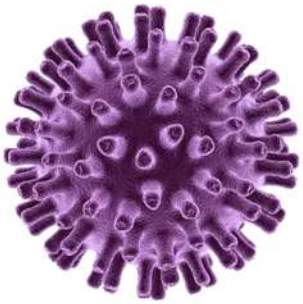
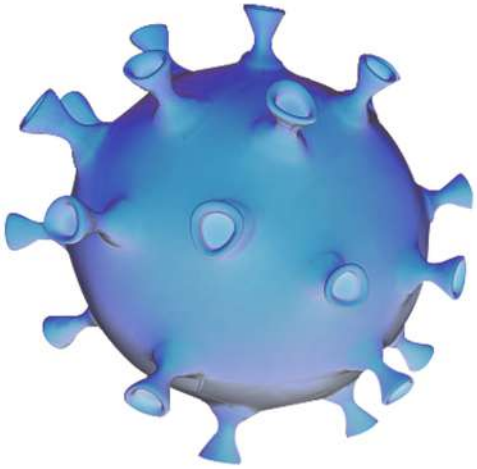
COVID-19 / Influenza A+B
Antigen Combo Rapid Test Cassette





Hangzhou Clongene Biotech Co., Ltd.
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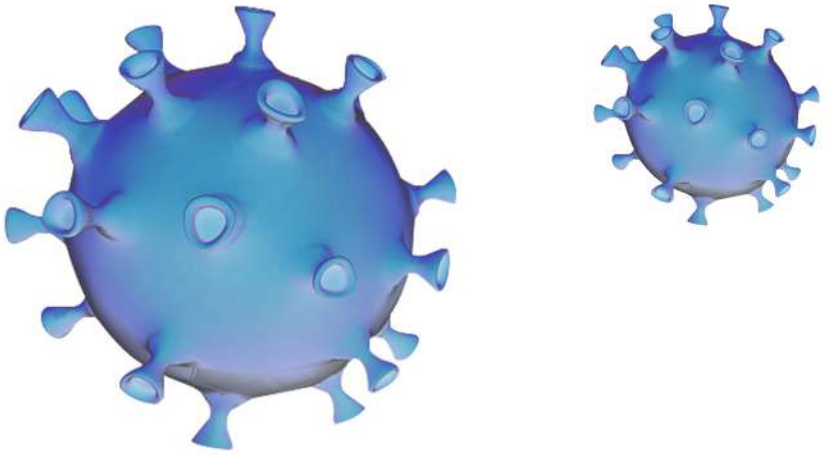
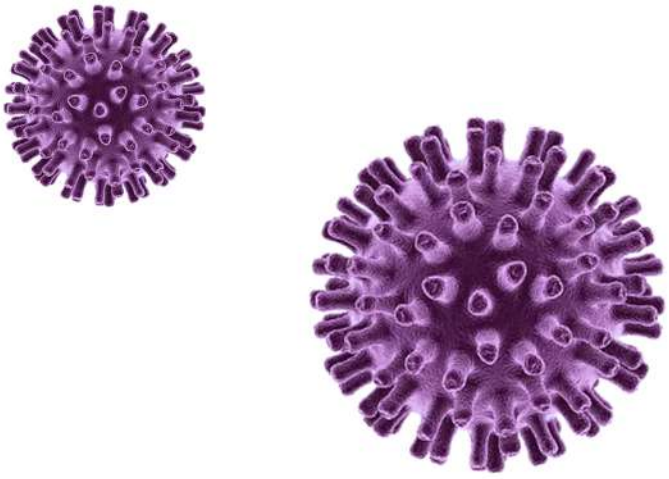
COVID-19 & Influenza

COVID-19 is an acute respiratory infectious disease and people are generally susceptible. The patients infected by the SARS-CoV-2 are the main source of infection and asymptomatic infected people can also be an infectious source.



COVID-19

Influenza (Flu) is a contagious respiratory illness caused by influenza viruses. It can cause mild to severe illness. Serious outcomes of Flu infection can result in hospitalization or death. There are two main types of influenza virus: Types A and B. Symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.



Influenza

COVID-19 /Influenza A+B Antigen Combo Rapid Test

Clongene has developed the COVID-19/Influenza A+B Antigen Combo Rapid Test Cassette. It is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2, influenza A+B viral nucleoprotein antigens in nasopharyngeal swab from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider.

