Ardi Research SARS-COV/COV2
RAPID POC TEST CE IVD TEST KIT (Colloidal Gold)

CoVard COVID-19 RAPID POC TEST KIT

INSTRUCTION

The CoVard Covid-19 Rapid POC (point-of-care) Test is a lateral flow immunoassay which qualitatively assesses the presence of IgM and IgG antibodies against SARS-CoV-2 in patient capillary whole blood, serum and plasma as an aid in the diagnosis of primary and secondary COVID-19 infection. The rapid test is quick and easy to perform, can be stored at room temperature and provides reliable test results in just 15 minutes.

SUMMARY AND EXPLANATION

SARS-CoV-2 virus causes acute respiratory infectious disease. Patients currently infected by the novel coronavirus are the main source of infection; people with asymptomatic infections can also be a source of contagion. According to current epidemiological research, the incubation period is between 1 and 14 days, mostly 3 to 7 days. The main symptoms are fever, tiredness, and dry cough. In a few cases, nasal congestion, runny nose, sore throat, myalgia and diarrhea are seen.

WORKING PRINCIPLE OF THE KIT

The CoVard COVID-19 IgM/IgG Antibody Test Cassette consists of four components: (1) Specimen (S) component, (2) IgM component, (3) IgG component and (4) Control (C) component.

The test contains anti-human IgM and anti-human IgG as the capture reagent, and SARS-CoV-2 antigen as the detection reagent. A rabbit anti-mouse IgG is employed in the control line system. The strip inside the cassette is provided with anti-human IgM coating at the IgM test line (2) region. During testing, the specimen reacts with SARS-CoV-2 antigen-coated particles in the test cassette. If the specimen contains patient-generated IgM antibodies to the SARS-CoV-2 virus, a colored line will appear in the IgM test line region as a result. IgM antibodies are the first antibodies to appear in response to a novel antigen. They imply a more recently initiated infection. Similarly, anti-human IgG is coated at the IgG test line (3) region and if the specimen contains patient-generated IgG antibodies to SARS-CoV-2 virus, the conjugate-specimen complex reacts with anti-human IgG and as a result a colored line appears in the IgG test line region. IgG antibodies are generated later in the course of the infection.

A sample can be positive if there are IgM, IgG, or both IgM and IgG antibodies present.
IgM and IgG antibodies can both be present in a sample. This implies that the conversion from a primarily IgM to IgG humoral response is underway. Therefore, testing for both IgM and IgG can give an indication of the stage of infection:

- IgM only: early stage
- IgM and IgG: mid stage
- IgG only: late stage

If the sample does not contain SARS-CoV-2 antibodies, no colored line will appear in either of the IgM and IgG test line regions, indicating a negative result. To serve as a procedural control, a colored line should always appear in the control line region. This control line indicates that the proper volume of sample has been added and membrane wicking has occurred.

CONTENTS OF THE KIT

Materials provided with test kits:

- Test Cassettes
- Sterile Alcohol Wipe
- Lancet
- Dropper Pipette
- Buffer Solution
- User Guide

Note: Components from different batches of the kit cannot be mixed.

SAMPLE COLLECTION AND PREPARATION

The CoVard COVID-19 IgG/IgM Rapid test can be performed using whole blood, serum or plasma. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Also, avoid turbidity, hyperlipidemic or polluted samples. Use only clear non-hemolyzed specimens.

- Serum: Use a serum separator tube (SST) and allow samples to clot for 30 minutes at room temperature before centrifugation for 15 minutes at 1000×g at 2-8°C. Collect the supernatant to carry out the assay.
- Plasma: Collect plasma by using an anticoagulant tube. Centrifuge samples for 15 min at 1000×g at 2-8°C within 30 min of collection. Collect the supernatant to carry out the assay.

Testing should be performed immediately after the sample is collected. Do not leave the sample at room temperature for prolonged periods. Serum and plasma samples may be stored at 2-8°C for up to 3 days, for long term storage, serum/plasma samples should be kept below -20°C.
Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly. EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as anticoagulant during sample collection. Heat treated samples may interfere with detection result. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.

