COVID-19 Antigen Rapid Test

Intended Use

COVID-19 is an acute respiratory infectious disease and people are generally susceptible. Currently, the patients infected by the SARS-CoV-2 are the main source of infection and asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

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

Performance Characteristics

➢ Clinical Performance

285 nasopharyngeal swabs were detected by COVID-19 Antigen Rapid Test and the RT-PCR.

COVID-19 Antigen		RT-PCR		Total
		Positive	Negative	
CLUNGENE®	Positive	64	0	64
	Negative	6*	215	221
Total		70	215	285

Sensitivity (PPA)= 91.4% (64/70), (95%CI: 82.5%～96.0%)

Specificity (NPA)= 100% (215/215), (95%CI: 98.2%～100%)

*The 6 discordant specimens had Ct values of 34, 36, 35.5, 34, 35, 33.

The PPA is 98.5% (64/65) (95%CI: 91.8%～99.7%) with specimens of a Ct count ≤33.

➢ Limit of Detection (Analytical Sensitivity)

The study used cultured SARS-CoV-2 virus, which is β-propiolactone and heat inactivated and spiked into nasopharyngeal swab specimen. The Limit of Detection (LoD) is $5\times10^{2.67}$ $TCID_{50}$/mL.

➢ Cross Reactivity (Analytical Specificity)

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

➢ 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.

COVID-19/Influenza A+B Antigen Combo Rapid Test

Intended Use

Influenza (Flu) is a contagious respiratory illness caused by influenza viruses. It can cause mild to severe illness. Serious outcomes of flu infection can result in hospitalization or death. COVID-19 is an acute respiratory infectious disease and people are generally susceptible. Symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

The COVID-19 / Influenza A+B Antigen Combo Rapid Test is a lateral flow immunoassay intended for the qualitative detection of SARS- CoV-2, influenza A and influenza B viral nucleoprotein antigens in nasopharyngeal swab from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider.

Performance Characteristics

➢ Clinical Performance

283 nasopharyngeal swabs were detected by COVID-19 Antigen Rapid Test and the RT-PCR. Summary of the performance of COVID-19/Influenza A+B Antigen Combo Rapid Test compared to RT-PCR:

Virus	Sensitivity	Specificity
Influenza A	88.5% (46/52), 95%CI: 77.0%~94.6%	100% (231/231), 95%CI: 98.4%~100%
Influenza B	84.4% (38/45), 95%CI: 71.2%~92.3%	99.6% (237/238), 95%CI: 97.7%~99.9%
SARS-CoV-2	91% (71/78), 95%CI: 82.6%~95.6%	100% (205/205), 95%CI: 98.2%~100%

➢ Limit of Detection (Analytical Sensitivity)

The study used cultured viruses, which are inactivated and spiked into nasopharyngeal swab specimen. The Limit of Detection (LoD) was confirmed as follows:

Virus Lineage	Limit of Detection (LoD)
SARS-CoV-2*	2.3×10^3 $TCID_{50}$/mL
Influenza A (H1N1)**	1.0×10^3 $TCID_{50}$/mL
Influenza A (H3N2)**	1.0×10^4 $TCID_{50}$/mL
Influenza A (H1N1pdm09)**	6.5×10^3 $TCID_{50}$/mL
Influenza B (Yamagata)**	3.7×10^4 $TCID_{50}$/mL
Influenza B (Victoria)**	1.0×10^3 $TCID_{50}$/mL

* Beta-propiolactone and heat-inactivated virus

** Heat-inactivated virus

➢ Cross Reactivity (Analytical Specificity)

We have evaluated 25 commensal and pathogenic microorganisms that may be present in the nasal cavity and no cross-reactivity was observed.