



# mLabs® SARS-CoV-2 IgG and IgM assay

REF M101-091060

For Health Care Professional Use Only

## INTENDED USE

The mLabs® SARS-CoV-2 IgG and IgM system consists of mLabs® m-101 Immunometer (small instrument) and mLabs® SARS-CoV-2 IgG and IgM cartridge. The mLabs® test system is designed to provide qualitative detection of the SARS-CoV-2 IgG and IgM antibodies results in fresh venous EDTA whole-blood or EDTA plasma. The system is intended for in vitro diagnostic use by health care professionals (HCPs).

The Micropoint Bioscience mLabs® SARS-CoV-2 IgG and IgM Assay is a microfluidic fluorescent microparticle immunoassay cartridge intended for the qualitative detection of the combination of IgM and IgG antibodies to SARS-CoV-2 in plasma (EDTA) or venous whole blood (EDTA) specimens from patients suspected of Covid-19 infection by a healthcare provider. The assay is a one step process with sample addition of whole blood or plasma to the cassette. The mLabs® SARS-CoV-2 IgG and IgM Assay is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

The IgG and IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary. False positive results for mLabs®SARS-CoV-2 IgG and IgM Assay may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

For in vitro diagnostic use only.

## BACKGROUND

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Severe Acute Respiratory Syndrome (SARS-CoV). SARS-CoV-2 is a new strain that has not been previously identified in humans. Coronaviruses are zoonotic, meaning they are transmitted between animals and people. Several known coronaviruses are circulating in animals that have not yet infected humans. 2019 Novel Coronavirus (SARS-CoV-2) is a coronavirus identified as the cause of an outbreak of respiratory illness. Patients with SARS-CoV-2 report a mild to severe respiratory illness with symptoms of: fever, cough, shortness of breath. There is an urgent need for rapid tests to manage the ongoing pandemic. The mLabs® SARS-CoV-2 IgG and IgM Assay is intended for qualitative detection of antibodies indicative of SARS-CoV-2 infection and is to be used as an aid for diagnosis of SARS-CoV-2 infection.

## TEST PRINCIPLE

The mLabs® SARS-CoV-2 IgG and IgM system is based on innovative rapid testing platform technology and consists of the mLabs® Immunometer and single use, disposable mLabs® SARS-CoV-2 IgG and IgM cartridges. The system delivers accurate, consistent and reliable results in less than 10 minutes from a small (250 uL) sample (whole blood or plasma) obtained from a venous draw.

The mLabs® SARS-CoV-2 IgG and IgM Assay is based on the sandwich immunoassay with Micropoint Bioscience's proprietary microfluidic technology. In this format, S and N antigens of SARS-CoV-2 are immobilized on the cartridge surface at its detection zones as captures, and mouse anti-human IgG and IgM antibodies labeled with a fluorescent dye are deposited at the reaction zone as reporters. As the sample solution flows along the cartridge channel, IgG and IgM to SARS-CoV-2 in the sample solution bind to the dye-labeled reporting antibodies and the complex continues flowing until the formation of a sandwich with the immobilized corresponding captures at the detection zones. The dye-labeled reporting antibodies without binding to IgG and IgM pass the detection zones and bind to immobilized goat anti-mouse IgG at the control zone. The fluorescence intensity measured at the detection zones are directly proportional to the concentration of the combination of IgG and IgM in the sample solution. Both the reporter and capture pairs and assay conditions on the microfluidic cartridge are optimized for the specificity and the dynamic range as required for the clinical assay of the SARS-CoV-2 IgG and IgM.

The mLabs® SARS-CoV-2 IgG and IgM Assay uses the following:

- mouse anti-human IgG
- mouse anti-human IgM
- N antigen of SARS-CoV-2
- S antigen of SARS-CoV-2

## MATERIALS PROVIDED

- 25 test cartridges
- Pipette tips
- 1 DataDrive (USB-disk or IC card)
- 1 package insert

## SAMPLE COLLECTION AND STORAGE

Always wear protective gloves and suitable lab coats when handling patient samples as they may potentially be infectious.

All samples should be regarded as potentially hazardous and/or contaminated.

- EDTA is the only coagulant used for mLabs test.
- Ensure that the collection tube is completely filled to maintain the correct anticoagulant to blood ratio.
- Thoroughly mix the whole blood sample by gentle inversion of the tube (2-3 times).
- Perform the whole blood test within 60 minutes after sample collection.
- Refrigerate whole blood samples if the test cannot be performed within 120 minutes after the

collection.

- To obtain plasma, centrifuge the EDTA tube of whole blood samples at 3,000 RPM (~ 1500 g) for 15 minutes within 60 min after the collection.
- Immediately aliquot the plasma into plastic sample vials and refrigerate at 2–8 °C or freeze at ≤ -18 °C.

## TEST SAMPLE STABILITY

EDTA Whole blood samples are stable at room temperature for a maximum of 120 minutes. Samples with a significant hemolysis should be avoided. EDTA Plasma samples are stable at room temperature for a maximum of 180 minutes.

Plasma sample storage and stability

Storage	Temperature	Stability
Room temperature	18–28 °C (64–82 °F)	≤ 3 hours
Refrigerated	2–8 °C (36–46 °F)	≤ 3 days
Frozen	≤-18 °C (≤0 °F)	≤ 6 months

Whole Blood sample storage and stability

Storage	Temperature	Stability
Room temperature	18–28 °C (64–82 °F)	≤ 2 hours
Refrigerated	2–8 °C (36–46 °F)	≤ 2 days

## TEST KIT STORAGE

Refrigerate the mLabs® SARS-CoV-2 IgG and IgM Assay Kit upon receipt. The kit is stable at 2-8°C until the listed expiration date. Only take required number of cartridges from refrigerator. The expectation is that the product will be stable for 12 months based on studies performed with the same technologies.

