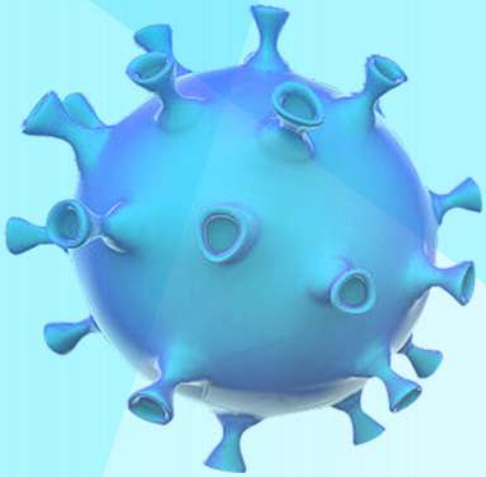
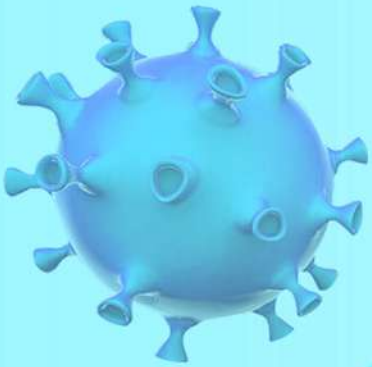
COVID-19 Antigen Rapid Test





Hangzhou Clongene Biotech Co., Ltd.
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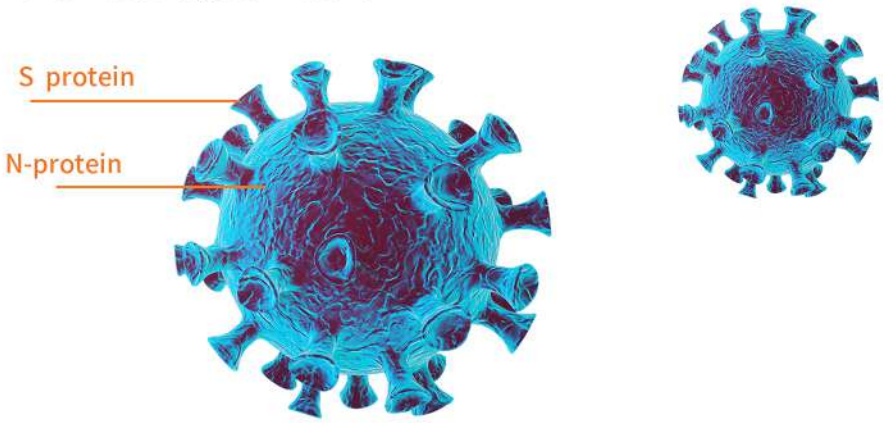
COVID-19 & SARS-CoV-2

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 nasal swab, nasopharyngeal swab and oropharyngeal swab from individuals who are suspected of COVID-19 by their healthcare provider.