Kit Contents

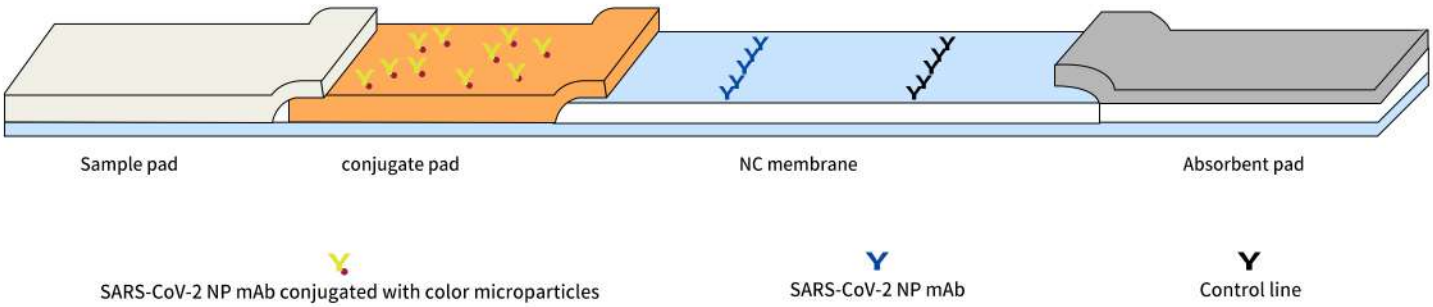
Extraction reagents	Test Cassette	Work Station	Extraction Tube & Dropper Tip	Sterilized Swab
				

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

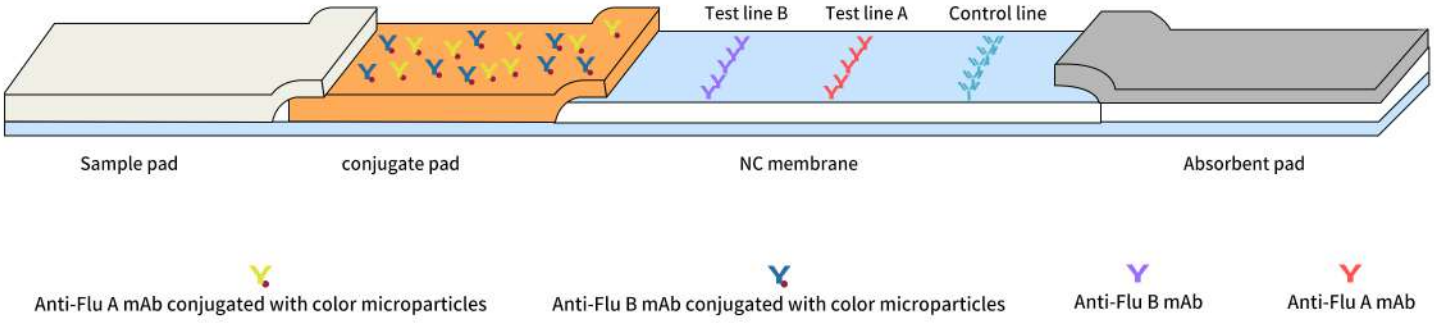
Principle

COVID-19 Antigen Rapid Test



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.

COVID-19/Influenza A+B Antigen Combo Rapid Test



The Influenza A+B Rapid Test is a lateral flow immunoassay based on the principle of the doubleantibody sandwich technique. If the specimen contains influenza A antigen, a colored line would be visible at the A region. If the specimen contains influenza B antigen, a colored line would be visible at the B region in the result window.

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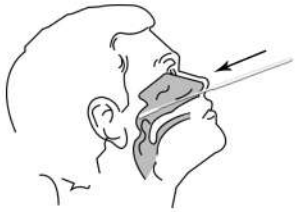
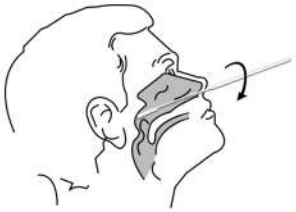
Test Procedure

1. Add all of the specimen extraction reagent into an extraction tube, and put it on the work station.

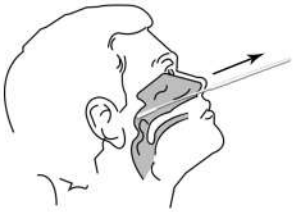
2. Insert sterilized swab through the nostril parallel to the palate.



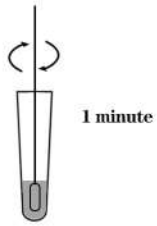
3. Gently rub and roll the swab, and leave swab in place for several seconds to absorb secretions.



4. Slowly remove swab while rotating it.

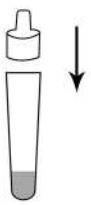


5. Insert the swab into the extraction tube. Roll the swab at least 5 times while pressing the head against the bottom and side of the extraction tube, and stay for 1 minute.

