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Technical evaluation of SARS-CoV-2 antigen self-tests with Omicron variant

Evaluation Report
Final

Version 1.2 TCID50 and Ct values added
Version 1.3 Strain name updated

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This investigation was performed by order, and for the account, of the Ministry of Health, Welfare and Sport, project number V/190002/01/PR.

Introduction

The aim of this evaluation was to assess the analytical sensitivity of the SARS-CoV-2 antigen self-test components (swab, extraction buffer and procedure and test cassette) with the Omicron variant of SARS-CoV-2. The evaluation was performed in a BSL-3 laboratory at the RIVM. The protocol was performed for all providers under comparable conditions (to the extent permitted by the manufactures instructions for use) by trained laboratory personnel. All tests were performed with the same dilution series of cultured SARS-CoV-2 Omicron variant.

Materials & Methods

To assess the analytical sensitivity, a 5-fold dilution series (5-15625) was made of cultured live Omicron variant in viral transport medium GLY (Mediaproducts B.V., Groningen, The Netherlands). The Omicron variant, hCoV-19/Netherlands/NH-71076/2021; $1.69*10^6$ TDIC50/ml, was cultured from the clinical specimen on Vero-E6 cells and passaged two times. The genome sequence of the cultured virus was confirmed similar to that of the clinical specimen. Each sample of the dilution series was tested by the following procedure. The sample was mixed well by vortexing. The swab that was provided with the self-test kit was dipped (only the tip of the swab where the fibres are located) into the sample. The swab was gently rotated between thumb and index finger in the sample for 10 seconds. Subsequently, the instructions provided with the SARS-CoV-2 antigen self-test after the instruction for sample collection was followed. For documenting the result of the self-tests, the read-out of the self-test was assessed by 1 laboratory employee in accordance with the enclosed manufactures instructions. Per test, all the samples of the dilution series were tested in triplicate.

***Table 1**. information of the SARS-CoV-2 antigen self-tests provided by Dienst testen.*

Number	Supplier	Self-test kit	Batch number	Expiration date	Remarks
1	Axon Lab BV	Beright, SARS-CoV-2 antigeen snelle test voor zelftesten	ATNCP2109032-S	2022-09	Oropharynx swab
2	AEnerG Holding BV	LYHER Coronavirus (COVID-19) Antigeen Sneltest Kit voor Zelftesten	2104061	20-10-2022	Oropharynx swab
3	Mediphos Medical supplies BV	BIOsynex AUTOtest Antigenique COVID-19	2108160	2023-07	Nasopharynx swab (small tip)
4	Siemens healthineers Nederland BV	CLINITEST Rapid COVID-19 Antigen Self-Test	2105301	30-4-2023	Nasopharynx swab (small tip)
5	Mediq Medeco	Boson Biotech Rapid SARS-CoV-2 antigen test card (nasalis anterior)	21072611	2023-01	Nasopharynx swab (long tip)
6	Core Supply Group BV	MP Biomedicals Rapid SARS-CoV-2 Antigen Test Card	21052412	2022-11	Nasopharynx swab (long tip)
7	Roche	SARS-CoV-2 Rapid Antigen Test (for professional use)	QC3020079	2022-07	Nasopharynx swab (small tip)

The acceptance criteria are based on the performance of the SARS-CoV-2 antigen Self-Test kits used in the 'Technical evaluation of SARS-CoV-2 antigen self-tests' (1) and listed in Table 1. In that evaluation all the tests performed with similar Lowest Detected Concentration (LDC).
The acceptance criteria for the current evaluation with Omicron variant are therefore:

1. All the SARS-CoV-2 antigen Self-Tests need to have a similar analytical sensitivity with the Omicron variant when compared with each other.

2. The TCID50/ml range for LDC in the evaluation with the Omicron variant should be similar to that of the previous evaluation using antigen LEQA specimens with SARS-CoV-2 clade B.11 19A (WT) virus (2), taking into account that TCID50/ml is not an absolute measure for the amount of antigen/ml.

Results

***Table 2**. Results of the Omicron variant dilution series, The samples are tested in triplicate in each SARS-CoV-2 antigen self-test. The table shows how often the SARS-CoV-2 antigen self-test was determined positive.*

Dilution	Dilution Factor	Concentration TCID50/ml	Ct-value E-gene[#]	Ct-value RdRp-gene[#]	Ct-value N-gene[#]	Self-test number (Table 1) (number positive/number tested)						
						1	2	3	4	5	6	7
1	5	3.38E+05	14.15	14.57	14.16	3/3	3/3	3/3	3/3	3/3	3/3	3/3
2	25	6.76E+04	16.78	17.09	16.97	3/3	3/3	3/3	3/3	3/3	3/3	3/3
3	125	1.35E+04	18.95	19.27	19.57	3/3	3/3	3/3	3/3	3/3	3/3	3/3
4	625	2.70E+03	21.49	21.79	21.75	3/3	3/3	3/3*	3/3*	3/3	3/3	3/3*
5	3125	5.41E+02	24.21	24.56	24.51	0/3	0/3	0/3	0/3	0/3	0/3	0/3
6	15625	1.08E+02	26.32	26.69	26.63	0/3	0/3	0/3	0/3	0/3	0/3	0/3

* weak positive

[#] mean of triplicate

Discussion and conclusion

The following four SARS-CoV-2 antigen self-tests meet the criteria without discussion: Beright, SARS-CoV-2 antigeen snelle test voor zelftesten; LYHER Coronavirus (COVID-19) Antigeen Sneltest Kit voor Zelftesten; Boson Biotech Rapid SARS-CoV-2 antigen test card (nasalis anterior); and MP Biomedicals Rapid SARS-CoV-2 Antigen Test Card. The antigen self-tests BIOsynex AUTOtest Antigenique COVID-19 and CLINITEST Rapid COVID-19 Antigen Self-Test have in dilution number 4 a weak positive signal whereas the other self-tests had a clear positive signal with this dilution. These results are comparable with the results using the Roche SARS-CoV-2 Rapid Antigen Test (for professional use). The most likely cause of this observation is that the nasopharynx swabs that came with these self-tests and the Roche kit for professional use have a smaller tip compared with the other evaluated self-tests. So, the swabs with small tip absorbs less sample compared to the oropharynx swabs with larger tip and the nasopharynx swabs with longer tip. In addition, a narrower dilution series (1:5) was used compared to the previous evaluation in which 1:10 dilution series was used (1, 2) and therefore this level of difference was not observed. Nevertheless, the Lowest Detection Concentration for Omicron variant was similar to that for the SARS-CoV-2 clade B.11 19A (WT) virus included in the previous evaluation, between 541 and 2700 TCID50/ml and between 75 and 750 TCID50/ml, respectively. Taking into account that the correlation between the amount of antigen and TCID50 is not absolute. In conclusion, the performance of all self-tests is similar and not affected by the Omicron variant, and therefore meeting the pre-set criteria.

References

1. Technical evaluation of SARS-CoV-2 Self-Tests_Final_Version1, RIVM, 25 November 2021.
2. External Quality Assessment of Sites Performing SARS-CoV-2 Antigen Test Diagnostics for the Dutch Population, April 2021. Available from: https://www.rivm.nl/en/news/quality-assessment-of-sars-cov-2-antigen-test-diagnostics-good-performance-at-public-test.