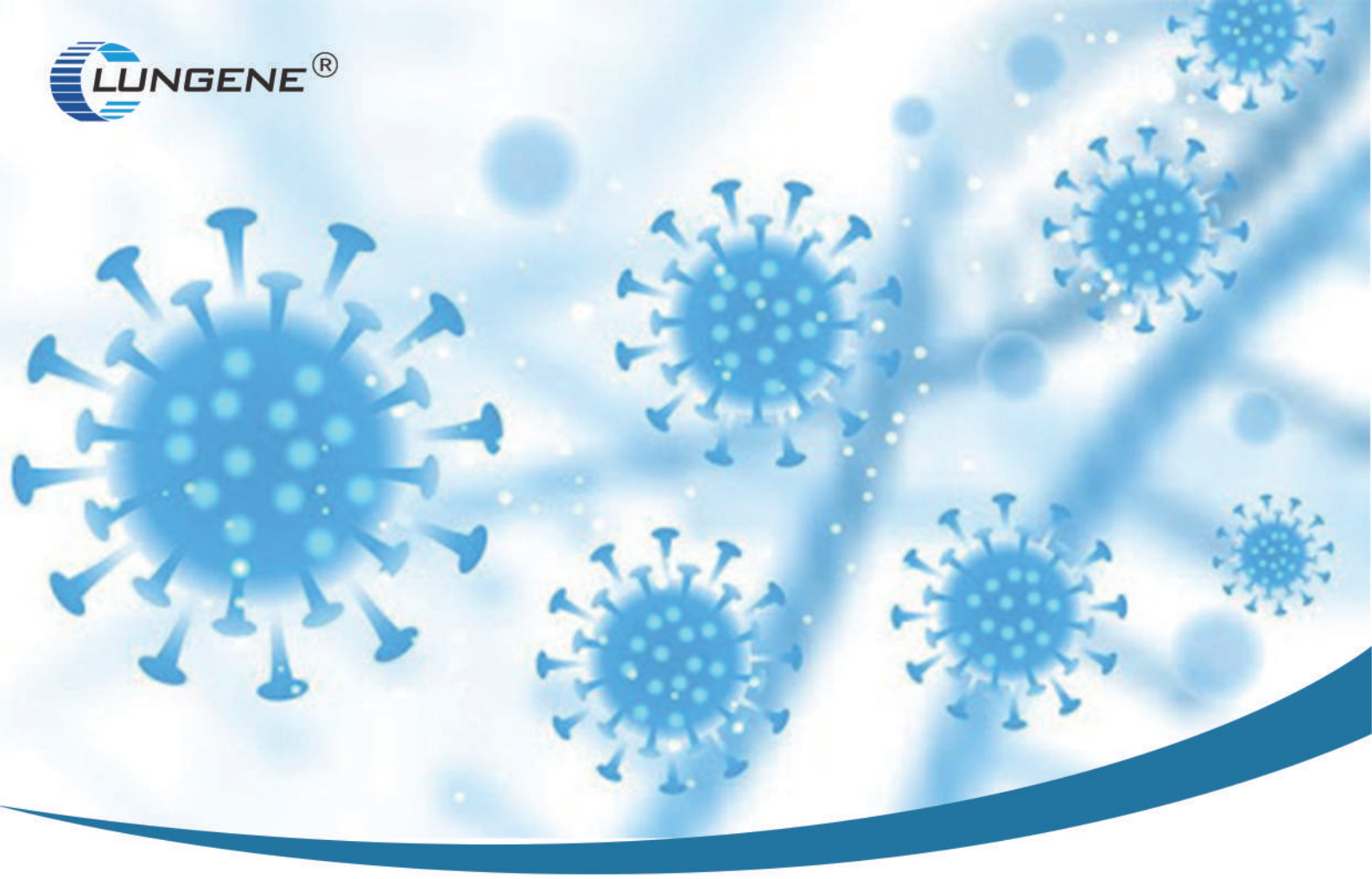
LUNGENE®



COVID-19 Antigen Rapid Test

CE

The COVID-19 Antigen Rapid Test is a lateral flow immunoassay intended for the qualitative detection SARS-CoV-2 nucleocapsid antigens in nasopharyngeal swab, nasal swab or oropharyngeal swab from individuals who are suspected of COVID-19 by their healthcare provider.

Features

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

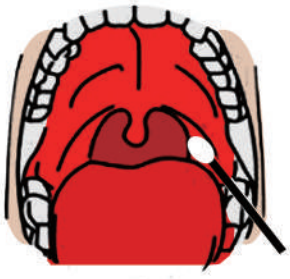
Components

Extraction Reagent Tube x 25	Sterilized Swab x 25	Test Cassette x 25	Work Station x 1	Package Insert x 1
				