FINGERSTICK BLOOD COLLECTION

- Clean the patient's hand with an alcohol wipe. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the punctured site.
- Add the fingerstick blood specimen to the test by using a capillary pipette: Avoid air bubbles.

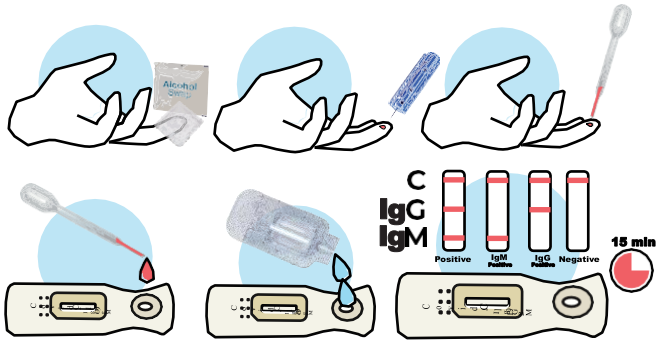
Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Blood collected by fingerstick should be tested immediately.

PROCEDURE

Allow the test, sample, buffer and/or controls to reach room temperature (15-30°C) prior to testing. Remove the test cassette from the sealed foil package and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil package. Place the cassette on a clean and horizontal surface and perform the next 3 steps.

1. After piercing the finger with a lancet, the blood is collected with the pipette and 1 full drop of blood is dropped in the sample compartment of the cassette

3. The combined sample flows down to the sample pad and moves via capillary lateral flow across the test. Subsequently, the sample-conjugate complex moves to the nitrocellulose membrane and here it comes in contact with the three test lines: IgM, IgG and control lines. Any IgM or IgG antibody will bind here. However, only human IgM and/or IgG antibody-COVID-19 antigen-gold nanoparticle complexes will produce a visible colored line. Finally, any excess will flow through to the absorption pad. Wait for the colored line(s) to appear. Within 15 minutes, the results of the test can be read. Do not interpret the result until after 15 minutes.



INTERPRETATION OF RESULTS

IgG Positive: Two lines appear
One colored line should appear in the control line region(C), and a colored line appears in IgG test line region. The result is positive for COVID-19 virus IgG.

IgM Positive: Two lines appear
One colored line should appear in the control line region (C), and a colored line appears in IgM test line region. The result is positive for COVID-19 virus IgM.

IgG and IgM Positive: Three lines appear
One colored line should always appear in the control line region(C), and two-colored lines should appear in IgG test line region and IgM test line region respectively. This result is positive for IgG & IgM antibodies to COVID-19 virus.

NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of COVID-19 antibodies in the sample. Therefore, any shade of color in the IgG and/or IgM test line region(s) should be considered positive.

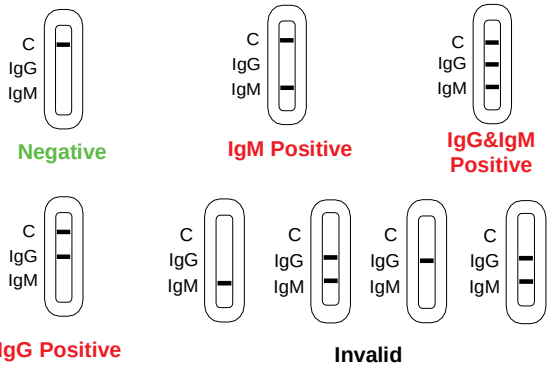
Negative: One line appears
One colored line should appear in the control line region (C). No line appears in either IgG or IgM test line region(s).

Invalid: Control line fails to appear
Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal valid procedural control, confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

V1.4/11.03.2021



STORAGE AND STABILITY

■ Do not use expired products or products with a broken sealing foil.
■ Handle all samples cautiously as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of samples.
■ Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
■ Do not eat, drink or smoke in the area where samples or kits are handled.
■ The used tests and samples will be potentially contaminated and should be discarded according to the local regulation.
■ Humidity and temperature could adversely affect results.
■ Do not use components from different batches of kits.

