

COVID-19 Antigen Rapid Test Cassette (Saliva)

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Some recent studies suggested the role of saliva in the detection of SARS-CoV-2. Most of studies reported that there is no statistically significant difference between nasopharyngeal or oropharyngeal swab and saliva samples regarding viral load.

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



Product Features



CE certification



Instant result at 15 minutes



Easy to collect samples



Results are clearly visible

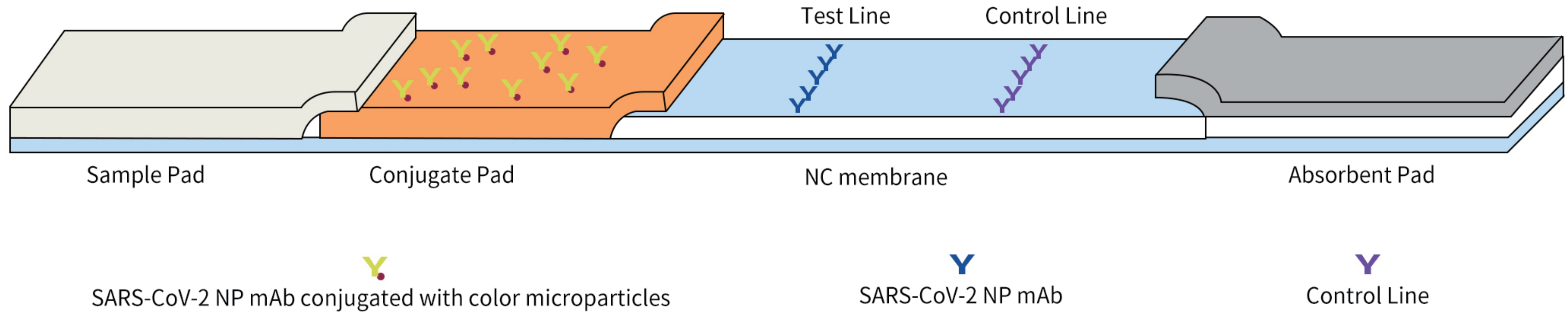


No equipment required



Suitable for large-scale rapid screening

