



todylaboratories®

Responsible diagnostic. Since 1993.

Coronavirus (SARS-CoV-2)

1. ELISA Reagents



ELISA Reagents

2. Rapid Tests Reagents



Rapid Tests

3. Virus Sample & Blood Collection Disposables



Laboratory Disposables

4. Laboratory Diagnostic



Laboratory Diagnostic

5. External Quality Assessment Schemes



EQA Schemes



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Serological response to SARS-CoV-2

Serological testing can expand the diagnostic window over the first two weeks (usual limit for the PCR tests). By means of serology, the persons who present a persisting (no longer acute) or past infection with SARS-CoV-2, can be identified. To what extent this serological response is associated with acquired immunity to the virus, this is still to be scientifically proven.

Antibody isotypes and state of infection



Characteristic of the primary antibody response.
High IgM titer suggests a **current** or **very recent** infection.



Follows IgM production. Characteristic of the secondary antibody response. May persist for several years.
High IgG titer with low IgM titer may indicate **past** infection.



Produced in mucosal linings throughout the body (protective barrier). Usually produced early in the course of the infection.
Recent study¹ suggests that the **IgA response appears and grows early, peaks at week 3, and is stronger and more persistent than the IgM response.**

¹Andrea Padoan, Laura Sciacovelli, Daniela Basso, Davide Negrini, Silvia Zuin, Chiara Cosma, Diego Faggian, Paolo Matricardi, Mario Plebani, IgA-Ab response to spike glycoprotein of SARS-CoV-2 in patients with COVID-19: A longitudinal study, Clinica Chimica Acta, Volume 507, 2020, Pages 164-166, ISSN 0009-8981

Why use a serology test for COVID-19?

As reported on the US-CDC web page, "CDC has developed a laboratory test to help estimate how many people in the United States have been infected with SARS-CoV-2, the virus that causes COVID-19. Clinicians and researchers refer to this as a serology test, and many commercial laboratories call it an antibody test... An antibody test looks for the presence of antibodies, which are specific proteins made in response to infections. Antibodies are detected in the blood of people who are tested after infection; they show an immune response to the infection. Antibody test results are especially important for detecting previous infections in people who had few or no symptoms."

<https://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html>

- **The test can be performed using human whole blood (venous or fingerstick), serum or plasma**
- **Suitable for large-scale screening**
- **Simultaneous detection of both IgM and IgG antibodies**



**Coronavirus (SARS-CoV-2) IgG/IgM
- Nucleocapsid (N protein)**



**Coronavirus (SARS-CoV-2) IgG/IgM
- Nucleocapsid (N protein)
+ Spike Glycoprotein S1 RBD**

Principle of the tests

PRICE **ECONOMIC range** Immunochromatographic assay for the differential determination of anti-SARS-CoV-2 IgG/IgM antibodies in human whole blood, serum or plasma. Viral nucleocapsid antigens (N-protein) are fixed in the T zone (test) on a nitrocellulose membrane. The Nucleocapsid (N) protein is an important antigen for the SARS-COV-2 virus, which is associated with RNA, increasing its stability. This protein is highly immunogenic and plays an important role in hosts immune response.

PRICE **PREMIUM range** Immunochromatographic assay for the differential determination of anti-SARS-CoV-2 IgG/IgM antibodies in human whole blood, serum or plasma. Along with the Nucleocapsid (N) protein, the Spike Glycoprotein S1 RBD is fixed in the T zone (test) on a nitrocellulose membrane. This mixture of viral antigens provides higher sensitivity and specificity to the rapid test. Spike Glycoprotein S1 RBD is responsible for binding to the host cell receptor angiotensin-converting enzyme 2 (ACE2) and is also a major immunogen which trigger the neutralizing-antibodies synthesis and T-cell response, as well as protective immunity.

Laboratory Disposables for collecting and transporting Coronavirus (SARS-CoV-2) biological samples

The nasopharyngeal and pharyngeal swabs are intended for the direct diagnosis of Coronavirus (SARS-CoV-2) by molecular biology techniques (eg. rtPCR). The rtPCR is used for the detection of SARS-CoV-2 viral RNA in the tested biological sample.



