

EDGC™ COVID-19 Ag Test

Rapid Diagnostic Test for the Detection of SARS-CoV-2 antigen

EDGC™ COVID-19 Ag Test is a rapid immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal or nasal swab from individuals who are suspected of COVID-19 by their healthcare provider.



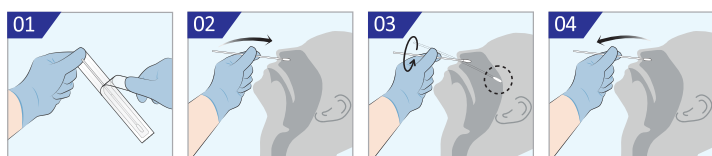
- ✓ Specimen : Nasopharyngeal and Nasal swab
- ✓ Testing time : Within 15 min.
- ✓ Packing Size : 20 Tests/Kit
- ✓ Storage Condition : 2-30°C(36-86°F)

Key Features

- Anywhere, Easy to use:** easy to use in point of care testing. (no special equipment and training)
- Specimen type:** Use for nasopharyngeal or nasal swab specimen.
- Fast results and stable:** Fast results within 15 minutes, store in room temperature.
- Accurate:** High sensitivity and specificity.

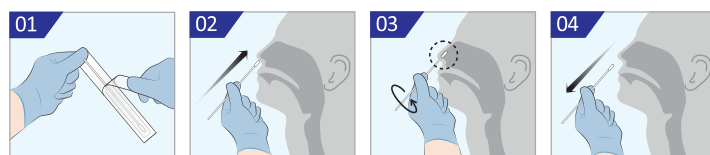
Test procedure

Specimen Collection Using Nasopharyngeal Swab



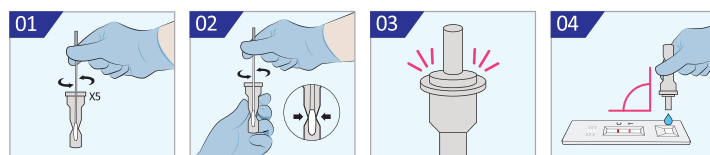
01. Remove a specimen collection swab from the pouch.
02. Place the swab into one of patient's nostrils until it reaches the posterior nasopharynx.
03. Slowly rotate 3-5 times the swab over the surface of the posterior nasopharynx.
04. Remove the swab from the nostril.

Specimen Collection Using Nasal Swab



1. Remove a specimen collection swab from the pouch.
2. Insert the swab into one of patient's nostrils up to 1 inch from the edge of the nostril.
3. Slowly roll the swab 5 times over the surface of the surface of the nostril. Using the same swab, repeat this collection process in the other nostril.
4. Remove the swab from the nostril.

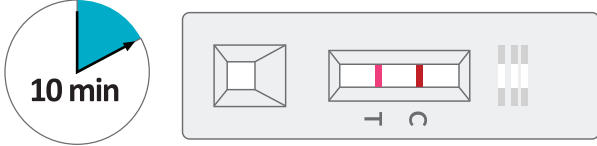
Test Procedure



01. Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.
02. Remove the swab while squeezing tightly the middle of the tube to take out the liquid from the swab.
03. Close the vial by pushing the cap firmly onto the vial.
04. Mix thoroughly by tapping the bottom of the vial, Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow three (3) drops of sample to fall.

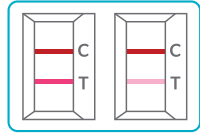
Manufacture information

Result Interpretation

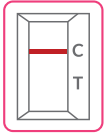


Read the result at 10-15 minutes.
The test result should not be read after 30 minutes.

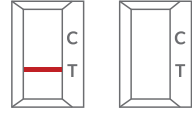
Positive



Negative



Note: The color intensity of the test line varies depending on the amount of SARS-CoV-2 antigen present in the specimen. Any faint colored-line in the test region should be considered as positive.

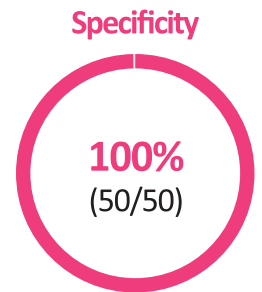
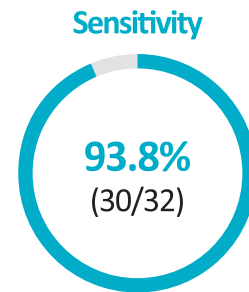


Note: Re-run the test once more using the remaining specimen in the extraction vial.

Clinical Characteristics

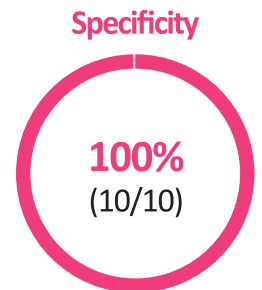
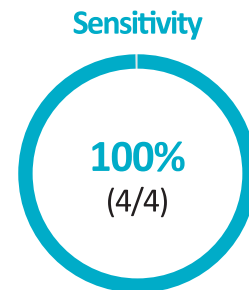
Nasopharyngeal swab

Method (Nasopharyngeal swab)		Comparator Method	
		Positive	Negative
EDGC™ COVID-19 Ag Test	Positive	30	-
	Negative	2	50
Total		32	50
PPA(Positive Percent Agreement)		30/32*100 = 93.8%	
NPA(Negative Percent Agreement)		50/50*100 = 100.00%	



Nasal swab

Method (Nasal swab)		Comparator Method	
		Positive	Negative
EDGC™ COVID-19 Ag Test	Positive	4	-
	Negative	-	10
Total		4	10
PPA(Positive Percent Agreement)		4/4*100 = 100%	
NPA(Negative Percent Agreement)		10/10*100 = 100.00%	



Limit of Detection (LoD): The LoD of EDGC™ COVID-19 Ag Test was 8×10^2 TCID₅₀/ml.