Principle

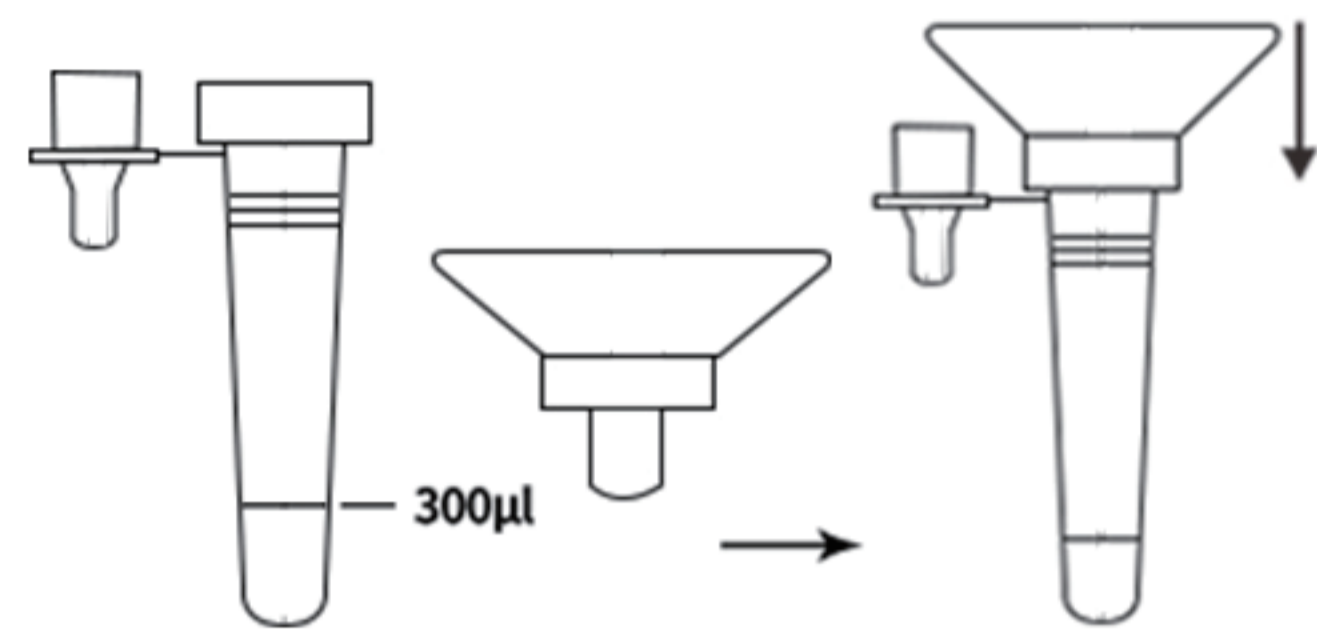


The COVID-19 Antigen Rapid Test (Saliva) is a lateral flow immunoassay based on the principle of the double-antibody sandwich technique. A colored test line (T) would be visible in the result window, if SARS-CoV-2 antigens are present in the specimen. Absence of the T line suggests a negative result.

Test Procedure

1

Use the collection tube and saliva collector to collect saliva.



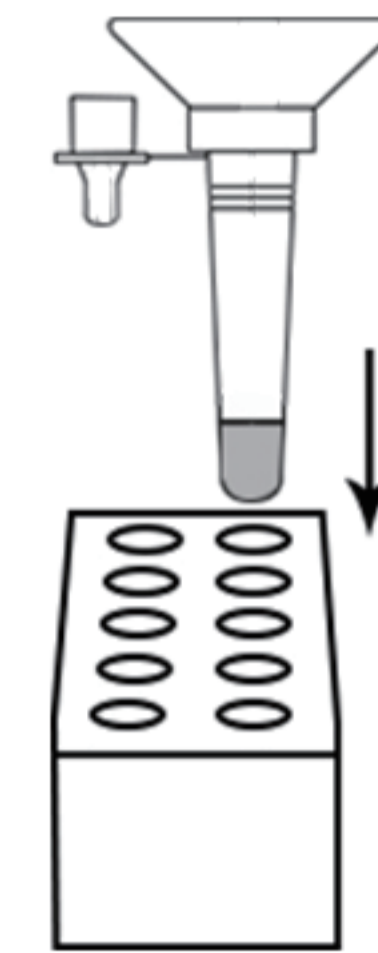
2

Put the saliva collector close to lips and let the saliva flow into the collection tube. The volume of saliva needs to be at the scale mark (approximately 300µL).



