-time PCR CFX96™ (Bio-Rad)
- Applied Biosystems™ 7500 Real-time PCR Instrument system (Thermo Fisher Scientific)
- Applied Biosystems™ 7500 Fast Real-time PCR Instrument system (Thermo Fisher Scientific)

❑ Regulatory Clearance

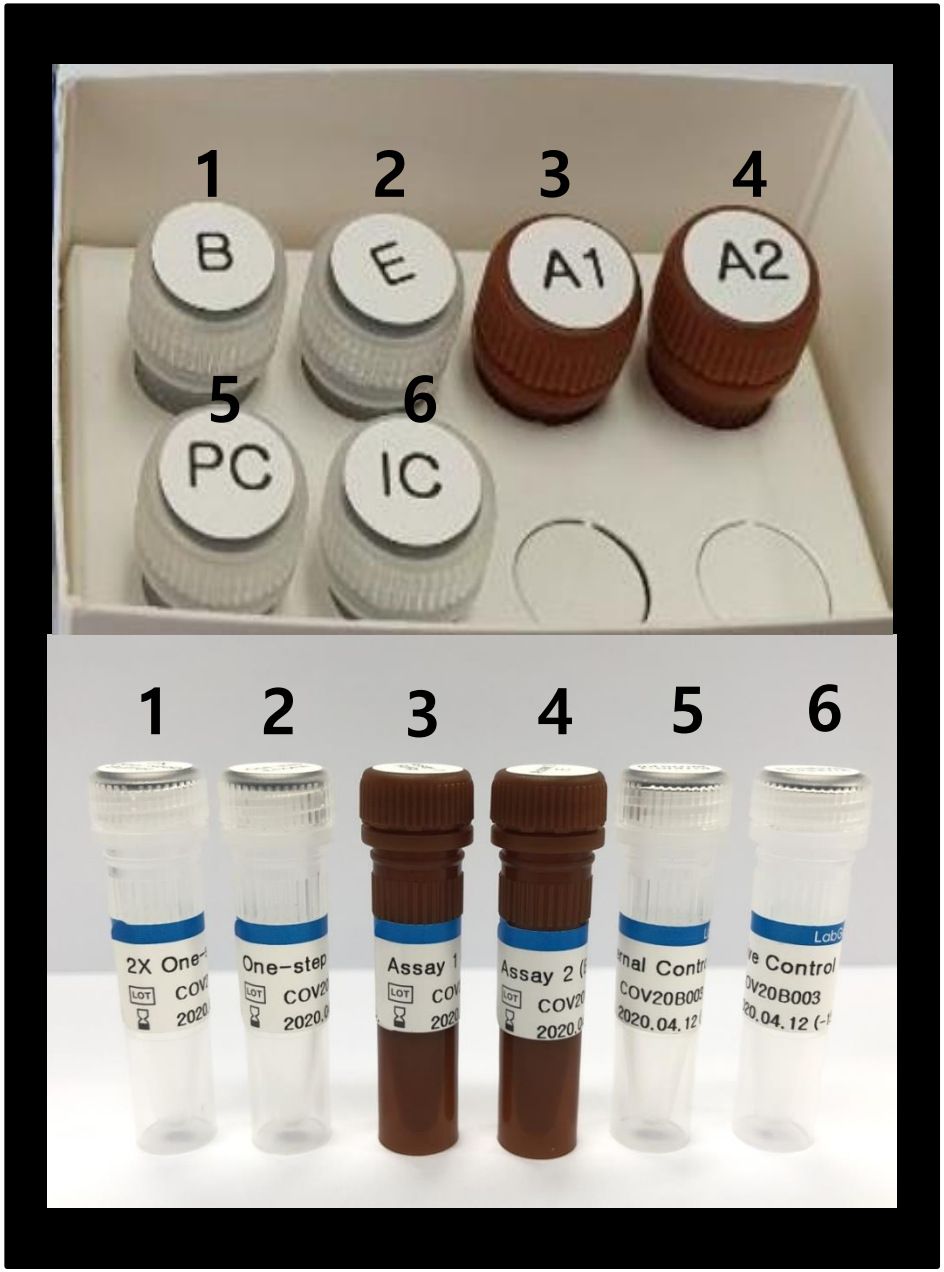
- Korean Ministry of Food and Drug Safety
  - EUA (Emergency Use Athorization)
  - CFS (Certificate of Free Sale)
- CE marking approval
- In preparation of FDA EUA (Emergency Use Athorization)

