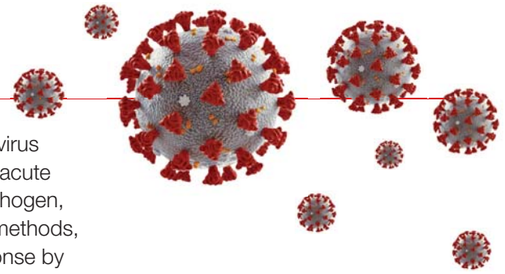
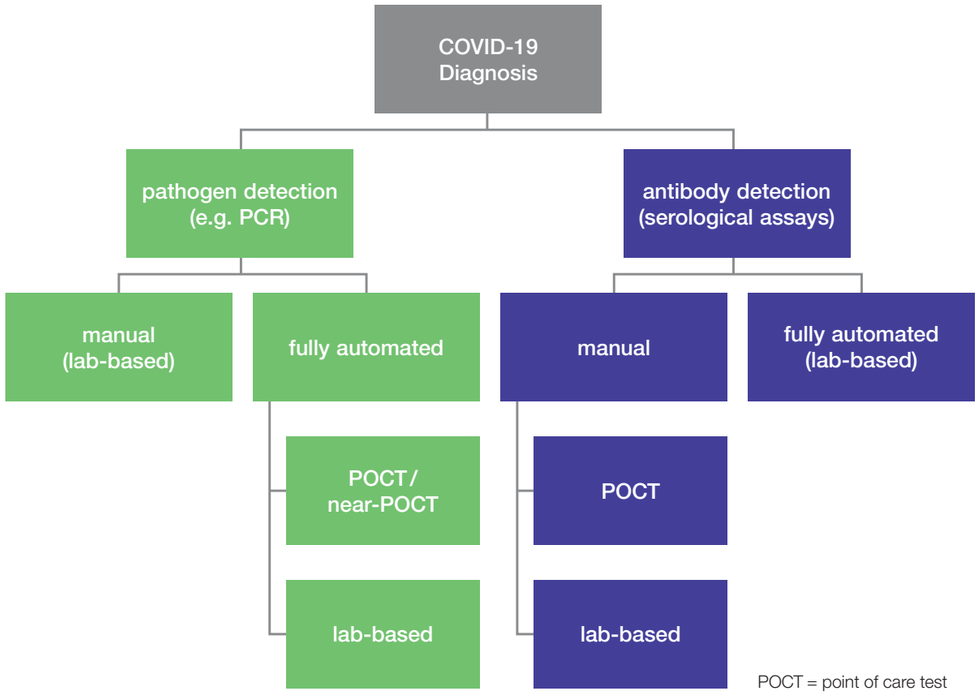
Methods & Products for COVID-19

SARSTEDT

Detection by various methods



The current outbreak of COVID-19 has been caused by the coronavirus SARS-CoV-2. A range of different methods is being used to detect acute infections or a cured disease. The presence of the virus, i.e. the pathogen, can either be confirmed directly using various molecular biological methods, e.g. PCR. Also, patients can be tested for an immune system response by indirect pathogen detection. This is done by detecting SARS-CoV-2 specific antibodies.