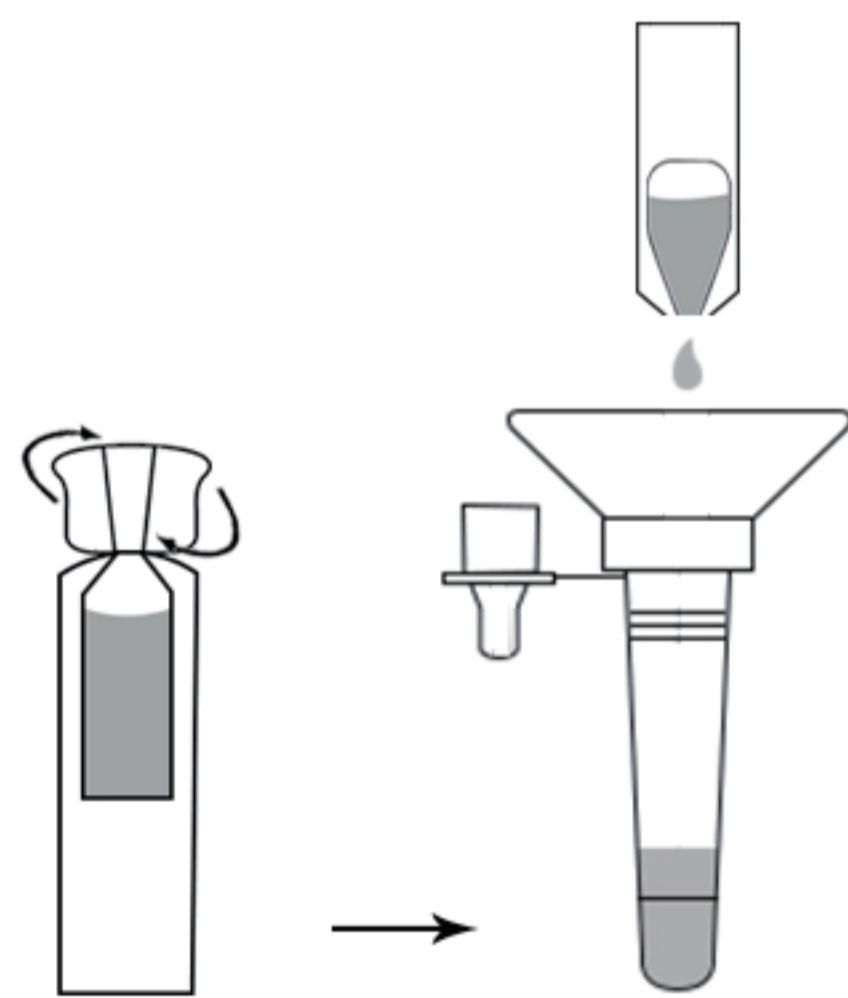
3

Place the collection tube with saliva collector which has saliva in the work station.



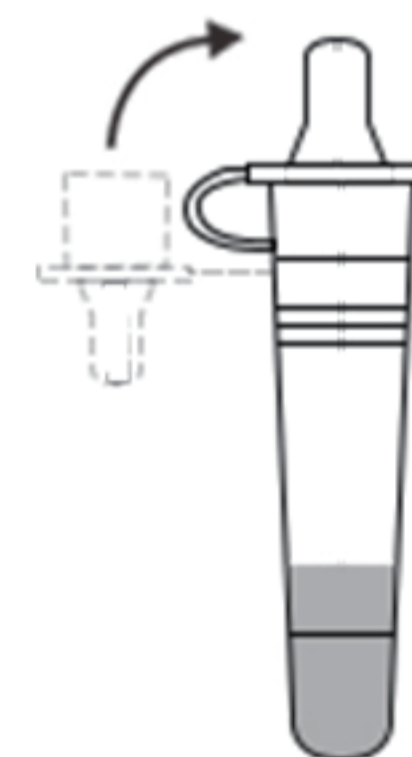
4

Unscrew the lid of an extraction reagent and add all of the extraction reagents into the collection tube.



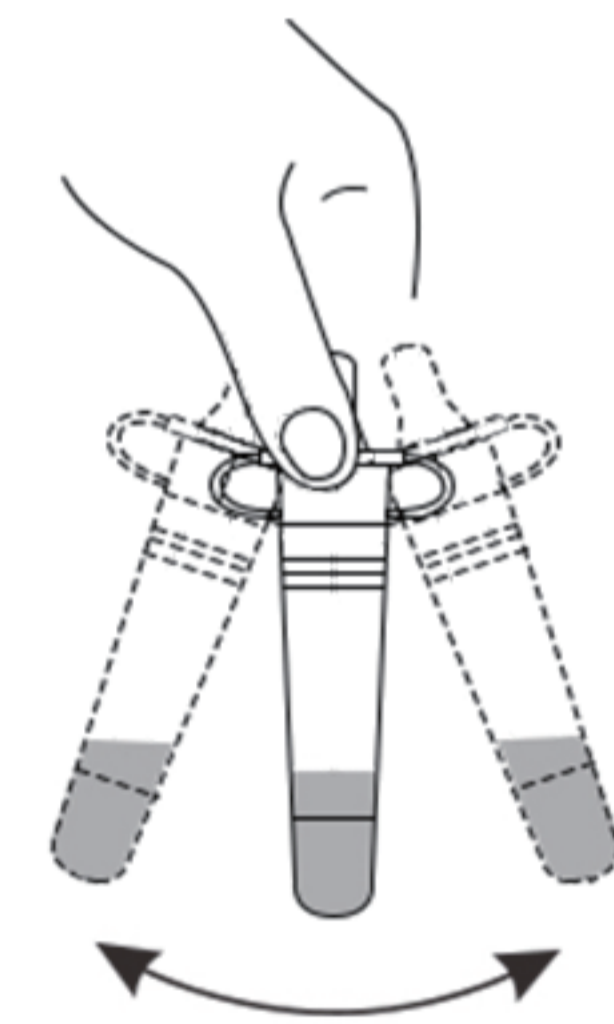
5

Discard the saliva collector and cover the collection tube with the dropper tip onto the collection tube.



