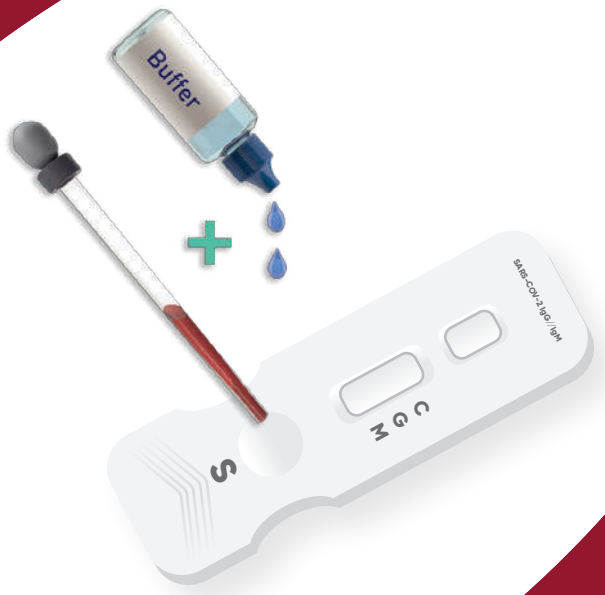


novacheck®

Diagnostic Kit for IgG/IgM Antibody to SARS-Cov-2

(Colloidal Gold)

ABOUT COVID-19 RAPID TEST KIT

This test has CE Marking for professional use only. The Novacheck ® COVID-19 quick test identifies the body's response to the corona virus after the onset of infection and gives a qualitative yes / no result within 15 minutes.Implementing rapid screening for COVID-19 saves a lot of time and cost compared to laboratory screening and will help control the spread of the virus by identifying the infection quickly and accurately.The test kit is easy to use, just like a blood glucose test, it just needs a drop of blood sample from the finger.In addition to whole blood, the test kit can also be run with serum or plasma samples.

Why Do We Need Antibody Tests for COVID-19?

Diagnosing viral infections currently relies on two major methodologies: Reverse Transcription Quantitative Polymerase Chain Reaction (RT-qPCR) and serological immunoassays that detect viral-specific antibodies (IgM and IgG) or antigens.Although, RT-qPCR is a highly sensitive test for SARS-CoV-2 (the virus that causes COVID-19) it has its limitations. RT-qPCR requires high-quality nasopharyngeal swabs containing sufficient amounts of viral RNA. This can be a challenge because the amount of viral RNA not only varies tremendously between patients, it can also varies within the same patient depending on the timing of the test and the start of the infection and/or the onset of symptoms. In addition, nasopharyngeal swabs are not only very unpleasant to the patient, the sampling techniques vary significantly from nurse to nurse. Without sufficient viral RNA RT-qPCR can return a false negative test result. RT-qPCR also requires highly trained personnel to perform complex RNA extraction steps and PCR. Normally, this would not be a problem when testing a few thousand samples. RT-qPCR becomes an issue when dealing with a global pandemic with potentially millions of people to test. This leads to delays in testing as medical facilities become overwhelmed with requests.

Benefits Of Covid-19 Rapid Test Kit

01 It provides significant time and cost savings compared to laboratory methods.

02 It gives fast results in 15 minutes. Easy to use and read without the need for expert equipment.

03 Identifies infection even in mild or asymptomatic cases

04 Helps control Viral transmission

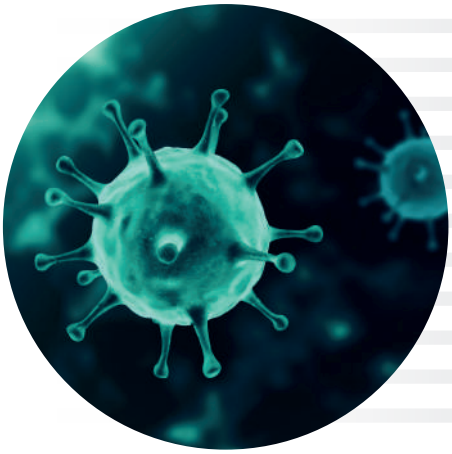
05 It is an ideal kit as a means of triage and elimination.

06 Sensitivity: %92,08; (%95 CI: %87,52-%95.07)
Specificity: %97,89; (%95 CI: %95,90- %98,93)
Total clinical coincidence rate: %95,88
(%95 CI: %93,94- %97,21)

novacheck®

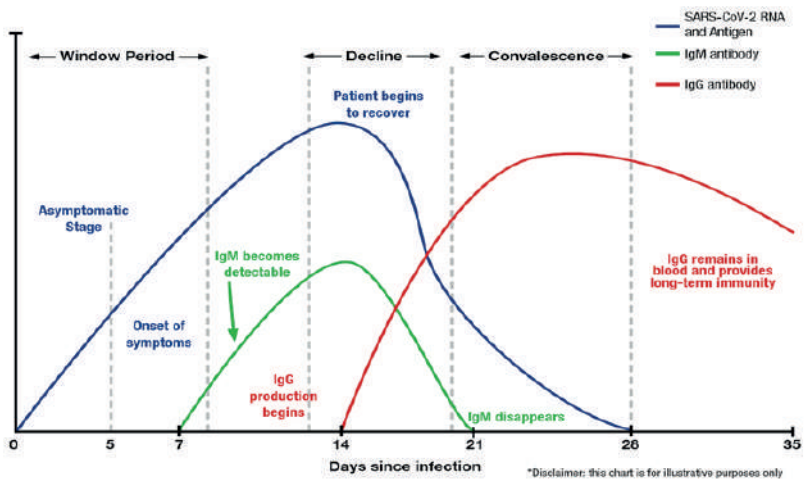
How Should We Interpret IgM/IgG Serological Test Results?