POCT = point of care test

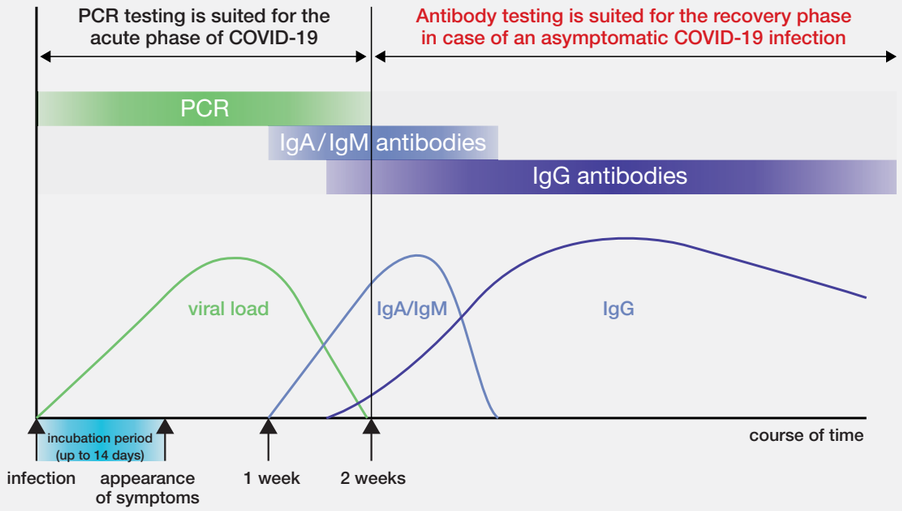
These different testing methods are applied in different stages of the disease. While direct pathogen detection is only possible in an early phase, antibodies are produced and traceable in the later course of the disease only (see diagram below). Pathogen detection provides information on whether the person tested is infected with the virus, and can infect other people. As the pandemic progresses, the detection of antibodies is also increasingly important, for example, to determine the number of undetected cases of infections ranging from mild to asymptomatic. At this current stage, there are no reliable data on whether the detection of antibodies implies reliable immunity and how long this immunity would last. Nonetheless, antibody testing is expected to increase in the coming weeks.

Direct detection of a SARS-CoV-2 infection using molecular-biological methods (e.g. PCR)

In direct pathogen detection, the genetic information of the virus is identified using molecular biological tests. In most cases, a swab is used to collect samples from the nasopharynx. A positive test result indicates an acute infection. Due to the novelty of the virus, only individual protocols from reference laboratories were available at the beginning of the outbreak. As the pandemic progresses, more and more commercial tests are being offered to further reduce the waiting time for results.

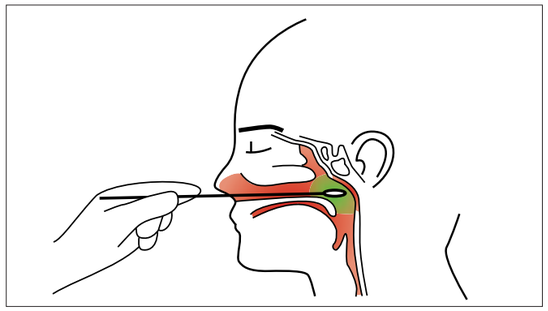
Indirect detection of a SARS-CoV-2 infection using serological antibody tests (ELISA)

The detection of antibodies (serology) can indicate if the disease has already progressed or the person tested has already recovered. The formation of antibodies varying with time plays a major role in this process. While antibodies of the acute phase (IgA & IgM) usually no longer show up in an individual's blood after recovering from the infection, immunoglobulin-G (IgG) antibodies of the late or post-illness phase can be detected far beyond the recovery phase. As a result, individuals can be released from quarantine quickly/quicker and safely/more safely.

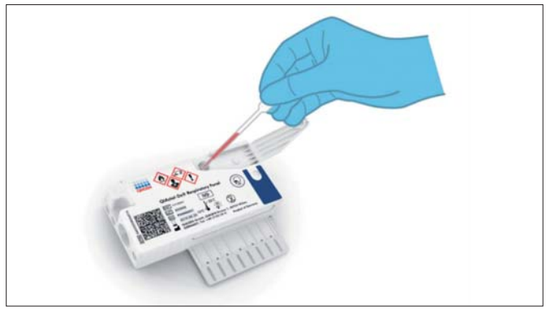


Direct pathogen detection using molecular-biological methods

For direct pathogen detection, the genetic information of the virus (in this case RNA) is identified. While naso-pharyngeal or oropharyngeal swabs provide the typical test specimens, liquid samples (oropharyngeal irrigation, sputum, pulmonary irrigation) can be used as well. Urine and faeces samples can also be analysed. Specimens must be packaged and transported in accordance with the P650 Packaging Regulations. Specimens can be analysed either manually using a range of kits or in a fully automated process.



nasopharyngeal swab



QIAstat-Dx® Respiratory Panel from QIAGEN

Manual pathogen detection

For a manual analysis, the RNA is first isolated from the specimen and then examined using the PCR method. For both steps, kits from a range of manufacturers are available, for example, QIAGEN, Macherey-Nagel, Thermo Fisher, PerkinElmer and Siemens Healthineers. SARSTEDT products that might be of relevance in this context are primarily our screw cap micro tubes. The laboratories carrying out these analyses additionally require pipette tips with filter and a wide range of tubes and micro tubes.

