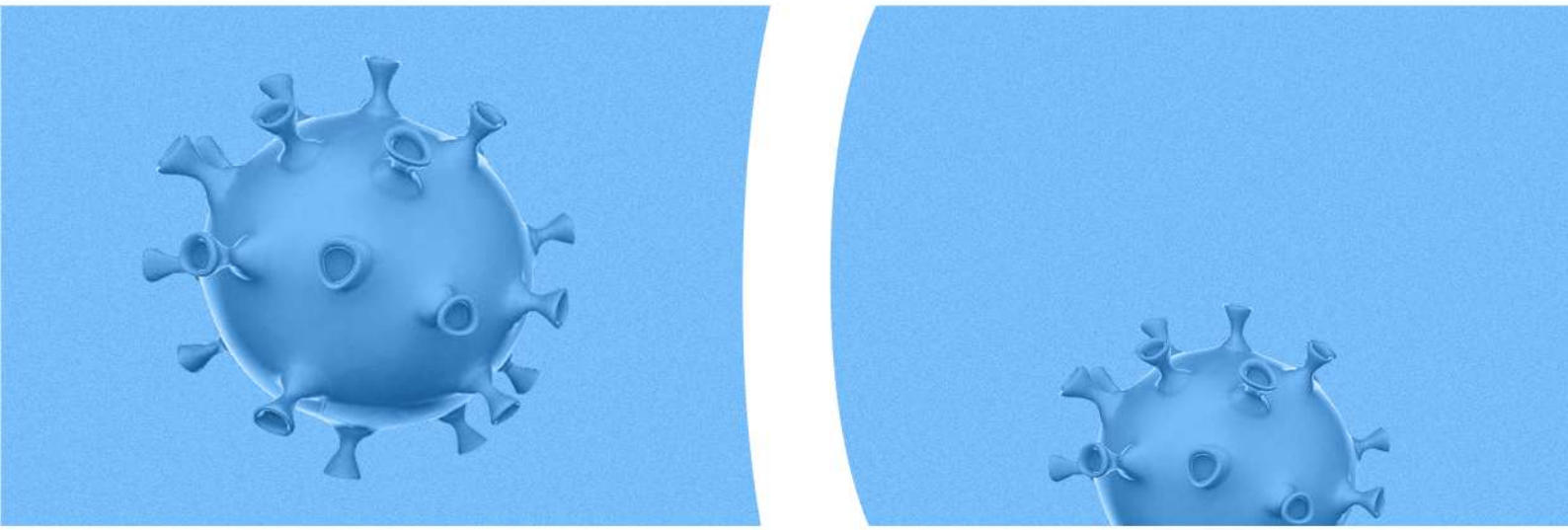
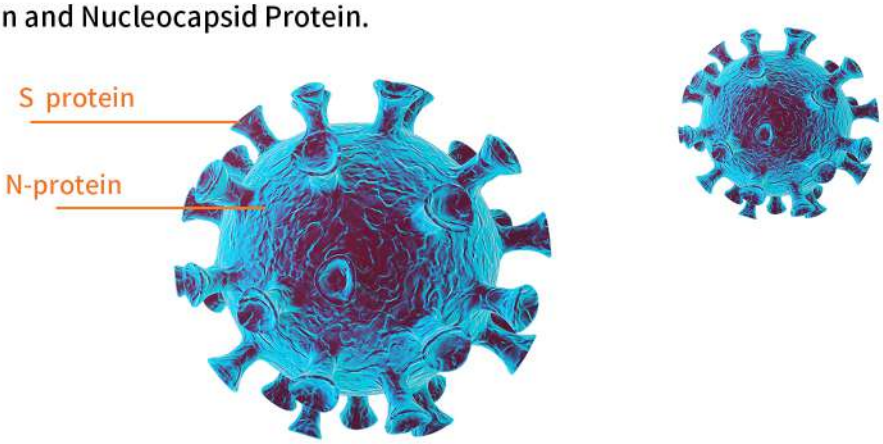
COVID-19 Antigen Rapid Test Cassette



