COVID-19 Antigen Rapid Test Cassette (Nasal Swab)

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

Performance Characteristics

➢ Clinical Performance

The clinical performance of COVID-19 Antigen Rapid Test Cassette (Nasal Swab) was established in prospective studies with nasal swabs collected from 617 individual symptomatic patients (within 7 days of onset) and asymptomatic patients who were suspected of COVID-19.

Summary data of COVID-19 Antigen Rapid Test Cassette (Nasal Swab) as below:

COVID-19 Antigen		RT-PCR(Ct value≤30)		Total
		Positive	Negative	
CLUNGENE®	Positive	117	3	120
	Negative	3	462	465
Total		120	465	585

PPA (Ct≤30):97.5% (117/120), (95%CI: 92.9%～99.2%)
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 (Isolate Hong Kong/ VM20001061/2020, NR-52282), which is heat inactivated and spiked into nasal swab specimen. The Limit of Detection (LoD) is 5.7 $\times 10^2$ $TCID_{50}$/mL.

➢ Cross Reactivity (Analytical Specificity)

Cross reactivity was evaluated by testing 32 commensal and pathogenic microorganisms that may be present in the nasal cavity.

- ✧ No cross-reactivity was observed with recombinant MERS-CoV NP protein when tested at the concentration of 50 μg/mL.

- ✧ No cross-reactivity was observed with the following viruses when tested at the concentration of 1.0×10^6 PFU/mL: Influenza A (H1N1), Influenza A (H1N1pdm09), Influenza A (H3N2), Influenza B (Yamagata), Influenza B (Victoria), Adenovirus (type 1, 2, 3, 5, 7, 55), Human metapneumovirus, Parainfluenza virus (type 1, 2, 3, 4), Respiratory syncytial virus, Enterovirus, Rhinovirus, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Human coronavirus HKU1.

- ✧ No cross-reactivity was observed with the following bacteria when tested at the concentration of 1.0×10^7 CFU/mL: Mycoplasma pneumoniae, Chlamy- dia pneumoniae, Legionella pneumophila, Haemophilus influenzae, Streptococcus pyogenes (group A), Streptococcus pneumoniae, Candida albicans,Staphylococcus aureus.

➢ Interference

The following potential interference substances were evaluated with the COVID-19 Antigen Rapid Test Cassette (Nasal Swab) at the concentrations listed below and were found not to affect test performance.

Substance	Concentration	Substance	Concentration
Mucin	2%	Whole blood	4%
Benzocaine	5 mg/mL	Menthol	10 mg/mL
Saline nasal spray	15%	Phenylephrine	15%
Oxymetazoline	15%	Histamine dihydrochloride	10 mg/mL
Tobramycin	5 μg/mL	Mupirocin	10 mg/mL
Oseltamivir phosphate	10 mg/mL	Zanamivir	5 mg/mL
Arbidol	5 mg/mL	Ribavirin	5 mg/mL
Fluticasone propionate	5%	Dexamethasone	5 mg/mL
Triamcinolone	10 mg/mL		

➢ High-dose Hook Effect

The COVID-19 Antigen Rapid Test Cassette (Nasal Swab) was tested up to 1.15×10^5 $TCID_{50}$/mL of inactivated SARS-CoV-2 and no high-dose hook effect was observed.