IVD

Cat. No. CV9017C (25 Samples)
CV9017A (50 Samples)
CV9017B (100 Samples)

LabGun™ COVID-19 Assay

Storage and expiration date :
1. Storage : below -20℃.
2. Expiration date : Indicated on the label.

1. INTENDED USE

LabGun™ COVID-19 Assay is an in vitro diagnostic test, based on Real-time reverse-transcription PCR technology, for the amplification and detection of SARS-CoV-2(COVID-19) of RdRp gene and Sarbecovirus of E gene from Sputum, Bronchoalveolar lavage fluid and Oropharyngeal, Nasopharyngeal swab. The Kit aids to diagnose COVID-19.

2. REAGENTS

(Storage at ≤-20℃)

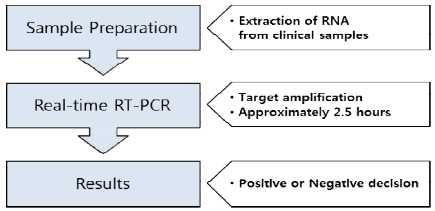
Reagents	Cap	Volume (㎕)
2 x One-step Buffer	B	1000 x 2
One-step Enzyme	E	200
Assay 1 (RdRp gene)*	A1	400
Assay 2 (E gene)*	A2	400
Internal Control	IC	200
Positive Control	PC	200

(Cat. No. CV9017B is presented) * Include ROX reference dye

3.STORAGE AND EXPIRATION DATE

1) Expiration date : 12 months from the date of manufacturing
2) Storage : below -20 ℃, avoid light
   ▶ Failure to comply with the storage method of this kit may result in poor performance of the kit.
   ▶ Do not use the kit beyond expiry date. Do not pool reagents from different lots or from different tubes of the same lot.

4. PROTOCOL



1) PRECAUTIONS

① Use disposable gloves, lab coat, and goggles when handling samples and test reagents.
② Thaw the samples and reagents on the ice and then use.
③ Be sure to wear Poly-gloves to prevent RNase contamination from hands.

2) RNA EXTRACTION

① Extract RNA from samples using RNA extraction kit according to the manufacture's instruction.
② Depending on the extraction method, the amount, purity, and real-time PCR results of RNA can be affected. It is recommended to use QIAGEN's QIAamp Viral RNA Mini or commercialized extraction kit(Cat. No. 52904, 52906) , GeneAll's Ribospin™ vRD Ⅱ(Cat. No. 322-150).

3) PREPARATION OF RT-PCR REACTION

① Prepare the reaction according to the table below.
   ▶ Be sure to use the Control after vortexing and spin-down.
   ▶ Positive Control : Use the "Positive Control" included in the kit instead of the template RNA. Be careful not to cause carry-over contamination when performing the PC amplification.
   ▶ Negative Control : Use the RNase free water instead of template RNA.
   ▶ Adjust the final volume by using RNase free water.

Components	Volume (㎕)
2 x One-step Buffer	10
One-step Enzyme	1
Each Assay(1 or 2)	4
Internal Control	1
Template RNA	X(control 4㎕)
Total volume	20

② Mix the reaction briefly and spin-down to gather the reaction in bottom of the tube.
   ▶Be careful not to form bubbles in the mixture.
③ After spin-down of the mixture, perform the PCR immediately.

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4) Real-time PCR INSTRUMENT SETTINGS

① Recommended PCR Instruments are below.
- CFX96™ Real-time PCR detection system (Bio-Rad)
- Applied Biosystems™ 7500 Real-time PCR Instrument system (Thermo Fisher Scientific)

② Run the PCR instrument after setting PCR dondition following the table below. The setting condition can be commonly applied to the PCR machines above.

<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

5) POST-EXPERIMENTAL

① Be sure to wash your hands after the test. If samples or reagents come into contact with the eyes or skin etc., immediately rinse out those with running water and then go to see a doctor for medical advice.
② Experimental equipment and workstation surfaces should be completely disinfected at all times after the test using 0.5% sodium hypochlorite or suitable disinfectant.
③ After the test, the remaining samples and PCR products, and other materials that may affect the results of the test, should be stored in a separate place from the reagent to be used.
④ All wastes generated from the test should be stored in a separate safe place or container and disposed of in accordance with legally designated treatment regulations.

5. RESULTS ANALYSIS

- After PCR reaction, set threshold for each PCR machine in its management program following the table below.

Instrument	Threshold
CFX96™	Auto threshold
AB7500	FAM, Cy5 : 3
	HEX : Auto threshold

- Check the Ct value of each target samples.
- If the Ct value is ≤40, interpret as "+", and >40 or NA, interpret as "-".
- Determine the results according to the following table.

Case	Positive Control	Negative Control	FAM	Cy5	HEX	Interpretation
1	+	-	+	+	+	SARS-CoV-2
2	+	-	+	+	-	Positive
3	+	-	-	+	+	Sarbecovirus
4	+	-	-	+	-	Positive
5	+	-	-	-	+	Negative
6	+	-	-	-	-	Invalid result / Retest
7	+	-	+	-	+ / -	
8	+	+	+ / -	+ / -	+ / -	
9	-	+	+ / -	+ / -	+ / -	
10	-	-	+ / -	+ / -	+ / -	

✓ IC signal is detected in NC results as this kit puts Internal Control material into the RT-PCR reaction.
✓ The signals of internal control is not required for positive results of targets. The IC signal may not be detected depending on the amplification of target.
✓ In case 6, If both signals of IC and the target are not detected, re-extract the nucleic acid and analyze it.
✓ If NC and PC well do not display all signals including IC, consider that there is an error during reagents preparation and proceed again from the process of "Method 3) RT-PCR reaction preparation".

6. RESULTS OF PERFORMANCE EVALUATION

1) Specificity

To check the specificity of LabGun™ COVID-19 Assay, 14 types of virus and 29 other infectious pathogens were tested for cross-reaction, and as a result, PCR amplification and detection of those were not observed except the specified targets.

2) Sensitivity

To check the Sensitivity of LabGun™ COVID-19 Assay, In vitro transcription RNA was diluted from $1X10^4$ to 10 RNA copies/reaction and analyzed. LabGun™ COVID-19 Assay's LoD(limit of detection) is 100 RNA copies/reaction.

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