Automated pathogen detection

Automated tests are available in a range of sizes. Bosch or QIAGEN, for example, provide cartridge-based tests which are mostly POCT or near-POCT, though with a limited sample throughput (one sample at a time) only. Automated laboratory tests, however, can analyse several samples at the same time enabling a high sample throughput and are available from Roche, Hologic and Becton Dickinson to name a few.

Due to the currently high dynamics in this market, the WHO website links to a constantly expanding list of available test kits.
www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance

cobas® 8800 from Roche

Vivalytic from Bosch

Direct pathogen detection — sample collection

SARSTEDT disposables	Type of sample		
	Swab	Liquid samples (oropharyngeal irrigation, sputum, pulmonary irrigation)	Faeces, urine
Sample tube	Dry swabs, primary tube w/o preparation or with saline solution	Disposable cup, 50 ml tubes	Faeces tubes, urine cups, Urine-Monovette®
Transport material	Direct analysis (POCT): no transport Transport (laboratory test): secondary tubes, mailing bags, transport boxes corresponding to sample material and type of transport (road, air)		

Direct pathogen detection — analytics

SARSTEDT disposables
Tubes, screw cap micro tubes, micro tubes, PCR tubes, pipette tips with filter, transfer pipettes

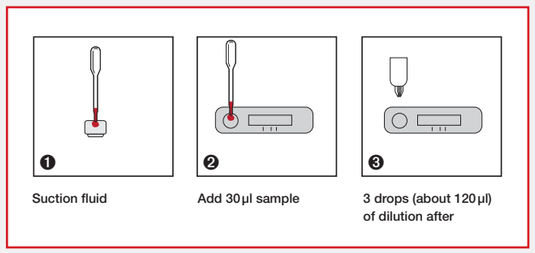
POCT antibody detection of SARS-CoV-2

Rapid tests from various manufacturers are available. Here, too, the WHO website links to a corresponding list: www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance

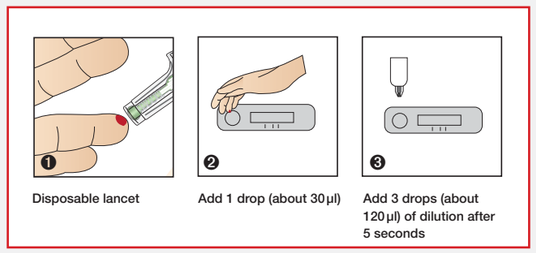
For rapid testing, venous serum and/or plasma samples as well as capillary plasma and/or whole blood samples (Lithium-Heparin and EDTA) can be used. Such rapid tests render a qualitative result as early as 10 minutes.

An antibody POC test is a supplement to existing tests and reveals right on the spot and within a very short time whether or not a diseased person already developed detectable antibodies and is suffering from COVID-19, without the need for laboratory analysis and complex examinations. The test provides a further benefit with regard to quarantine requirements. Even though a patient has recovered from the coronavirus disease, virus fragments may still be detectable in the nasopharynx so that the standard PCR test is positive. This is where the rapid test turns out to be of significant advantage, because antibodies of the acute phase (IgM) are usually no longer present in the blood after the infection has been cured. Only IgG antibodies are present in the late or post-illness phase.

However, the clinical accuracy of rapid tests needs to be evaluated before they are released for COVID-19 mass screening. Most recent reports from European countries indicate that, in individual cases, COVID-19 rapid tests do not render good analytical performance. As with all other test methods, the selection and use of these POCT tests is subject to the decision of the responsible medical officer.



