

## Sammenligning af selvtest købt i november – december 2021

Nedenstående viser hvorledes de selvtest der er indkøbt i perioden november – december 2021 performer i forskellige studier og lister over selvtest.

### 1. Titel: Comparative sensitivity evaluation for 122 CE-marked rapid diagnostic tests for SARS-CoV-2 antigen, Germany, September 2020 to April 2021

Udgivet af: Scheiblaue et al.

Udgivet i: Euro Surveill. 2021;26(44):pii=2100441)

Udgivet d. 4. november 2021

Kommentar: Studiet blev anvendt til validering af test ved de tyske myndigheder.

Resultater for indkøbte tests:

TESTS	PRODUCENT	SENSITIVITET			
		Cq $\leq$ 25	25<Cq<30	Cq>30	Cq 17-36
Biosynex COVID-19 Ag BSS	Biosynex SA	100,0%	78,3%	11,1%	74,0 %
SD Biosensor Roche	SARS-Cov2 Rapid Antigen Test	88,9%	30,4%	0,0%	46,0 %
Xiamen Boson Biotech Co., Ltd	Boson SARS-CoV2 antigenest	100,0%	43,5%	0,0%	54,0 %
Flowflex SARS-CoV2-antigenest	Acon Biotech Co, Ltd	94,1%	4,3%	0.0%	34,0 %

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

Udgivet af: Statens Serum Institut

Udgivet i: <https://www.ssi.dk/aktuelt/nyheder/2022/antigenest-undersoger-for-varianter>

Senest opdateret d. 02.02.2022

Kommentar: De to selvtest med Acon Biotech som fabrikant er samme test. Den ene er blot markedsført under Acon Biotechs eget varemærke mens den anden er under varemærket Hughes Healthcare. Afprøvningsne af de to tests er ikke sket på samme tid, hvilket kan begrunde forskellen på testresultatet på Wildtype varianten med en fortynding på 1:1000

Resultater for indkøbte tests:

Navn på test	Fabrikant/Varemærke	Type	Fortyndet variant		
			1:10	1:100	1:1000
SARS-COV-2 Antigen Self test Nasal	Roche	Wildtype	+	+	-
		Delta	+	+	(+)
		Omnikron	+	+	(+)
Flowflex SARS-CoV-2 Antigen Rapid Test	Acon Biotech	Wildtype	+	+	+
		Delta	+	+	+
		Omnikron	+	+	+

Rapid SARS-COV-2 Antigen Test Card	Boson Biotech	Wildtype	+	+	(+)
		Delta	+	+	(+)
		Omnikron	+	+	(+)
SARS-COV-2 Antigen Rapid test (Self-testing)	Acon Biotech/Hughes Healthcare	Wildtype	+	+	(+)
		Delta	+	+	+
		Omnikron	+	+	+
BIOSYNEX COVID-19 Ag BSS	Biosynex	Wildtype	+	+	(+)
		Delta	+	+	(+)
		Omnikron	+	+	(+)

Forklaring:

+: positive

(+): weak positive

-: negative

### 3. Titel: A nationwide analytical and clinical evaluation of 46 rapid antigen tests for SARS-CoV-2 compared to RT-qPCR

Udgivet af: Schneider et al.

Udgivet i: Afventer publicering

Kommentar: Det danske valideringsstudie blev gennemført på Hvidovre Hospital med støtte fra Danske Regioner. Bemærk at Boson testen ikke blev indmeldt til at deltage i studiet.

Navn på test	Fabrikant/Leverandør	Sensitivitet
Flowflex SARS-CoV-2 Antigen Rapid Test	Acon Biotech	94%
SARS-COV-2 Antigen Self test Nasal	Roche	87%
BIOSYNEX COVID-19 Ag BSS	Biosynex	84%
Rapid SARS-COV-2 Antigen Test Card	Boson Biotech	Deltog ikke i studiet

### 4. Titel: A common list of COVID-19 rapid antigen tests

Udgivet af: EU Kommissionen

Link: [https://ec.europa.eu/health/system/files/2022-02/covid-19\\_rat\\_common-list\\_en.pdf](https://ec.europa.eu/health/system/files/2022-02/covid-19_rat_common-list_en.pdf)