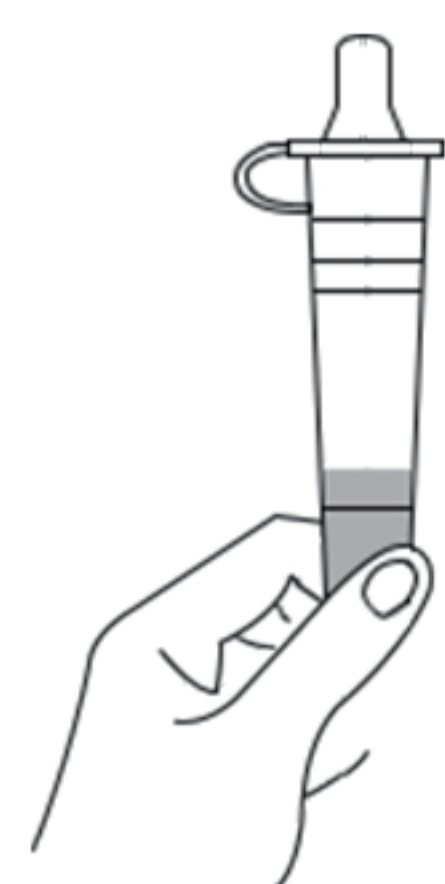
6

Shake the collection tube more than three times vigorously to mix the saliva and the extraction reagent.



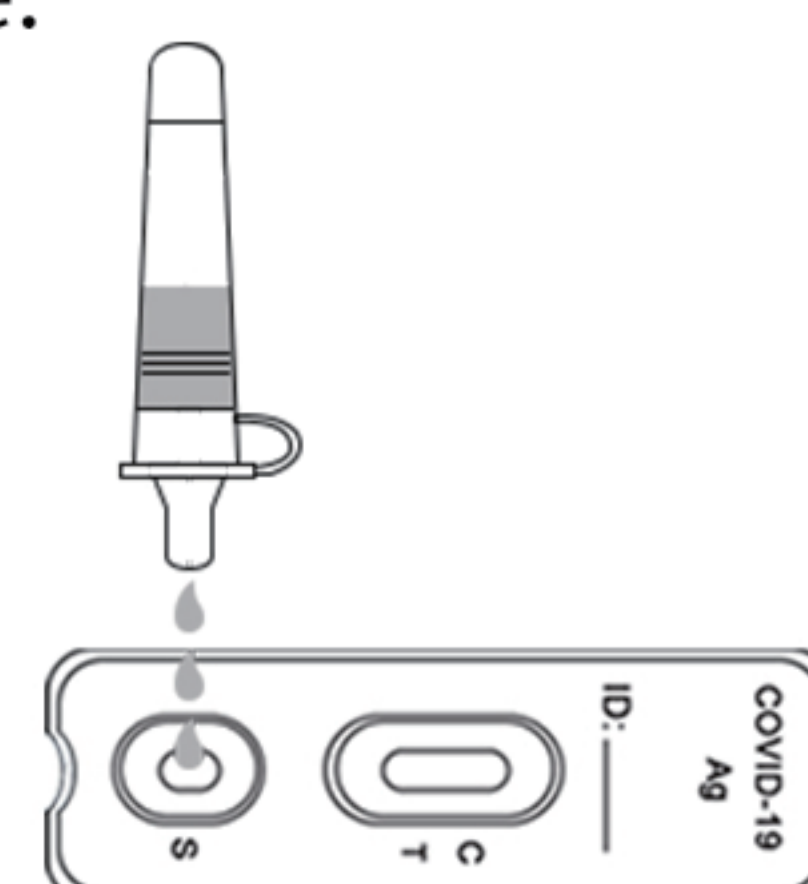
7

Squeeze the mixed solution ten times to allow the saliva to be thoroughly mixed.



