Humasis

Paul-Ehrlich-Institut

Humasis

COVID-19 Ag Test

provides accurate and reliable results in **15 minutes**, allowing for testing of patients suspected of COVID-19/2019-nCoV in near-patient testing environments.

Benefit

- ✓ Approved by MFDS(kFDA).
- ✓ Nasopharyngeal or Nasal Swab available
- ✓ High sensitivity and specificity at the early stage of infection.
- ✓ Easy to use and to interpret.
- ✓ Detect COVID-19 virus variants (UK, SA, Brazil, CA, NY, etc.)
- ✓ All components included in Kit. (swab approved by cytotoxicity test)

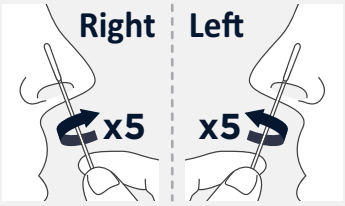
COVID-19 Antigen test can be suitable for

1) Highly growing infection rate
2) Site or environment limited in using RT-PCR Test

Ref. : European Centre for Disease Prevention and Control

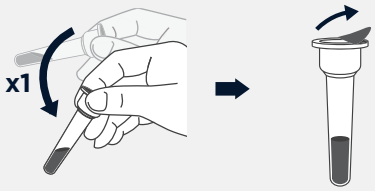
Test Procedure

Preparation of sample

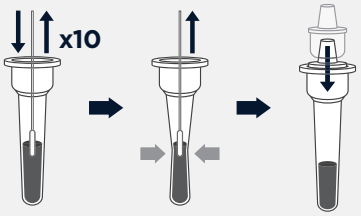


Insert the swab 1-2cm into one of the anterior nares. Rotate the swab against the nasal wall more than 5 times and withdraw.
Repeat the other anterior nare using the same swab.

1



2



3

4

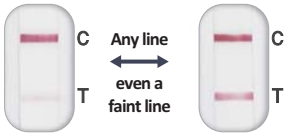
Interpretation of result

Negative

If there is ONE LINE, next to the "C" and NO LINE next to the "T", your test result is negative.

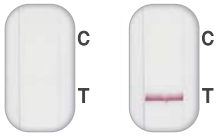
Positive

If there is TWO LINES, next to the "C" and any line next to the "T" even a faint one, you may be infected with COVID-19.



Invalid

If there is NO LINE next to the "C" like above examples, your test is not working.
Please contact the place of purchase.



Clinical Performance

● Prospective Study in various countries

1. USA

COVID-19 (Nasopharyngeal)		US FDA Emergency Use Authorized RT-PCR		Total
		Positive	Negative	
Humasis COVID-19 Ag test	Positive	28	1	29
	Negative	2	111	113
	Total	30	112	142

Clinical Sensitivity : 93.3% / Clinical Specificity: 99.1%

[Site] Hometown URGENT CARE & RESEARCH in USA, Hospital AGEL, Ruiba Hospital, Trutest laboratories. Lab VIDA

2. Algeria, Czech, India and Brazil

COVID-19 (Nasal)		US FDA Emergency Use Authorized RT-PCR		Total
		Positive	Negative	
Humasis COVID-19 Ag test	Positive	40	0	40
	Negative	3	34	37
	Total	43	34	77

Clinical Sensitivity : 93.0% (40/43 95% CI 81.4~97.6%)
Clinical Specificity: 100.0% (34/34 95% CI 89.8~100%)

3. Positive agreement by Ct value

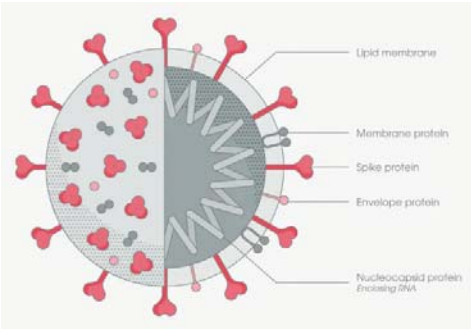
Clinical Evaluation		Nasopharyngeal
Positive Agreement % by Ct value	Ct≤24 (95% CI)	100% (63/63, 95% CI 92.3~100.0%)
	Ct≤27 (95% CI)	98.8% (82/83, 95% CI 93.5~99.8%)
	Ct≤30 (95% CI)	97.0% (96/99, 95% CI 91.5~99.0%)
	Ct>30 (95% CI)	79.2% (19/24, 95% CI 59.5~90.8%)
Positive agreement % by days from symptom onset	0~4 days (95% CI)	96.3% (78/81, 95% CI 89.87~98.7%)
	5~7 days (95% CI)	88.1% (37/42, 95% CI 75.0~94.8%)

● Variant SARS-CoV-2 inclusivity testing including live virus

Type* / Concentration	S	G	GR	UK Variant / GR Variant	GH	SA Variant / GH Variant
LoD (Limit of Detection)	Detected	Detected	Detected	Detected	Detected	Detected

*Type: sourced from Chungbuk National University, National Culture collection for Pathogens

● Humasis is continually observing spike protein occurring mutations.



Spike variant	Pseudo virus			Antigen				
	D614G	L452R	E484K	S477N	N501Y	L452R	E484K	N439K
Area	All	Europe, US(California)	South Africa, Brazil, U.K, US(New York)	Europe (20A.EU2)	U.K, South Africa, Brazil	Europe, US(California)	South Africa, Brazil, U.K, US(New York)	Europe

Humasis COVID-19 Ag Test detects various mutations.

Ordering Information

Cat No.	Product	Package	Specimens
ACOVA-7025	Humasis COVID-19 Ag Test	25 Tests/Kit	Nasopharyngeal swab

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