Schematic of serum, plasma and whole blood sampling in a clinical laboratory

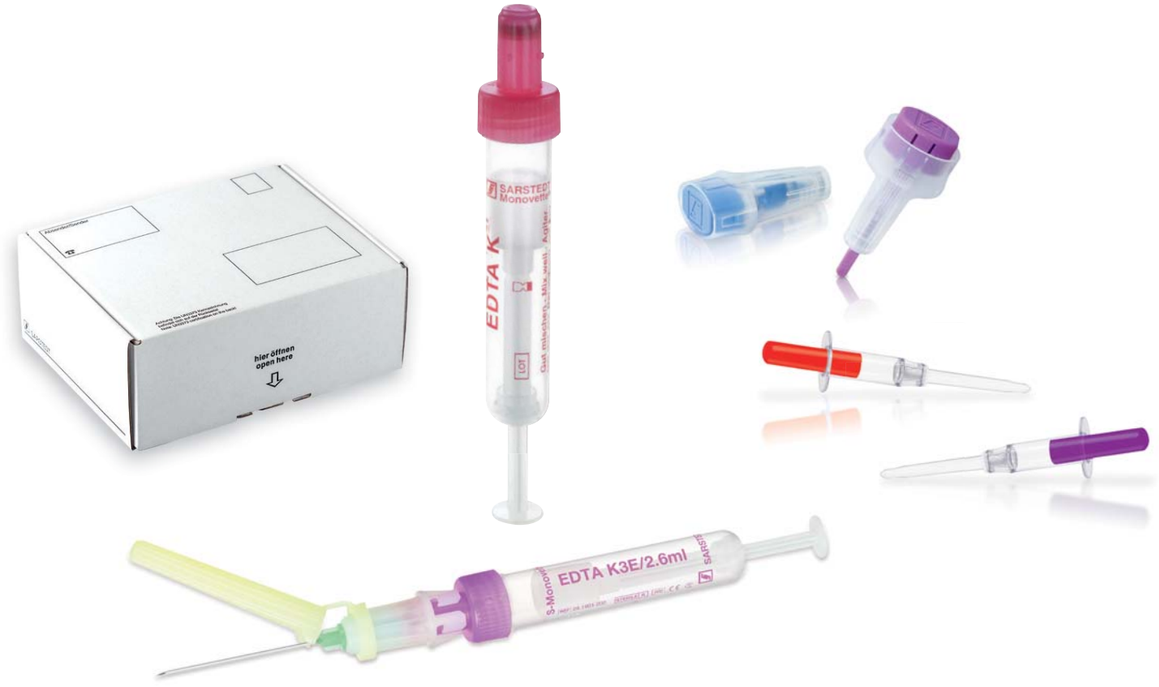


Schematic of peripheral whole blood sampling

Recommended conditions for sample transport for COVID-19 testing*

Sample material	Storage temperature before transport	Duration of transport (approx.)	Recommended temperature during transport	Transport category
Serum / Plasma	2-8 °C	≤ 5 days	2-8 °C	"Biological substances, Category B" - UN 3373 / P650 Packaging Instructions
Whole blood		> 5 days	-70 °C (dry ice)	

* Guidance for laboratories shipping specimens to WHO reference laboratories that provide confirmatory testing for COVID-19 virus.



POCT Antibody detection — Sampling

Sample processing: Decentralised, manually with POCT / rapid tests

SARSTEDT disposables	Type of sample	
	Venous large volumes > 5 ml*	Capillary
Sample tube / preparation	SERUM: S-Monovette® Serum / Serum-Gel (PLASMA: S-Monovette® Lithium Heparin, EDTA	Whole blood Heparin / EDTA: Minivette® POCT Heparin / EDTA, End-to-End capillary EDTA → Refer to the test kit manufacturer's package insert.
Puncturing systems	S-Monovette® needles, (Safety)-Multifly® needles	Safety-Lancet, incision lancet
Venous constriction	Paper single-use tourniquet, single patient use tourniquet	–
Transport materials	Secondary tubes, mailing bags, transport boxes depending on the sample material and type of transport (road, air)	Direct analysis, no transport
Freezing*	Seraplas filters, transfer pipettes, micro tubes	–

