Serology-based tests for COVID-19

Serology testing for SARS-CoV-2 is at increased demand in order to better quantify the number of cases of COVID-19, including those that may be asymptomatic or have recovered. Serology tests are blood-based tests that can be used to identify whether people have been exposed to a particular pathogen by looking at their immune response. In contrast, the RT-PCR tests currently being used globally to diagnose cases of COVID-19 can only indicate the presence of viral material during infection and will not indicate if a person was infected and subsequently recovered. These tests can give greater detail into the prevalence of a disease in a population by identifying individuals who have developed antibodies to the virus.

This page serves to provide up to date information on serology tests that are in development or available for use. Importantly, many of these tests have been approved for research use only, which indicates that they are not yet approved for use as a public health diagnostic tool or for at-home diagnosis. Some of these tests may move forward to approval for diagnostic use, while others may be appropriate for research only.

This page was last updated on April 10, 2020.

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Description of types of serology assays

Rapid diagnostic test (RDT): This is typically a qualitative (positive or negative) lateral flow assay that is small, portable, and can be used at point of care (POC). These tests may use blood samples from a finger prick, saliva samples, or nasal swab fluids. RDTs are often similar to pregnancy tests, in that the test shows the user colored lines to indicate positive or negative results. In the context of COVID-19, these tests most frequently test for patient antibodies (IgG and IgM), or viral antigen. In some cases, it can be beneficial to measure baseline (before infection) of IgG and IgM titers.

Enzyme-linked immunosorbent assay (ELISA): This test can be qualitative or quantitative and is generally a lab-based test. These tests usually use whole blood, plasma, or serum samples from patients. The test relies on a plate that is coated with a viral protein of interest, such as Spike protein. Patient samples are then incubated with the protein, and if the patient has antibodies to the viral protein they bind together. The bound antibody-protein complex can then be detected with another wash of antibodies that produce a color or fluorescent-based readout. In the contest of COVID-19, these tests most frequently test for patient antibodies (IgG and IgM).

Neutralization assay: This test relies on patient antibodies to prevent viral infection of cells in a lab setting. Neutralization assays can tell researchers if a patient has antibodies that are active and effective against the virus, even if they have already cleared the infection. These tests require whole blood, serum, or plasma samples from the patient. Neutralization assays depend on cell culture, a lab-based method of culturing cells that allow SARS-CoV-2 growth (like VeroE6 cells). When virus and cells are grown with decreasing concentrations of patient antibodies, researchers can visualize and quantify how many antibodies in the

patient serum are able to block virus replication. This blocking action can happen through the antibody binding to an important cell entry protein on the virus, for example.

Type of test	Time to results	What it tells us	What it cannot tell us	Figure
Rapid diagnostic test (RDT)	10-30 minutes	The presence or absence (qualitative) of antibodies against the virus present in patient serum.	The quantifiable amount of antibodies in the patient serum, or if these antibodies are able to protect against future infection	RDT figure
Enzyme linked immunosorbent assay (ELISA)	1-5 hours	The presence or absence (quantitative) of antibodies against the virus present in patient serum.	If the antibodies are able to protect against future infection.	ELISA figure
Neutralization assay	3-5 days	The presence of active antibodies in patient serum that are able to inhibit virus growth ex vivo, in a cell culture system. Indicates if the patient is protected against future infection.	It may miss antibodies to viral proteins that are not involved in replication.	PRNT figure

Tests that have been approved for diagnostic use in the United States

Country of development	US/China
Type of Serological Test	RDT
Authors/Company	Cellex Inc.
Description	RDT, lateral flow assay, which detects IgM and IgG to the nucelocapside protein of SARS-CoV-2. The sensitivity is 93.8% and

	specificity is 95.6%, when tested at 2 Chinese hospitals in a total of 128 COVID19 positive patients, and 250 COVID19 negative patients (as detected by RT-qPCR).
Phase of development	Approved by FDA for EUA on diagnostics, has CE approval
Proposed release	available for purchase by research labs/healthcare providers (product number 5513)
Date	April 1, 2020

