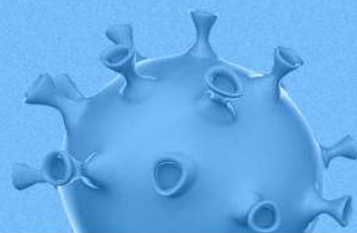
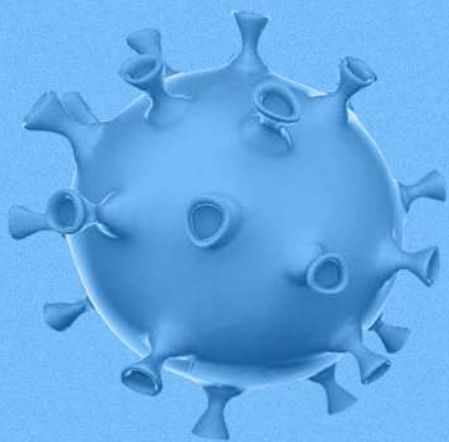




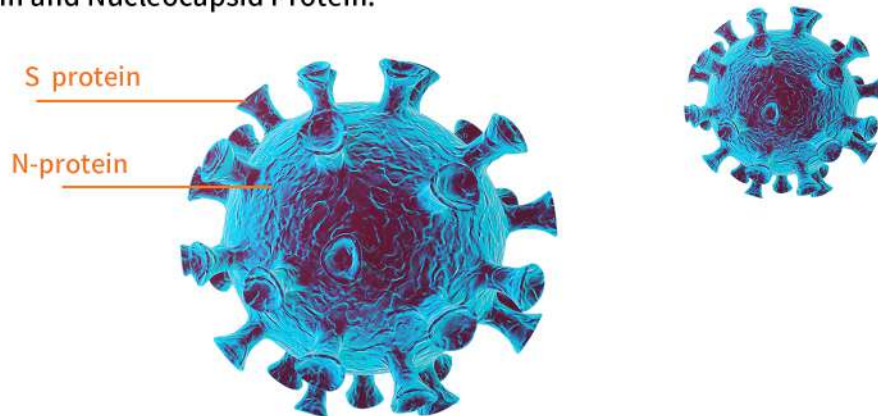
# COVID-19 Antigen Rapid Test Cassette



Hangzhou Clongene Biotech Co., Ltd.  
[en.clongene.com](http://en.clongene.com)

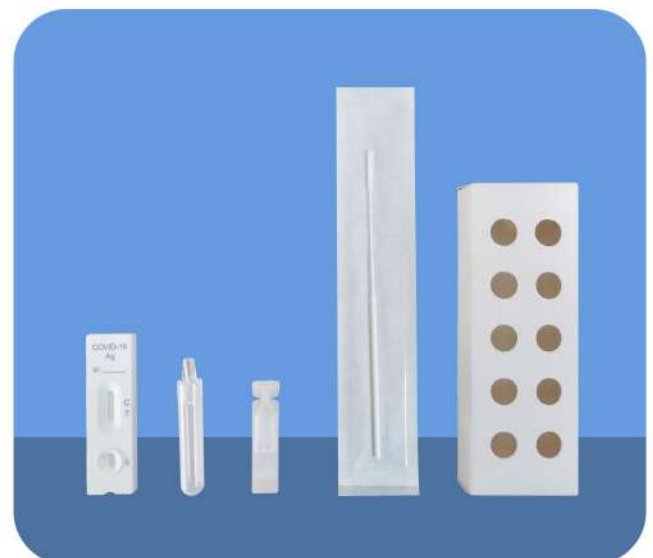
## COVID-19 & SARS-CoV-2

COVID-19 is an acute respiratory infectious disease caused by novel coronavirus (SARS-CoV-2), and people are generally susceptible. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. Novel coronavirus includes four typical structural proteins: Spike Protein, Envelope Protein, Membrane Protein and Nucleocapsid Protein.



Nucleocapsid (N) protein is the most abundant protein with highly conserved in SARS-CoV-2. N protein is used as the core raw material of rapid diagnostic reagent for immunology in the market.

Clongene has developed the COVID-19 Antigen Rapid Test Cassette. The COVID-19 Antigen Rapid Test is a lateral flow immunoassay intended for the qualitative detection SARS-CoV-2 nucleocapsid antigens in nasopharyngeal swab and oropharyngeal swab from individuals who are suspected of COVID-19 by their healthcare provider.