❑ Kit Components

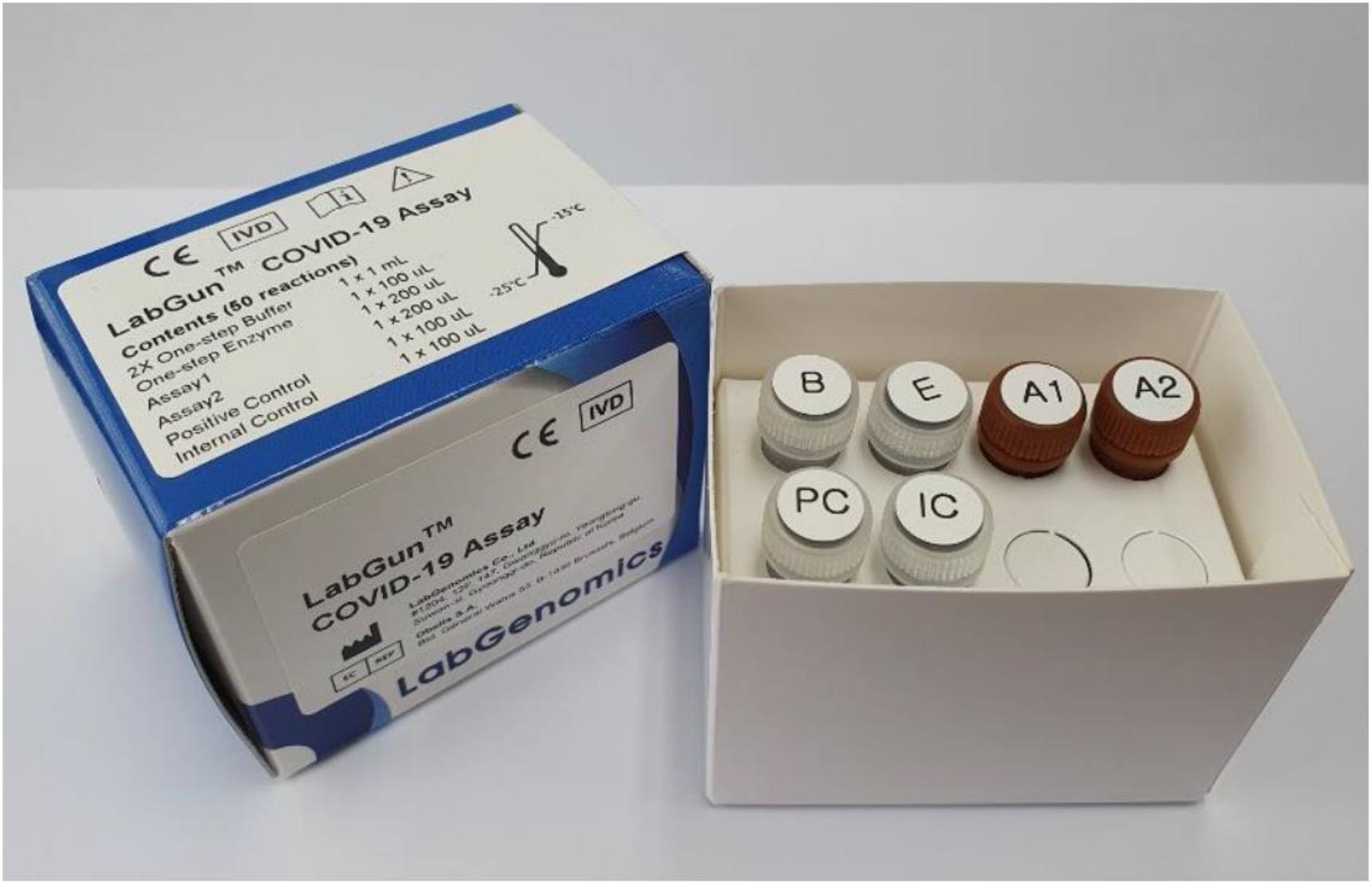
Reagent	Cap Label	Volume (µl)#
2X One-step Buffer	B	1,000
One-step Enzyme	E	100
Assay 1 (RdRp gene)*	A1	200
Assay 2 (E gene)*	A2	200
Internal Control	IC	100
Positive Control	PC	100