Tests that have been approved for diagnostic use in other countries

Country of development	US/China
Type of Serological Test	RDT, solid phase immunochromatographic assay
Authors/Company	Aytu Biosciences/Orient Gene Biotech
Description	The (COVID-19) IgG/IgM Rapid Test will assay patient antibodies to SARS-CoV-2 from blood or plasma samples. The sensitivity is 87.9% and specificity is 100% for IgG, and for IgM it is 97.2% and 100%, respectively.
Phase of development	CE approved, used in China in clinical settings, awaiting FDA approval
Proposed release	Shipments should be ready by early April
Date	March 10, 2020

Country of development	US/China
Type of Serological Test	Proprietary

Authors/Company	ScanWell Health/INNOVITA
Description	This kit is for detection of IgG and IgM for SARS-CoV-2 in the blood, taking only 15 minutes, and is an at-home test. The test has 87.3% sensitivity and 100% specificity.
Phase of development	Cleared by China's National Medical Products Administration (NMPA), and pending approval by US FDA
Proposed release	6-8 weeks (May 1 to May 15), depending on FDA approval date
Date	March 20, 2020

Country of development	Singapore
Type of Serological Test	Not explicity stated, though their "gold standard" is a neutralization assay
Authors/Company	Singapore/ Wang Lab
Description	The Wang lab developed two tests. One, which has about 90% sensitivity, is rapid and uses recombinant viral proteins to detect reactive antibodies. The second is their "gold standard" and utilizes a viral neutralization assay but takes 3-5 days.
Phase of development	Deployed in Singapore
Proposed release	Not stated
Date	March 1, 2020

Country of development	China
Type of Serological Test	Lateral flow assay (RDT)
Authors/Company	Guangzhou Wondfo Biotech Co Ltd
Description	Wondfo SARS-CoV-2 Antibody Test, which is a lateral flow assay that assays patient IgG and IgM. The article did not specify target antigens, sensitivity, or specificity
Phase of development	CE/IVD, approved by NMPA in China for point of care testing
Proposed release	CE/IVD in the EU

Date	Feb. 22, 2020

Country of development	China
Type of Serological Test	RDT (colloidal gold lateral flow assay)
Authors/Company	Guangdong Hecin-Scientific
Description	Tests for IgM against SARS-CoV-2.
Phase of development	Cleared by China's National Medical Products Administration (NMPA)
Proposed release	Approved for use in China
Date	Feb. 22, 2020

Country of development	China
Type of Serological Test	RDT
Authors/Company	Dynamiker
Description	The test, DNK-1419-1, assays for patient IgG and IgM with 92% accuracy.
Phase of development	The NMPA has approved it in the 7th edition of Diagnostic and treatment protocol of COVID-19
Proposed release	Used in China, no other approvals to date
Date	Date not given

Country of development	The Republic of Korea
Type of Serological Test	RDT
Authors/Company	SD Biosensor
Description	US supplier Henry Schein will distribute the test for IVD use only

Phase of development	Approved for diagnostic us outside the US, Research use only in US
Proposed release	2-3 weeks
Date	March 26, 2020

Country of development	US
Type of Serological Test	ELISA
Authors/Company	MayoClinic/University of Minnesota
Description	MayoClinic is developing an ELISA to test for antibodies to SARS-CoV-2. The types of antibodies are not stated, nor is sensitivity or specificity.
Phase of development	Clinical
Proposed release	April 6, 2020
Date	April 1, 2020

Country of development	USA
Type of Serological Test	RDT
Authors/Company	Advaite
Description	RapCov Rapid COVID-19 Test is an in vitro diagnostic test for IgM and IgG antibodies. In a study with 18 healthy and 18 COVID-19 positive patients, the sensitivity was 89% and specificity was 100%. It should be noted that "specificity" was only performed on healthy patient samples, not patient samples from related viruses. Further testing is necessary to validate the test. It is currently being used to study community prevalence in Chester County, PA. https://advaite.com/press-release/advaite-deploys-covid-19-rapid-antibody-test-kits-to-chester-county-and-collaborates-with-pennsylvania-companies-to-scale-up-manufacturing/
Phase of development	Research use only (IVD), not approved for diagnostic use. This company was not found on any FDA categorization of tests

