

# COVID-19 Antigen Rapid Test Cassette ( Saliva )

## COVID-19 Antigen Rapid Test Cassette

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



Easy to collect samples



No equipment required



Suitable for large-scale rapid screening



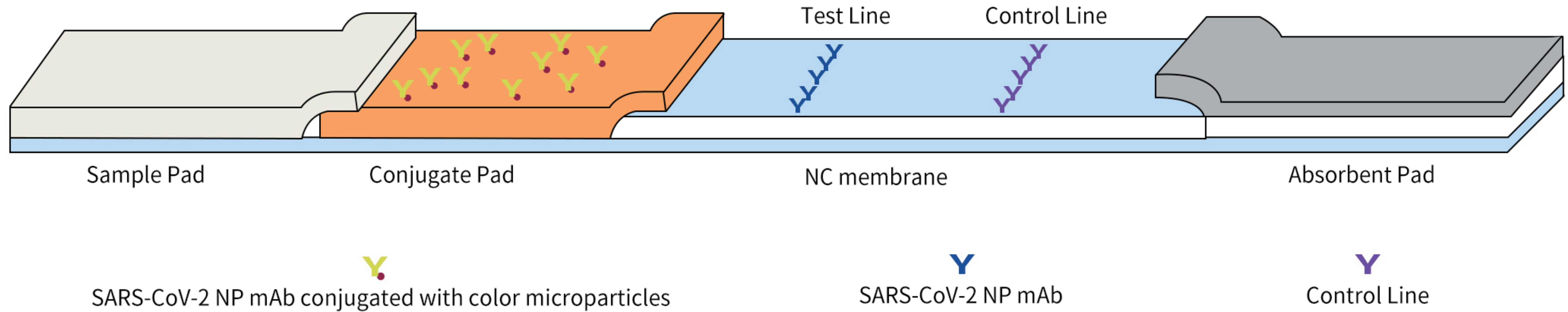
Instant result at 15 minutes



Results are clearly visible



## Principle



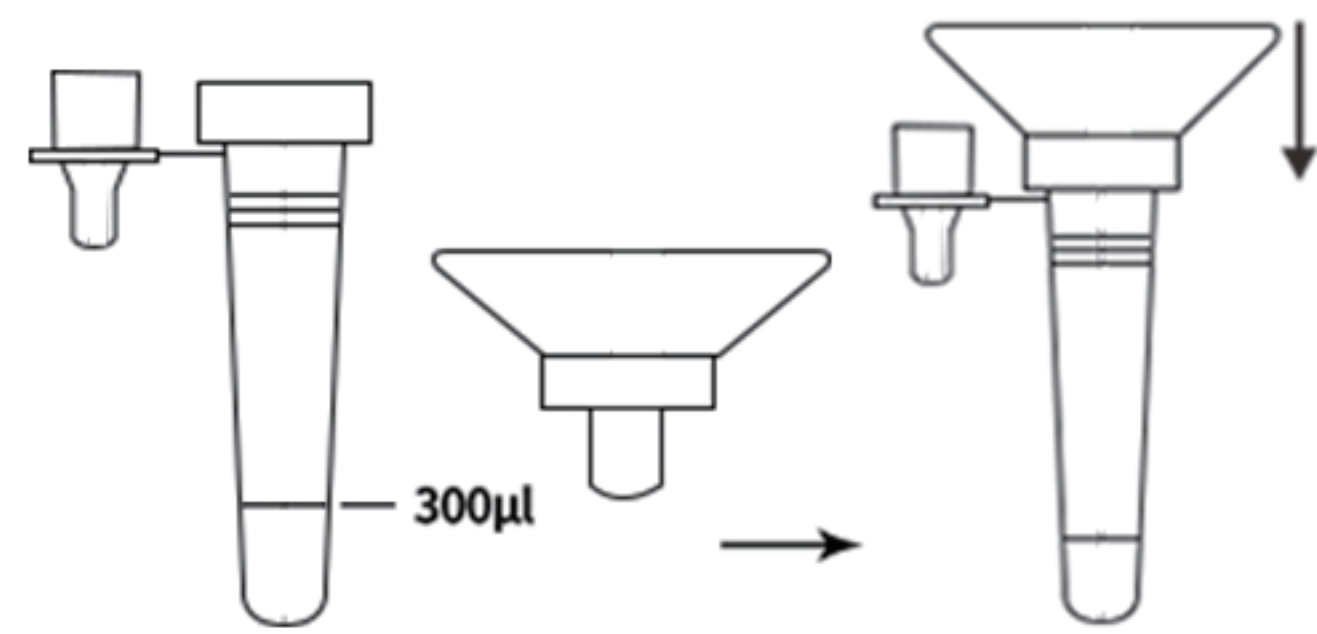
The COVID-19 Antigen Rapid Test (Saliva) is a lateral flow immunoassay based on the principle of the double-antibody sandwich technique. A colored test line (T) would be visible in the result window, if SARS-CoV-2 antigens are present in the specimen. Absence of the T line suggests a negative result.



