

# Afprøvning af SARS-CoV-2 Antigen tests for påvisning af varianter (Delta og Omikron BA.1 og BA.2)

Testing of SARS-CoV-2 rapid antigen tests detection of variants (Delta and Omicron BA.1 and BA.2)

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## Testing of SARS-CoV-2 rapid antigen tests detection of variants (Delta and Omicron)

The SARS-CoV-2 epidemic changes repeatedly with the different number of infected persons and with new variants. This means that it is necessary to change test strategy depending on the test capacity and the prevalence of the infection. Hence, it is expected that the use of rapid antigen tests will increase whenever there is a high need or demand for tests, and the PCR capacity is not sufficient.

Therefore, it is important to make sure that the antigen-tests in use – both for professional use and for self-tests – can detect the SARS-CoV-2 variants that at any given time exist in Denmark. Lately, there has been uncertainty about whether the antigen-tests in use can detect the Omicron-variants.

The goal of this testing is to examine if the antigen-tests in use in Denmark can detect the variants of SARS-CoV-2, which exist in Denmark.

The testing at Statens Serum Institut (SSI) is a simple, quick and lab-based qualitative testing, where it is assessed whether an antigen-test can detect the Delta and Omicron variants BA.1 and BA.2 (+/-) comparable to the wild-type (the original variant, “Wuhan”). Hence, the testing cannot be considered as a quantitative performance comparison between the different types of antigen-test kits. Such examinations are investigated in comprehensive clinical studies.

The testing is performed by comparing the ability to detect the new variants (Delta and Omicron BA.1 and BA.2) with the ability to detect the wild-type by the use of dilution series of cultivated virus diluted in cell culture media.

The efficiency of detection of variants will appear in relation to the wild-type virus in the reporting for testing of each test kit. Furthermore, it will appear whether it is assessed to be satisfactory.

SSI invites manufacturers and suppliers of antigen-tests to send test kits (100 pcs.), which are in use in Denmark, for SSI to test. SSI will, when the test kits have been received, relatively quickly (app. one week from reception of the test) report if the given antigen-test are capable of detecting a new variant (for now Omicron). When future new variants occur, SSI will first be able to test the test kits when SSI has isolated the new type of virus.

Test-kits can by appointment be sent to:

Claus Nielsen  
Building 85, room 322  
Statens Serum Institut  
Artillerivej 5  
2300 Copenhagen S  
Mail: [cn@ssi.dk](mailto:cn@ssi.dk)  
Phone: +45 3268 3280

## Protocol for testing of SARS-CoV-2 rapid antigen tests for detection of variants (Delta and Omicron)

### SARS-CoV-2 isolates

Wild-type: Strain SARS-CoV-2/hu/DK/SSI-H5

Delta: Strain SARS-CoV-2/hu/DK/SSI-H11

Omicron BA.1: Strain SARS-CoV-2/hu/DK/SSI-H46

Omicron BA.2: Strain SARS-CoV-2/hu/DK/SSI-H53

The four variants of cultivated SARS-CoV-2 virus, Wuhan-like (wild-type), Delta and Omicron (BA.1 and BA.2), were all cultivated in VERO E6 cells.

Upon cytopathic effect, supernatants were frozen. Virus preparations were made from thawed and centrifuged supernatant before aliquoting and storage at -80°C. All variants had a similar Ct-value measured using E-gene RT-PCR. Portions of all three variants were on the day of the testing thawed and diluted in a 10-fold dilution series.

Variant	Isolate
Wild-type	Strain SARS-CoV-2/hu/DK/SSI-H5
Delta	Strain SARS-CoV-2/hu/DK/SSI-H11
Omicron BA.1	Strain SARS-CoV-2/hu/DK/SSI-H46
Omicron BA.2	Strain SARS-CoV-2/hu/DK/SSI-H53

### The method of testing of antigen-tests:

The wild-type variant was diluted in five steps (1:10-1:100.000) in the calibration of dilutions for every test kit. Since the wild-type virus only showed positive signals in the three first steps, these three first dilutions were used in duplicate to the assessment of the wild-type variant, Delta variant and Omicron variants BA.1 and BA.2.