Proposed release	April 2020
Date	April 6, 2020

Country of development	USA
Type of Serological Test	RDT
Authors/Company	Premier Biotech
Description	The Premier Biotech COVID-19 rapid test assays for patient IgG and IgM. Sensitivity and specificity were not reported. It is currently being provided to urgent care centers in Charlotte, NC for testing. It has not been approved by the FDA for EUA.
Phase of development	Research use only (IVD), not approved for diagnostic use. This company was not found on any FDA categorization of tests
Proposed release	April 2020
Date	April 9, 2020

Tests that have been approved for research or surveillance purposes only

Country of development	US
Type of Serological Test	ELISA
Authors/Company	Epitope Diagnostics, Ltd
Description	KT-1032 tests for IgG to SARS-CoV-2, while KT-1033 tests for IgM to SARS-CoV-2. The kits do not state the antigens of interest.
Phase of development	Approved by FDA, for clinical use only and for research use. Not for at home testing. The test itself has not been evaluated by the FDA
Proposed release	Ongoing

Date	March 3, 2020

Country of development	US
Type of Serological Test	RDT
Authors/Company	CTK Biotech
Description	The test, COVID-19 IgG/IgM Rapid Test, tests for patient IgG and IgM in a lateral flow assay.
Phase of development	Not approved for use in the US, but available for purchase by research labs/healthcare providers
Proposed release	available for purchase by research labs/healthcare providers and export out of the US
Date	March 12, 2020

Country of development	US
Type of Serological Test	RDT (colloidal gold lateral flow assay)
Authors/Company	BioMedomics
Description	This assay detects patient antibodies, IgG and IgM, on a lateral flow assay. It uses a recombinant viral antigen, though it does not state the specific antigen. The test is a 3 line read-out, one line for a control, one line to detect IgM, and one to detect IgG. Three lines indicates the patient has both IgG and IgM.
Phase of development	CE/IVD, approved by FDA but only for research use
Proposed release	CE/IVD, available for purchase by research labs/healthcare providers in the US, but only for research use
Date	March 16, 2020

Country of development	US
Type of Serological Test	RDT

Authors/Company	Ray Biotech
Description	This test, the Coronavirus (COVID-19) IgM/IgG Rapid Test Kit, detects patient IgM and IgG to SARS-CoV-2 in patient blood samples. It detects antibodies against the viral N protein.
Phase of development	CE/IVD, approved for research use only in the US. Approved for research use under FDA EUA.
Proposed release	available for purchase by research labs/healthcare providers, CE/IVD approved
Date	March 19, 2020

Country of development	US
Type of Serological Test	ELISA
Authors/Company	Creative Diagnostics
Description	Kit DEIASL019 detects patient IgG for SARS-CoV-2, and uses the whole virus lysate as the antibody binding target. The reported sensitivity and specificity are 100% (from 16 and 30 samples, respectively). The DEIA2020 kit only tests for patient IgG that reacts to N protein.
Phase of development	Not approved for diagnostic use; for research use only
Proposed release	available for purchase by research labs/healthcare providers, but not for diagnostic use
Date	March 20, 2020

Country of development	US
Type of Serological Test	ELISA
Authors/Company	Eagle Biosciences
Description	This company has two kits, one (KTR-1032) which targets patient IgG, and one (KTR-1033) that targets IgM. The target antigen is an "HRP-labeled-COVID-19 antigen." They did not list sensitivity or specificity

Phase of development	Research use only, CE/IVD outside the US
Proposed release	available for purchase by research labs/healthcare providers, but not for diagnostic use
Date	Date not given

Country of development	China/US
Type of Serological Test	RDT
Authors/Company	Sure Biotech
Description	The Coronavirus Rapid Test assays for IgG and IgM antibody in blood or plasma samples, with 92-96% accuracy.
Phase of development	CE approved
Proposed release	available for purchase by research labs/healthcare providers, CE approved
Date	Feb. 2020

