



CLINICAL DIAGNOSTICS

PROGNOSIS BIOTECH

is an innovative biotechnology company based in Greece, specialized in developing and manufacturing modern in-vitro testing technologies for use in the clinical diagnostics, food, beverage, agriculture, and veterinary markets. It is an export-oriented enterprise which through a large network of distributors, exports ELISA kits and Lateral-flow tests to more than 40 countries worldwide.

We are devoted in producing immunological tests that are easy to use, reliable and accurate.

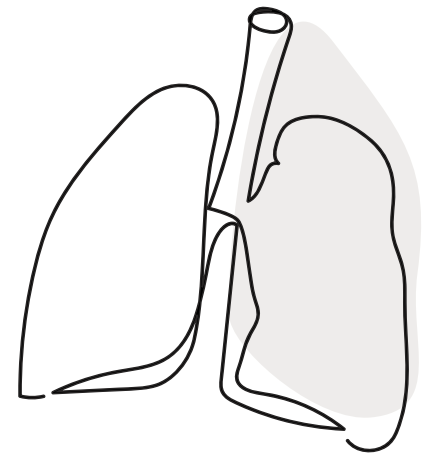
As far as the product quality is concerned, ProGnosis Biotech adheres to the rules of Good Manufacture Practices (GMP) and the International Organization for Standardization (ISO), while being certified with ISO 9001:2015 and ISO 13485:2016 in Development, Manufacturing and Marketing of Diagnostic and Laboratory Products.

We Provide innovative, accurate and simple testing solutions to the challenges presented in the clinical diagnostics industry.

**Where accuracy
meets simplicity**



RESPIRATORY VIRUSES' TESTS



Respiratory viruses are responsible for influenza-like illness morbidity within the community and can also cause the common cold. Certain respiratory viruses of interest are respiratory syncytial virus (RSV), coronaviruses (including SARS and MERS CoV), adenoviruses, and influenza viruses. Other than COVID-19 and until recently, it hasn't been observed a routine surveillance on any other virus.

People at high risk (those with certain underlying conditions, the elderly, the very young, and pregnant women) could potentially develop severe illness that could result in hospitalization or death, if not diagnosed and treated on time.

As most of the tests in this category developed by Prognosis Biotech refer to the detection of antigens, due to SARS-CoV-2 there is also a line of tests for the detection of antibodies.

Antigen VS Antibody

The main difference between antigen and antibody is that one detects the virus in the body at its most contagious stage, while the antibody test detects whether the body has developed a defense against the virus. The procedure for the two tests is completely different. While the antigen test takes the sample through a swab, the antibody test requires a blood sample.

1.1 Antigen tests

Qualitative, lateral flow tests designed for Antigen detection in human nasal or nasopharyngeal specimens in 15 min.

With the following non-invasive tests, medical professionals add a few more tools in their portfolio to diagnose the seasonal respiratory viruses and have more testing options to distinguish the viruses appearing with similar symptoms. The tests help to rapidly identify infected individuals, enabling prompt clinical decisions and preventing a potential virus outbreak.

The Rapid Test does not require any special instrument or skill set and can be used in all types of premises where testing is required.

SARS-CoV-2

Rapid test for the detection of SARS-CoV-2 antigens

Product Name	Product Code	Sample	Time
Rapid Test Ag 2019-nCoV (cassette)	V1301/02/05/20/40	Nasal or nasopharyngeal swab	15 min
Rapid Test Ag 2019-nCoV (dipstick)	V1310/30/60	Nasal or nasopharyngeal swab	15 min

INFLUENZA & SARS-CoV-2

Rapid test for the detection of SARS-CoV-2 and Influenza (A & B)

Product Name	Product Code	Sample	Time
Rapid Test FLU_COVID	V1601/05/20	Nasal or nasopharyngeal swab	15 min

Professional use:

INFLUENZA

Rapid test for the detection of Influenza A or B

Product Name	Product Code	Sample	Time
Rapid Test FLU A_B	V1701/05/20	Nasal or nasopharyngeal swab	15 min

ADENOVIRUS

Rapid test for the detection of Adenovirus

Product Name	Product Code	Sample	Time
Rapid Test Adenovirus	V1801/05/20	Nasal or nasopharyngeal swab	15 min

RSV

Rapid test for the detection of RSV

Product Name	Product Code	Sample	Time
Rapid Test RSV	V1501/05/20	Nasal or nasopharyngeal swab	15 min

Professional use:

At home use:

Home Test COVID-19 Ag is a self-administrated and reliable rapid antigen test that delivers results in as few as 15 minutes. This test detects COVID-19 and all its variants, including Omicron, Omicron-2 and Delta and offers to individual users the necessary tool for self-diagnosis.