Hangzhou Clongene Biotech Co., Ltd.
en.clongene.com

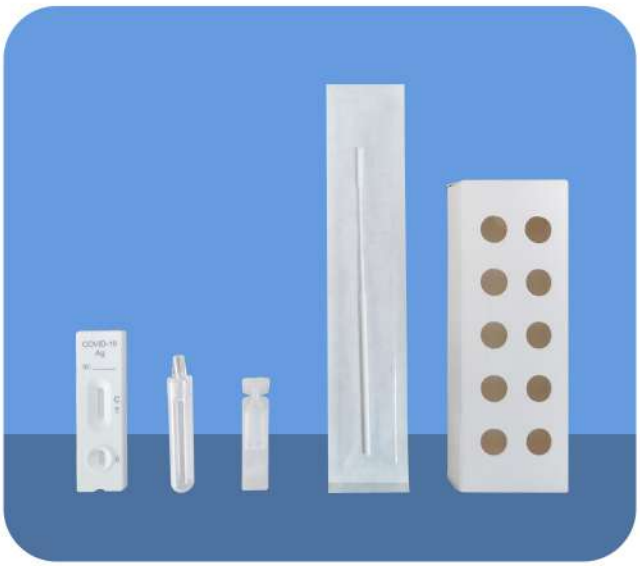
COVID-19 & SARS-CoV-2

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.



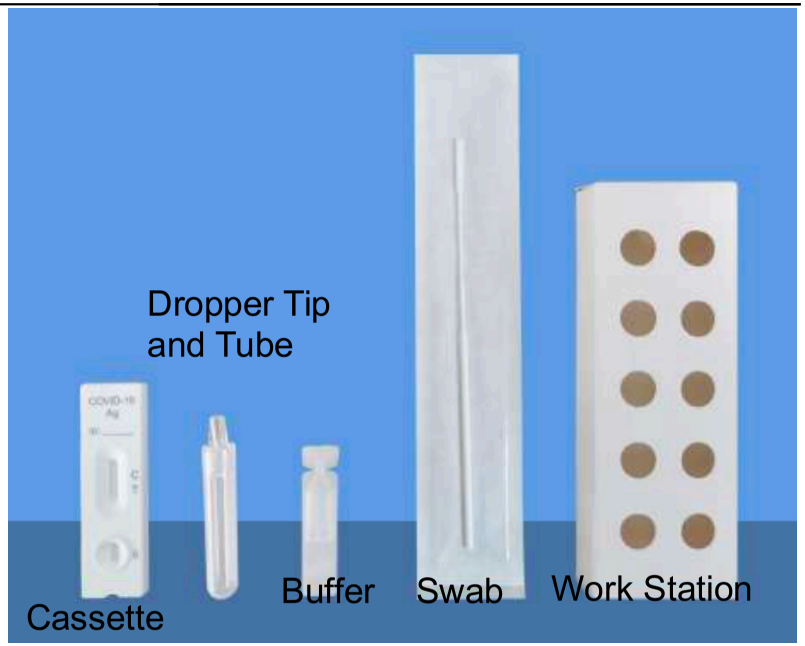
Nucleocapsid (N) protein is the most abundant protein with highly conserved in SARS-CoV-2. N protein is used as the core raw material of rapid diagnostic reagent for immunology in the market.

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.



SARS-CoV-2 Antigen Rapid Test Kit

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.

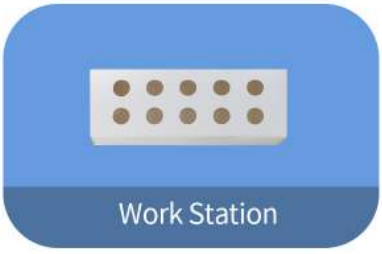


Include:25 Test Kit,25 pcs/box
Export Carton:64x34x55cm
Weight:17kg
Include:50 box,1000pcs

Color box Size:268x124x65mm


LUNGENE®
RAPID TEST
COVID-19 Antigen Rapid Test Cassette
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.
Contains:25 Test Cassettes
25 Extraction Tubes
25 Sterilized Swabs
1 Work Station
1 Package Insert
25 Dropper Tips
25 Extraction Reagents
LOT 2020080128
2022-04
http://en.clongene.com
CONFORMITY ASSESSMENT PROCEDURE:DIRECTIVE 98/79/EC ANNEX III
REGISTRATION NO.:DE/CA05/IVD-238321-1547-00
QC
PASSED
合格证 Certificate of Quality
Product name: COVID-19 Antigen Rapid Test Cassette
Specification: 25 Tests/box
Lot NO.: 202008128
MFD.: 2020-08
EXP.: 2022-04
Manufacturer: Hangzhou Clongene Biotech Co.,Ltd
Address: No.1 Yichuang Road, Yuhang Sub-district, Yuhang District, Hangzhou 311121,China
质量专用章
LUNGENE® COVID-19 Antigen Rapid Test Cassette
English
For professional use only.
For in vitro diagnostic use only.
[INTENDED USE]
The COVID-19 Antigen Rapid Test Cassette 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.
Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in nasopharyngeal swab and oropharyngeal swab during the acute phase of infection. Positive results indicate the presence of virat antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary for patient management.
The COVID-19 Antigen Rapid Test Cassette is intended for use by trained clinical laboratory personnel specifically instructed and trained in vitro diagnostic procedures.
[SUMMARY]
COVID-19 Ag Extraction Reagent
Vol:300 ul*25 Lot:2008050
Store at:2-30℃ Exp:2023-07
LUNGENE®
RAPID TEST
• For In Vitro Diagnostic Use Only • Store Sealed at 4-30°C (40-86°F)
COVID-19 ANTIGEN RAPID TEST CASSETTE
LOT:2020080128 EXP:2022-04
Hangzhou Clongene Biotech Co., Ltd.
No.1 Yichuang Road, Yuhang Sub-district, Yuhang District, 311121 Hangzhou, China
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, D-20537 Hamburg, Germany