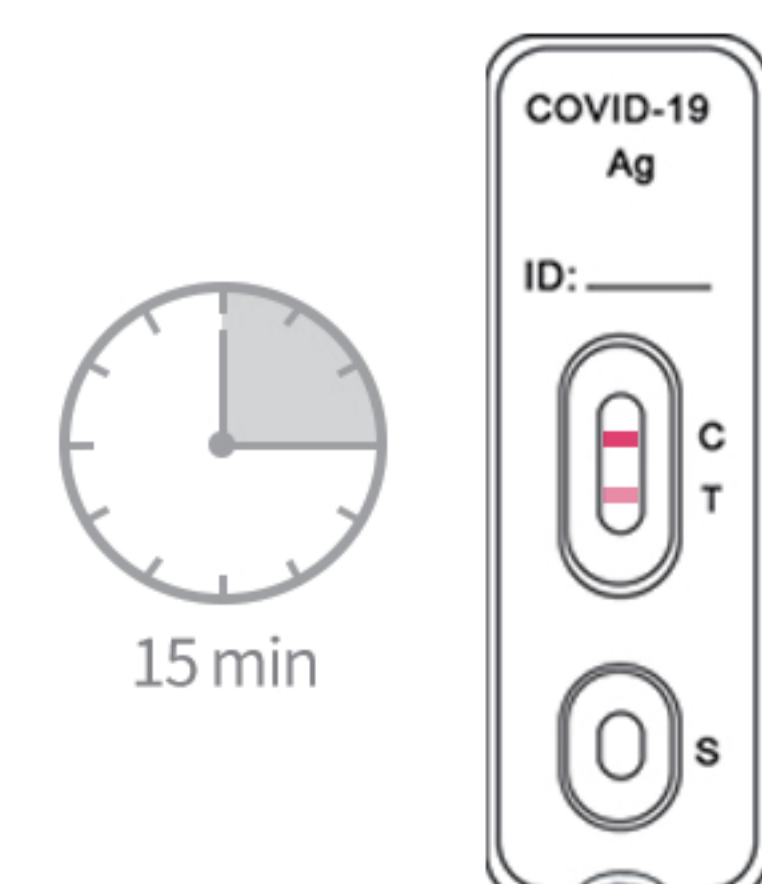
8

Holding the collector upright and transfer 3 drops (approximately 100µL) slowly to the specimen well (S) of the test cassette.