Country of development	China/US
Type of Serological Test	RDT, immunofluorescence, colloidal gold
Authors/Company	BioEasy/Shenzhen BioEasy Biotechnology Co.
Description	There are three tests: 1) the 2019 nCoV Ag test, which assays sputum or nasal swabs for SARS-CoV-2 antigens and gives a fluorometric read out, 2) the 2019-nCoV Ag GICA test, which uses colloidal gold, and 3) the 2019 nCoV IgG/IgM GICA rapid test which assays for patient antibodies to the virus from blood samples
Phase of development	CE/IVD approved
Proposed release	available for purchase by research labs/healthcare providers, CE/IVD approved
Date	Date not given

Country of development	The Republic of Korea
Type of Serological Test	RDT (colloidal gold lateral flow assay)
Authors/Company	Sugentech
Description	This test is a colloidal gold lateral flow assay that can be read in 10 minutes, and measures presence of patient IgG and IgM.
Phase of development	CE/IVD approved
Proposed release	available for purchase by research labs/healthcare providers, CE/IVD approved
Date	Date not given

Country of development	The Republic of Korea
Type of Serological Test	RDT
Authors/Company	SD Biosensor
Description	This company currently offers 3 tests. 1) The Standard Q COVID-19 IgM/IgG Duo which tests for both IgG and IgM patient antibodies to SARS-CoV-2. Sensitivity was 82% and specificity was 97% (based on data from 30 healthy donors and 33 COVID-19 positive individuals. 2) Standard Q COVID-19 Ag, which detects virus antigen from nasopharyngeal swabs, and 3) Standard F COVID-19 Ag FIA, which detects viral N protein present in nasopharyngeal swabs in a fluorescence based assay.
Phase of development	Korea EUA approved
Proposed release	available for purchase by research labs/healthcare providers, but not for diagnostic use
Date	Date not given

Country of development	Singapore
Type of Serological Test	RDT, prescreen step

Authors/Company	Sensing self
Description	This is a pre-screening, at home test (though not authorized for at-home use yet). It tests for IgG and IgM antibodies, and is reported to be 92% accurate.
Phase of development	CE certified awaiting FDA EUA.
Proposed release	available for purchase by research labs/healthcare providers, CE/IVD approved
Date	Date not given

Country of development	Germany
Type of Serological Test	ELISAs
Authors/Company	Euroimmun AG
Description	This company has two tests, including EI 2606-9601 A, which tests for patient IgA, and EI 2606-9601 G, which tests for patient IgG. The target antigens were not stated, nor were specificity or sensitivity of tests.
Phase of development	Research use only, CE/IVD in EU
Proposed release	CE/IVD in the EU
Date	March 12, 2020

Country of development	Germany
Type of Serological Test	RDT, lateral flow assay
Authors/Company	PharmACT
Description	This RDT tests for IgM and IgG of patients, with 92-98% sensitivity in later stages of the infection (day 11-24) with 100% sensitivity.
Phase of development	Research use only
Proposed release	Appears available for purchase by research labs/healthcare providers, but no clear approvals
Date	Date not given

Country of development	China
Type of Serological Test	RDT (colloidal gold lateral flow assay)
Authors/Company	Liming Bio
Description	COVID-19 IgG/IgM Combo Rapid Test Device is an RDT that tests for patient IgG and IgM antibodies. The sensitivity and specificity for total antibodies were 93.1 and 100%, respectively. For IgG, sensitivity is 82% and specificity is 100%. For IgM, the sensitivity is 62% and specificity is 100%.
Phase of development	CE/IVD
Proposed release	CE/IVD
Date	Feb. 2020

Country of development	China
Type of Serological Test	Not listed
Authors/Company	Snibe Co
Description	The company provides two tests the 2019-nCoV IgG , and 2019-nCoV IgM tests. The test is a chemiluminescent immunoassay (CLIA). It has been clinically tested in China, though the exact specificity and sensitivity was not stated.
Phase of development	CE/IVD approved
Proposed release	available for purchase by research labs/healthcare providers, CE/IVD approved
Date	Feb. 19, 2020