Hence, the Delta- and Omicron-variants were subsequently diluted in three steps (1:10 – 1:1.000). 100 µL diluted virus was also used as a sample in all the test kits. Dilutions of the virus were made in the cell culture media; Dulbecco's Modified Eagle's Medium (DMEM).

The use of DMEM as a negative media for dilution was tested for each antigen kit in duplicate, and found negative.

### Results of testing of antigen test-kits week 51 2021:

Name of test	Manufacturer/ supplier	Variant	Dilution of variant			
			1:10	1:100	1:1.000	1:10.000
Panbio - COVID-19 Ag RAPID TEST (NASOPHYNGEAL)	Abbott	Wild-type	+	+	-	-
		Delta	+	+	(+)	nd
		Omicron BA.1	+	+	(+)	nd
		Omicron BA.2	+	+	(+)	nd
SARS-COV-2 Rapid Antigen test	Roche	Wild-type	+	+	(+)	-
		Delta	+	+	(+)	nd
		Omicron BA.1	+	+	(+)	nd
		Omicron BA.2	+	+	(+)	nd
Flowflex SARS-CoV-2 Antigen Rapid Test	Acon Biotech	Wild-type	+	+	+	-
		Delta	+	+	+	nd
		Omicron BA.1	+	+	+	nd
		Omicron BA.2	+	+	+	nd
Onsite Covid-19 Ag Rapid Test	CTK Biotech	Wild-type	+	(+)	-	-
		Delta	+	(+)	-	nd
		Omicron BA.1	+	(+)	-	nd
		Omicron BA.2	+	+	(+)	nd

Name of test	Manufacturer/ supplier	Variant	Dilution of variant			
			1:10	1:100	1:1.000	1:10.000
SARS-COV-2 Rapid Antigen test Nasal	Roche	Wild-type	+	+	(+)	-
	(Falck)	Delta	+	+	(+)	nd
		Omicron BA.1	+	+	(+)	nd
		Omicron BA.2	+	+	(+)	nd
Standard Q, Covid-19 Ag Nasal	SD Biosensor	Wild-type	+	+	-	-
	(CPH Med)	Delta	+	+	(+)	nd
		Omicron BA.1	+	+	(+)	nd
		Omicron BA.2	+	+	(+)	nd
BIOSYNEX COVID-19 Ag BSS	BIOSYNTEX	Wild-type	+	+	(+)	-
	(Carelink)	Delta	+	+	(+)	nd
		Omicron BA.1	+	+	(+)	nd
		Omicron BA.2	+	+	(+)	nd
SARS-COV-2 Antigen Self test Nasal	Roche	Wild-type	+	+	-	-
		Delta	+	+	(+)	nd
		Omicron BA.1	+	+	(+)	nd
		Omicron BA.2	+	+	(+)	nd
Rapid SARS-COV-2 Antigen Test Card	Boson Biotech	Wild-type	+	+	(+)	-
		Delta	+	+	(+)	nd
		Omicron BA.1	+	+	(+)	nd
		Omicron BA.2	+	+	(+)	nd
Covid-Rapid, SARS-COV-2 Antigen	api Pharma	Wild-type	+	(+)	-	-
(N/OP/NP)	(VINGMED/ Vicare)	Delta	+	(+)	-	nd
		Omicron BA.1	+	(+)	-	nd
		Omicron BA.2	+	+	-	nd

+: positive

(+): weak positive

-: negative

The testing showed the same results for all duplicates. Therefore, the table only shows one result for every dilution/variant.

### Results of testing of antigen test-kits week 3 2022:

Name of test	Manufacturer/ supplier	Variant	Dilution of variant			
			1:10	1:100	1:1.000	1:10.000
SARS-COV-2 Antigen Rapid test	HUGHES	Wildtype	+	+	(+)	-
(Self-testing)		Delta	+	+	+	nd
		Omicron BA.1	+	+	+	nd
		Omicron BA.2	+	+	(+)	nd
Covid-19 Antigen Detection Kit	Zhuhai Lituo	Wildtype	+	(+)	-	-
(Colloidal Gold) Self test	Biotechnology	Delta	+	+	-	nd
		Omicron BA.1	+	(+)	-	nd
		Omicron BA.2	+	+	-	nd
Covid-19 Antigen Detection Kit -	NEWGENE	Wildtype	+	(+)	-	-
Nasal Swap	Bioengineering	Delta	+	+	(+)	nd
		Omicron BA.1	+	+	-	nd
		Omicron BA.2	+	+	-	nd
One Step Test for SARS-CoV-2 An- tigen	Getein Biotech	Wildtype	+	+	(+)	-
(Colloidal Gold) Self test		Delta	+	+	(+)	nd
		Omicron BA.1	+	+	(+)	nd
		Omicron BA.2	+	+	(+)	nd
Rapid COVID-19 Antigen Self-Test	HEALGEN	Wildtype	+	(+)	-	-
		Delta	+	+	(+)	nd
		Omicron BA.1	+	+	-	nd
		Omicron BA.2	+	+	(+)	nd

