Orawell® COVID-19 IgM/IgG Rapid Test
Instructions for Use

For professional use only.
For in vitro diagnostic use only.

V2.1 Effective date: 13-Apr-2021

Intended Use

Orawell® COVID-19 IgM/IgG Rapid Test is based on Lateral Flow Immunoassay (LFI) intended for qualitative detection of IgM and IgG antibodies to SARS-CoV-2 in human whole blood (fingertip), serum or plasma. This test is for in vitro diagnostic use only. It is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection or a response to the COVID-19 vaccine. Currently, it is unknown how long antibodies persist after infection or vaccination and how long will protective immunity last.

Principle of the Test

This test is based on immunochromatography - lateral flow detection technology (LFD), with anti-human IgM antibody and anti-human IgG antibody on a nitrocellulose membrane and SARS-CoV-2 antigen labelled microspheres.
The SARS-CoV-2 antigen is conjugated with colloidal gold that is present in the specimen well. The anti-human IgM antibody and IgG antibody is immobilized as a narrow band at the test line labelled "M" and "G" respectively. If SARS-CoV-2 IgM and / or IgG antibodies are present in the specimen, it forms a complex with the colloidal gold labelled antigen when mixed in the "S" well. The complex moves along the test strip due to the chromatographic effect and is captured by the anti-human protein antibody at the test line where it forms a sandwich complex and agglomerates to develop colour when SARS-CoV-2 IgM and / or IgG antibodies are present in the specimen. Otherwise there will be no colour.
Regardless of whether there are SARS-CoV-2 IgM and / or IgG antibodies in the specimen, a colour band will appear at the quality control "C" line. This is to confirm that the chromatography process is normal and the test result is valid.

Materials Provided

				
Test cassette	Micropipette	Diluent vial	Blood lancet	Alcohol swab

Component name	Specification	Description
Test Cassette	1 piece	Made of nitrocellulose membrane and a conjugated pad containing SARS-CoV-2 antigen and colloidal gold
Micropipette	1 piece	Disposable clear polyethylene pipette
Diluent Vial	1 piece	Disposable clear plastic dropper vial containing phosphate diluent
Blood Lancet	1 piece	Disposable sterile stainless-steel lancet
Alcohol Swab	2 pieces	Individually sealed disposable 70% isopropyl alcohol preparation pads
Product Insert	1 copy	Instruction for Use

Materials required but are not provided: Specimen collection containers, centrifuge (for plasma only), Personal Protective Equipment (PPE), pair of gloves, timer.

Warning and Precautions

- Do not use the product after the expiration date printed on the outer pack.
- This test is developed to detect the presence of the SARS-CoV-2 IgM and IgG antibodies.
- Follow this "Instructions for Use" for optimal performance of this test.
- Follow standard precautions when handling specimens, using the product and disposing of used materials.
- Only open the foil pack immediately before use. Do not use if it is damaged or has been exposed to environmental conditions outside of those specified. The test cassette is sensitive to humidity and heat.
- Only use the swab and diluent solution provided. Do not use the diluent if it is discoloured or turbid.
- Do not reuse any materials or components.
- The test should be performed at 15°C to 30°C (59°F to 86°F).

Storage and Stability

Orawell® COVID-19 IgM/IgG Rapid Test should be stored between 2°C and 30°C, away from direct sunlight. The product is stable until the expiration date indicated on the outer package.

Quality Control

There are two types of quality controls available for the Orawell® COVID-19 IgM/IgG Rapid Test (i) internal built-in procedural controls; and (ii) external positive and negative controls.
For internal procedural controls, regardless of whether there are SARS-CoV-2 IgM and / or IgG antibodies in the specimen, a coloured bar will appear at the quality control "C" line as an internal control standard to confirm whether the chromatography process is normal.
External positive and negative controls are available for laboratory use and are not included in this product package. If required, please contact info@aristabio.com.

Methods for Sample Collection

I. Whole Blood

1. Wash and dry your hands well.
2. Choose the fingertip where you will be obtaining blood, massage it and wipe with alcohol swab.
3. Break the safety seal on the lancet. Prick slightly on the side of the fingertip, 2-3 mm deep, and pull the needle out immediately.
4. After drop flows naturally, wipe away the first drop with another alcohol swab.
5. Using the micropipette draw up the blood from the fingertip to the marked line on the micropipette and then press wound with alcohol swab to stop bleeding; if the blood flow is not enough, press the finger (from the palm towards the finger) slightly to make blood flow out.

II.Serum

Collect the blood specimen obtained by venipuncture into a tube without anticoagulant and allow sample to clot for about 30 minutes. Separate serum from the supernatant by centrifugation.