LUNGENE®

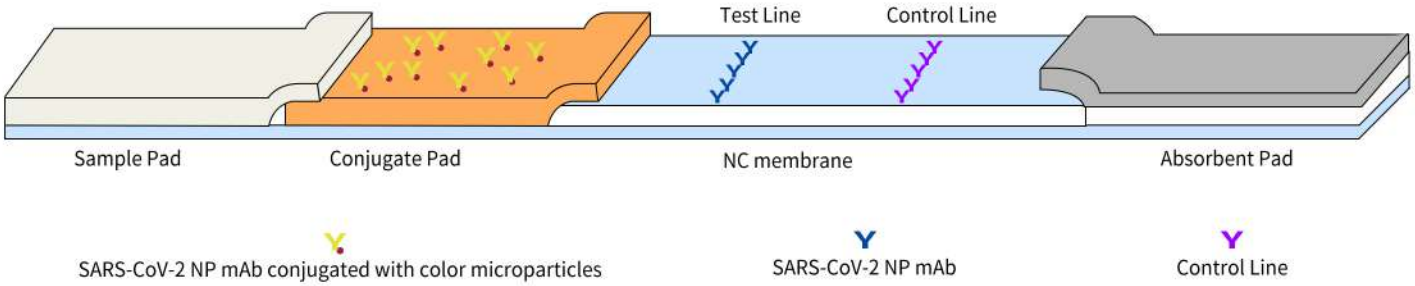
Kit Contents

Contents				
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

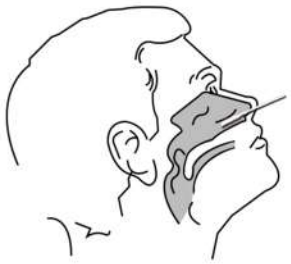


The COVID-19 Antigen Rapid Test is a lateral flow immunoassay based on the principle of the double-antibody sandwich technique. If the specimen contains SARS-CoV-2 antigen, a colored test line (T) would be visible in the result window. Absence of the T line suggests a negative result. The control line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

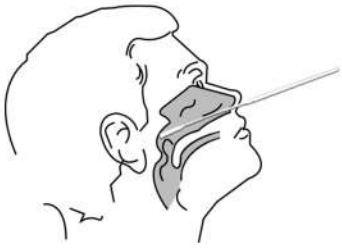
Specimens

The detect specimens include nasal swab, nasopharyngeal swab and oropharyngeal swab.

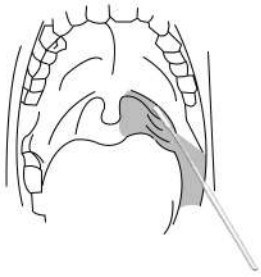
Nasal Swab



Nasopharyngeal Swab



Oropharyngeal Swab

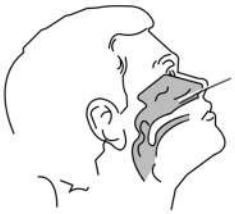


Inadequate specimen collection, improper specimen handling and/or transport may yield false results; therefore, training in specimen collection is highly recommended due to the importance of specimen quality to obtain accurate test results.

Sample Collection

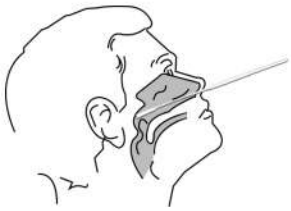
Nasal Swab

Gently rotating the swab, insert swab about 2.5 cm (1 inch) into nostril until resistance is met at turbinates. Rotate the swab several times and repeat in other nostril using the same swab.



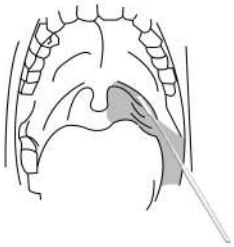
Nasopharyngeal Swab

Insert the swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. Gently rub and roll the swab.



Oropharyngeal Swab

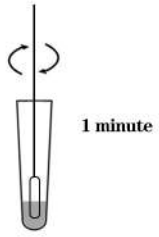
Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.



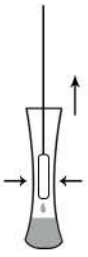
Test Procedure

1 Add all of the extraction reagent into an extraction tube.

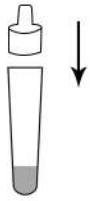
2 Insert the swab specimen into the extraction tube. Roll the swab at least 5 times and leave the swab in the extraction tube for one minute.



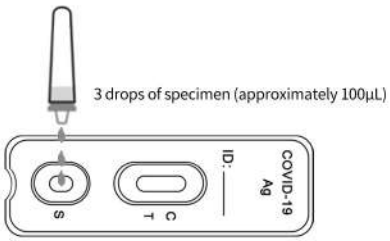
3 Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.



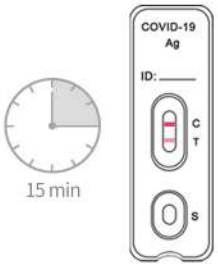
4 Cover the extraction tube with a dropper tip tightly.