## Test Procedure

1

Use the collection tube and saliva collector to collect saliva.



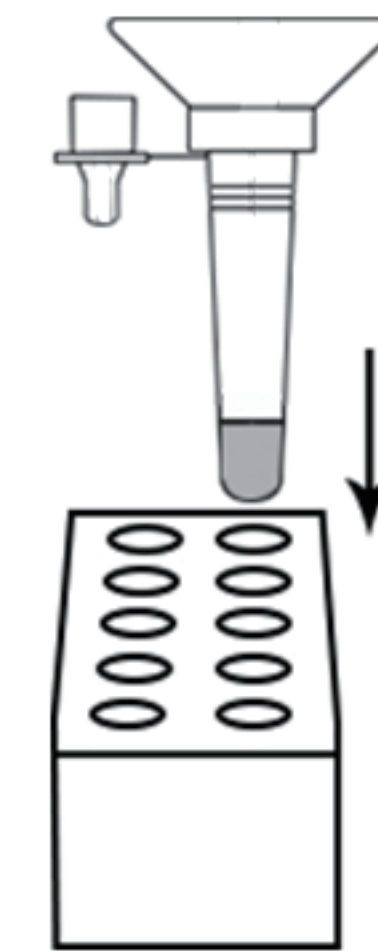
2

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).