Country of development	China
Type of Serological Test	ELISA

Authors/Company	Beijing Wantai
Description	They offer, 1. Wantai SARS-CoV-2 Ab Rapid Test Kit, 2. Wantai SARS-CoV-2 IgM ELISA kit, and 3. Wantai SARS-CoV-2 Ab ELISA kit. The kits do not state which antigens are used as targets. 93.1% sensitivity and 100% specificity.
Phase of development	Approved for Research use only, unclear if available in the US
Proposed release	Released in China
Date	Feb. 25, 2020

Country of development	China
Type of Serological Test	ELISA
Authors/Company	Shenzhen Yhlo Biotech Company
Description	This company provides 2 tests, the iFlash-SARS-CoV-2-IgG and the iFlash-SARS-CoV-2-IgM, which test for patient antibodies to the virus. The target antigen is not specified. The sensitivity of the IgG assay is over 90%, and specificity is over 95%. For the IgM test, the sensitivity and specificity are both over 95%, based on assaying over 1200 Chinese patient samples.
Phase of development	CE/IVD approved
Proposed release	available for purchase by research labs/healthcare providers, CE/IVD approved
Date	Feb. 27, 2020

Country of development	China
Type of Serological Test	RDT (colloidal gold lateral flow assay)
Authors/Company	Sanuo Biotech
Description	The SARS-Cov-2 Antibody Test strip tests for patient IgG and IgM. The press release did not disclose sensitivity or specificity of the test.
Phase of development	CE/IVD approved

Proposed release	available for purchase by research labs/healthcare providers, CE/IVD approved
Date	March 12, 2020

Country of development	China
Type of Serological Test	RDT (colloidal gold lateral flow assay)
Authors/Company	BioTime
Description	The SARS-CoV-2 IgG/IgM kit tests for patient antibodies to the virus from blood or plasma samples. There is no reported sensitivity or specificity.
Phase of development	Only approved for in vitro diagnostic use
Proposed release	available for purchase by research labs/healthcare providers
Date	Date not given

Country of development	The Republic of Korea
Type of Serological Test	RDT
Authors/Company	GenBody
Description	GenBody FIA COVID-19 IgM/IgG (COVI025)
Phase of development	Research use only, CE/IVD in EU
Proposed release	CE/IVD in the EU
Date	March 2, 2020

Country of development	United Kingdom
Type of Serological Test	RDT
Authors/Company	Mologic
Description	Seems to be an RDT (probably to IgM and IgG). No description

	was given, other than 3.5 million tests were ordered.
Phase of development	UK has purchased 3.5 million, they are validating now with Liverpool Trop Med and St. Georges, London
Proposed release	Date not given
Date	March 29, 2020

Country of development	China
Type of Serological Test	RDT
Authors/Company	Livzon Diagnostics
Description	RDT, lateral flow assay, which detects IgM and IgG to the nucelocapside protein of SARS-CoV-2.
Phase of development	Research use only, CE/IVD approved
Proposed release	available for purchase by research labs/healthcare providers
Date	Date not given

Tests that are still in development

Country of development	US
Type of Serological Test	CRISPR-based lateral flow assay
Authors/Company	Broughton et al (Mammoth Biosciences)
Description	Using a CRISPR-Cas12 based method, they can specifically detect virus RNA for the E and N genes. This is called the DETECTR assay, and does not assay for patient antibodies, but the presence of viral RNA. The CRISPR-Cas12 RNA targeting is followed by isothermal amplification of the target, resulting in a visual readout with a fluorophore.This was 90% sensitive and 100% specific.
Phase of development	Pre-clinical

Proposed release	In development
Date	March 10, 2020

Country of development	US
Type of Serological Test	Not stated
Authors/Company	CDC
Description	They are now beginning testing in specific populations, 1) people who have not been diagnosed but live in a COVID-19 hotspot, 2) a later national survey, and 3) populations like healthcare workers.
Phase of development	Clinical
Proposed release	Not given
Date	April 4, 2020

Country of developmentU	US
Type of Serological Test	ELISA
Authors/Company	Amanat et al.
Description	An ELISA based method using recombinant receptor binding domain (RBD) regions of the spike protein or the full length spike protein. COVID-19 patient sera was most reactive to the full length spike protein, while non-COVID-19 patient sera did not react to either protein above background
Phase of development	Pre-clinical
Proposed release	Not stated
Date	March 18, 2020

