novacheck®

SARS CoV-2 COVID-19 Antigen Rapid Test Kit

Science&Care

PEI evaluated

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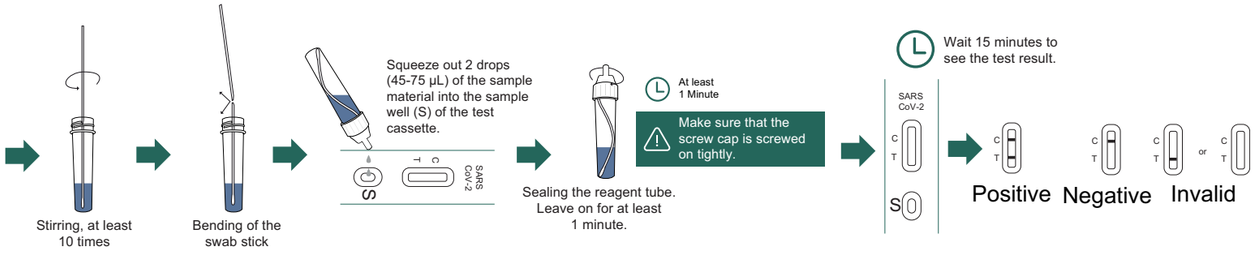
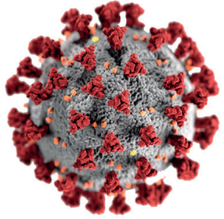


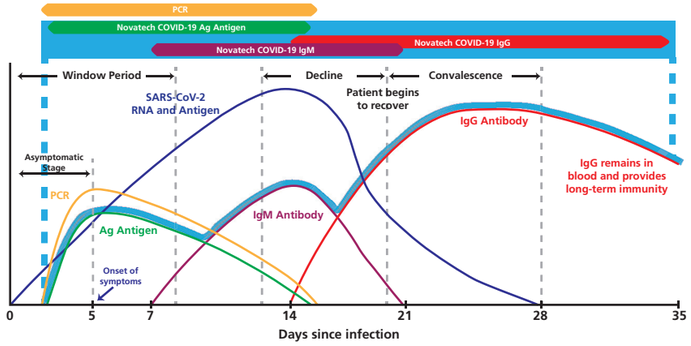
Assay Format	Lateral flow test Immuno-chromatographic in vitro test
Test Type	Qualitative
Instrument	Device-free
Sample Material	Nasopharyngeal, Nasal, Oropharyngeal
Target Antigen	Nucleocapsid (N)
Readout time	15 minutes
Sensitivity	97.54%
Specificity	100.00%
Storage temperature	2- 30 °C



Novacheck-Ag Antigen Rapid Test

The Novacheck® SARS-COV-2 NASAL 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; for nasopharyngeal sampling, the sample is collected from the nasopharynx; and for oropharyngeal, the sample is collected from the oropharynx.

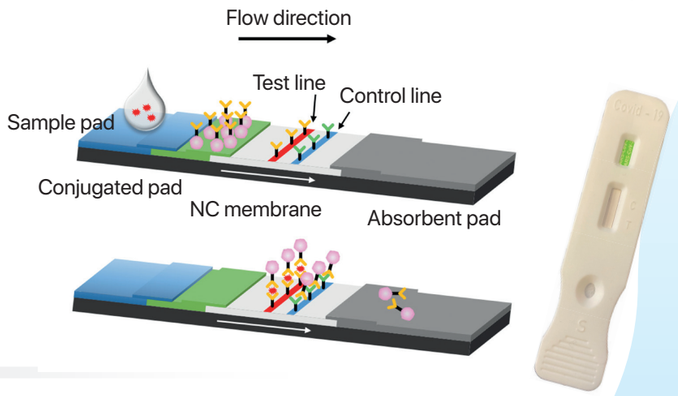
Screening



Pandemic can only be contained by interrupting the transmission of infection. Considering that most transmission is caused by asymptomatic 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.

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 epidemiological studies, the incubation period varies from 1 to 14 days, but mostly from 3 to 7 days.

How does Lateral Flow Antigen Rapid Test work?



Clinical Validation

The SARS-COV-2 rapid test kit was performed on 163 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 = 163). The sample size was relatively significant, positive agreement 97.54% (159/163) and negative agreement 100.00% (257/257). The test is designed for professional use.