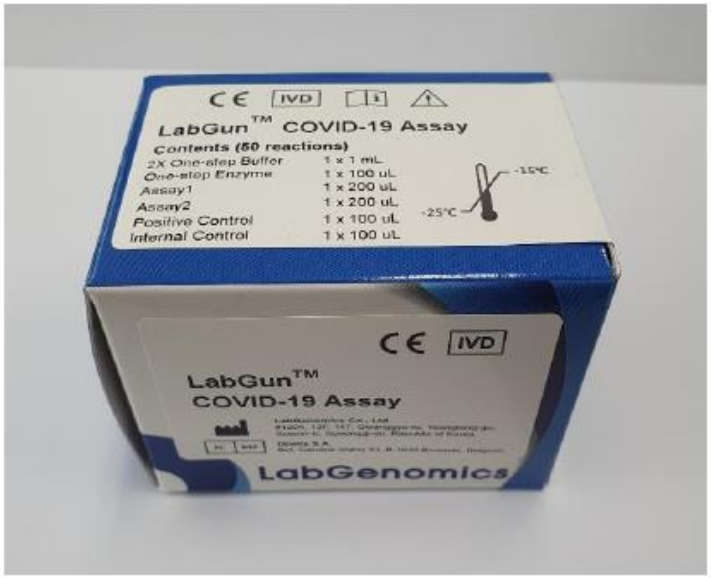
* Including ROX reference dye

Sufficient for 50 tests



	Component
1	2x One-step Buffer
2	One-step Enzyme
3	Assay 1 (RdRp gene)
4	Assay 2 (E gene)
5	Internal Control
6	Positive Control


LabGun™ COVID-19 Assay
Contents (50 reactions)
2X One-step Buffer 1 x 1 mL
One-step Enzyme 1 x 100 uL
Assay1 1 x 200 uL
Assay2 1 x 200 uL
Positive Control 1 x 100 uL
Internal Control 1 x 100 uL
-25°C
-15°C
IVD
LabGun™
COVID-19 Assay
LabGenomics
B
E
A1
A2
PC
IC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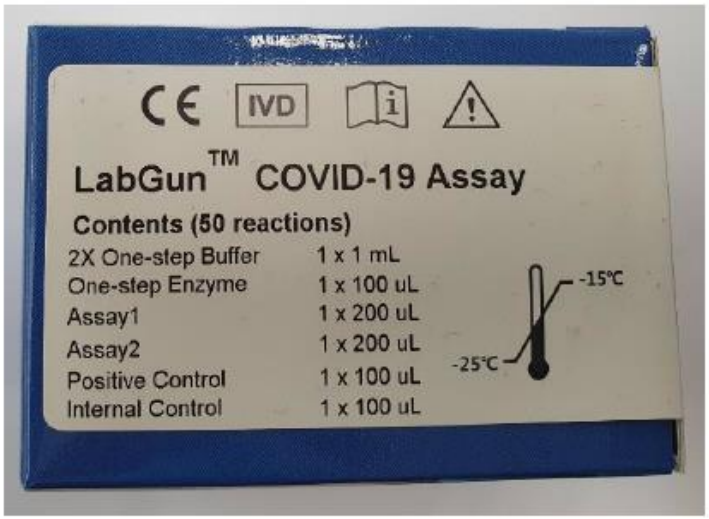
IVD
LabGun™
COVID-19 Assay
LabGenomics


