INDICAID® CE

INSTRUCTIONS FOR USE

INDICAID® COVID-19 IgM/IgG Rapid Test

Intended Use

INDICAID® COVID-19 IgM/IgG Rapid Test is an *in vitro* diagnostic test for the qualitative determination of SARS-CoV-2 IgM and IgG antibodies in human whole blood (venous or fingerstick), serum or plasma. The test kit consists of test devices and a buffer. The product should only be used by trained clinical professionals.

Principle

The test devices, which employ immunoassay technology, contain: 1) A conjugate pad containing recombinant SARS-CoV-2 antigen labeled with colloidal gold and a separate antibody-gold conjugate for quality control. 2) a nitrocellulose membrane coated with two detection lines (IgG line and IgM line) and one quality control line (C line). The IgM line is coated with mouse anti-human IgM monoclonal antibodies and detects the SARS-CoV-2 IgM antibody. The IgG line coated with mouse anti-human IgG monoclonal antibodies and detects the SARS-CoV-2 IgG antibody. The C line is coated with a quality control antibody.

When a sample is added to the sample well of the test device, it will move forward along the test device. If the sample contains SARS-CoV-2 IgM antibodies, the antibodies will bind to the antigen-gold conjugate. The immunocomplex will then bind to the anti-human IgM antibodies at the IgM line, forming a visible purple-red line that indicates a positive result for SARS-CoV-2 IgM.

If the sample contains SARS-CoV-2 IgG antibodies, the antibodies will bind to the antigen-gold conjugate. The immunocomplex will then bind to the anti-human IgG antibodies at the IgG line, forming a visible purple-red line that indicates a positive result for SARS-CoV-2 IgG.

The absence of both IgM and IgG lines indicates a negative result.

The test device also contains a control line (C) which is coated with a quality control antibody and should appear purple-red regardless of the test result. if the control line does not appear, the test is invalid and the sample should be retested on a new test device.

Composition

Each test kit contains 25 test devices, 25 safety lancets (for fingerstick blood), 25 alcohol pads, 25 pipettes, a buffer, and product insert.

Storage and Handling

Store the test kit in a cool, dry place between 2-30°C (36-86°F) for short-term storage and between 2-8°C (65-77°F) for long-term storage. Keep away from light. Exposure to temperature and/or humidity outside the specified conditions may result in inaccurate results.

Do not freeze.

Use the test kits at temperatures between 18-25°C (65-77°F) and between 10-90% humidity. Do not use the test kits beyond the expiration date.

Limitations

The test result cannot be used for diagnosis of COVID-19. If the result does not match the clinical evaluation, a confirmatory test may be required. Do not use highly hemolytic samples. Do not reuse the test device.

The test kit can only be used with whole blood (from venous or fingerstick), serum or plasma. Using other samples may produce inaccurate results.

Read the result at 10 minutes. Do not interpret the result after 15 minutes.

Please follow the product insert when testing.

Test Procedure

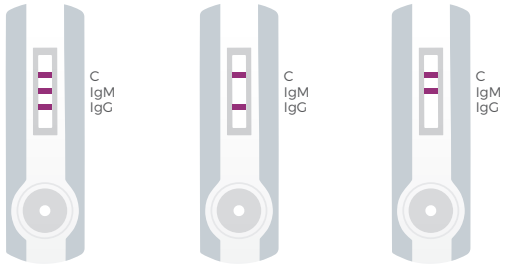
1. Take out the test kit and leave it at room temperature for minimum 30 minutes.
2. Put a test device on a clean, dust-free surface.
3. Apply 10 µL whole blood (venous or fingerstick), serum or plasma onto the sample well of a test device. If using fingerstick, apply approx. 1 drop of blood using pipette to transfer. Then apply 2 drops (about 60-80 µL,) of buffer onto the sample well of a test device.
4. Read the result after 10 minutes.

Note:

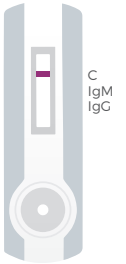
For in vitro diagnostic use. Avoid contact with eyes and skin. Flush abundantly with water upon disposal if reagents are spilled. If you apply fingertip blood with pipette, wipe the rest of blood on the fingertip with alcohol pad.

Interpretation of the test results

1. **Positive result:**
   a. The presence of the control line (C) and only the IgM line (IgM) indicates the presence of IgM against SARS-CoV-2. The result is consistent with an active or recent SARS-CoV-2 virus infection.
   b. The presence of the control line (C) and only the IgG line (IgG) indicates the presence of IgG against SARS-CoV-2. The result is consistent with a recent or previous SARS-CoV-2 virus infection.
   c. The presence of the control line (C) and both the IgM line (IgM) and IgG line (IgG) indicates the presence of IgM and IgG against SARS-CoV-2. The result suggests current or recent SARS-CoV-2 virus infection.

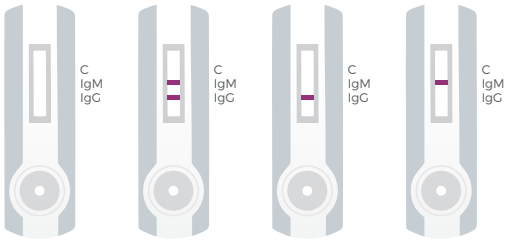


2. **Negative result:**
   The presence of only the control line (C) and neither IgM or IgG line indicates no detection of IgM or IgG against SARS-CoV-2.



IC01PI2051 | PI-2010500-ENG | Rev A

3. **Invalid result:**
   If the control line (C) does not appear, the result is invalid regardless of the color development of the IgM and IgG lines. Repeat the assay with a new test device.



Notes for clinical use:

1. *Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.*
2. *Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.*
3. *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.*

Performance Characteristics

The 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 sample	
Negative Cases (By PCR)	60
Negative coincidence rate (COVID-19 IgM)	60 (100%)
Negative coincidence rate (COVID-19 IgG)	60 (100%)
Negative coincidence rate (Total)	60 (100%)
Clinical Performance of positive sample	
Positive Cases (By PCR)	70
Positive coincidence rate (COVID-19 IgM)	68 (97.1%)
Positive coincidence rate (COVID-19 IgG)	67 (95.7%)
Positive coincidence rate (Total)	68 (97.1%)

The results show that the relative specificity is 100%, the relative sensitivity is 97.1%, and the overall accuracy is 98.5%.

Quality Control

Each lot of INDICAID® COVID-19 IgM/IgG Rapid Test is tested against predetermined specifications to ensure consistent product quality in accordance with PHASE Scientific's Quality Management System.

Manufactured For

PHASE Scientific Int'l Ltd
32 & 33F, Gravity, 29 Hing Yip St.,
Kwun Tong, Kowloon, Hong Kong

EC REP

LOTUS NL B.V.
Koningin Julianaplein 10
1e Verd, 2595AA, The Hague
The Netherlands

For more information, please visit www.phasescientific.com.

IC01PI2051 | PI-2010500-ENG | Rev A | Edition Oct 2020 | For *in-vitro* diagnostics |

CE Marking

Caution, Consult accompanying documents

Temperature Limitation

Sufficient for Use

Keep away from sunlight

Keep away from moisture

Do not reuse

IVD In-Vitro Diagnostic Medical Device

LOT Batch code

Use by

Manufacturer

PHASESCIENTIFIC

IC01PI2051 | PI-2010500-ENG | Rev A