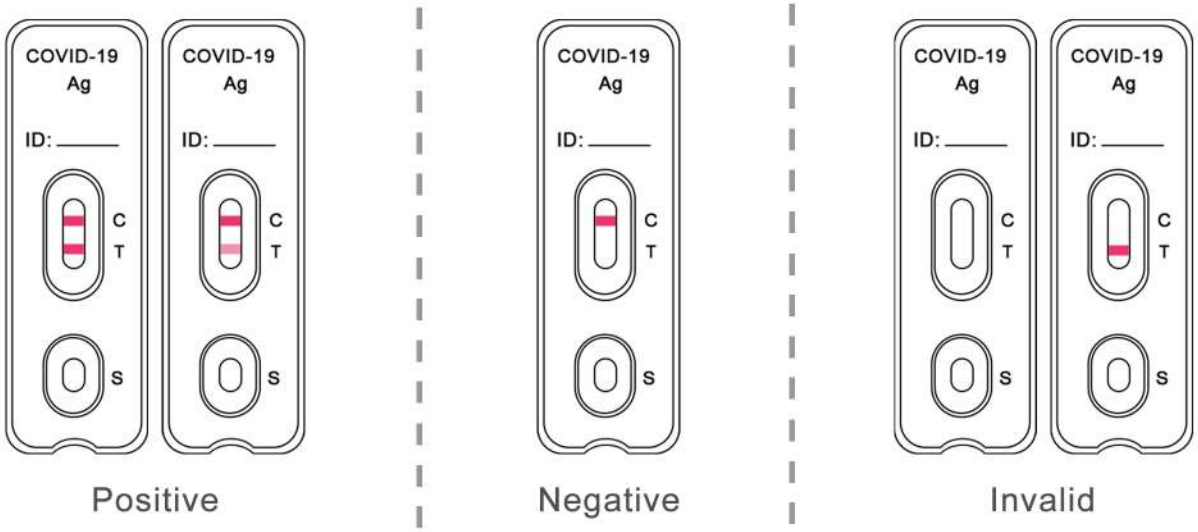
5 Transfer 3 drops (approximately 100µL) to the specimen well of the test cassette.



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



Interpretation of Results



Performance Characteristics

Clinical Performance

■ For nasopharyngeal swab:

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≤33)		Total
		Positive	Negative	
CLUNGENE®	Positive	145	2	147
	Negative	3	593	596
Total		148	595	743

PPA (Ct≤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)

For nasal swab:

617 nasal 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 as below:

COVID-19 Antigen		RT-PCR (Ct value≤33)		Total
		Positive	Negative	
CLUNGENE®	Positive	132	3	135
	Negative	4	462	466
Total		136	465	601

PPA (Ct≤33): 97.1% (132/136), (95%CI: 92.7%～98.9%)

NPA: 99.4% (462/465), (95%CI: 98.1%～99.8%)

COVID-19 Antigen		RT-PCR (Ct value≤37)		Total
		Positive	Negative	
CLUNGENE®	Positive	139	3	142
	Negative	13	462	475
Total		152	465	617

PPA (Ct≤37): 91.4% (139/152), (95%CI: 85.9%～94.9%)

NPA: 99.4% (462/465), (95%CI: 98.1%～99.8%)

- 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 $\times 10^2$ $TCID_{50}$/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 $1.0\times10^{5.67}$ $TCID_{50}$/mL of inactivated SARS-CoV-2 and no high-dose hook effect was observed.

National List

Validated by Paul-Ehrlich-Institut (PEI) in Germany.

Validated by Nationalen Referenzzentrum für neu auftretende Virusinfektionen (NAVI) in Switzerland, with comments as "Diese Ergebnisse liegen deutlich über den Empfehlungen der WHO für Ag-Schnelltests" by BAG.

BfArM

PEI

EU

NAVI

Listed by BfArM.

Listed in the EU common list of COVID-19 rapid antigen tests on 17 February 2021.

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