Samples

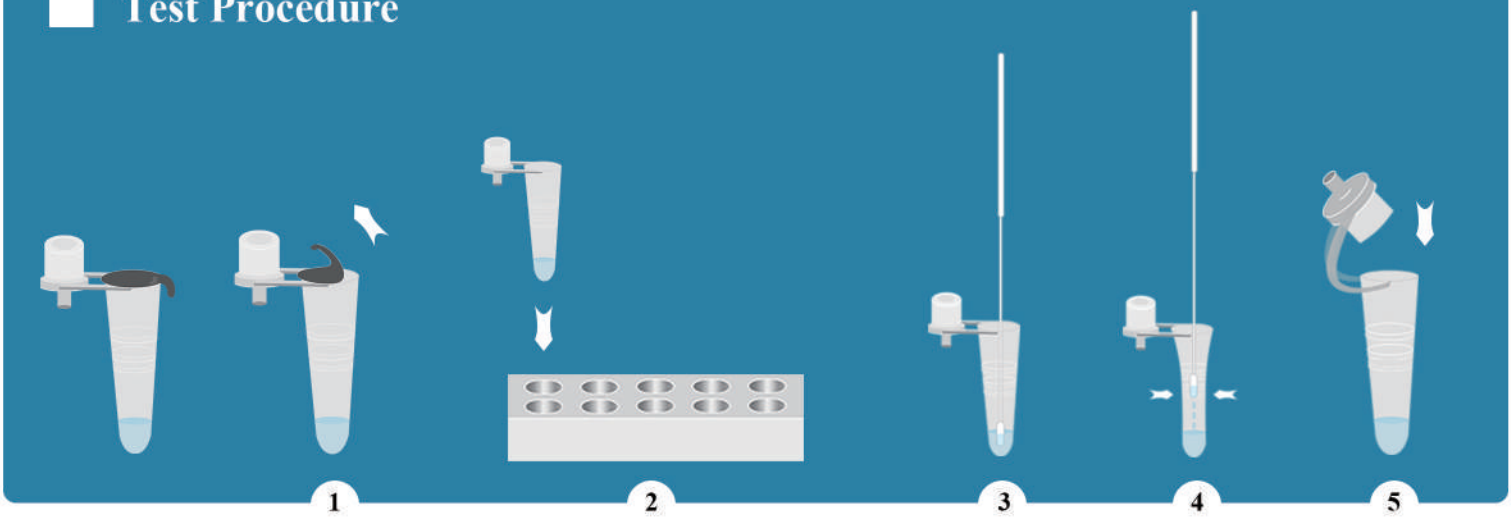
Nasopharyngeal Swab

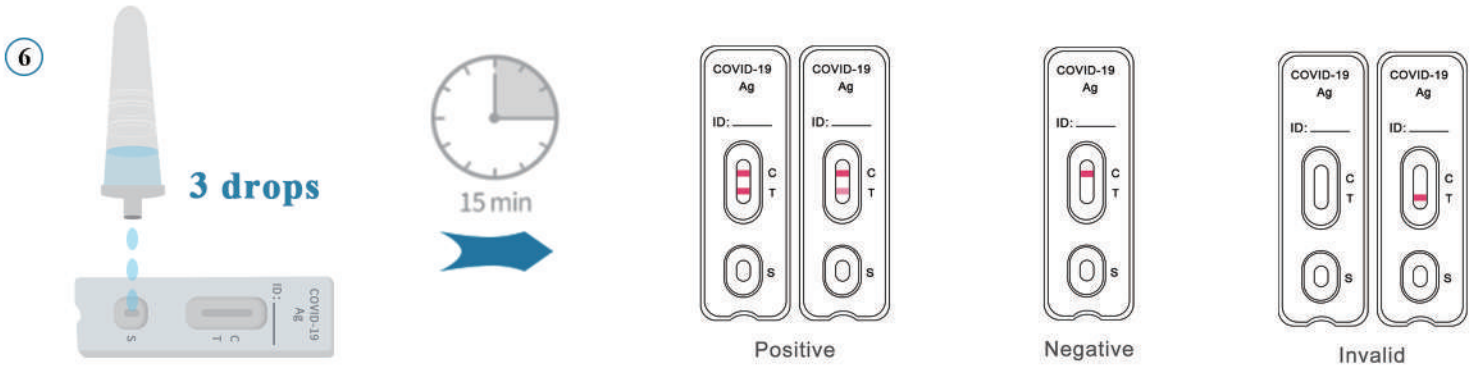
Nasal Swab



Oropharyngeal Swab

Test Procedure





Performance Characteristics

Clinical Performance

Nasopharyngeal Swab

770 nasopharyngeal swabs were collected from individual symptomatic patients by using CLUNGENE® COVID-19 Antigen Rapid Test. The RT-PCR cycle threshold (Ct) is the relevant signal value. Lower Ct value indicate higher viral load. The sensitivity was calculated for the different Ct value range (Ct value≤33 and Ct value≤37).

Summary data 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)

Nasal Swab

617 nasal swabs were collected from individual symptomatic patients by using CLUNGENE® COVID-19 Antigen Rapid Test. The sensitivity was calculated for the different Ct value range (Ct value≤33 and Ct value≤37).

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 5.7×10^2 $TCID_{50}$/mL.

Cross Reactivity (Analytical Specificity)

32 commensal and pathogenic microorganisms that may be present in the nasal cavity have been evaluted and no cross-reactivity was observed.

Interference

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

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