Virus collection kit with VTM-N transport medium (neutralizer effect of viral activity)

- VTM-N storage and transport medium contains buffers based on Tris-HCl, EDTA and guanidine salts that act as protein denaturants and nuclear inhibitors, with inactivating effect on the virus;
- the integrity of nucleic acids is not affected;
- facilitates the extraction and analysis of nucleic acids;
- do not use on samples from which you want to obtain viral cultures and viral isolates.

The kit contains: 10 ml tube with 3 ml VTM-N medium, sterile exudate swab (150mm) and BIOHAZARD bag for specimen transport.



Virus collection kit with VTM transport medium (maintains viral activity)

- VTM storage and transport medium contains bovine serum albumin and HEPES buffers that maintain the stability and activity of viruses in the sample;
- stability and viral activity are maintained at several temperature differences;
- the integrity of nucleic acids is not affected;
- facilitates the extraction and analysis of nucleic acids;
- intended for the preservation and transport of samples from which you want to obtain viral cultures and viral isolates.

The kit contains: 10 ml tube with 3 ml VTM medium, sterile exudate swab (150mm) and BIOHAZARD bag for specimen transport.

Disposables for collecting capillary blood samples used for Rapid Tests (e.g. Coronavirus SARS-CoV-2 IgG/IgM rapid tests)

Our offer includes sterile lancets for finger prick collection of capillary blood samples. Blood samples are intended for indirect serological diagnosis (serology) of Coronavirus (SARS-CoV-2) by immunochromatographic tests (eg rapid tests). Rapid tests are used for the detection of specific IgG/IgM anti-SARS-CoV-2 antibodies in the tested biological sample.



Sterile lancets, set x 100 pieces

- sterile disposable lancets;
- efficient and safe for capillary collection of capillary human blood;
- automatic irreversible needle retraction mechanism that prevents accidental punctures;
- easy to use;
- pain-free.

Coronavirus (SARS-CoV-2) serology (IgG/IgM/IgA antibodies)

Serology testing enables the detection and quantification of IgG, IgM or IgA type antibodies in the serum of a patient who has been in contact with the virus. Thus, it is possible to identify people who were previously infected or who are infected at the time of testing, either symptomatic or not.

Antibodies types and infection status



- antibodies characteristic for the primary immune response;
- are detectable in blood starting from the 2nd week after the onset of symptoms;
- **elevated IgM titers** suggest **acute** or **very recent** Coronavirus (SARS-CoV-2) infection.



- immunoglobulin G synthesis begins after IgM synthesis, IgG being antibodies characteristic for the secondary immune response;
- **elevated IgG titers** along with a **IgM low titer** or the **absence of IgM** suggest infection **in the past** (the patient has been infected and recovered).



- antibodies present in the mucous membranes secretions of the body as a protective barrier against pathogens that enter through mucosa (eg. respiratory mucosa used by SARS-CoV-2);
- IgA synthesis usually begins at the **onset of infection**.

At present, the kinetics of antibodies are still poorly characterized for asymptomatic patients or for those with mild symptoms.

Recommendations for serology testing

- to identify patients who have developed immunity to SARS-CoV-2, either symptomatic or not;
- to identify, in certain circumstances, patients who are at the moment or have been previously infected with SARS-CoV-2;
- to determine the serological status of exposed individuals who may or may not have shown symptoms (e.g. healthcare workers);
- to establish epidemiological data related to COVID-19 (patients actually infected, mortality rates etc.).

IMPORTANT! Serology tests can only determine whether a person has produced antibodies in response to an infection with the virus, in other words, whether or not that person has triggered an immune response against the Coronavirus (SARS-CoV-2). Serological tests cannot confirm the diagnosis of COVID-19 and the presence of antibodies cannot guarantee the protection of the individual against further reinfection.