III. Plasma

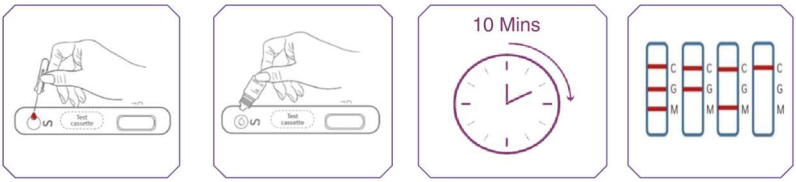
Collect the blood specimen obtained by venipuncture into a tube/container containing anticoagulant (ACD), and separate plasma from the supernatant centrifugation.

Sample Transportation and Storage

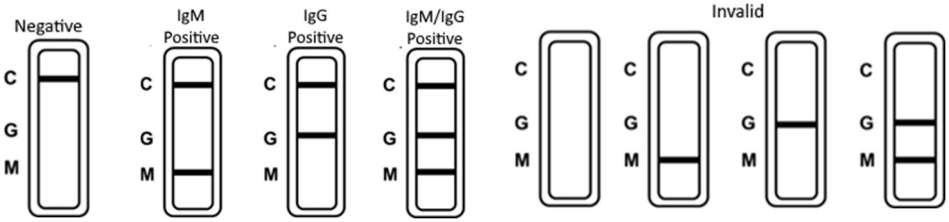
It is recommended to test the specimen as soon as possible.
If the specimen has been refrigerated, bring it to room temperature before conducting the test procedure. Whole blood samples should be tested at room temperature within 8 hours after collection. Serum/plasma samples can be stored for up to 3 days at 2°C to 8°C, or up to 6 months at -20°C. Specimen stored in corresponding conditions beyond the time limit should be disposed of, and a new sample should be collected for testing.

Conducting the Test

1. Bring the test kit components to room temperature.
2. Place the test cassette on a level surface and squeeze 2 drops of whole blood, serum or plasma from micropipette to the "S" well of the test cassette.
3. Add 2 drops of the diluent to the "S" well of the test cassette.
4. Wait 10 to 15 minutes. Ensure no disturbance to the test cassette.
5. Read the test results.
6. Dispose all materials in a plastic bag and wash your hands thoroughly.



Interpreting the Test Result



1. The "M" line detects the presence of the SARS-CoV-2 IgM antibody, and the "G" line detects the presence of SARS-CoV-2 IgG antibody. The "C" line is an internal control to confirm that the test is valid.
2. **Negative result:** The "M" and "G" lines do not display visible coloured bands. The "C" line displays a visible coloured band.
3. **Positive result:** The "M" and / or "G" lines display a visible coloured band. The "C" line displays a visible coloured band.
4. **Invalid result:** There is no visible coloured band on the "C" line.

Note: *After 20 minutes, test results are no longer considered valid.*

Trouble shooting

It is important to read the Instructions for Use before beginning the test operation. Troubleshooting steps are as follows:

Table 1 Trouble shooting

Conditions	Troubleshooting methods
Delay in reading test results beyond 20 minutes	Repeat the test
Faint or missing colour band on the "C" line	Check if the right number of drops is added to the sample well; Check if the test cassette is placed on an even surface; Check if test is conducted within the recommended 15°C to 30°C room temperature range. Make the corrections where necessary. Repeat the test
Other significant disturbances during operation such as dropping the cassette after activation	Repeat the test

Clinical Performance

I. Serum sample

The clinical performance of the Orawell® COVID-19 IgM/IgG Rapid Test was measured using serum specimens collected which were confirmed by RT-PCR to be positive or negative for SARS-CoV-2.
All the blood specimens were tested in a sequentially blinded fashion and the results were compared to results of matched specimens which were subsequently tested with RT-PCR for the detection of SARS-CoV-2 IgM and IgG antibodies. The results are summarized in Table 2 below.

Table 2 Performance summary of Orawell® COVID-19 Antibody Test compared to RT-PCR test results on the detection of SARS-CoV-2 IgM and IgG antibodies in 130 study specimens

Orawell® COVID-19 Antibody Test results	Rt-PCR Results (reference)		Total
	Positive	Negative	
Positive (70)	68	0	68
Negative (60)	2	60	62
Total (130)	70	60	130

Positive Percent Agreement (PPA)	97.14%	Estimated Sensitivity = 97.14% (95% CI: 90.17%~99.21%) Estimated Specificity = 100.00% (95% CI: 93.98%~100.00%)
Negative Percent Agreement (NPA)	100.00%	
Positive Predictive value (PPV)	100.00%	
Negative Predictive Value (NPV)	96.77%	
Total agreement rate	98.46%	

I. Plasma sample

The Orawell® COVID-19 IgM/IgG Rapid Test was tested at the Frederick National Laboratory for Cancer Research (FNLCR), United States and sponsored by the National Cancer Institute (NCI) using 2 panels of previously frozen samples consisting of a total of 58 independent SARS-CoV-2 antibody-positive serum samples and 97 independent antibody-negative serum and anticoagulant citrate dextrose (ACD) plasma samples. Each of the antibody-positive samples were confirmed with a nucleic acid amplification test (NAAT) and both IgM and IgG antibodies were confirmed to be present in all samples.

