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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
1	Humasis COVID-19 Ag Test
2	Humasis COVID-19 Ag Home Test

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.**

VivaMed Africa

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

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

ANALYTICAL METHOD VALIDATION and REPORT

Humasis COVID-19 Ag Test **Humasis Co., Ltd.**

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ANALYTICAL METHOD VALIDATION SUMMARY REPORT

Analytical Method validation Protocol Summary		
Ref. No.	**Test Data Sheet Title**	**Result (Pass/Fail)**
7.1	Analytical Method Validation Data	Pass
7.1.1	Method Suitability and Performance	Pass
7.1.2	Method Variability	Pass

Analytical Method Validation Report Summary	
Method Name	**Type**
Humasis COVID-19 Ag Test	Antigen detection of SARS-CoV-2

Validation Parameter	Requirements	Results (Approved / Rejected)	Pass/ Fail
Method Suitability	Humasis COVID-19 Ag Test is suitable for its intended purpose. i.e.) In terms of clinical diagnosis, the method suitability test confirms that the sample stored in PBS is suitable for use.	Approved	Pass
Method Performance	Humasis COVID-19 Ag Test meets required performance criteria. i.e.) Sensitivity is higher than 80% Specificity is higher than 80% "	Approved	Pass
Method Variability	Limited / insignificant variability observed	Approved	Pass

Statement of Conformance:	
√	The validation for this test method has been successfully completed.
N/A	Notifications were raised due to discrepancies noted during execution. These have been resolved or have been noted for further action before closure of the validation report.

FINAL REPORT APPROVAL FORM

This is to certify that the undersigned have reviewed this executed protocol and have found that all applicable requirements and criteria have been met.

Section 1: Reviewed and Approved by

Company	Name	Designation	Signature	Date
VivaMed Africa	Prof Veron Ramsuran	Senior Scientist		16 December 2021