INDICAID® COVID-19 IgM/IgG Rapid Test – CE: User Manual ENGLISH

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Intended Use

INDICAID® COVID-19 IgM/IgG Rapid Test is an in vitro diagnostic rapid test for the qualitative detection of IgG and IgM antibodies against SARS-CoV-2 in human serum, plasma, venous and fingerstick whole blood. It is for professional use only.

Summary

The COVID-19 pandemic is due to infection and rapid transmission of the coronavirus SARS-CoV-2. As of August 2021, seven COVID-19 vaccines have been approved by the World Health Organization (WHO) for emergency use in preventing severe illness or death in humans. Anti-SARS-CoV-2 IgM and IgG antibodies are common biomarkers for human immune response and are generally detectable for several months after infection or after vaccination. Therefore, serology tests can identify individuals who have developed an adaptive immune response against SARS-CoV-2, which will help track the progression of the pandemic.

Principle

The INDICAID® COVID-19 IgM/IgG Rapid Test is a rapid lateral flow chromatographic immunoassay that detects IgM and IgG antibodies against the receptor-binding domain (RBD) of the spike protein of SARS-CoV-2. This may include neutralizing antibodies that block SARS-CoV-2 from infecting host cells. The test comprises of 3 steps:

Sample loading: Human blood, serum, or plasma specimen is loaded onto the sample well (S) and is followed by Buffer Solution, which will resolubilize any anti-SARS-CoV-2 IgM or IgG antibodies from the specimen.

Antibody labeling: The Buffer Solution migrates from the Sample Pad and resolubilizes the contents of the purple Conjugate Pad. These include RBD and a quality control antibody, both of which are conjugated to colloidal gold nanoparticles. Upon mixing, the IgM and IgG antibodies form complexes with the RBD-gold, which puts a colorimetric label on those antibodies.

Antibody detection: The Buffer Solution will continue to migrate into the nitrocellulose membrane, which contains 3 distinct lines of anti-human IgM antibodies ("IgM"), anti-human IgG antibodies ("IgG"), and control antibody ("C"). The line labeled (C) will turn purplish-red when enough quality control antibody binds and accumulates in this region, indicating a successful run. When enough labeled IgM and IgG bind to the IgM and IgG lines, respectively, the resulting purple-red line indicates presence of those antibodies.

Materials Provided in Kit

- 25 Individually Wrapped Test Devices
- 25 Buffer Solution Vials
- 25 Safety Lancets
- 25 Droppers
- 25 Alcohol Pads
- 1 User Manual

Materials Required but Not Provided

- Timer
- Biohazard sharps container and regular biohazard waste bag
- Cotton wool or gauze pad (for fingerstick whole blood only)
- Specimen collection equipment and container (for plasma, serum or venous whole blood)
- General laboratory equipment (e.g. centrifuge and micropipette for plasma and serum)

Usage precautions for best results

Instructions: Read the User Manual prior to performing the test. All instructions must be strictly followed.

Storage environment: Store the test kit at 2°C – 30°C (36 – 86°F). Avoid direct sunlight. Do not freeze.

Shelf life: Do not use the kit beyond the expiration date.

Operating environment: The test must be performed at a temperature between 15-30°C and humidity below 70 %.

Pouch seal: The Test Device must remain in the sealed pouch until use. Do not use if the pouch is damaged or the seal is broken. Perform test as soon as possible, or within 1 hour after removing the test device from its foil pouch.

Specimen volume: Do not dilute the specimen, and do not add more or less than 10 µL of specimen.

Test operation: Apply the specimen to the sample well (S) quickly to avoid coagulation, and immediately add the Buffer Solution. Do not touch the sample well directly with your finger.

Read time: Interpret the test results between 10 and 15 minutes after the addition of Buffer Solution. Do not interpret results before 10 minutes or after 15 minutes.

Safety Warnings

Specimen handling: Handle all specimens as if they are potentially infectious.

Prevent oral ingestion: Do not eat, drink, or smoke in the area where the specimens or kits are handled. Never pipette by mouth.

Skin protection: Do not use the safety lancet if the protective cap has been removed. Wear protective clothing such as laboratory coats and disposable gloves to prevent Buffer Solution or specimen from contacting your skin.

Spills: Clean up spills thoroughly using appropriate disinfectant, such as 70 % alcohol. If Buffer Solution contacts the eyes or skin, flush with plenty of water.

Disposal: Dispose of all specimens and used kit materials as if they are infectious waste. Handle in accordance with all local and national regulations for infection control.