SARS-CoV-2

Rapid test for the detection of SARS-CoV-2 antigens

Product Name	Product Code	Sample	Time
Home Test COVID-19 Ag	H1301/02/05/20	Nasal or nasopharyngeal swab	15 min

ONE COMMON SAMPLE FOR ALL TESTS

1.2 Antibody tests:

This test is designed to detect a body's immune response to SARS-CoV-2 and comes in two different formats for application.

1.2.1 Lateral Flow tests:

Rapid Test 2019-nCov Total Ig kits for the detection of SARS-CoV-2 Immunoglobulin antibodies in blood specimens.

SARS-CoV-2

Rapid test for the detection of antibodies against SARS-CoV-2

Product Name	Product Code	Sample	Time
Rapid Test 2019-nCov Total Immunoglobulins	V1210/V1230	Blood	10 min
Rapid Test 2019-nCov IgG	V1401/V1420	Blood	15 min

Professional use:

1.2.2 ELISA tests:

ELISA format is made for testing laboratories. **Bio-Shield 2019-nCoV** product series are 4 semi quantitative in vitro diagnostics ELISA tests for the determination of IgA, IgM, IgG antibodies against SARS-CoV 2 in human serum or plasma (Heparin, EDTA or Citrate specimens).

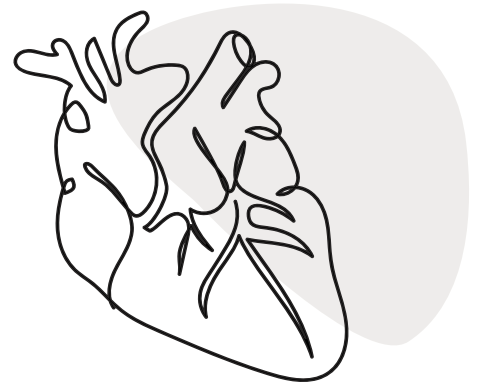
SARS-CoV-2

Rapid test for the detection of IgA, IgG & IgM antibodies against SARS-CoV-2

Professional use:

Product Name	Product Code	Sample	Time
Bio-Shield 2019-nCoV IgA	C1048/C1096	Serum/Plasma	90 min
Bio-Shield 2019-nCoV IgG	C1148/C1196	Serum/Plasma	90 min
Bio-Shield 2019-nCoV IgM	C1248/C1296	Serum/Plasma	90 min
Bio-Shield 2019-nCoV Total Immunoglobulins	C1348/C1396	Serum/Plasma	120 min

CARDIAC MARKERS' TESTS



Acute myocardial infarction is caused by the sudden blockage of a coronary artery. It is a common cause of death that could be avoided with more timely and effective diagnosis. Detection of troponins is the most common method verifying the existence of heart damage.

In recent years a new index, the MYBPC3, may also be used in cardiac diagnosis episodes. MYBPC3 encodes the cardiac isoform of myosin-binding protein C and its testing is utilized to confirm a diagnosis of Hypertrophic Cardiomyopathy in patients with clinically evident disease. Its blood levels rise sharply after a heart attack and they remain for days giving the possibility of a quick and reliable result. The test provides a preliminary test result as an aid in the diagnosis of myocardial infarction.

TROPONIN

Rapid Test for the detection of Troponin

Professional use:

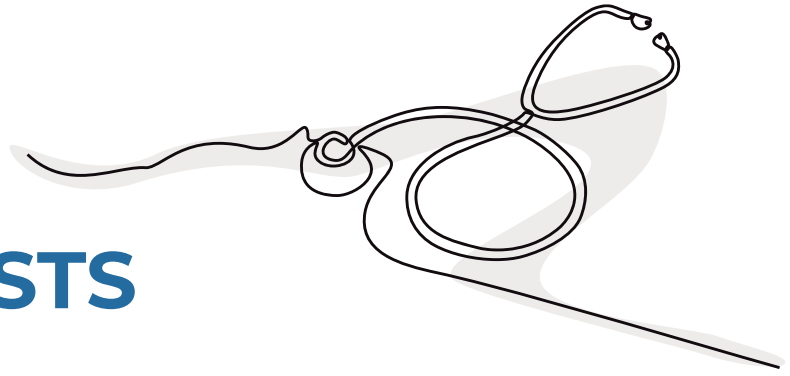
Product Name	Product Code	Sample	Time
Rapid Test TROPONIN PLUS	V2201/05/20	Blood/Serum/Plasma	15 min