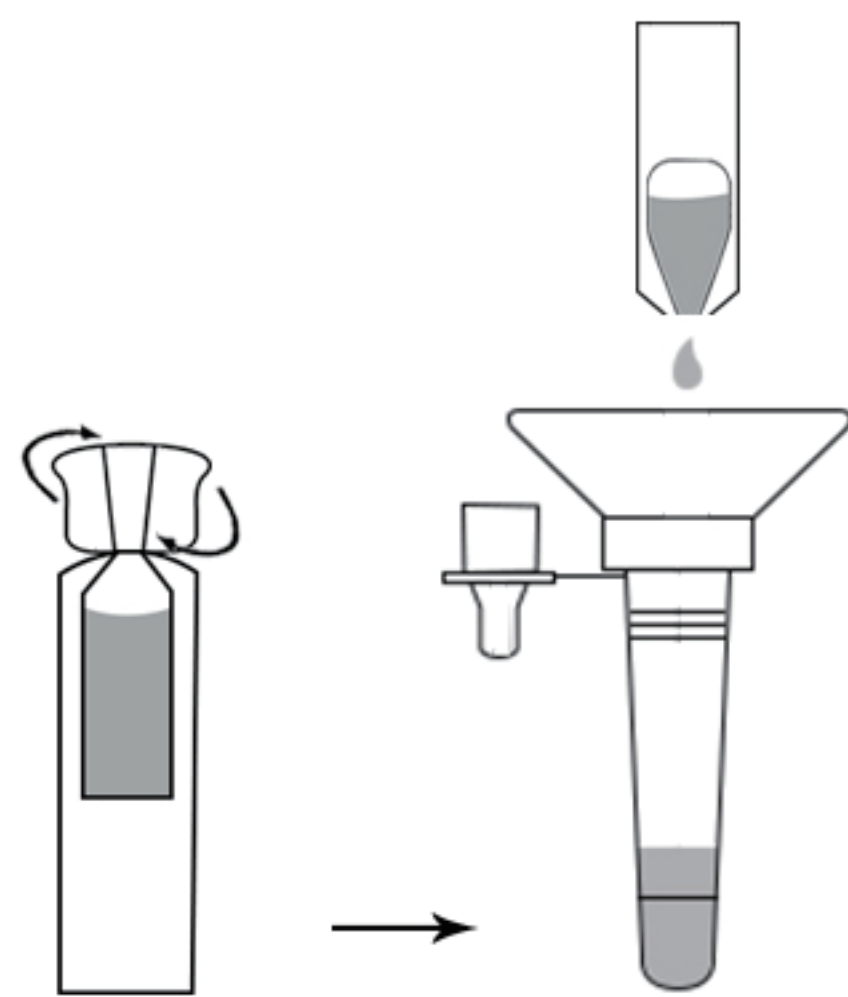
3

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



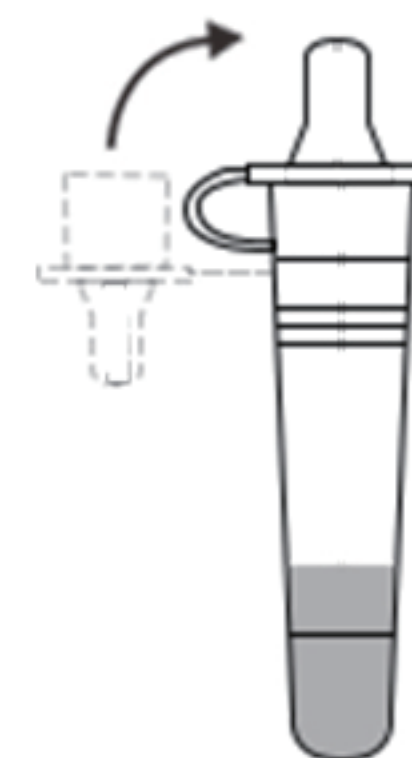
4

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



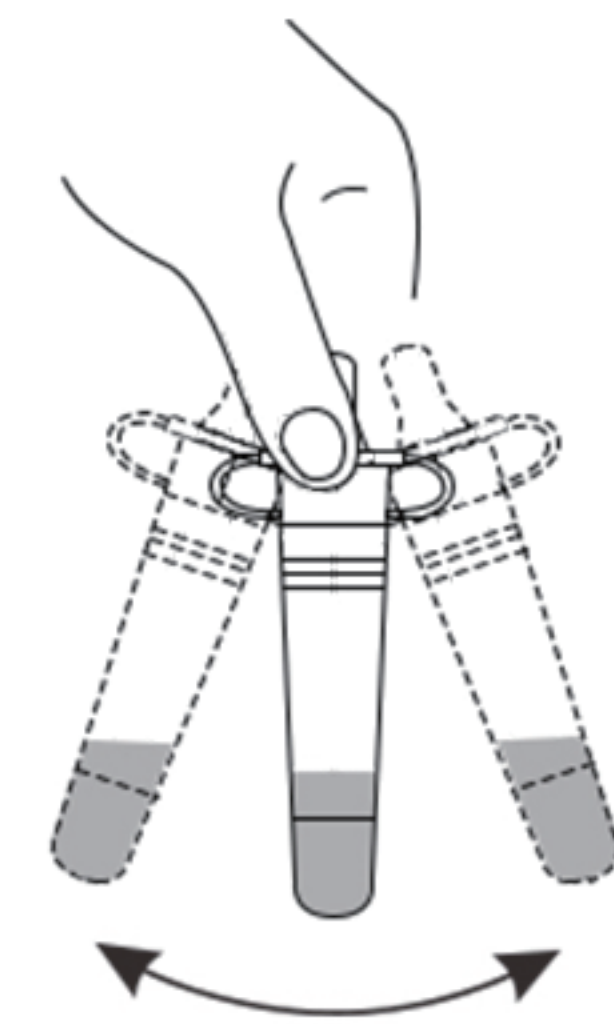
5

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



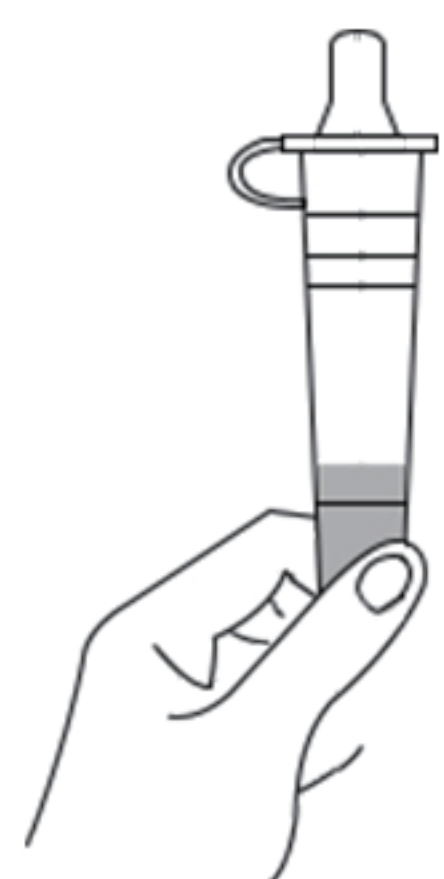
6

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