No Cross-reactions: There was no cross-reaction with potential cross-reactive substances except SARS-coronavirus

Not Affected by Interfering Substances: There was no interference with endogenous/exogenous interfering substances (Antibiotics, Relevant medicines, Anti-inflammatory drugs, Autoimmune disease, Nasal sprays or drops, Serum protein)

Ordering information

Cat. No	GQLAI
Package Unit	20 test/kit (235 X 165 X 70 mm)
Kit componets	20 Test Devices, 20 Extraction tubes/cap, 20 Specimen collection swabs, 1 Instructions for use

Manufacture information

Epithod[®] SARS-CoV-2 qAg

Lab quality result in 3 min at Point-Of-Care



3min

Fast assay time

10 μ L

Small sample volume

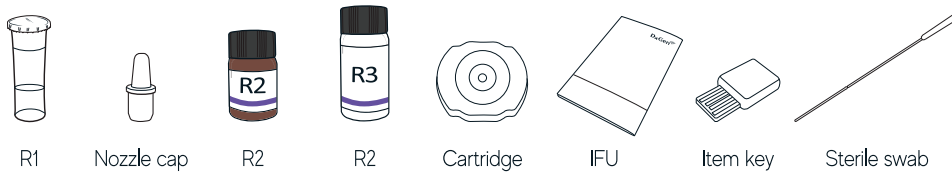
1.36

Quantitative results

Epithod® SARS-COV-2 qAg Test kit

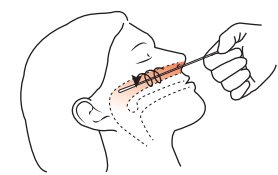
Sales Representative
Ace Global co.
 Korea's IVDs
 e-mail: park@aceglobal.co

PREPARATION

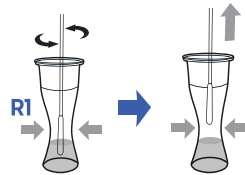


SAMPLING

[Nasopharyngeal swab]



1 Insert a sterile swab into the patient's nostril, reaching the surface of the posterior nasopharynx.



2 Insert the swab into R1 tube. Swirl the swab while squeezing the R1. Remove the swab while squeezing the R1 extract the liquid from the swab.

SAMPLING

[Specimen in the transport medium]

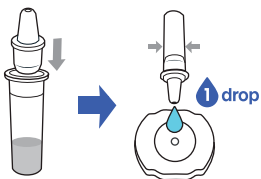


1 Collect 50 µL of the sample in transport medium (UTM / VTM) using a micropipette.

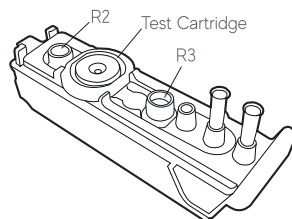


2 Mix the sample thoroughly with R1 more than 10 times.

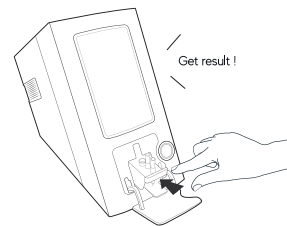
TESTING



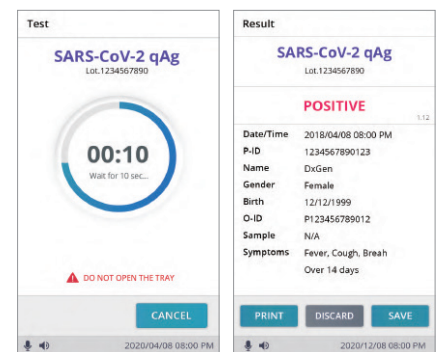
1 Close the nozzle cap tightly. Gently squeeze the R1 tube to apply a single drop to the cartridge.



2 Load R2 bottle, cartridge, R3 bottle and 2 new pipette tips on the tray in an order as shown on the analyzer screen.



3 Load the tray into the analyzer and push the tray in all the way until you hear the click sound. Tap 'START' on the display screen.



CLINICAL PERFORMANCE

Epithod® SARS-COV-2 qAg Test Kit		RT-PCR Method		Total	PPA, Sensitivity	NPA, Specificity
		Positive	Negative			
Antigen	Positive	48	0	48	96.0% (48/50) [95% CI, 86.5% ~ 98.9%]	100% (100/100) [95% CI, 96.3% ~ 100%]
	Negative	2	100	102		
Total		50	100	150		

* Percent Positive Agreement (PPA) : 34/35 (97.1%), 95 % CI : 85.5 ~ 99.5 %, Negative Percent Agreement (NPA) : 50/50 (100 %)

* More clinical studies are on going.

AVAILABLE MARKERS



CRP Test Kit



HbA1c Test Kit



SARS-CoV-2 qAb
SARS-CoV-2 IgG



U-Albumin Test Kit