



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

RIVM
Centre for Infectious Diseases
A. van Leeuwenhoeklaan 9
3721 MA Bilthoven
Postbus 1
3720 BA Bilthoven
www.rivm.nl

T 0031 (0)30 274 91 11
info@rivm.nl

Technical evaluation of SARS-CoV-2 antigen self-tests

Evaluation Report Final

Authors:

Gabriel Goderski
Hanae Abba
Wanda Han
Kamelia Stanoeva
Adam Meijer

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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). The evaluation was performed in a laboratory of 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 batch of SARS-CoV-2 antigen panel. The batch was equal to the batch used for the national external quality assessment from which the criteria were derived (1). This evaluation is intended as a direct mutual comparison of the analytical sensitivity of the SARS-CoV-2 antigen self-tests in relation to the SARS-CoV-2 antigen tests used in the Netherlands for professional use.

Material & Methods

To assess the analytical sensitivity, selected samples from the national external quality assessment panel were used (1). Samples that were selected are LEQA1_AG21-02, LEQA1_AG21-04, LEQA1_AG21-09, LEQA1_AG21-11, LEQA1_AG21-13 and LEQA1_AG21-15. Each sample was tested by the following procedure; The sample was thawed at room temperature, then the contents was mixed well by vortexing. The swab that was provided by the self-test kit was dipped (only the tip of the swab where the fibers are located) into the sample. The swab was 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 nasal collection instruction) was followed. For documenting the result of this self-tests, the read-out of the self-test was independently assessed by 2 laboratory employees in accordance with the enclosed manufactures instructions. Per test, all the samples 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
1	Siemens healthineers Nederland BV	CLINITEST Rapid COVID-19 Antigen Self-Test	2105301	30-4-2023
2	AEnerG Holding BV	LYHER Coronavirus (COVID-19) Antigeen Sneltest Kit voor Zelftesten	2104061	20-10-2022
3	Core Supply Group BV	MP Biomedicals Rapid SARS-CoV-2 Antigen Test Card	21052412	2022-11
4	Axon Lab BV	Beright, SARS-CoV-2 antigeen snelle test voor zelftesten	ATNCP2109032-S	2022-09
5	Mediphos Medical supplies BV	BIOsynex AUTotest Antigenique COVID-19	2108160	2023-07
6	Mediq Medeco	Boson Biotech Rapid SARS-CoV-2 antigen test card (nasalis anterior)	21072611	2023-01

Criteria based on performance of SARS-CoV-2 antigen tests used in Netherlands for professional use (1):

1. The test must give at least a positive result at 74989 and 7499 TCID₅₀/ml; SARS-CoV-2 variant B.11.19A (WT) (LEQA1_AG21-15 and LEQA1_AG21-02, respectively).
2. The test must give a negative result on the negative sample (LEQA1_AG21-09) from the test panel.

Results

Table 2. Results of the selected national external quality assessment panel samples, 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.

Sample ID	Concentration TCID50/ml	Self-test number (Table 1) (number positive/number tested)					
		1	2	3	4	5	6
LEQA1_AG21-02	7499	3/3	3/3	3/3	3/3	3/3	3/3
LEQA1_AG21-04	75	0/3	0/3	0/3	0/3	0/3	0/3
LEQA1_AG21-09	0	0/3	0/3	0/3	0/3	0/3	0/3
LEQA1_AG21-11	7	0/3	0/3	0/3	0/3	0/3	0/3
LEQA1_AG21-13	750	3/3	3/3	3/3	3/3	3/3	3/3
LEQA1_AG21-15	74989	3/3	3/3	3/3	3/3	3/3	3/3

Conclusion

The following SARS-CoV-2 antigen self-tests meet the criteria: CLINITEST Rapid COVID-19 Antigen Self-Test, LYHER Coronavirus (COVID-19) Antigeen Sneltest Kit voor Zelftesten, MP Biomedicals Rapid SARS-CoV-2 Antigen Test Card, Beright, SARS-CoV-2 antigeen snelle test voor zelftesten, BIOSynex AUTotest Antigenique COVID-19 and Boson Biotech Rapid SARS-CoV-2 antigen test card (nasalis anterior)

References

1. [EQA of Sites Performing SARS-CoV-2 Rapid Antigen Test Diagnostics for the Dutch Population 20210525 V2 Final](#)