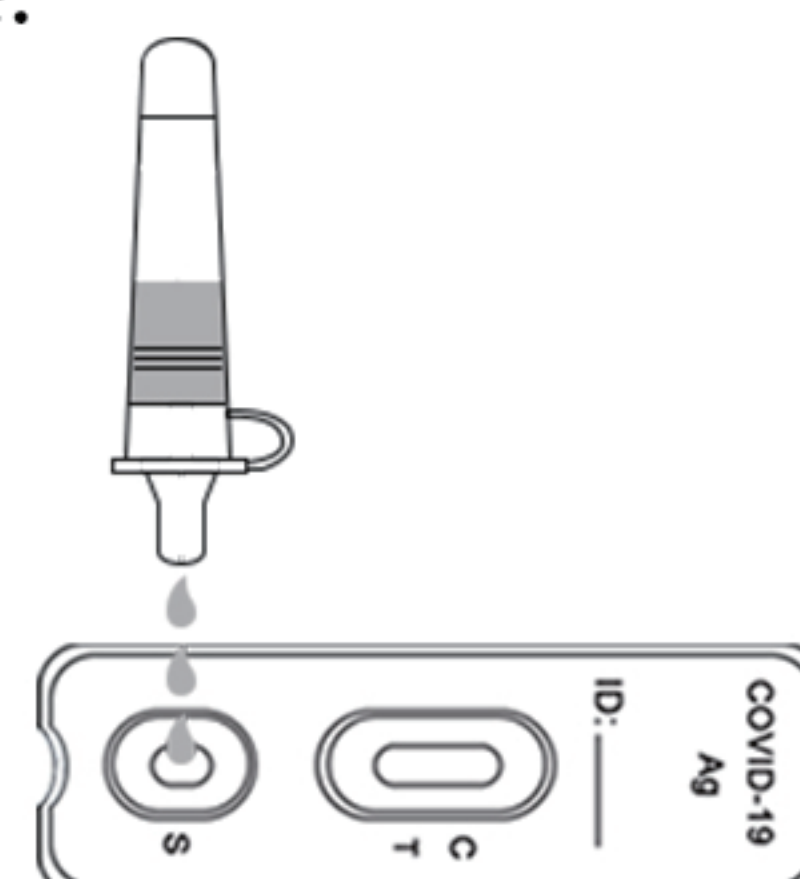
7

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



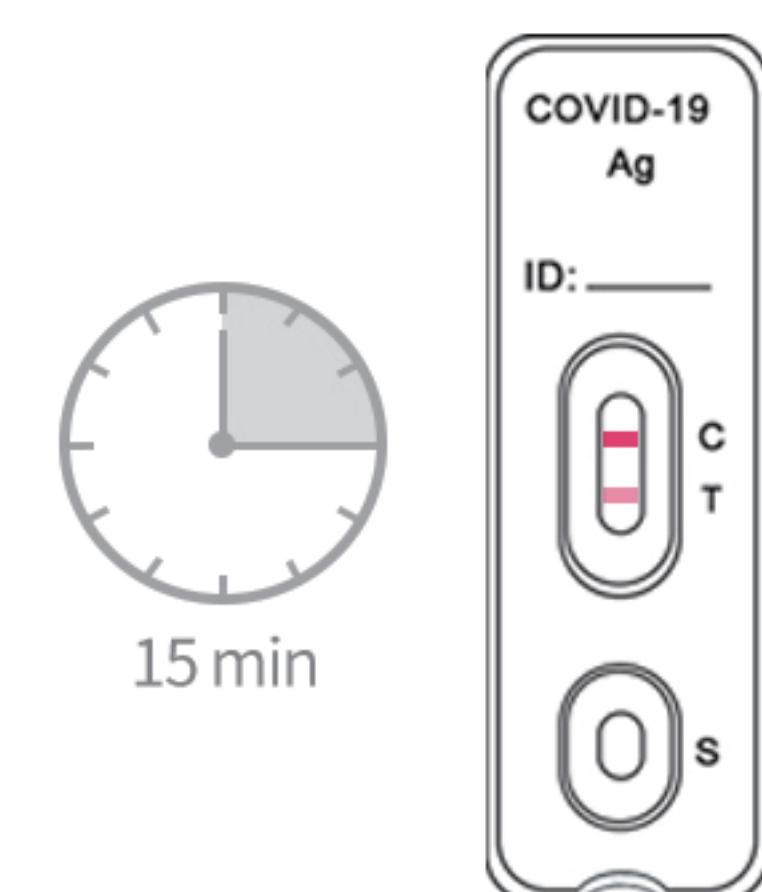
8

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



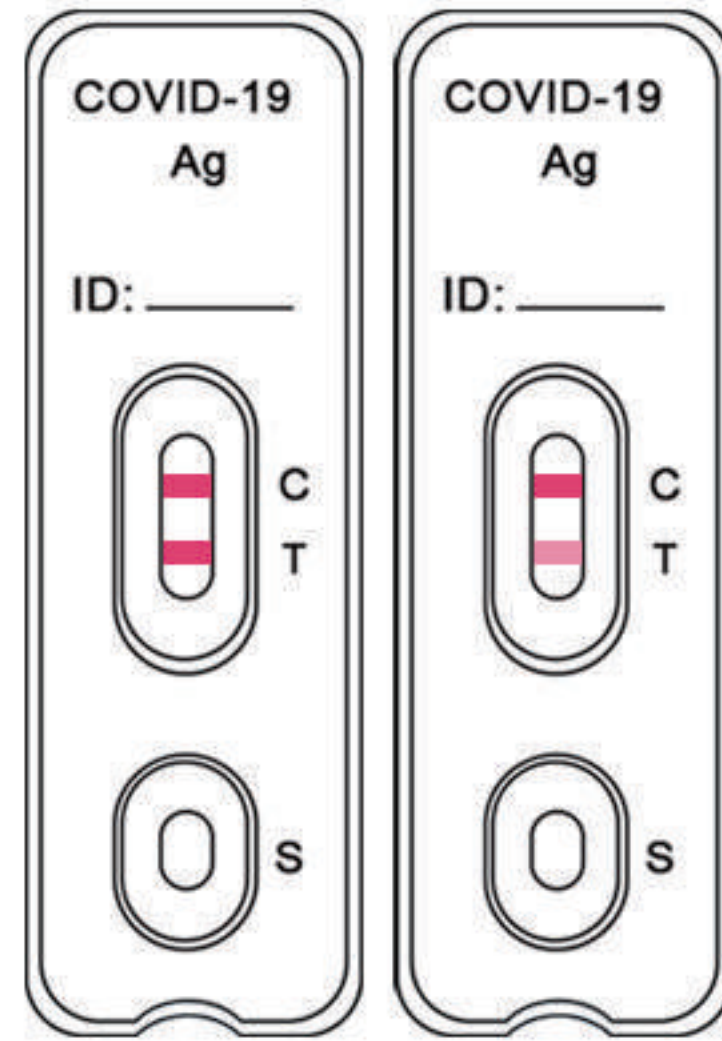
9

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





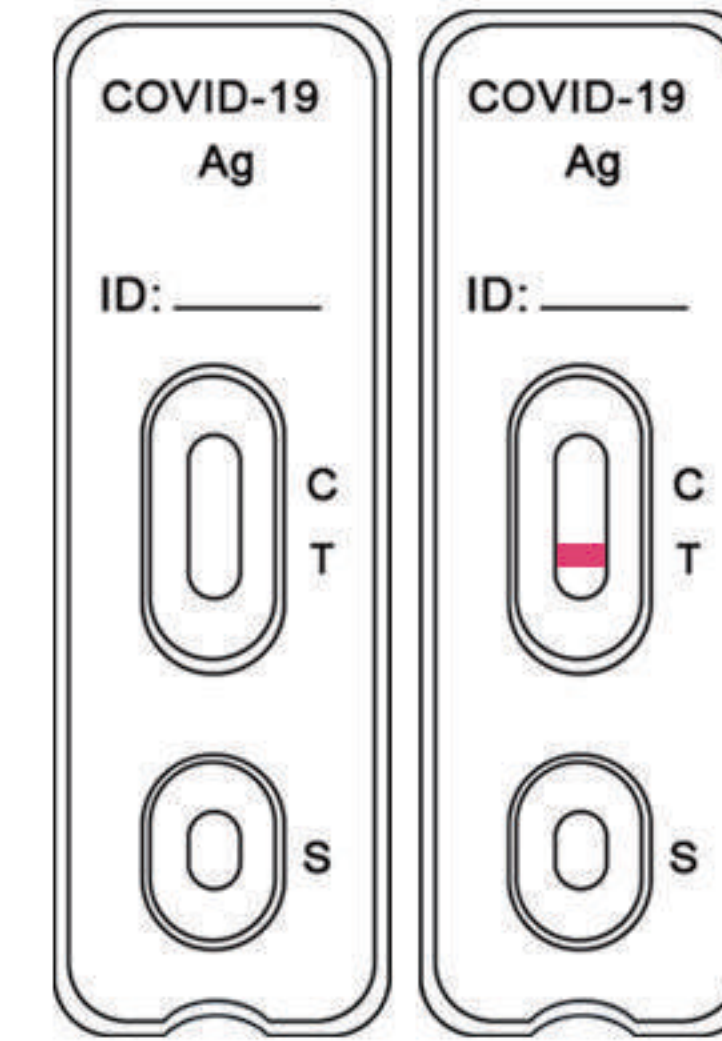
## Interpretation of Results



**Positive**



**Negative**



**Invalid**



## Performance Characteristics

### 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 $\leq 30$ )		Total
		Positive	Negative	
CLUNGENE <sup>®</sup>	Positive	120	2	122
	Negative	4	483	487
Total		124	485	609

PPA (Ct $\leq 30$ ): 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 $\leq 37$ )		Total
		Positive	Negative	
CLUNGENE <sup>®</sup>	Positive	146	2	148
	Negative	14	483	497
Total		160	485	645

PPA (Ct $\leq 37$ ): 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  $8.6 \times 10^2$  TCID<sub>50</sub> /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

18 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  $1.15 \times 10^5$  TCID<sub>50</sub> /mL of inactivated SARS-CoV-2 and no high-dose hook effect was observed.