LIMITATIONS

■ The CoVard COVID-19 RAPID POC IgM/IgG Antibody Test kit is a qualitative test that detects antibodies against 2019 nCoV in blood, serum or plasma. Results were obtained under optional conditions. Results for individual researchers may vary.
■ The CoVard COVID-19 RAPID POC IgM/IgG Antibody Test will only indicate the presence of IgM and IgG antibodies to SARS-CoV-2 in the sample and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
■ If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of SARS-CoV-2 infection.
■ The test will show negative results under the following conditions: The titer of the novel coronavirus antibodies in the sample is lower than the minimum detection limit of the test, or the novel coronavirus antibody has not appeared at the time of sample collection (asymptomatic stage).

PERFORMANCE FEATURES

Our external verification of performance characteristics (sensitivity and specificity) was performed by the Ardi Medical Laboratories in Kadıköy/Istanbul.

Sensitivity

To determine sensitivity, whole blood samples from N=140 SARS Cov-2 positive (RT-PCR) symptomatic subjects were tested for the detection of SARS Cov-2 IgG and IgM antibodies using both the classical ELISA method and the present test kit. 139 samples resulted in a rate of true positive results and thus a sensitivity of 99.29% (95% CI=96.08%-99.98%) for the detection of IgG antibodies. On the other hand, 136 samples resulted in a rate of true positive results and thus a sensitivity of 97.14% (95% CI=92.85%-99.22%) for the detection of IgM antibodies.The mean optical density (OD) of the ELISA method for the detection of antibodies in whole blood was 26.43 OD (min 13.20-max 40.80) for IgG and 18.11 OD (min 12.00-max 26.50) for IgM.

Specificity

Whole blood samples from N=60 SARS Cov-2 IgG and IgM antibody negative healthy volunteers were applied to determine specificity. The resulting rate of true negative test results and thus specificity was 98.33%

(95% CI=91.06%-99.96%) for IgG and 96.67% (95% CI=88.47%-99.59%) for IgM.

Sensitivity

	ELISA IgG and IgM positive	Antibody test IgG positive	Antibody test IgM positive	Sensitivity	
	N	N	N	IgG%	IgM%
	140	139	136	99,29	97,14

Specificity

	ELISA IgG and IgM negative	Antibody test IgG negative	Antibody test IgM negative	Specificity	
	N	N	N	IgG%	IgM%
	60	59	58	98,33	96,67

CROSS-REACTIVITY

The SARS Cov-19 IgG/IgM rapid test was tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-adenovirus, HBsAb, anti-H.Pylori and anti-HIV positive samples. The results showed no cross-reactivity.

INTERFERENCE

Triglycerides, hemoglobin, bilirubin as well as ascorbic acid were tested with the rapid test kit and no interferences were observed.

REFERENCE

On the True Number of COVID-19 Infections: Effect of Sensitivity, Specificity and Number of Tests on Prevalence Ratio Estimation.
Altman E, Mounir I, Najid FZ, Perlaza SM.
Int J Environ Res Public Health. 2020 Jul 24;17(15):5328. doi: 10.3390/i-jerph17155328.
PMID: 32722110 Free PMC article.

Detecting the Coronavirus (COVID-19).
Pokhrel P, Hu C, Mao H.

ACS Sens. 2020 Aug 28;5(8):2283-2296. doi: 10.1021/acssensors.0c01153. Epub 2020 Jul 17.
PMID: 32627534 Free PMC article.

ISO 15223 Symbols

CE	This product fulfils the requirements of the Directive 98/79/EC on in vitro diagnostic medical device
	Read instructions for use
	Use by
	Do not re- use
	Do not use if package is damaged
2°C 30°C	Temperature limit
	Keep away from sunlight
Σ	Contains sufficient for 25 tests
25	
LOT	Batch code
IVD	In vitro diagnostic medical
	Manufacturer
	Date of manufacture
	For Use by Qualified Personnel Only
	Protect from moisture
	Biohazard

Merdivenköy Dis. Nur St. No: 1/1
Business Istanbul Plaza
A Block 12 , Floor No: 119-120
Kadıköy / ISTANBUL / TURKEY
+90 216 443 05 44
info@ardimed.com
www.ardimed.com

V1.4/11.03.2021