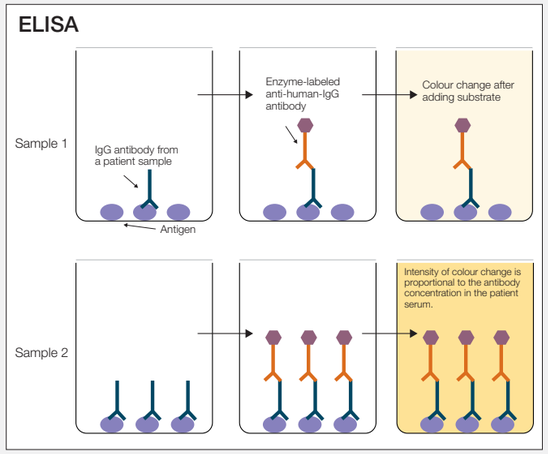
* Residual material (serum, plasma) is frozen for subsequent analysis.

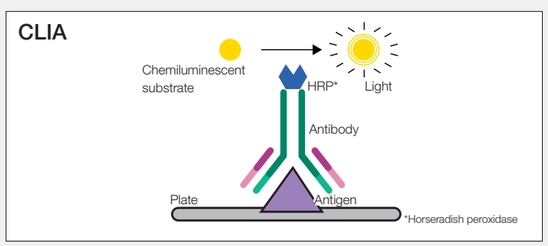
Automated detection of SARS-CoV-2 antibodies

For fully automated determination of SARS-CoV-2 antibodies, the Chinese manufacturer YHLO is one of the first providers apart from EUROIMMUN. Both suppliers offer reagent kits designed to fit their own system platform. While YHLO relies on Chemiluminescence Immunoassays (CLIA), EUROIMMUN AG with headquarters in Lübeck/Germany applies the enzyme-linked immunosorbent assay (ELISA) technology. For both assays, serum and plasma can be used as sample materials.
The measurement results rendered are semiquantitative (EUROIMMUN) and quantitative (YHLO). Fully automated determination of SARS-CoV-2 antibodies in large-scale testing will be primarily used to collect epidemiological data. In addition, screening of individuals after having been in contact with SARS-CoV-2 will also help to answer the question of possible immunity. All leading device/assay manufacturers such as, for example, Abbott, BeckmanCoulter, Diasorin, Ortho Clinical Diagnostics, Roche Dianostics, Siemens Healthineers, are working hard to develop, or have already launched, a serological assay for antibody detection.

EUROLabWorkstation ELISA

iFlash 1800 Chemiluminescence Immunoassay Analyzer





Both the **enzyme-linked immunosorbent assay** (ELISA) and the **chemiluminescence immunoassay** (CLIA) are immunoassays. Immunoassays are summarised as a series of methods whose common basic principle is the identification and, thus, the detection of an analyte when an antigen binds to an antibody.

Enzyme-linked immunosorbent assay (ELISA)
defines an antibody-based detection method (assay) based on an enzymatic colour reaction.

Chemiluminescence Immunoassay (CLIA)
defines an antibody-based detection method (assay) that combines the chemiluminescence technique with immunochemical reactions. Chemiluminescence (CL) describes the emission of electromagnetic radiation that "generates" light caused by a chemical reaction.

Antibody detection — Sampling

Sample processing: Automated in central labs

SARSTEDT disposables	Type of sample Venous large volumes > 5 ml*
Sample tube / preparation	SERUM: S-Monovette® Serum / Serum-Gel PLASMA: S-Monovette® Lithium Heparin, EDTA
Secondary accessories	Transfer pipettes, pipette tips
Puncturing systems	S-Monovette® needles, (Safety)-Multifly® needles
Venous constriction	Paper single-use tourniquet, single patient use tourniquet
Transport materials	Secondary tubes, mailing bags, transport boxes depending on the sample material and type of transport (road, air)
Freezing*	Seraplas filters, transfer pipettes, micro tubes

Antibody detection — Analytics

SARSTEDT disposables
ELISA plates

* Residual material (serum, plasma) is frozen for subsequent analysis.
** Please check your local market for suitable kit suppliers.