LabGun™
COVID-19 Assay
IVD
LabGenomics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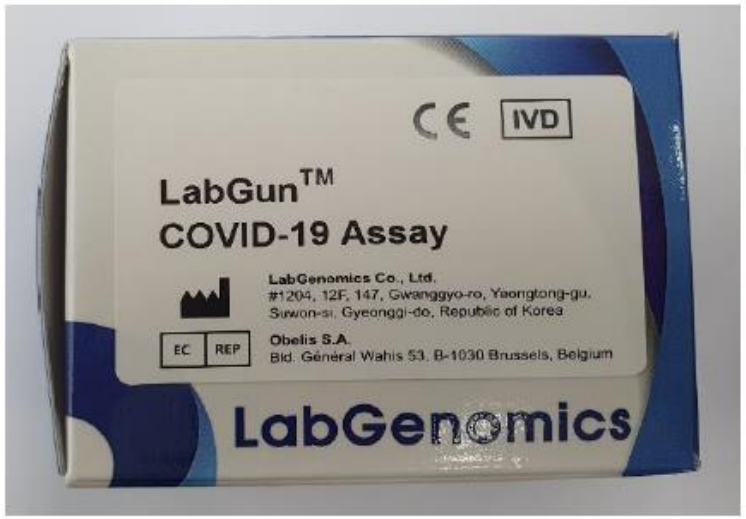
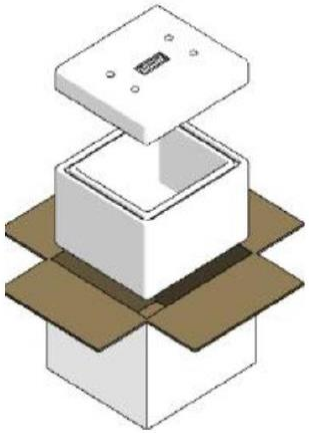

IVD
LabGun™
COVID-19 Assay
LabGenomics Co., Ltd.
#1204, 12F, 147, Gwanggyo-ro, Yeongtong-gu,
Suwon-si, Gyeonggi-do, Republic of Korea
EC REP
Obelis S.A.
Bld. Général Wahis 53, B-1030 Brussels, Belgium
LabGenomics

❑ Storage & Shelf life

- Storage temperature: Less than -20℃
- Shelf life: 12 month from Date of Manufacture

- Failure to follow this kit's storage may result in reduced kit performance.
- Do not use an expried kit and not mix with different lots of reagents

❑ Packing & Handling



- Dry Ice Packing (-20℃ temperature condition)

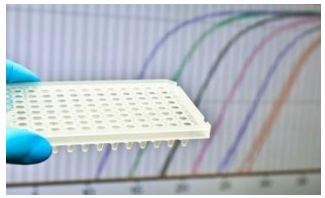
- [3,000T case] : 1 box (395 x 395 x 455 mm) → 16 Liter
- [5,000T case] : 1 box (575 x 518 x 455 mm) → 45 Liter
- [50,000T case] : 2 boxes (641 x 552 x 742 mm) → 123 Liter

❑ Process Overview

Sampling

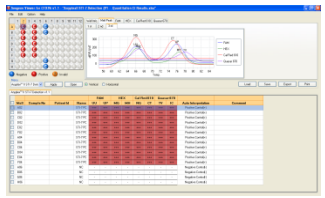
Sample Preparation

- Extraction of RNA from clinical samples
- 10 mins to 1 hr depending on extraction methods



