

COVID-19 IgG Semi-Quantitative Rapid Test Cassette (WB/S/P)



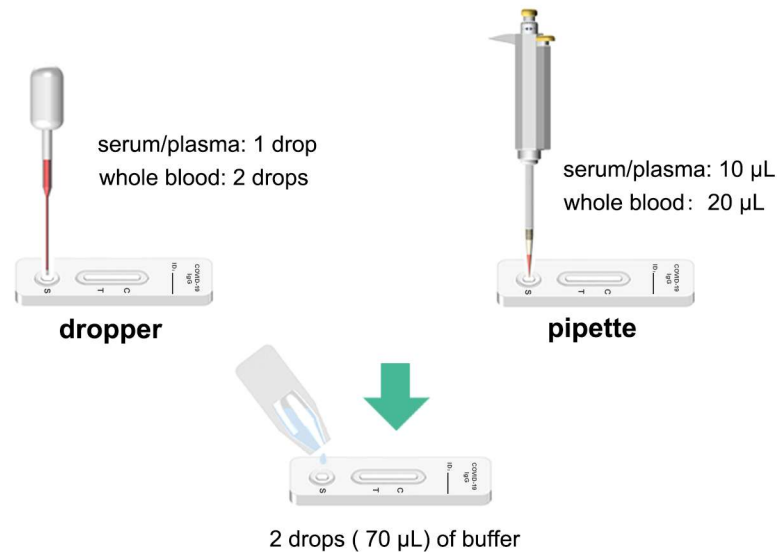
PRODUCT



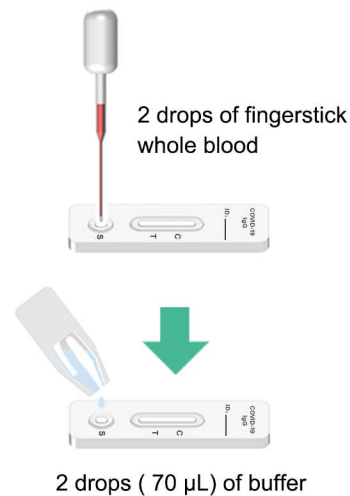
- **Target:** IgG antibody to the SARS-CoV-2
- **Sample:** Venous whole blood, serum, plasma and fingerstick whole blood
- **Quick:** Results can be read at 15 minutes
- **Results:** Accurate and reliable
- **Simple:** No equipment required
- **Valid:** 24 months

TEST

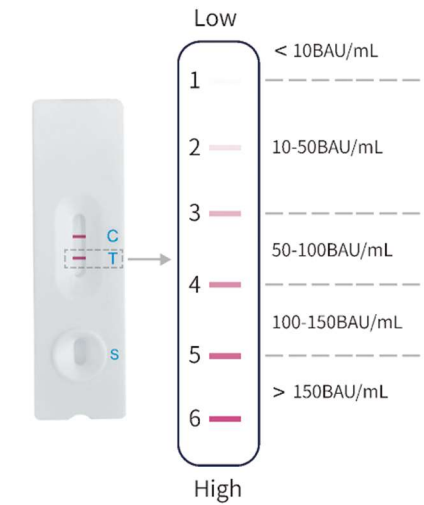
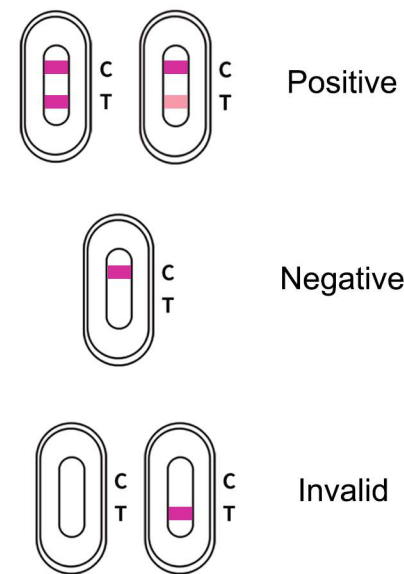
Venous whole blood/serum/plasma



Fingerstick whole blood



INTERPRETATIONS OF RESULTS



- When colored line appears at the test region (T), use the Color Card printed on the sealed pouch to compare.
- The Limit of Detection (LoD) is 10 BAU/mL with the anti-S1 IgG (NIBSC code: 20/268) which spiked into negative plasma specimens.
- IgG concentrations just for reference only.

PRODUCT PERFORMANCE

Clinical study in 386 individuals with symptoms of COVID-19

Table 1: PPA of IgG According to Days Post Onset of Symptoms

Days post symptom onset	# RT-PCR Total positive	CLUNGENE [®]		
		# of positive	PPA	95%CI
≤7	20	11	55.0%	34.21%-74.18%
8-14	65	62	95.4%	87.29%-98.42%
≥15	70	70	100.0%	94.8%-100.00%
Total	155	143	92.3%	86.57%-95.75%

Table 2: NPA

PCR Total Negative Results	CLUNGENE [®]		
	# of negative	IgG NPA	95% CI
261	260	99.6%	97.86%~99.93%

Clinical study in vaccinated individuals

Samples were collected two weeks after vaccination.

# of people vaccination	CLUNGENE [®]		
	# of positive	PPA	95% CI
26	26	100.0%	87.13%~100.00%