novacheck®

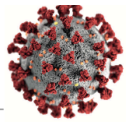
CE 1434

Science&Care

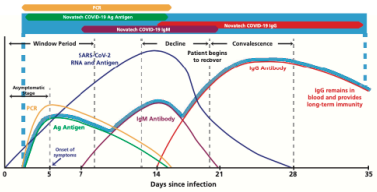
Novacheck® SARS-CoV-2 Antigen Rapid Test Selftest

PEI evaluated

Assay Format	Lateral flow test Immuno-chromatographic in vitro test
Test Type	Qualitative
Instrument	Device-free
Sample Material	Nasal
Target Antigen	Nucleocapsid (N)
Readout time	15 minutes
Sensitivity	95.91%
Specificity	99.9%
Storage temperature	2- 30 °C



Screening

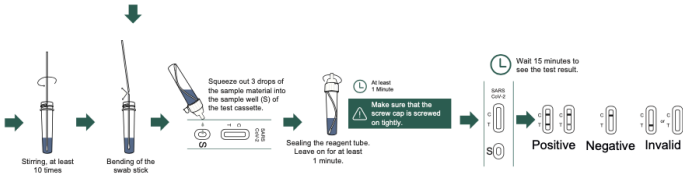


SARS- CoV-2, also known as the Covid-19 virus, causes an acute respiratory infectious disease. The main source of infection is currently people infected with the virus, even those who have an asymptomatic course. According to recent epide-miological studies, the incubation period varies from 1 to 14 days, but mostly from 3 to 7 days.

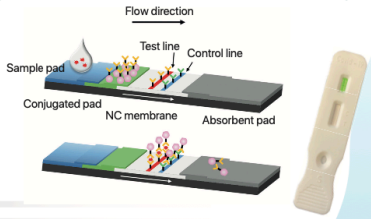
Pandemic can only be contained by interrupting the transmission of infection. Considering that most transmission is caused by asym-ptomatic virus carriers, systematic and repeated screening of the population has a very special role. Without screening, we deprive ourselves of the opportunity to prevent further de-escalation.

Novacheck® SARS-CoV-2 Antigen Rapid Test

The Novacheck® SARS-COV-2 Antigen Rapid Test is an immunochromatographic assay for the qualitative detection of SARS-COV-2 nucleocapsid antigen in human nasal swabs. For nasal sampling, the sample is collected from the anterior region of the nose.



How does Lateral Flow Antigen Rapid Test work?



Clinical Validation

The SARS-COV-2 rapid test kit was performed on 342 nasal swabs collected from symptomatic patients who had symptom onset within 7 days. A limited number of patients with symptom onset for more than 7 days and asymptomatic patients were included in the clinical study (n=342). The sample size was relatively significant, positive agreement 95.91% (328/342) and negative agreement 99.9% (517/517). The test is designed for lay user.

Method		PCR		
	Result	positive	negative	Final result
Novacheck	positive	328	0	328
	negative	14	517	531
Final result		**342**	**517**	**859**

Sensitivity: 95.91% [328/342] (95% CI: 93.86-99.04)
Specificity: 99.9% [517/517] (95% CI: 98.53-100.00)
Accuracy: 98.37% (517+328) ÷ (328+0+14+517)

Eurosurveillance Evaluation

Eurosurveillance

EU common list

Experts from the Paul Ehrlich Institute, in collaboration with researchers from other institutions, examined a total of 122 COVID-19 antigen rapid tests for sensitivity and thus for their ability to detect the SARS-CoV-2 virus.

The result:
The quality of the tests varied widely. The Novacheck® SARS-CoV-2 Antigen Rapid Test was among 96 rapid antigen tests that met the required criteria; 26 tests did not provide the required sensitivity.

CERTIFICATE

EC Certificate No. 1434-IVDD-009/2022
EC Design-examination
Directive 98/79/EC concerning
in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that manufactured by:

NOVATECH TIBBI CIHAZ ÜRÜNLERI SANAYI VE TICARET A.Ş.
2.Organize Sanayi Bölgesi Hacı Sani Konukoğlu Bulvarı
83228 Nolu, Sokak No: 17 Sehitkamil / Gaziantep, Turkey

in vitro diagnostic medical devices
for self-testing

Novacheck® SARS-CoV-2 Antigen Rapid Test MY-28

in terms of design documentation, comply with requirements
of Annex II (Section 4) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 21.01.2022 to 27.05.2025
The date of issue of the Certificate: 21.01.2022
The date of the first issue of the Certificate: 21.01.2022

CE 1434

Issued under the Contract No. MD-154/2021
Application No: 272/2021
Certificate bears the qualified signature.
Warsaw, 21/01/2022
Module: A1

Aleksandra Kostrzewa
Digitally signed by Aleksandra Kostrzewa
President

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PEI evaluiert

EU common list

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