Specimen Collection and Preparation

	Venous Whole Blood	Plasma	Serum
Collection tubes	lithium heparin, K2 EDTA, acid citrate dextrose (ACD), sodium citrate, sodium fluoride and potassium oxalate blood tube	lithium heparin, K2 EDTA, acid citrate dextrose (ACD), sodium citrate, sodium fluoride and potassium oxalate blood tube	Serum tubes, SST serum tubes
Short-term storage	2-8°C (36-46°F) for 2 days before testing	2-8°C (36-46°F) for 1 week before testing	2-8°C (36-46°F) for 1 week before testing
Long-term storage	N/A, do not freeze	below -20°C (-4°F), avoid freeze thaw	below -20°C (-4°F), avoid freeze thaw
Before testing	Bring to room temperature	Bring to room temperature	Bring to room temperature

Fingerstick Whole Blood

1. Open the safety lancet by twisting and pulling the white cap.
2. Disinfect the fingertip with an alcohol pad. Allow alcohol to evaporate completely.
3. Pierce the clean fingertip by pressing the safety lancet firmly against it until an audible click is heard.
4. Release blood from the fingertip by repeatedly applying pressure near the puncture site.
5. Draw blood by placing the tip of the dropper to the blood drop. Do not squeeze the bulb. The dropper is designed to automatically suspend blood to the marked line.
6. Apply blood into the sample well (S) of the test device immediately, or no longer than 3 minutes after collection.
7. Stop the bleeding from the fingertip by applying pressure with a gauze pad or a cotton ball at the puncture site. Wipe all excess blood with the alcohol pad.

Venous Whole Blood

- Collection: Follow manufacturer instructions to collect venous whole blood into a lithium heparin, K2 EDTA, acid citrate dextrose (ACD), sodium citrate, sodium fluoride and potassium oxalate blood tube by venipuncture.
- Storage: 2-8°C (36-46°F) for 2 days before testing. Do not freeze whole blood specimens or use hemolyzed blood specimen.
- Testing: Bring the specimen to room temperature before testing.

Serum or Plasma

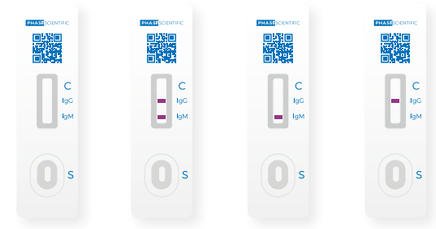
- Collection and processing: Collect venous whole blood into a plain, lithium heparin, K2 EDTA, acid citrate dextrose (ACD), sodium citrate, sodium fluoride or potassium oxalate blood tube by venipuncture. Process the blood tube in accordance with blood tube manufacturer's specimen preparation instructions.
- Short-term storage: 2-8°C (36-46°F) for 1 week before testing.
- Long-term storage: specimens should be frozen below -20°C (-4°F). Repeated freeze thaw cycles may impact the test result.
- Testing: Specimen should be bought to room temperature before testing

Test Procedure

1. Remove the test device from its packaging. Place the test device on a clean horizontal surface for running the test.
2. Apply 10 µL of specimen (serum, plasma, venous or fingerstick whole blood) onto the sample well (S) of the test device. Note: the provided dropper automatically fills to the black line at 10 µL.
3. Apply 2 drops of buffer solution into the sample well of the test device.
4. Read the test lines (IgM and IgG) and control line (C) results promptly at 10 minutes.

Interpretation of Results

1. Determine Test Validity:



If a line appears in region (C), the test is valid. If a line does not appear in this region, DO NOT interpret the test result (Step 2), the test is invalid regardless of the appearance of the test line. Invalid results may occur due to insufficient specimen volume or incorrect procedural technique, review the procedure in the User Manual and repeat with a new INDICAID® COVID-19 IgM/ IgG Rapid Test. If problems persist, contact PHASE Scientific.

2. Interpret Test Result

Positive Result			Negative Result
IgG ✓ IgM ✓	IgG ✓ IgM ✘	IgG ✘ IgM ✓	IgG ✘ IgM ✘
			
(a)	(b)	(c)	(d)

a) A line appears in regions (C), (IgG) and (IgM) indicates the presence of IgG and IgM against SARS-CoV-2.
b) A line appears in regions (C) and (IgG) indicates the presence of IgG against SARS-CoV-2.
c) A line appears in regions (C) and (IgM) indicates the presence of IgM against SARS-CoV-2.
d) A line appears in regions (C) indicates no detection of IgG or IgM against SARS-CoV-2.

Limitations

Users: For professional in vitro diagnostic use only

Plasma/serum collection: Lithium heparin, K2 EDTA, acid citrate dextrose (ACD), sodium citrate, sodium fluoride and potassium oxalate have been validated and can be used as anticoagulants. Other anticoagulants have not been validated.

Specimen composition: It is not recommended to use high-fat chyle, jaundice and high rheumatoid factor sample. Do not use hemolyzed samples. Use fresh samples whenever possible.

Diagnostics: Results of this test should not be used as sole basis to diagnose or exclude SARS-CoV-2 infection. Test results must be considered with other information, including clinical history and local disease prevalence in assessing the need for a serology test to confirm an immune response. It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.

Line intensity: Test line intensity does not indicate the quantity of the antibodies or correlate to antibody titer in the specimen.

False positive results: Positive results does not rule out co-infections with other pathogens. It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.

