

Technical Bulletin

Date: December 17, 2021

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

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 variants.

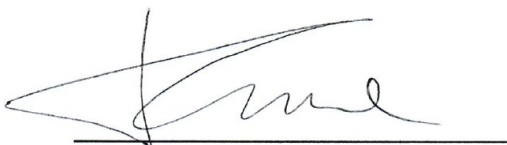
We conducted the test in South Africa, a head-to-head comparison of SARS-CoV-2 Omicron variant positive clinical samples using the TaqPath COVID-19 CE-IVD RT-PCR Kit against the Humasis COVID-19 Ag Test kits revealed a 93.3% sensitivity. Refer to the followed pages.

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.

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Figure. Ten SARS-CoV-2 Omicron Positive samples (as determined by TaqPath COVID-19 CE-IVD RT-PCR kit) run on the Humasis COVID-19 Ag Test.

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 4).

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 |

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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. | | |

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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 |