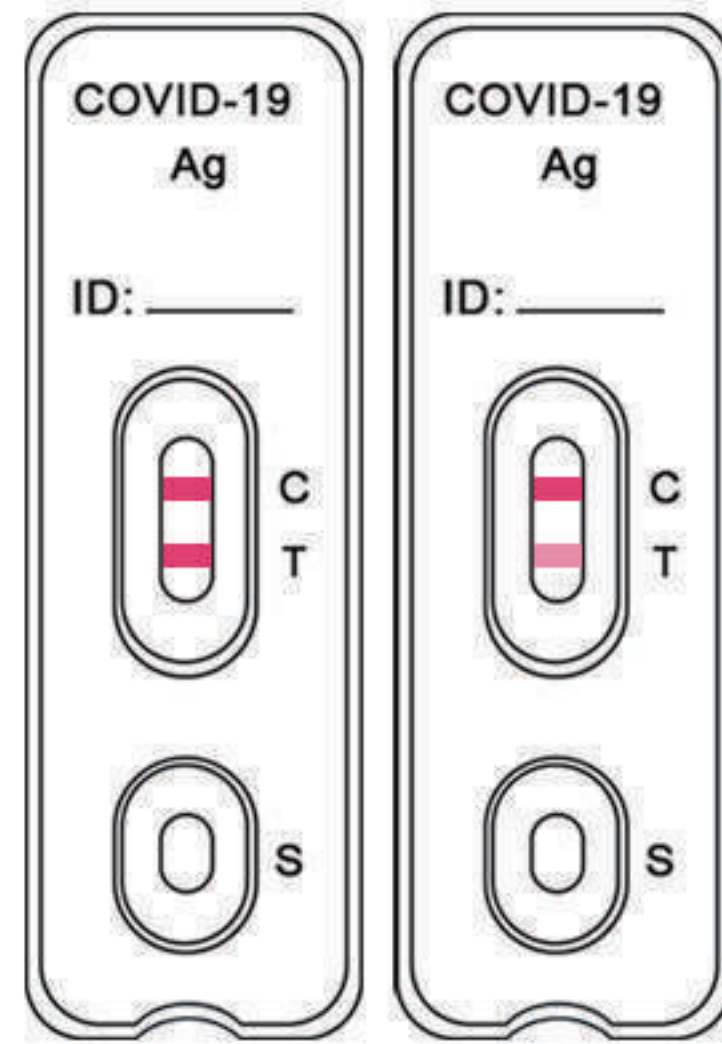


9

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



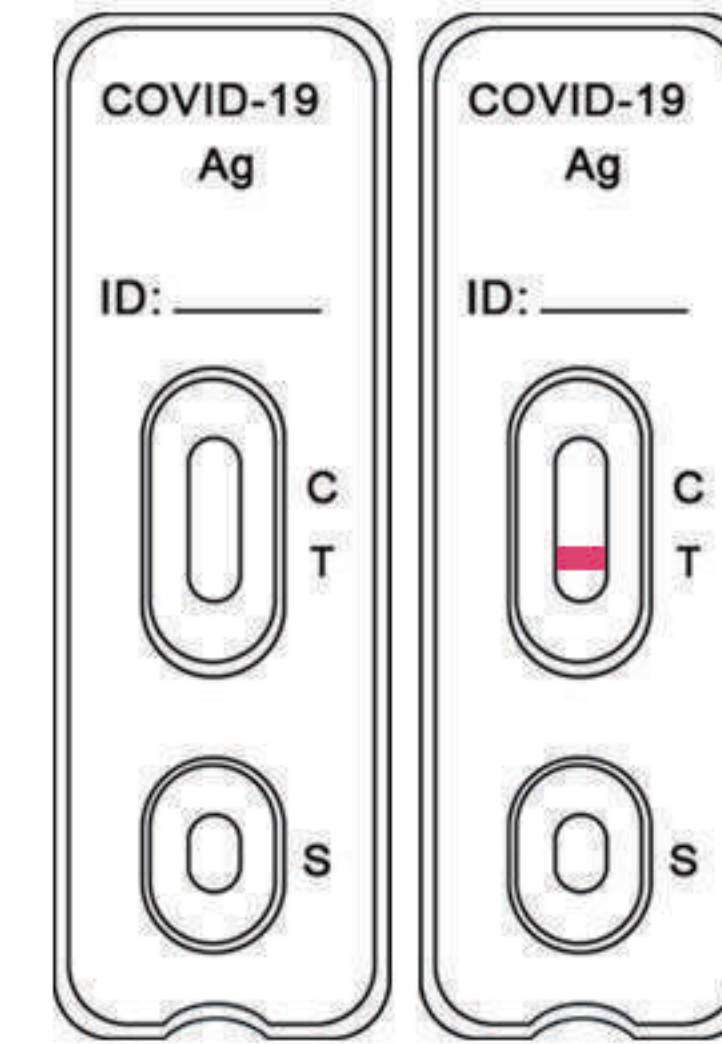
Interpretation of Results



Positive



Negative



Invalid

Clinical Performance

645 individual symptomatic patients and asymptomatic patients who were suspected of COVID-19. The specimens were detected by COVID-19 Antigen Rapid Test and RT-PCR. The test results showed as the tables below

COVID-19 Antigen		RT-PCR (Ct value ≤ 30)		Total
		Positive	Negative	
CLUNGENE [®]	Positive	120	2	122
	Negative	4	483	487
Total		124	485	609

PPA (Ct ≤ 30): 96.8% (120/124), (95%CI: 92.0%~98.7%)

NPA: 99.6% (483/485), (95%CI: 98.5%~99.9%)

COVID-19 Antigen		RT-PCR (Ct value ≤ 37)		Total
		Positive	Negative	
CLUNGENE [®]	Positive	146	2	148
	Negative	14	483	497
Total		160	485	645

PPA (Ct ≤ 37): 91.3% (146/160), (95%CI: 85.9%~94.7%)

NPA: 99.6% (483/485), (95%CI: 98.5%~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 (Isolate Hong Kong/VM20001061/2020, NR-52282), which is heat inactivated and spiked into saliva. The Limit of Detection (LoD) is 8.6×10^2 TCID₅₀/mL.

Cross Reactivity (Analytical Specificity)

32 commensal and pathogenic microorganisms that may be present in the oral cavity were evaluated, 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 Cassette was tested up to 1.15×10^5 TCID₅₀/mL of inactivated SARS-CoV-2 and no high-dose hook effect was observed.