INDICAID® INSTRUCTIONS FOR USE

COVID-19 IgM/IgG RAPID TEST Ref # 2010500

CE IVD

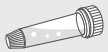
INTENDED USE

INDICAID® COVID-19 IgM/IgG Rapid Test is an in vitro diagnostic test for determining the presence of SARS-CoV-2 IgM and IgG antibodies in human whole blood.

PRINCIPLE

Antibodies produced by the human body to fight viral infections can be used as markers for disease exposure. They can be detected as early as one week after infection.

CONTAINED IN THIS BOX

1 individually-wrapped test device	1 vial of buffer solution	1 safety lancet	1 dropper	1 alcohol pad	1 instruction sheet
					

HOW TO USE

Follow these instructions closely to achieve the best results:

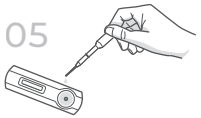
Open the package and take out the test device.

Wipe the fingertip with an alcohol pad.

Prick the cleaned fingertip with the lancet.

Collect blood from the fingertip using the dropper.

Apply all of the blood into the sample well of the test device.



Apply 2 drops of the buffer solution onto the sample well of the device.

Leave for 10 minutes and read the results. Do not read after 15 minutes. Refer to "Interpreting Your Results" section below.

INTERPRETING YOUR RESULTS:

	INDICATOR	RESULT	INTERPRETATION
	A line appears in regions (C), (IgG) and (IgM)	Positive	The presence of the control line (C) and both the IgM line (IgM) and IgG line (IgG) indicates the presence of both SARS-CoV-2 IgM and IgG antibodies. The result suggests current or recent COVID-19 infection.
	A line appears in regions (C) and (IgM)	Positive	The presence of the control line (C) and only the IgM line (IgM) indicates the presence of SARS-CoV-2 IgM antibodies. The result suggests an active or recent COVID-19 infection.
	A line appears in regions (C) and (IgG)	Positive	The presence of the control line (C) and only the IgG line (IgG) indicates the presence of SARS-CoV-2 IgG antibodies. The result suggests a recent or previous COVID-19 infection.
	A line appears in the region (C)	Negative	The presence of only the control line (C) and neither the IgM line (IgM) or the IgG line (IgG), indicates no detection of SARS-CoV-2 IgM or IgG antibodies.
	No line appears in the region (C)	Invalid	If the control line (C) does not appear, the result is invalid, regardless whether the IgM line (IgM) or the IgG line (IgG) is present. Repeat the test with a new test device.

IMPORTANT

- For in vitro diagnostic use
- User should not make any decision of medical relevance without first consulting his/her health care provider
- All components in this test kit should remain sealed until ready for use
- The test must be performed between 18-25˚C
- All components in this test kit are for one-time use only. Do not reuse
- Store at 2-30˚C. Do not freeze. Avoid direct sunlight
- Do not swallow
- Avoid contact with your eyes. If contact occurs, flush with water immediately and seek medical help
- Do not use the test kit after the expiration date

LIMITATIONS

- The test is designed for using whole blood.
- Negative results do not rule out COVID-19 infection, especially if you have been in contact with the virus. Follow-up molecular testing should be considered to rule out infection.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude COVID-19 infection.
- If you have questions about your results, please contact Customer Service at +852-9135-2570 or indicaid@phasesci.com.

FREQUENTLY ASKED QUESTIONS (FAQs)

I ACCIDENTALLY SPILLED THE TEST SOLUTION. IS IT HARMFUL?

The test solution is not harmful. Flush abundantly with water upon disposal.

Avoid having the test solution come into contact with your eyes, skin and mouth. If contact occurs with the eyes, flush with water immediately and seek medical help. If contact occurs with your skin or mouth, wash the area with soap and rinse with water.

WHAT DO I DO WITH THE TEST UNIT AFTER READING THE RESULTS?

After recording your results, carefully wrap and seal all product components and dispose by throwing it into the garbage just like any household trash. Use a sharps box if one is available.

HOW DOES THE TEST WORK?

This test is designed to detect the presence of SARS-CoV-2 virus fighting antibodies in human whole blood. Antibodies produced by the human body to fight viral infections can be used as markers for disease exposure.

WHAT ARE IgM and IgG ANTIBODIES?

As your body starts to fight off infection, your immune system produces immunoglobulin M (IgM) antibodies. IgM is the first class of antibody to be produced by the human body, and may indicate active or recent infection. IgM antibodies generally appear several days after symptoms begin and can last 1-8 weeks.

As your body continues to fight off infection, it produces fewer IgM antibodies and more long lasting immunoglobulin G (IgG) antibodies. IgG antibodies are produced at a later stage and remain even after disease resolution, which may indicate recent or prior infection.

WHAT IF I TESTED NEGATIVE?

Rapid antibody tests can only detect the presence of antibodies at the time of the test, and do not rule out COVID-19 infection. If you had contact with a known or suspected COVID-19 cases, as a best practice, performing the test once every week is recommended.

WHAT IF I TESTED POSITIVE?

If you tested positive for COVID-19 antibodies, we recommend contacting your local health authorities to organize a follow-up molecular diagnostics test for diagnosis.

HOW ACCURATE IS THE TEST?

The INDICAID® COVID-19 IgM/IgG Rapid Test has been clinically validated reach a high detection accuracy, reaching a relative detection specificity of 99% and a relative detection sensitivity of 97.1%.

In our clinical study, the INDICAID® COVID-19 IgM/IgG Rapid Test device was tested on clinical specimens from 60 healthy persons and 70 identified COVID-19 patients, using PCR as the reference method. The results are summarized as below.

CLINICAL PERFORMANCE OF NEGATIVE SAMPLES		CLINICAL PERFORMANCE OF POSITIVE SAMPLES	
Negative Cases (By PCR)	80	Positive Cases (By PCR)	70
Negative coincidence rate (COVID-19 IgM)	80 (100%)	Positive coincidence rate (COVID-19 IgM)	68 (97.1%)
Negative coincidence rate (COVID-19 IgG)	80 (100%)	Positive coincidence rate (COVID-19 IgG)	67 (95.7%)
Negative coincidence rate (Total)	80 (100%)	Positive coincidence rate (Total)	68 (97.1%)

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