Real-time RT-PCR

- Target Amplication
- Approximately 2.5 hrs



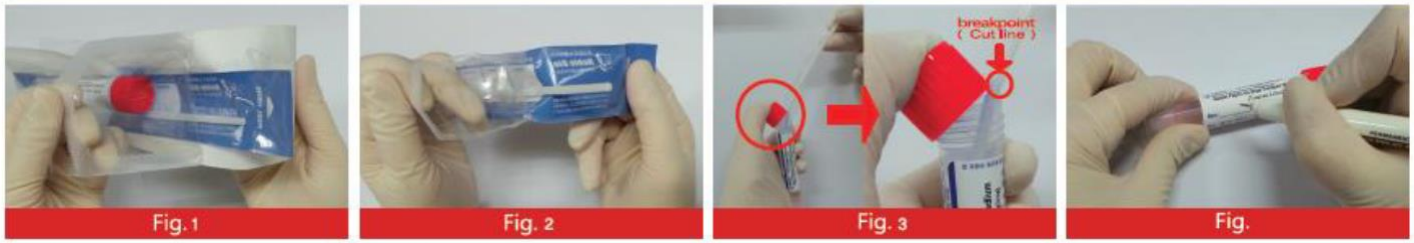
Analysis of Results

- Positive or Negative Decision
- Less than 1 min

Laboratory

❑ Process_1. Sampling

Universal Viral Transport Medium (UTM) [Specimen Collection Procedure]



❑ Process_2. Sample Preparation

- Exract RNA from samples using RNA extraction kit according to the manufacturer instructions.
- Manual extraction (40~60 min per 1 sample)

  QIAGEN' QIAamp Viral RNA Mini kit (Cat# 52904)

  GeneAll's Riospin vRD II (Cat# 322-150)
- Automatic extraction (10 min per upto 48 samples)

  Genolution's Nextractor NX-48 & NX-48 Viral NA kit
- The amount and purity of RNA, and the real-time RT-PCR results can be affected by the extraction methods.

❑ Process_3. Real-time RT-PCR

- Mix the reagents, aliquot to each well of 96-well plate, and add the template (~10 min).
- Run the PCR instrument after setting the PCR condition (2 hr and 15 min).

<Fluorescence condition>

Target	Fluorophore
SARS-CoV-2 (RdRp gene)	FAM
Sarbecovirus (E gene)	Cy5
Internal Control	HEX (VIC)