False negative results: Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. False negative results can occur if:

1. the quantity of antibodies against the SARS-CoV-2 present in the specimen is below the test limit of detection
2. the virus has undergone minor amino acid mutation(s) in the epitope recognized by the anti-human antibodies used in the test
3. the antibodies are not present at the time of sample collection.

Performance Characteristics

Clinical evaluation

The clinical performance of INDICAID® COVID-19 IgM/ IgG Rapid Test was evaluated with XXX prospective samples. These samples consisted of venous or fingerstick whole blood specimens from individuals who were (1) unvaccinated & uninfected, (2) vaccinated, or (3) infected with SARS-CoV-2. The Abbott Alinity SARS-CoV-2 IgG II Quant and SARS-CoV-2 IgM were used to detect IgG and IgM, respectively.

Table 1:

			INDICAID® COVID-19 IgM/ IgG Rapid Test			Sensitivity	Specificity
			Positive	Negative	Total		
Venous Whole Blood	SARS-CoV-2 IgG II Quant	Positive					
		Negative					
		Total					
	SARS-CoV-2 IgM	Positive					
		Negative					
		Total					

Table 2:

			INDICAID® COVID-19 IgM/ IgG Rapid Test			Sensitivity	Specificity
			Positive	Negative	Total		
Venous Whole Blood	Abbott Alinity SARS-CoV-2 IgG II Quant	Positive					
		Negative					
		Total					
	Abbott Alinity SARS-CoV-2 IgM Qualitative Assay	Positive					
		Negative					
		Total					

Cross-reactivity

Plasma or serum samples containing antibodies against other virus species (Table 3) showed no cross-reactivity when tested on the INDICAID® COVID-19 IgM/IgG Rapid Test.

Table 3:

Sample Categories	N
Coronavirus OC43 IgG Serum	3
Coronavirus OC43 IgM Serum	3
Coronavirus 229E IgG Serum	3
Coronavirus 229E IgM Serum	3
Coronavirus HKU1 IgG Serum	3
Coronavirus HKU1 IgM Serum	3
Coronavirus NL63 IgG Serum	3
Coronavirus NL63 IgM Serum	3
Adenovirus IgG Serum	3
Adenovirus IgM Plasma	3
Chlamydia pneumoniae IgG positive plasma	3
Chlamydia pneumoniae IgM positive Plasma	3
Haemeophilus influenzae IgG Serum	3
Haemeophilus influenzae IgM Plasma	3
Influenza A IgG positive Plasma	3
Influenza A IgM positive Plasma	3
Influenza B IgG positive Plasma	3
Influenza B IgM positive Plasma	3
Respiratory Syncytial Virus (RSV) IgG positive Plasma	3
Respiratory Syncytial Virus (RSV) IgM positive Plasma	3
Rheumatoid Factor IgG Serum	3
Rheumatoid Factor IgM Serum	3
Mycoplasma pneumoniae IgG Serum	3
Mycoplasma pneumoniae IgM Plasma	3
HIV Antibodies Positive Plasma	3
Hepatitis C Antibodies Positive Plasma	3
Hepatitis B Antibodies Positive Plasma	3
Antinuclear Antibodies ANA Nucleolar Positive Plasma	3
TOTAL	**84**

Interference Study

Contrived IgM/IgG positive and negative serum samples were spiked with the substances listed in Table 4. These samples produced no false results in the INDICAID® COVID-19 IgM/ IgG Rapid Test.

Table 4:

Substance Name	Concentration
Ascorbic acid	342 µmol/L
Uric acid	1400 µmol/L
Triglyceride	37 mmol/L
Albumin	20 mg/mL
Bilirubin	342 µmol/L
Oseltamivir	551 ng/mL
Tobramycin	51.4 µmol/L
Ribavirin	3.2 µg/mL
Zanamivir	142 ng/mL
Hemoglobin	2 g/L
Levofloxacin	48.6 µmol/L
Acetylsalicylic Acid	3.62 µmol/L
Azithromycin	15.3 µmol/L

Matrix Equivalency

25 identified IgM/IgG positive and 25 identified IgM/IgG negative donors were evaluated for each of the following specimen types:

- fingerstick whole blood
- venous whole blood
- serum
- lithium heparin plasma
- K2 EDTA plasma
- acid citrate dextrose (ACD) plasma
- sodium citrate plasma
- sodium fluoride and potassium oxalate plasma

Donors received consistent results across all specimen types.

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.

Manufacturer

PHASE Scientific Int'l Ltd
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For more information, please visit www.phasescientific.com.

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Symbol	Definition
CE	CE Marking
⚠	Caution
2°C 30°C	Temperature Limitation
Σ 25	Sufficient for Use
	Keep away from sunlight
	Keep dry
	Do not reuse
IVD	In-Vitro diagnostic medical device
REF	Catalog number
LOT	Batch code
	Use by
	Manufacturer
	Consult Instructions for Use
EC REP	European Authorized Representative