The present IgM/IgG serological assay is designed to complement RT-qPCR in the diagnosis of SARS-CoV-2 infections. Table 1 shows the clinical interpretation of all possible scenarios that can be encountered when testing a patient with both RT-qPCR and an IgM/IgG serological test.



Test results			Clinical Significance
RT-qPCR	IgM	IgG	
+	−	−	Patient may be in the window period of infection.
+	+	−	Patient may be in the early stage of infection.
+	+	+	Patients is in the active phase of infection.
+	−	+	Patient may be in the late or recurrent stage of infection.
−	+	−	Patient may be in the early stage of infection. RT-qPCR result may be false-nagative.
−	−	+	Patient may have had a past infection and has recovered.
−	+	+	Patient may be in the recovery stage of an infection or the RT-qPCR result may be false-negative.

The key takeaway is that the results of RT-qPCR and IgM/IgG serological tests do not necessarily need to agree. A disagreement between the two tests, if any, can often be traced to the after-infection time points at which the tests were performed. Overall, while RT-qPCR testing may be appropriate for the detection of the SARS-CoV-2 virus during the acute phase, IgM/IgG is an appropriate test during the chronic phase. Since the exact time of infection is often unknown, combining RT-qPCR and IgM/IgG testing can improve the accuracy of the COVID-19 diagnosis.



This table is based on the current knowledge about the rise and fall of SARS-CoV-2 RNA and antigens, IgM antibody and IgG antibody (Figure 1) and the correlation of these level variations with the initial time of infection, onset of symptoms and recovery phase3-5. As shown in Figure 1, serological tests are recommended to be used on patients at least 3 days after onset of symptoms or 7-10 days after infection with the virus3-5.

Symbols

Reference:
1. Weaver, C. Questions About Accuracy of Coronavirus Tests Sow Worry. The Wall Street Journal. April 2nd, 2020. Retrieved from https://www.wsj.com/articles/questions-about-accuracy-of-coronavirus-tests-sow-worry-11585836001
2. Li R, Pei S, Chen B, Song Y, Zhang T, Yang W, Shaman J2. Substantial undocumented infection facilitates the rapid dissemination of novel coronavirus (SARS-CoV2). Science. 2020 Mar 16. pii: eabb3221.
3. Lauer, S. et al., 2020. The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. Annals of Internal Medicine.
4. National Health Commission of the People's Republic of China, New Coronavirus Pneumonia Diagnosis and Treatment Program (Trial Version 7)
5. To KK, Tsang OT, Leung WS, Tam AR, Wu TC, Lung DC et al. (2020). Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study. Lancet Infect Dis. 2020 Mar 23. pii: S1473-3099(20)30196-1.

CE

novacheck®

What is the shelf life of the test kit?

Shelf life is 12 months from the date of production. The validity period of the product is printed on the packaging for reference. Do not use after the expiration date

How should I keep the tests?

The recommended storage temperature is 2 - 30 ° C, but we do not recommend storing it in the refrigerator unless there is a risk of overheating. Do not freeze test kits or buffer solution. Tests should be carried out at room temperature (15 - 30 ° C), so if you have done tests in the refrigerator, you should allow them to reach room temperature before doing a test.

Is the test CE marked? Is there an IVD certificate?

Yes, the COVID-19 test is CE marked for professional use and is therefore a registered IVD device.

How accurate is the test?

We conducted a clinical trial comparing the test lab with conventional lab tests for the diagnosis of COVID-19, which also detects the presence of IgG / IgM in the blood sample. We have achieved the following results:
Sensitivity>%92,08; (%95 CI: %87,52-%95,07)
Specificity>%97,89; (%95 CI: %95,90-%98,93)
Accuracy>%95,88 (%95 CI: %93,94- %97,21)
This clinical trial is evidence of the usability and effectiveness of the test.

Is the test accredited?

The COVID-19 test is CE marked for professional use and has Affiliated Hospital (Group) of putian universtity Clinical studies, so it is convenient and ready for use by a healthcare professional.


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

ŞEHİTKAMİL - 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 Reissue Date : --

Date of Audit : 13.03.2020 Expiry Date : 03.05.2021

Date of Registration : 04.05.2020

Technical Universal Verification


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

ŞEHİTKAMİL - GAZİANTEP - TURKEY

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 Reissue Date : --

Date of Audit : 13.03.2020 Expiry Date : 03.05.2021

Date of Registration : 04.05.2020

Technical Universal Verification

Novatech Tıbbi Cihaz Ürünleri San. ve Tic. A.Ş
2. Organize Sanayi Bölgesi Hacı Sanikonukoğlu Bulvarı
83228 Nolu Cadde No:17 Şehitkamil/GAZİANTEP/TÜRKİYE
Tel: +90 342 502 27 27 Fax: +90 342 503 01 30
Posta Kodu: 27620 www.novadiag.com

novacheck® bir/is a brand of novatech DIAGNOSTICS markasıdır.