

Technische Blatt 1

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 ≤ 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

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 1.15×10^5 TCID₅₀/mL of inactivated SARS-CoV-2 and no high-dose hook effect was observed.