Sample type and transport condition

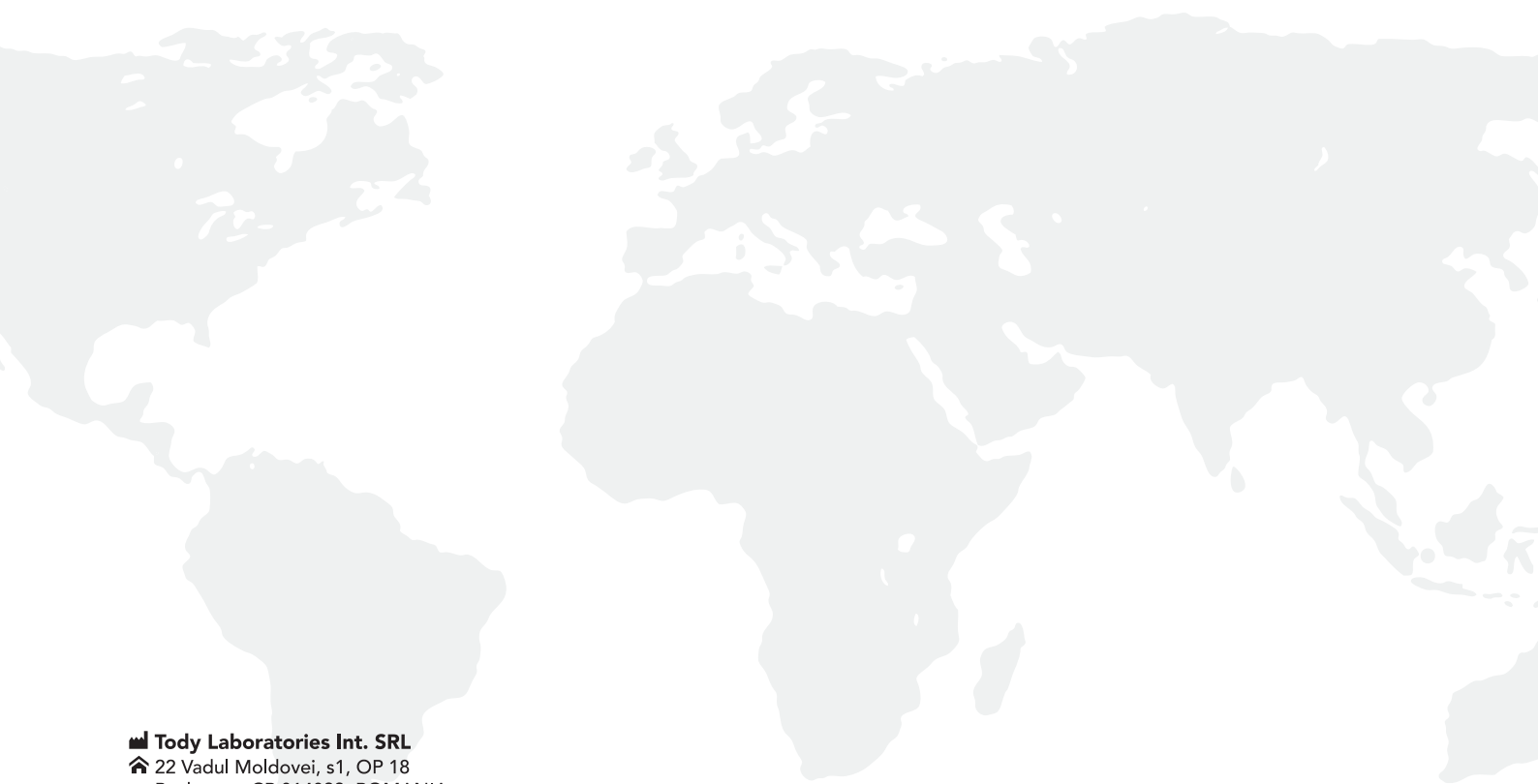
- **1 ml human serum**; the sample is transported in refrigerated conditions, if testing is performed in max. 5 days after collection; otherwise, the sample must be frozen and transported on dry ice.

TAT

- **48 hours** after sample reception

Method

- **ELISA**



🏢 **Tody Laboratories Int. SRL**
🏠 22 Vadul Moldovei, s1, OP 18
Bucharest, CP 014033, ROMANIA
📞 ISO 15189, 17043, 9001, 13485
🌐 www.todylaboratories.com

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