All antibody-negative samples were collected prior to 2020 and include i) eighty-seven (87) samples selected without regard to clinical status, labelled "Negatives" and ii) ten (10) samples selected from a plasma bank of HIV+ patients, labelled "HIV+". The results and data analysis are shown the tables below.

	Antibody Positive			Antibody Negative		
Test Device	IgM+, IgG+	IgM, IgG-	IgM-, IgG+	Neg.	HIV+	Total
IgM+, IgG+	54					54
IgM+, IgG-				3	1	4
IgM-, IgG+	4			1		5
IgM-, IgG-				83	9	92
Total	58			87	10	155

Measure	Estimate	95% CI
IgM Sensitivity	93.1% (54/58)	(83.6%; 97.3%)
IgM Specificity	95.9% (93/97)	(89.9%; 98.4%)
IgG Sensitivity	100% (58/58)	(93.8%; 100%)
IgG Specificity	99.0% (96/97)	(94.4%; 99.8%)
Combined Sensitivity	100% (58/58)	(93.8%; 100%)
Combined Specificity	94.8% (92/97)	(88.5%; 97.8%)
Combined PPV for prevalence = 5.0%	50.5%	(30.0%; 70.3%)
Combined NPV for prevalence = 5.0%	100%	(99.6%; 100%)
Cross-reactivity with HIV+	10.0% (1/10), may be present	

Cross Reactivity (Analytical Specificity)

Cross reactivity of the Orawell® COVID-19 IgM/IgG Rapid Test was evaluated by testing a panel of high prevalence respiratory pathogens that could potentially cross-react with Orawell® COVID-19 IgM/IgG Rapid Test.
No cross-reactivity or interference was observed with the following microorganisms when tested at the concentration presented in Table 3 below.

Table 3 Potential cross-reactants

No	Virus Antibody positive	IgM	IgG
1	anti-Influenza A IgG	5/5-/-	5/5-/-
2	anti- Influenza A IgM	5/5-/-	5/5-/-
3	anti- Influenza B IgG	5/5-/-	5/5-/-
4	anti- Influenza B IgM	5/5-/-	5/5-/-
5	anti-respiratory syncytial virus IgM	5/5-/-	5/5-/-
6	anti-respiratory syncytial virus IgG	5/5-/-	5/5-/-
7	anti-Haemophilus influenza IgM	5/5-/-	5/5-/-
8	anti-Haemophilus influenza IgG	5/5-/-	5/5-/-
9	anti-Hepatitis C Virus IgG	5/5-/-	5/5-/-
10	anti-Hepatitis C Virus IgM	5/5-/-	5/5-/-
11	anti-Hepatitis B Virus IgG	5/5-/-	5/5-/-
12	anti-Hepatitis B Virus IgM	5/5-/-	5/5-/-
13	anti-*Chlamydia pneumonia* IgM	5/5-/-	5/5-/-
14	anti-*Chlamydia pneumonia* IgG	5/5-/-	5/5-/-
15	anti-*Legionella pneumophila* IgM	5/5-/-	5/5-/-
16	anti-Legionella pneumophila IgG	5/5-/-	5/5-/-

17	anti-*Mycoplasma pneumonia* IgM	5/5-/-	5/5-/-
18	anti-*Mycoplasma pneumonia* IgM	5/5-/-	5/5-/-
19	anti-TP IgG	5/5-/-	5/5-/-
20	RF 118	-	-
21	RF 222	-	+
22	RF 800	-	-
23	RF4 68.7	-	-
24	RF 21,1	-	-

Limitations

1. This product can only be used for qualitative detection of SARS-CoV-2 IgM and IgG antibodies in human blood, serum and plasma.
2. The test results of this product are for clinical reference only and should not be used as the only basis for clinical diagnosis and treatment. The clinical management of patients should be comprehensively considered in conjunction with their symptoms/signs, medical history, other laboratory tests, and treatment responses.
3. Improper sample collection, storage, transportation, processing, and low antibody titers in the sample may lead to false negative results.
4. Due to the limitations of immunochromatographic methodology, it is recommended for negative test results, nucleic acid amplification testing or virus culture identification methods be used for review and confirmation.

Ordering information

AWB-AB-SBEN-001: Orawell® COVID-19 IgM/IgG Rapid Test (1 test in single pack)

AWB-AB-BPEN-020: Orawell® COVID-19 IgM/IgG Rapid Test (20 tests in aggregated pack)

Symbols

	Medical device manufacturer		Catalog number
	Authorized Representative in the European Community /European Union		Do not re-use
	Consult instructions for use or consult electronic instructions for use		Use-by-date
	CE Marking		Batch code
	*In vitro* diagnostic medical		Keep away from moisture
	Temperature limit		Contains sufficient for <n> tests
	Caution, Consult accompanying documents		Keep away from sunlight

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