## TEST PROCEDURE

### 1. Sample Preparation

- The mLabs® SARS-CoV-2 IgG and IgM Assay cartridge is only used together with mLabs® Immunometer.
- Thoroughly mix the collected whole blood sample by gentle inverting the tube (2-3 times) before test. For plasma sample, a brief vortex (~5 seconds) is recommended.
- Allow refrigerated plasma samples to equilibrate to room temperature and mix well prior to use.

### 2. mLabs® Immunometer Preparation

- A single DataDrive (USB-disk or IC card) is provided along with each kit of cartridges.
- For U-disk, insert it into the USB port at the rear of the Immunometer prior to performing test.
- For IC card, insert the IC Card into the IC card port located in the right side of the meter.
- Press "DataDrive Installation" button on the main screen and select "Sample DataDrive", as for U-disk, press "USB Drive"; as for IC card, press "IC card". The meter will automatically install DataDrive.
- Once the DataDrive has been uploaded into the Immunometer, the DataDrive can be removed for all subsequent related measurements.
- Store the DataDrive in a clean and dry location for future use.

**Note: For different software and meter version test procedure may be different, user can refer to meter's user manual sample test part to get more detailed operation information.**

### 3. Sample Loading

- Remove test cartridge from pouch and label it with the patient's ID on the front with a permanent marker.
- Using the provided pipette, transfer 250 uL of sample into the inlet of the cartridge, dropwise.
- Do not place the pipette tip into the inlet during sample transfer as air bubbles may be generated. Test the cartridge right after sample addition.

### 4. Performing Test and Reading Results

- Insert the test cartridge to the cartridge holder of the Immunometer.
- Press "Sample Test" from the main screen of the Immunometer.
- Select the assay and sample type if needed.
- Enter patient ID if needed.
- Press "Confirm" to start testing.
- The results will be displayed on the screen as positive or negative after test is complete.
- Remove and properly discard the used cartridge per biohazard procedures.

## CLINICAL PERFORMANCE

PCR Test Comparator – EDTA Whole blood			
mLabs Test		Positive	Negative
	Positive	38	3
	Negative	2	68
	PPA =	0.9500	
	NPA =	0.9577	
PCR Test comparator - Plasma			
mLabs Test		Positive	Negative
	Positive	38	3
	Negative	2	147
	PPA =	0.9500	
	NPA =	0.9800	

## Cross-Reactivity/Analytical specificity

Cross-reactivity of the mLabs® SARS-CoV-2 IgG and IgM Assay was evaluated using whole blood or plasma samples which contain antibodies to the pathogens listed below. No false positivity or false negativity was found with the following:

Human coronavirus panel (collected before Dec 2019)

anti-influenza A (IgG and IgM)  
anti-influenza B (IgG and IgM)  
anti-HCV (IgG and IgM)  
anti-HBV (IgG and IgM)  
anti-Haemophilus influenzae (IgG and IgM)  
anti-229E (alpha coronavirus)  
anti-NL63 (alpha coronavirus)  
anti-OC43 (beta coronavirus)  
anti-HKU1 (beta coronavirus)  
ANA  
anti-respiratory syncytial virus (IgG and IgM)  
anti-HIV

## Sample Type/Matrix equivalency

There is no impact to the test result from the sample matrix for either whole blood or plasma.

## LIMITATIONS

Carefully inspect the integrity of mLabs® SARS-CoV-2 IgG and IgM Assay pouch before use. If the pouch is found to be damaged, e.g. torn or punctured, do NOT proceed and utilize a different test cartridge.

The mLabs® SARS-CoV-2 IgG and IgM Assay kit is strictly for In Vitro Diagnostics use only. Instructions and procedures provided in this insert should be carefully followed.

The measurement with mLabs® SARS-CoV-2 IgG and IgM Assay kit is not intended to be used as absolute evidence for SARS-COVID-19 infection. The test results should be consulted with physician in addition with other test results.

All the provided items in the test kit are for single use and should be properly discarded after usage as the test sample may be potentially infectious.

## INTERFERENCE

Potentially Endogenous Interfering Substances

Low titer SARS-CoV-2 antibody positive serum samples and SARS-CoV-2 antibody negative serum samples were spiked with one of the following substances to specified concentrations and tested in multiple replicates. No false positivity or false negativity was found with the following:

Bilirubin	10 mg/dL
Hemoglobin	1000 mg/dL
Ascorbic Acid	20 mg/dL
Triglycerides	500 mg/dL
Albumin	2000 mg/dL














## WARNINGS

- This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
- Do not open the sealed pouch until you are ready to conduct the assay. Once opened, the cartridges should be used within 2 hours.
- Do not use expired devices.
- Bring all reagents to room temperature (15-30°C) before use.
- Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
- Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and materials used to perform the test as biohazardous waste.
- Handle the negative and positive controls in the same manner as patient specimens for operator protection.
- Do not perform the test in a room with strong air flow, e.g. an electric fan or strong air-conditioning.

## REFERENCES

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011; 81:85-164.
2. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016; 24:490-502.

## SYMBOLS EXPLANATION

Symbols	Explanation
	In vitro diagnostics
	Name and Address of Manufacturer
	European Authorized Representative
	CE Marking
	Temperature limitation
	Lot number
	Date of Manufacture
	Expiry Date
	Do not reuse
	Catalogue number
	Contains sufficient for n tests
	Caution! Read Carefully.
	Consult instructions for use

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