+: positive

(+): weak positive

-: negative

The testing showed the same results for all duplicates. Therefore, the table only shows one result for every dilution/variant.

Results of testing of antigen test-kits week 5 2022:

Name of test	Manufacturer/ supplier	Variant	Dilution of variant			
			1:10	1:100	1:1.000	1:10.000
Coronavirus (2019-nCoV)-Anti- gentest-Self Test	HOTGEN	Wildtype	+	+	-	-
		Delta	+	+	(+)	nd
		Omicron BA.1	+	+	-	nd
		Omicron BA.2	+	+	-	nd
Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Kit	Jinwofu	Wildtype	+	(+)/-	-	-
		Delta	+	(+)	-	nd
		Omicron BA.1	+	(+)	-	nd
		Omicron BA.2	+	+	-	nd
COVID-19 (SARS-CoV-2)-Antigen test Kit	Easy Diagnosis Wuhan	Wildtype	+	(+)	-	-
		Delta	+	+	(+)/-	nd
		Omicron BA.1	+	+	-	nd
		Omicron BA.2	+	+	(+)	nd

+: positive

(+): weak positive

-: negative

nd: not done

When testing showed the same results for all duplicates, the table only shows one result for every dilution/variant.  
Different results for the duplicates are shown as (+)/-.

### Results of testing of antigen test-kits week 9 2022:

Name of test	Manufacturer/ supplier	Variant	Dilution of variant			
			1:10	1:100	1:1.000	1:10.000
SARS-CoV-2 Antigen Rapid test	Liming Bio,	Wildtype	+	(+)	-	-
	StrongStep	Delta	+	(+)	-	nd
		Omicron BA.1	+	(+)	-	nd
		Omicron BA.2	+	+	(+)	nd
SARS-CoV-2 Antigen Test Kit	Shenzhen Micro-profit Biotech	Wildtype	+	+	-	-
(Colloidal Gold)		Delta	+	+	(+)	nd
		Omicron BA.1	+	+	-	nd
		Omicron BA.2	+	+	(+)	nd
SARS-CoV-2 Spike Protein Test Kit	Shenzhen Micro-profit Biotech	Wildtype	+	(+)	-	-
(Colloidal Gold)		Delta	+	(+)	-	nd
		Omicron BA.1	+	(+)	-	nd
		Omicron BA.2	+	+	(+)	nd
COVID-19 NASAL Self test	toda pharma	Wildtype	+	(+)	-	-
		Delta	+	+	(+)	nd
		Omicron BA.1	+	+	-	nd
		Omicron BA.2	+	+	(+)	nd
SARS-CoV-2 Antigen Rapid test kits for self testing	LEPU MEDICAL	Wildtype	+	(+)	-	-
		Delta	+	(+)	-	nd
		Omicron BA.1	+	(+)	-	nd
		Omicron BA.2	+	+	+	nd

+: positive

(+): weak positive

-: negative

The testing showed the same results for all duplicates. Therefore, the table only shows one result for every dilution/variant.

### Conclusion:

The testing of the 23 tested antigen tests shows that all tests can detect Delta and Omicron BA.1 and BA.2 on a comparable level with the wild-type (Wuhan). Differences in the general level of detection of variants (positive with different dilutions) between the different tests can be due to differences in applicability of using a uniform cell culture media to dilute virus in the testing. Therefore, these differences should not be interpreted as differences in the performance of the tests to detect SARS-CoV-2 in clinical tests.

The overall conclusion is that the antigen tests, which are currently in use in Denmark, can detect the variants Delta and Omicron BA.1 and BA.2.