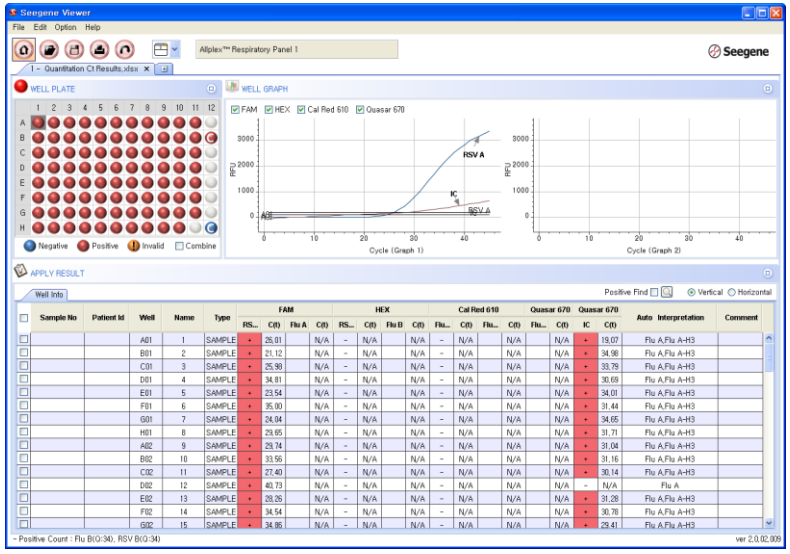
<Reaction condition>

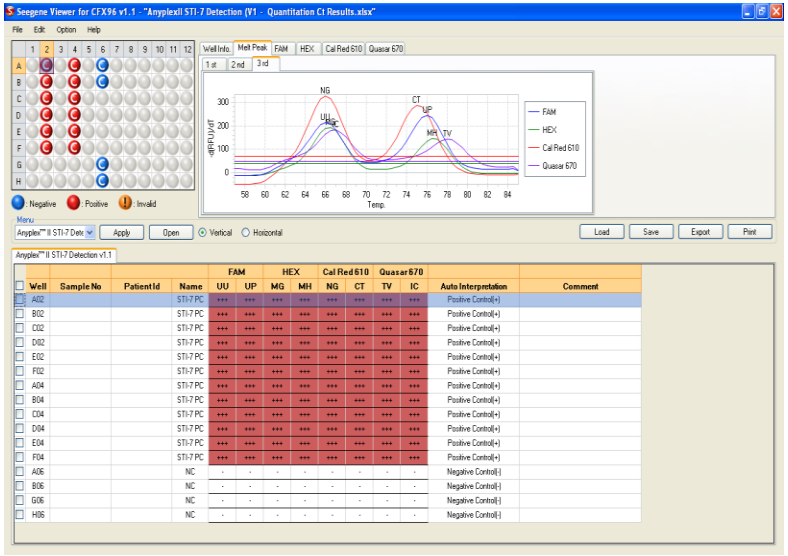
Temperature (℃)	Time	Cycles
50	30 min	1
95	15 min	1
95	15 sec	45
60	1 min*	

* Collect the fluorescence data

❑ Process_4. Analysis of Results

- Export the data to the analysis software provided by the manufacturer.
- Analyze the data and decide the positvity or negativity automatically (~1 min).





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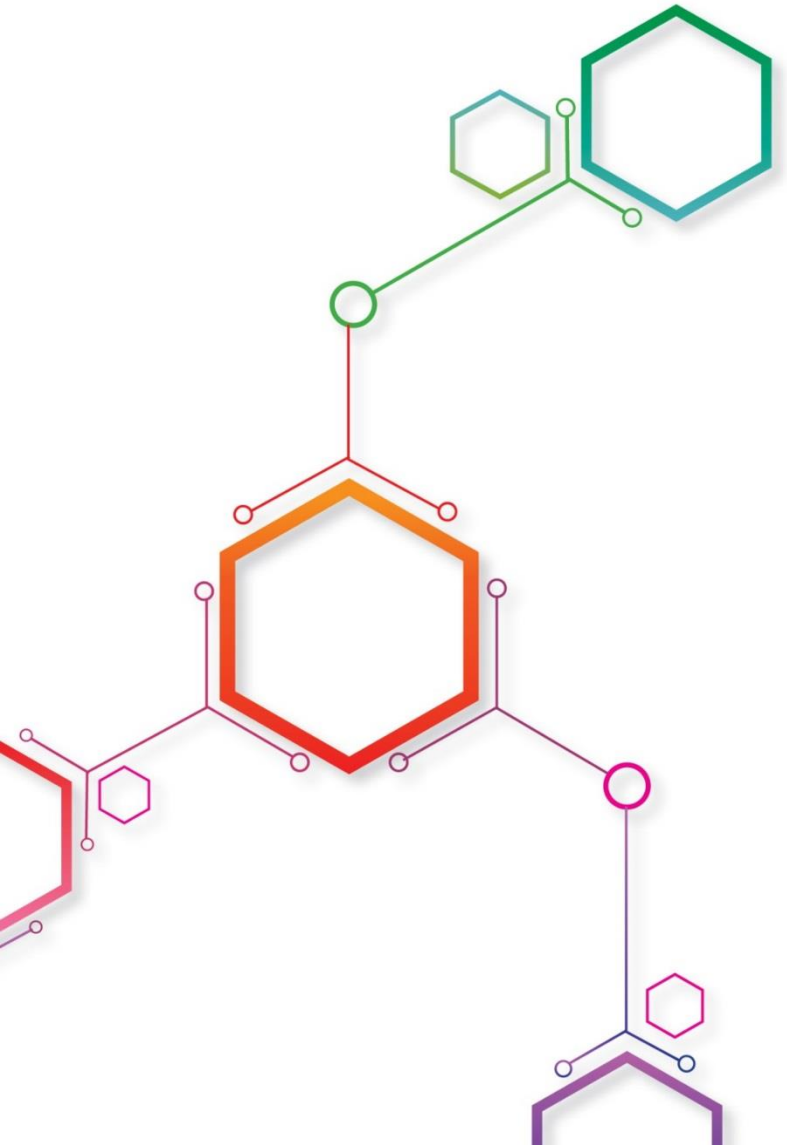

Thank you