

Technical Bulletin

Date: December 17, 2021

Humasis COVID-19 Ag Test – The reactivity with the omicron variant

As a leading company in the IVD field, Humasis is dedicated to supporting healthcare providers. As a part of the response to the COVID-19 pandemic, Humasis is continually observing occurring mutation.

The Humasis COVID-19 Ag Test can detect the omicron variant.

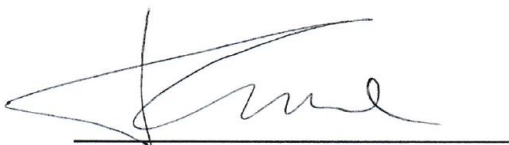
We conducted the test in South Africa, a head-to-head comparison of SARS-CoV-2 Omicron variant positive clinical samples using the TaqPath COVID-19 CE-IVD RT-PCR Kit against the Humasis COVID-19 Ag Test kits. The test revealed a 93.3% sensitivity. Please refer to the followed pages for the details.

The above statement is true for the below products.

	Product name	Catalog No.
1	Humasis COVID-19 Ag Test	ACOVA-7025
2	Humasis COVID-19 Ag Home Test	ACOVGS-7002 ACOVGS-7005 ACOVGS-7025

Thank you in advance.

Best regards,



S.H. PARK / General Manager of R&D Center
HUMASIS Co., Ltd.

ANALYTICAL METHOD VALIDATION and REPORT

Humasis COVID-19 Ag Test

Humasis Co., Ltd.

DOCUMENT NO.: CD001/21 v1.0

A head-to-head comparison of SARS-CoV-2 Omicron variant positive patients using the TaqPath COVID-19 CE-IVD RT-PCR Kit against the Humasis COVID-19 Ag Test kits revealed a **93.3% sensitivity**.

Table: Comparison of SARS-CoV-2 Omicron variant positive patients using TaqPath COVID-19 CE-IVD RT-PCR Kit and this Humasis COVID-19 Ag Test on 40 samples.

Sample ID	TaqPath COVID-19 CE-IVD RT-PCR Kit				Humasis COVID-19 Ag Research Kit Test	Result
	ORF1ab	N Gene	S Gene	IC	Positive/Negative	Pass/Fail
Neg 1	N/A	N/A	N/A	23.606	Negative	Pass
Neg 2	N/A	N/A	N/A	22.912	Negative	Pass
Neg 3	N/A	N/A	N/A	21.330	Negative	Pass
Neg 4	N/A	N/A	N/A	22.945	Negative	Pass
Neg 5	N/A	N/A	N/A	26.321	Negative	Pass
Neg 6	N/A	N/A	N/A	26.652	Negative	Pass
Neg 7	N/A	N/A	N/A	21.636	Negative	Pass
Neg 8	N/A	N/A	N/A	20.845	Negative	Pass
Neg 9	N/A	N/A	N/A	24.924	Negative	Pass
Neg 10	N/A	N/A	N/A	25.362	Negative	Pass
1	13.93	16.823	N/A	18.642	Positive	Pass
2	24.501	20.234	N/A	18.706	Negative	Fail
3	22.318	20.573	N/A	25.442	Positive	Pass
4	17.583	19.063	N/A	23.505	Positive	Pass
5	22.637	23.813	N/A	17.314	Positive	Pass
6	16.324	19.480	N/A	20.365	Positive	Pass

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7	17.892	14.641	N/A	20.630	Positive	Pass
8	23.784	23.383	N/A	23.008	Positive	Pass
9	19.787	19.588	N/A	24.741	Positive	Pass
10	14.989	11.525	N/A	22.423	Positive	Pass
11	24.737	24.364	N/A	24.977	Positive	Pass
12	23.928	20.745	N/A	23.256	Positive	Pass
13	19.490	18.296	N/A	24.120	Positive	Pass
14	21.252	20.535	N/A	15.746	Positive	Pass
15	19.375	21.017	N/A	19.574	Positive	Pass
16	21.958	18.421	N/A	23.164	Positive	Pass
17	18.214	17.116	N/A	23.771	Positive	Pass
18	19.968	19.336	N/A	17.612	Positive	Pass
19	22.542	20.394	N/A	26.626	Positive	Pass
20	14.181	15.863	N/A	16.454	Positive	Pass
21	14.030	13.916	N/A	16.671	Positive	Pass
22	16.588	11.714	N/A	20.679	Positive	Pass
23	12.419	14.019	N/A	18.755	Positive	Pass
24	23.968	24.811	N/A	24.137	Positive	Pass
25	24.098	23.818	N/A	23.997	Positive	Pass
26	18.795	17.415	N/A	23.997	Positive	Pass
27	18.788	16.981	N/A	22.704	Negative	Fail
28	20.860	19.866	N/A	24.913	Positive	Pass
29	21.71	19.866	N/A	24.913	Positive	Pass
30	17,666	16,073	N/A	19,926	Positive	Pass