ICOV5002-100596



Work Station

Test Cassette

Extraction reagents

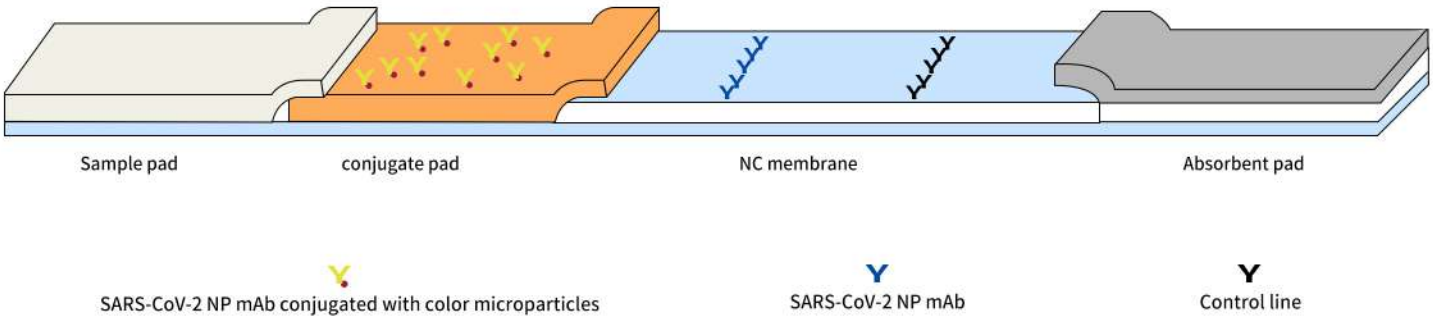
Sterilized Swab

Extraction Tube & Dropper Tip

Product Features

- CE Marked
- Instant result at 15 minutes
- Easy to collect samples
- Results are clearly visible
- No equipment required
- Suitable for large-scale rapid screening

Principle

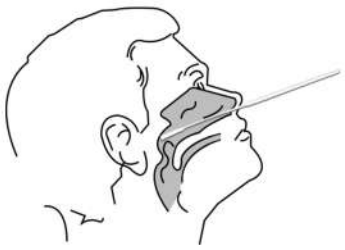


The COVID-19 Antigen Rapid Test is a lateral flow immunoassay based on the principle of the double-antibody sandwich technique. If the specimen contains SARS-CoV-2 antigen, a colored test line (T) would be visible in the result window. Absence of the T line suggests a negative result. The control line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

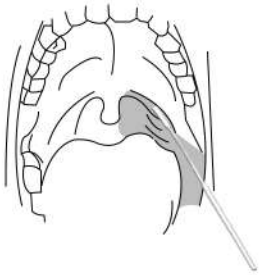
Specimens

The detect specimens include nasopharyngeal swab and oropharyngeal swab.

Nasopharyngeal swab



Oropharyngeal swab



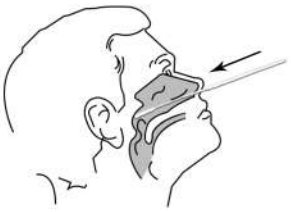
Inadequate specimen collection, improper specimen handling and/or transport may yield false results; therefore, training in specimen collection is highly recommended due to the importance of specimen quality to obtain accurate test results.

Test Procedure

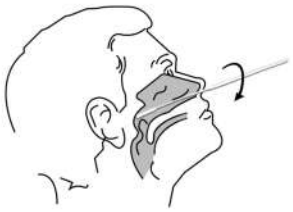
Take nasopharyngeal swab for example.