MYOSIN BINDING PROTEIN C3

Rapid Test for the detection of Myosin

Product Name	Product Code	Sample	Time
Rapid Test MYBPC3	V2401/05/20	Blood/Serum/Plasma	15 min

INFECTIOUS DISEASES' TESTS



Infectious diseases are caused by pathogenic microorganisms, such as bacteria, viruses, parasites or fungi; the diseases can be spread, directly or indirectly, from one person to another.

Diagnosis of such diseases usually takes place through blood tests and symptoms assessment by medical professionals and there are cases that biochemical and molecular genetic testing is also required. Thus, the option of a rapid test for the detection of such diseases consists of an ultra-useful tool in the hands of healthcare practitioners for a faster diagnosis.

MONONUCLEOSIS

Rapid test for the detection of IgM antibodies against the Epstein Barr (EBV)

Product Name	Product Code	Sample	Time
Rapid Test MONONUCLEOSIS	V1901/05/20	Blood, Serum, Plasma	15 min

STREPTOCOCCUS A

Rapid test for the detection of group A Streptococcus antigen

Product Name	Product Code	Sample	Time
Rapid Test STREP A	V2001/05/20	Throat swab	15 min

ADENOSINE DEAMINASE

Rapid test for the detection of ADA enzyme

Product Name	Product Code	Sample	Time
Rapid Test ADA PLUS	V2101/05/20	Blood, Serum, Plasma	15 min

C-REACTIVE PROTEIN & MYXOVIRUS A

Rapid test for the detection of C-reactive and Myxovirus A protein

Product Name	Product Code	Sample	Time
Rapid Test CRP MxA	V2301/05/20	Blood, Serum, Plasma	15 min

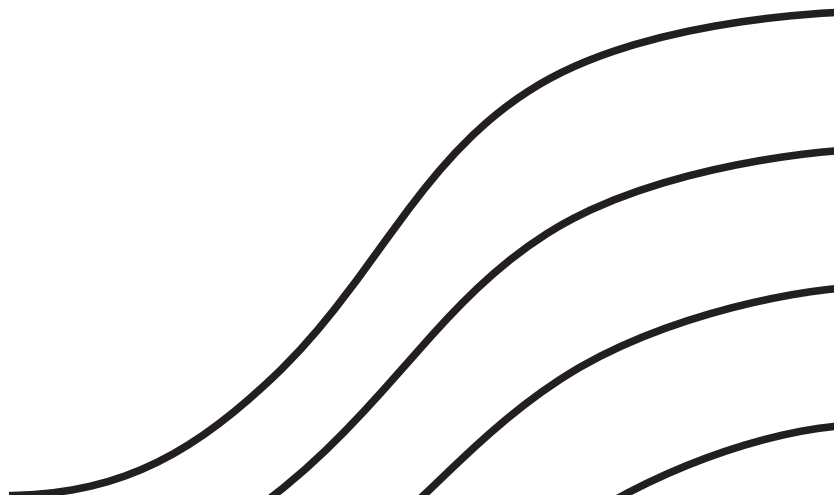
For professional use:

REGISTRATIONS

- National Organization for Medicines of the Greek Ministry of Health
- Ministry of Health of Cyprus: ProGnosis Biotech is an official supplier of country's Covid-19 testing scheme which is considered as one of the most extensive in the EU*
- Italian Ministry of Health (Ministero della Salute) database*
- German Federal Institute of Drugs and Medical Devices (BfArM). The test is also evaluated by the Paul Ehrlich Institute**
- Medicines and Medical Devices Agency of Serbia*
- European Commission's database for COVID-19 Test methods*
- Find database (WHO Collaborating partner)*
- South African Health Products Regulatory Authority*
- INFARMED –National Authority of Medicines and Health Products, I.P. (Portugal)*
- M.O.H Ministry of Health (Vietnam)*
- AEMPS Spain

* Rapid Test Ag 2019-nCoV

** Home Test COVID-19 Ag



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