When COVID-19 patients need intensive care treatment

The COVID-19 disease is an infection of the respiratory tract including fever and cough as the most common symptoms. In 81 % of patients a mild course is observed while 14 % suffer from a severe disease, and 5 % are critically ill. The reason for intensive care treatment is usually dyspnea with an increased respiratory rate (> 30/min), the main cause being a lack of oxygen in the arterial blood (hypoxaemia). Often, inflammation of the pulmonary tissue is then already visible on imaging.

Possible courses are the development of an acute respiratory distress syndrome (ARDS) and, though more rarely to date, a bacterial coinfection with septic shock. Further complications described are arrhythmias, myocardial damage and the occurrence of acute renal failure. The time between the onset of symptoms and the requirement of intensive care treatment is approximately 10 days.

During continuous monitoring of these patients, the SARSTEDT product portfolio can be used in the following fields:

1. Blood Gas Monovette® to ensure adequate oxygen supply (oxygenation); and

2. Blood culture adapter when coinfections are suspected

ROCHE Diagnostics cobas b 221

SIEMENS Healthineers RapidLab 1200

In-patient monitoring — Sampling

ICM

SARSTEDT disposables	Type of sample	
	Venous large volumes > 5 ml*	Capillary
Important sample tubes	Blood Gas Monovettes	Blood gas capillaries
Blood culture sampling	Blood culture adapter	–
Sample tube / preparation	SERUM: S-Monovette® Serum / Serum-Gel PLASMA: S-Monovette® Lithium Heparin, EDTA	–
Puncturing systems	Connection to IV lines: Multi-Adapter, Multi-Adapter-Luer-Lock Direct puncturing: S-Monovette® needles, (Safety)-Multifly® needles, membrane adapters	Safety lancets
Transport materials	In-house transport: mailing bags, In-house transport cases	Direct analysis, no transport
Freezing*	Seraplas filters, transfer pipettes, micro tubes	–

* Residual material (serum, plasma) is frozen for subsequent analysis.

COVID-19 Pre- and Postanalytics

Analysis instruments (e.g. the EUROLab workstation Elisa) usually require open sample tubes in a compatible rack for sample processing.

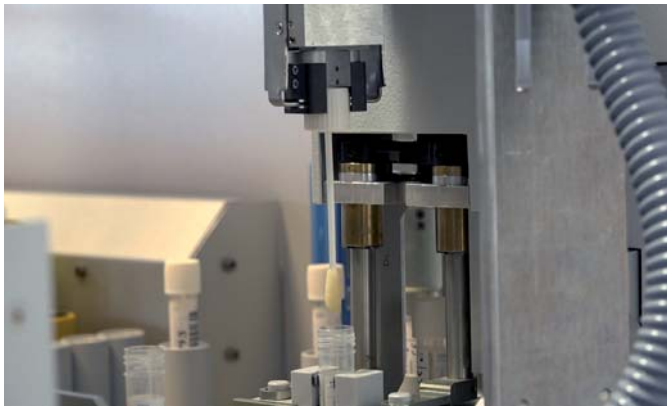
Automated opening of the sample tubes prior to analysis reduces the risk of infection for laboratory staff and helps to prevent the chronic strain syndrome (RSI - repetitive strain injury). In particular, opening of sample tubes with attached swab (eSwab™ tubes) requires appropriate technical solutions. The pre- and postanalytical automation systems DC RC 900 Flex and DC 1200 from SARSTEDT provide these solutions.

Link to Video:
https://youtu.be/yiCdT8kFazs

or via QR Code:

DC 1200

DC RC 900 Flex



DC RC 900 Flex (eSwab™)

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All devices, products and methods listed here are examples only and not meant to be exhaustive.

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