Methode		PCR		
	Ergebnis	Positiv	Negativ	Endergebnis
Novacheck	Positiv	159	0	159
	Negativ	4	257	261
Endergebnis		**163**	**257**	**420**

Sensitivität: 97,54% [159/163] (95% CI: 93.86-99.04)
Spezifität: 100,00% [257/257] (95% CI: 98.53-100.00)
Genauigkeit: 99,04% (257+159) ÷ (159+0+4+257)

Eurosurveillance

EU common list

Eurosurveillance Evaluation

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.


Technical Universal Verification

CERTIFICATE

This Certificate has been awarded to:

NOVATECH TIBBİ CİHAZ ÜRÜNLERİ SANAYİ VE TİCARET A.Ş.

BAŞPINAR OSB MAH. 2. BÖLGE 83228 NOLU CAD. CİNDİOĞLU SİT. NO:17

ŞEHİTKÂMİL - GAZİANTEP - TURKEY

In Recognition of the Organisation's Management System which complies with:

ISO 13485 : 2016

For the Scope of Activities described below:

COVID 19 AND PREGNANCY TEST KIT PRODUCTION AND SALES

Certificate No : 4172

Date of Audit : 13.03.2020

Date of Registration : 04.05.2020

Reissue Date : -

Expiry Date : 03.05.2021

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NAC

FR 32/02.04.2020/REV.04


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In Recognition of the Organisation's Management System which complies with:

ISO 9001 : 2015

For the Scope of Activities described below:

COVID 19 AND PREGNANCY TEST KIT PRODUCTION AND SALES

Certificate No : 1298

Date of Audit : 13.03.2020

Date of Registration : 04.05.2020

Reissue Date : -

Expiry Date : 03.05.2021

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Technical Universal Verification

CERTIFICATE

OF ATTESTION FOR TECHNICAL FILING FOR

Üreticinin Ticari Ünvanı & Legal Entity : NOVATECH TIBBİ CİHAZ ÜRÜNLERİ SANAYİ VE TİC. A.Ş.

Adres & Address : 2. Organize San. Bölgesi Hacı Sani Konukoglu Bulvarı 83228 Nolu Cadde No:17 Şehitkamil - Gaziantep / TÜRKİYE

Listelenen ürünlerine ait üretim yerlerini, kritik tedarikçilerini, yapım özelliklerini ve uygulanabilir teknik düzenleme standartlara ait raporları da içeren teknik dosyaları incelenmiş, Covering production place, critical suppliers, construction specifications and reports regarding applicable technical regulations and standards of below its listed products has been reviewed and concluded that it fulfils the requirements of.

98 / 79 / EC Vucut Dışında Kullanılan Tanı Cihazları Yönetmeliği Ek III & 98 / 79 / EC In-Vitro Diagnostic Devices Directive Annex III.

AT Direktifleri şartlarını karşıladığı kanaatine varılmıştır. İş bu sertifika Bir Şahitlik sertifikası olup Onaylanmış Kuruluş gerektirmeyen ürünler için düzenlenmiştir. EU directives it has come to the conclusion that it meets the conditions. This certificate is a Witness certificate and is issued for products that do not require a Notified Body.

Ürünler(& Product(s): SARS - COV-2 Tıbbi Tanı Test Kiti (Koloidal Altın) IgG / IgM Antikor

GMDN Kodu & GMDN Code: 64756

Teknik Doküman & Technical Documentation: 10/07/2020 Rev.00

İlgili Standartlar & Relevant Standards: EN ISO 13485:2016, EN ISO 18153-1:2004,EN 13612:2002, EN ISO 15223-1:2016, EN ISO 18113-2:2014, EN ISO 17511:2004, EN ISO 14971:2019, EN ISO 18113-1:2004

Verilme Tarihi & Date of Issue: 30.11.2020 Geçerlilik Tarihi & Expiry Date: 29.11.2022 Sertifika No & Certificate No: MDD/2020/1055

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GAZİANTEP - TURKEY

In Recognition of the Organisation's Management System which complies with:

ISO 22716 - GMP

For the Scope of Activities described below:

PRODUCTION, SALES AND STORAGE SARS CoV-2 (COVID 19) ANTIBODY AND ANTIGEN TESTS, PREGNANCY TEST KIT AND BLOOD GLUCOSE MONITORING SYSTEMS FOR SELF-TESTING IN MANAGING DIABETES MELLITUS

Certificate No : 10015

Date of Audit : 02.06.2020

Date of Registration : 19.08.2020

Reissue Date : 30.04.2021

Expiry Date : 18.08.2022

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FR 32/17.03.2021/REV.02

PEI evaluiert

EU common list

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