## Kit Contents

ICOV5002-100569				
Extraction reagents	Work Station	Test Cassette	Sterilized Swab	Extraction Tube & Dropper Tip
				

ICOV5002-100596				
Extraction reagents	Work Station	Test Cassette	Sterilized Swab	Extraction Tube & Dropper Tip
				

## Product Features



CE certification



Instant result at 15 minutes



Easy to collect samples



Results are clearly visible

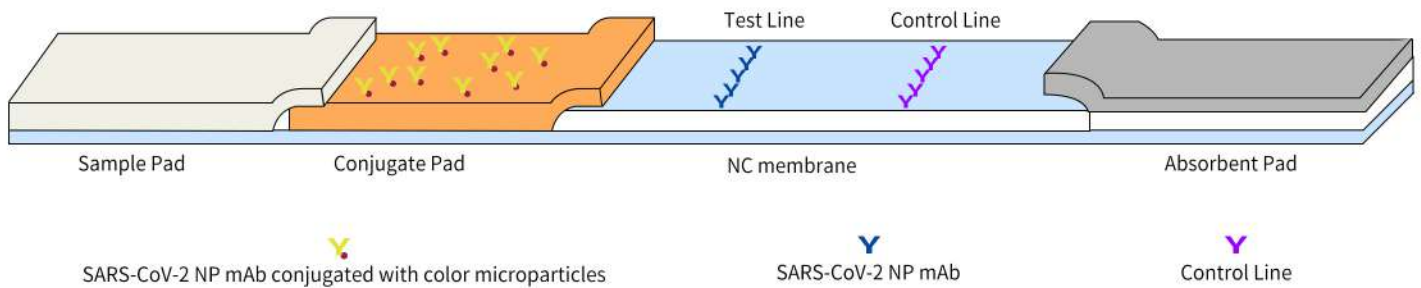


No equipment required



Suitable for large-scale rapid screening

## Principle

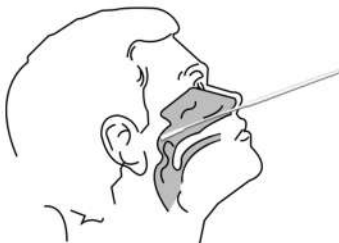


The COVID-19 Antigen Rapid Test is a lateral flow immunoassay based on the principle of the double-antibody sandwich technique. If the specimen contains SARS-CoV-2 antigen, a colored test line (T) would be visible in the result window. Absence of the T line suggests a negative result. The control line (C) is used for procedural control, and should always appear if the test procedure is performed properly.

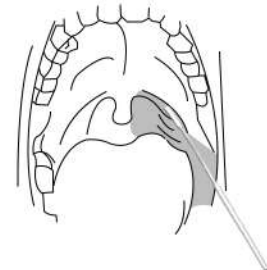
## Specimens

The detect specimens include nasopharyngeal swab and oropharyngeal swab.

Nasopharyngeal swab



Oropharyngeal swab



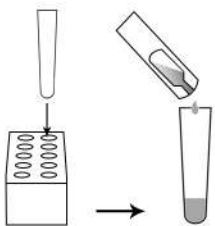
Inadequate specimen collection, improper specimen handling and/or transport may yield false results; therefore, training in specimen collection is highly recommended due to the importance of specimen quality to obtain accurate test results.

## Test Procedure

Take nasopharyngeal swab for example.

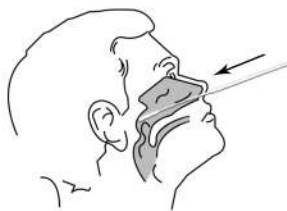
1

Put an extraction tube on the work station. Add all of the extraction reagent into an extraction tube.



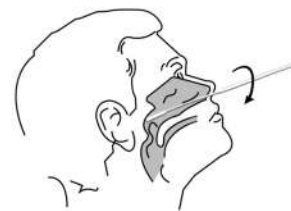
2

Tilt patient's head back about 70°. Insert sterilized swab through the nostril parallel to the palate.



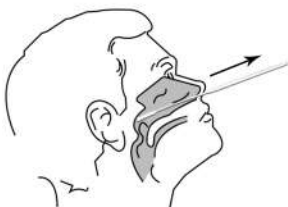
3

Gently rub and roll the swab, and leave swab in place for several seconds to absorb secretions.



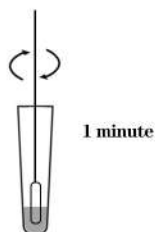
4

Slowly remove swab while rotating it.



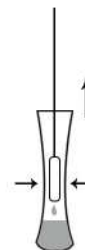
5

Insert the swab specimen into the extraction tube. Roll the swab at least 5 times and leave the swab in the extraction tube for one minute.



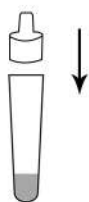
6

Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.