Senest opdateret d. 10 februar

Manufacturer	RAT commercial name	Clinical performance As reported by independent validation studies	Clinical performance Data by manufacturer
Acon Biotech	Flowflex SARS-CoV-2 Antigen Rapid Test	<i>Prospective clinical field study</i>	Nasal swab

		<p><b>FIND evaluation</b> CH (9 June 2021) 279 samples, nasal swab. Sensitivities: Days &lt; 7: 92.2%; Ct &lt; 33: 98.3%; Ct &lt; 25: 100%. Specificity: 99.5%</p> <p><b>Retrospective in vitro study</b></p> <p><b>DE:</b> Positive evaluation by Paul-EhrlichInstitut (PEI): Sensitivity of 94,1% at Ct &lt; 25;</p> <p>Manufacturer specificity: 99.54%</p>	<p>Clinical Sensitivity: 97.1 % Clinical Specificity: 99.5 %</p> <p>NP swab Clinical Sensitivity: 97.6 % Clinical Specificity: 99.4 %</p>
Roche (SD BIOSENSOR)	SARS-CoV-2 Rapid Antigen Test Nasal	<p><b>Prospective clinical field study</b></p> <p><b>FIND evaluation DE</b> (12 April 2021) 179 samples, nasal swab.</p> <p>Clinical sensitivities: Days &lt; 7: 81.2%; Ct &lt; 33: 87.5%; Ct &lt; 25: 100%; Clinical specificity: 99.3%</p> <p><b>Brazil</b> (12 April 2021) 214 samples, nasal swab.</p> <p>Clinical sensitivities: Days &lt; 7: 81.2%; Ct &lt; 33: 91.7%; Ct &lt; 25: 100%;</p> <p>Clinical specificity: 99.3%</p> <p><b>Retrospective in vitro study</b></p> <p><b>DE:</b> Positive evaluation by Paul-EhrlichInstitut (PEI): Sensitivity of 89.6% at Ct &lt; 30;</p>	<p>Clinical Sensitivity: 89.6 % ( Ct ≤ 30) 93.1 % (Ct ≤ 27) Clinical Specificity: 99.1 % Nasal swab</p>

		Manufacturer specificity: 99.1%	
BIOSYNEX SWISS S.A.	BIOSYNEX COVID-19 Ag BSS	<b>Prospective clinical field study</b>	96% sensitivity, 100% specificity, NP/Nasal swab
		<p><b>BE[6]:</b> Small-scale head-to-head comparison of 5 RATs in Belgian hospital lab. Biosynex overall sensitivity (Ct range 14.6 – 35.5): 52/58 samples (89.7%). Sensitivity for Ct≤25: 18/18 samples. Overall specificity only 46.2%, probably linked to the use of transport medium instead of the swab included in the kit.</p> <p><b>FR:</b> NP swabs, prospective study (71/71) : sensitivity 100% (45/45, specificity 100%</p> <p><b>NL:</b> Independent field study, mainly symptomatic individuals (n=568, PCR positive n=39), NP swab ; sensitivity Ct≤30: 96.0%, sensitivity ≤25:100%; Specificity overall: 100%</p> <p><b>NL:</b> Independent field study, symptomatic individuals (n=270, PCR positive n=17), NP+OP swab; sensitivity Ct≤30: 94.1%, sensitivity Ct≤25: 100%; specificity overall: 100%</p> <p><b>SE:</b> Karolinska hospital evaluation of Lot 20100103. Patient samples; 95 PCR positive, 150 negative.</p>	

		<p>No detailed sample description available. Sensitivity 76%, specificity 96%. Sensitivity Ct</p> <p><b><u>Retrospective in vitro study</u></b></p> <p>DE: Positive evaluation by Paul-EhrlichInstitut (PEI): Sensitivity of 100% at Ct &lt; 25; Manufacturer specificity: 100%</p>	
Xiamen Boson Biotech Co. Ltd	Rapid SARS-CoV-2 Antigen Test Card	<p><b><u>Retrospective in vitro study</u></b></p> <p><b>DE:</b> Positive evaluation by Paul-EhrlichInstitut (PEI): Sensitivity of 100% at Ct &lt; 25; Manufacturer specificity: 99.03%</p>	<p>96.08% sensitivity 99.14% specificity NP swab</p> <p>96.19% sensitivity 99.2% specificity Nasal swab</p> <p>96.23% sensitivity 99.2% specificity OP swab</p>