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

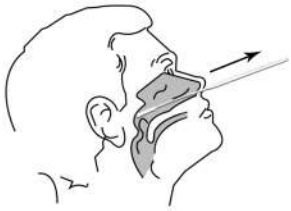
2. Tilt patient's head back about 70°. Insert sterilized swab through the nostril parallel to the palate.



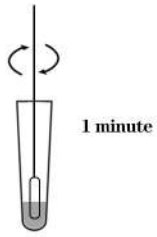
3. Gently rub and roll the swab, and leave swab in place for several seconds to absorb secretions.



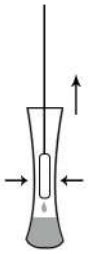
4. Slowly remove swab while rotating it.



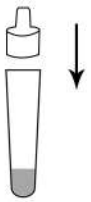
5. Insert the swab specimen into the extraction tube. Roll the swab at least 5 times and leave the swab in the extraction tube for one minute.



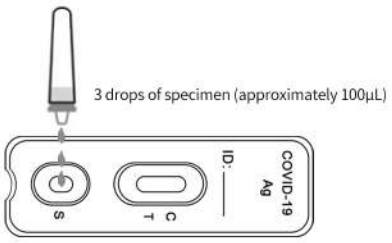
6. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.



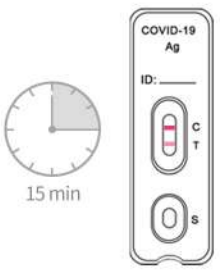
7. Cover the extraction tube with a dropper tip tightly.



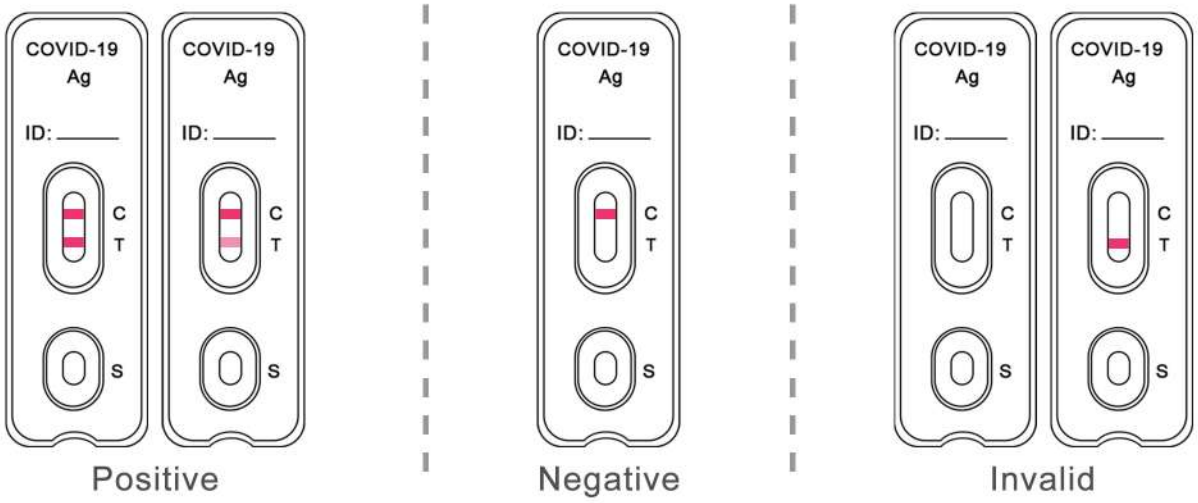
8. Transfer 3 drops (approximately 100µL) to the specimen well of the test cassette.



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



Interpretation of Results



Performance Characteristics

Clinical Performance

285 nasopharyngeal swabs were detected by COVID-19 Antigen Rapid Test and the RT-PCR.

COVID-19 Antigen		RT-PCR		Total
		Positive	Negative	
CLUNGENE®	Positive	64	0	64
	Negative	6	215	221
Total		70	215	285

Sensitivity (PPA)= 91.4% (64/70), (95%CI: 82.5%~96.0%)

Specificity (NPA)= 100% (215/215), (95%CI: 98.2%~100%)

The 6 discordant specimens had Ct values of 34, 36, 35.5, 34, 35, 33

The PPA is 98.5% (64/65) (95%CI: 91.8%~99.7%) with specimens of a Ct count ≤33

Limit of Detection (Analytical Sensitivity)

The study used cultured SARS-CoV-2 virus, which is β-propiolactone and heat inactivated and spiked into nasopharyngeal swab specimen. The Limit of Detection (LoD) is $5\times10^{2.67}$ $TCID_{50}$/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.

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.