Country of development	US

Type of Serological Test	Proprietary
Authors/Company	United Biomedical (UBI)/ c19
Description	This kit is being tested in a small community in Colorado, in partnership with the Public Health Department of San Miguel County, to test all residents for a SARS-Cov-2 antibody. The assay is testing for antibodies to recombinant fragments of the S, N, and M proteins. So far, the test has 100% sensitivity and specificity after day 10 of symptoms, according to their website. This has not been approved by the FDA. They also state that "Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E"
Phase of development	In testing in San Miguel, CO
Proposed release	Ongoing trials in Colorado, no stated release date
Date	March 19, 2020

Country of development	Netherlands
Type of Serological Test	ELISA
Authors/Company	Okba et al
Description	Modifying existing beta version ELISA kits (EUROIMMUN Medizinische Labordiagnostika AG) for IgG or IgA, and an in-house ELISA kit, they coated plates with recombinant S1 domain of the spike protein. The commercially available kits are not yet approved for use. They found that the kits were sensitive and specific for the S1 region of SARS-CoV-2, looking at 45 samples overall.
Phase of development	Pre-clinical
Proposed release	Not stated
Date	March 20, 2020

Country of development	China
Type of Serological Test	RDT

Authors/Company	Jiangsu bioPerfectus technologies
Description	This company has two tests, the PerfectPOC Novel Corona Virus (SARS-CoV-2) IgM/IgG Rapid Test Kit and the PerfectPOC Novel Corona Virus (SARS-CoV-2) Ag Rapid Test Kit. The IgM/IgG test assays for patient antibodies to the virus from a blood sample, while the Ag Rapid test assays for SARS-CoV-2 antigen from nasal swab samples.
Phase of development	Developed, awaiting approval
Proposed release	Appears available for purchase by research labs/healthcare providers in China, but no clear approvals
Date	March 3, 2020

Country of development	China
Type of Serological Test	RDT
Authors/Company	Wuhan EasyDiagnosis Biomedicine Ltd
Description	The SARS-CoV-2 IgM/IgG Antibody test kit uses blood or plasma samples to detect patient antibodies. There is no listed sensitivity or specificity
Phase of development	No clear approvals
Proposed release	available for purchase by research labs/healthcare providers, but no clear CE or FDA approvals
Date	Date not given

Country of development	Belgium
Type of Serological Test	Dipstick (lateral flow assay)
Authors/Company	Coris Bioconcept
Description	This lateral flow assay detects SARS-CoV-2 antigen in nasal mucus samples. The sensitivity was approximately 60% when tested in two different hospitals.
Phase of development	Clinically testing

Proposed release	available for purchase by research labs/healthcare providers, does not appear to have any approvals
Date	March 24, 2020

Country of development	US
Type of Serological Test	ELISA
Authors/Company	Vitalant/UCSF
Description	It appears that Vitalant (a blood donation company) and UCSF have teamed up to make an in-house antibody test for SARS-CoV-2. It is an ELISA based assay, though they have not disclosed which antibodies are detected.
Phase of development	In development
Proposed release	Date not given
Date	March 31, 2020

Country of development	US
Type of Serological Test	ELISA
Authors/Company	Klein lab, JHSPH
Description	They have adapted an ELISA, based on Amanat et al 2020, that tests for IgG and IgM to the full length Spike protien and to the receptor binding domain (RBD). They are now working to get a mucosal IgA ELISA working. So far, they are using the kit to test samples from Johns Hopkins Hospital.
Phase of development	Pre-clinical
Proposed release	Not given, but being used for research use
Date	April 6, 2020

Country of development	China

Type of Serological Test	ELISA
Authors/Company	Zhang et al
Description	This group developed an in-house ELISA testing for patient antibodies (IgM and IgG) to the SARSr-CoV Rp3 nucleocapside (N) protein. They found that on day 5, 81% of patients were positive for IgM and 100% were positive for IgG (of 16 COVID-19 positive patients).
Phase of development	Pre-clinical
Proposed release	Not given
Date	February 17, 2020

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