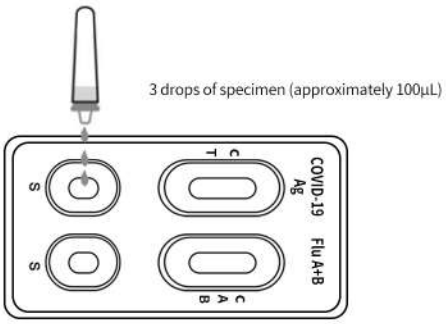


6. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

7. Insert a dropper tip into the extraction tube tightly.



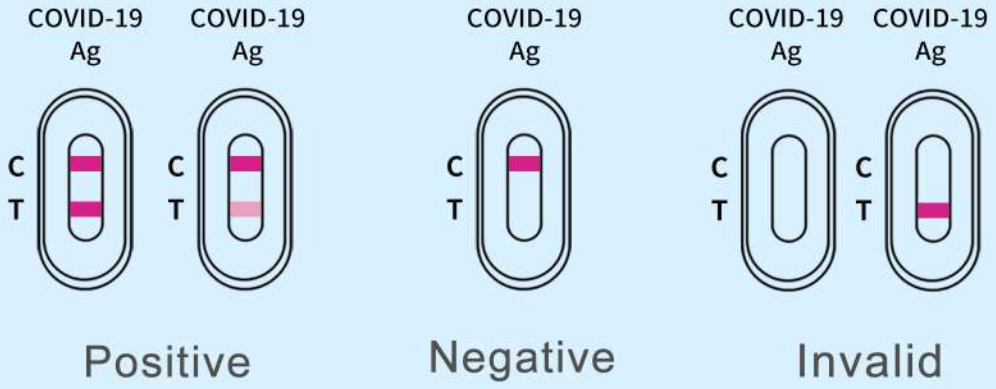
8. Transfer 3 drops (approximately 100µL) to each specimen well (S) of the test cassette.



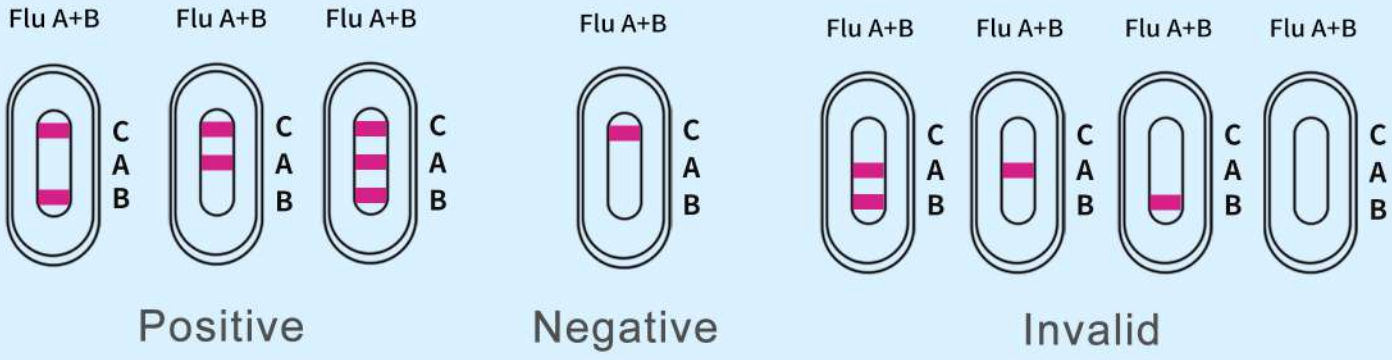
9. Interpret the test results at 15 minutes. Do not read results after 20 minutes.

Interpretation of Results

For COVID-19 Antigen Rapid Test



For Influenza A+B Rapid Test



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Performance Characteristics

Clinical Performance

283 nasopharyngeal swabs were detected by COVID-19/Influenza A+B Antigen Combo Rapid Test Cassette and the RT-PCR. Summary of the performance of COVID-19/Influenza A+B Antigen Combo Rapid Test compared to RT-PCR:

Virus	Sensitivity	Specificity
Influenza A	88.5% (46/52), 95%CI: 77.0%~94.6%	100% (231/231), 95%CI: 98.4%~100%
Influenza B	84.4% (38/45), 95%CI: 71.2%~92.3%	99.6% (237/238), 95%CI: 97.7%~99.9%
SARS-CoV-2	91% (71/78), 95%CI: 82.6%~95.6%	100% (205/205), 95%CI: 98.2%~100%

Limit of Detection (Analytical Sensitivity)

The study used cultured viruses, which are inactivated and spiked into nasopharyngeal swab specimen. The Limit of Detection (LoD) was confirmed as follows:

Virus Lineage	Limit of Detection (LoD)
SARS-CoV-2*	2.3×10^3 $TCID_{50}$ /mL
Influenza A (H1N1)**	1.0×10^3 $TCID_{50}$ /mL
Influenza A (H3N2)**	1.0×10^4 $TCID_{50}$ /mL
Influenza A (H1N1pdm09)**	6.5×10^3 $TCID_{50}$ /mL
Influenza B (Yamagata)**	3.7×10^4 $TCID_{50}$ /mL
Influenza B (Victoria)**	1.0×10^3 $TCID_{50}$ /mL

* Beta-propiolactone and heat-inactivated virus

** Heat-inactivated virus

Cross Reactivity (Analytical Specificity)

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

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