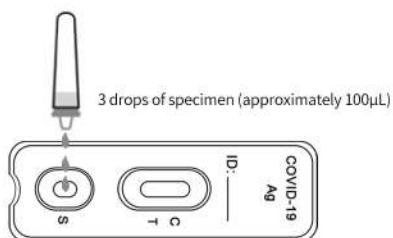
7

Cover the extraction tube with a dropper tip tightly.



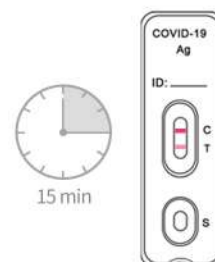
8

Transfer 3 drops (approximately 100µL) to the specimen well of the test cassette.

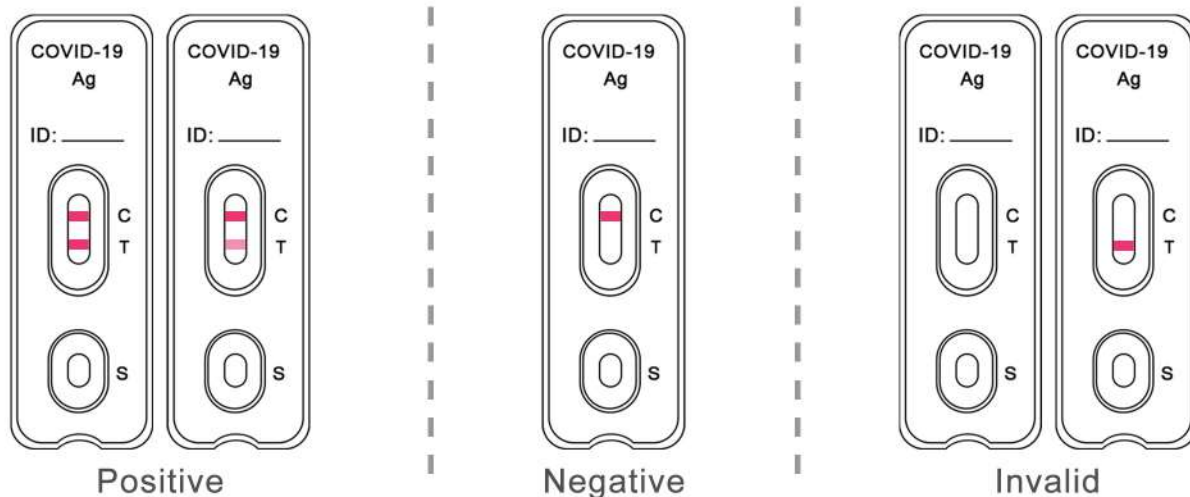


9

Interpret the test results at 15 minutes. Do not read results after 20 minutes.



## Interpretation of Results



## Performance Characteristics

### Clinical Performance

770 nasopharyngeal swabs were collected from individual symptomatic patients. The swabs were detected by COVID-19 Antigen Rapid Test of Clongene and the RT-PCR. Summary data was showed as below:

COVID-19 Antigen		RT-PCR (Ct value $\leq 33$ )		Total
		Positive	Negative	
CLUNGENE <sup>®</sup>	Positive	145	2	147
	Negative	3	593	596
Total		148	595	743

PPA (Ct $\leq 33$ ): 98.0% (145/148), (95%CI: 94.2% ~ 99.3%)

NPA: 99.7% (593/595), (95%CI: 98.8% ~ 99.9%)

COVID-19 Antigen		RT-PCR (Ct value ≤ 37)		Total
		Positive	Negative	
CLUNGENE®	Positive	161	2	163
	Negative	14	593	607
Total		175	595	770

PPA (Ct ≤ 37): 92.0% (161/175), (95%CI: 87.0% ~ 95.2%)

NPA: 99.7% (593/595), (95%CI: 98.8% ~ 99.9%)

- PPA - Positive Percent Agreement (Sensitivity)
- NPA - Negative Percent Agreement (Specificity)

## Limit of Detection (Analytical Sensitivity)

The study used cultured SARS-CoV-2 virus, which is heat inactivated and spiked into nasopharyngeal swab specimen. The Limit of Detection (LoD) is  $5.7 \times 10^2$  TCID<sub>50</sub>/mL.

## Cross Reactivity (Analytical Specificity)

We have evaluated 32 commensal and pathogenic microorganisms that may be present in the nasal cavity and no cross-reactivity was observed.

## Interference

17 potentially interfering substances with different concentration were evaluated and found no affect to the test performance.

## High-dose Hook Effect

The COVID-19 Antigen Rapid Test was tested up to  $1.0 \times 10^{5.67}$  TCID<sub>50</sub>/mL of inactivated SARS-CoV-2 and no high-dose hook effect was observed.



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