



# ASSURE<sup>®</sup> SARS-CoV-2 IgG/IgM Rapid Test

## Instructions For Use



REVISION DATE: 2020-11  
MDC0011-ENG-3

**REF** 43140-020 (20 tests)

### TRADE NAME AND INTENDED USE

The MP Diagnostics ASSURE<sup>®</sup> SARS-CoV-2 IgG/IgM Rapid Test is a qualitative in vitro immunochromatographic test to detect and differentiate IgG / IgM antibodies against SARS-CoV-2 in human plasma, serum, finger pricked whole blood or whole blood with anti-coagulants. It is intended for professional use.

The results from this test is not to be used for confirmatory testing or as sole basis for diagnosis. The results will have to be interpreted together with clinical presentation and are to be confirmed with supplemental testing (e.g. RT-PCR).

### INTRODUCTION

Coronaviruses are enveloped non-segmented positive-sense RNA viruses belonging to the family Coronaviridae and the order Nidovirales and broadly distributed in humans and other mammals<sup>1</sup>. Although most human coronavirus infections are mild, the epidemics of the two betacoronaviruses, severe acute respiratory syndrome coronavirus (SARS-CoV)<sup>2-4</sup> and Middle East respiratory syndrome coronavirus (MERS-CoV)<sup>5,6</sup>, have caused more than 10,000 cumulative cases in the past two decades, with mortality rates of 10% for SARS-CoV and 37% for MERS-CoV<sup>7,8</sup>.

Coronavirus Disease 2019 (COVID-19) is a newly emerged disease that causes pneumonia<sup>9-11</sup>. This disease was first reported on December 2019 and to-date was widely spread to 28 countries with total confirmed case of 45,170. The mortality rate for this disease was up to 2.5% with 1,115 mortality recorded worldwide. The causative agent for COVID-19 was confirmed to be betacoronavirus<sup>12</sup>, also known as SARS-CoV-2. Current available diagnostic methods for COVID-19 relies on molecular diagnostic method targeting the RNA genome of this virus with real-time PCR<sup>13</sup>. The availability of antibody rapid test may facilitate the identification of asymptomatic population and estimation of infected cases via a seroprevalence study.

MP Diagnostics ASSURE<sup>®</sup> SARS-CoV-2 IgG/IgM Rapid Test is an immunochromatographic test which uses immobilized mouse anti-human IgG and IgM antibodies for capturing IgG and IgM antibodies in the human serum, plasma, finger pricked whole blood or whole blood with anti-coagulants. The presence of IgG and IgM antibodies against SARS-CoV-2 are detected by the colloidal gold-labeled SARS-CoV-2 recombinant proteins.

### CHEMICAL AND BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The MP Diagnostics ASSURE<sup>®</sup> SARS-CoV-2 IgG/IgM Rapid Test is a direct solid-phase immunochromatographic assay for simultaneous and differential detection of SARS-CoV-2 antibodies in human serum, plasma, finger pricked whole blood or whole blood with anti-coagulants.












Mouse anti-human IgG and IgM are striped on the membrane as 2 separate test lines.

The SARS-CoV-2 antibodies in the test sample (human serum, plasma, finger pricked whole blood or whole blood with anti-coagulants) form antibody-antigen complexes with anti-human antibodies immobilized on nitrocellulose membrane in the test viewing window as the test sample migrates upward from the sample well.





The bound antibody-antigen complexes are subsequently detected by SARS-CoV-2 recombinant proteins conjugates carried by chase buffer that flows upwards giving a dark red color. In addition, immobilized Biotinylated-BSA which can be recognized by colloidal gold-labeled goat anti-biotin is used as a control for proper function of the reagents.

### DESCRIPTION OF SYMBOLS USED

The following are graphical symbols used in or found on MP Diagnostics' products and packaging. These symbols are the most common ones appearing on medical devices and their packaging.

	Use by		In vitro diagnostic medical device
	Authorized representative in the European Community		MP Diagnostics ASSURE <sup>®</sup> SARS-CoV-2 IgG/IgM Rapid Test has received Provisional Authorisation from the Health Sciences Authority in Singapore
	Batch code <i>Synonyms for this are:</i> Lot Number Batch Number		Catalogue Number <i>Synonyms for this are:</i> Reference Number Reorder Number
	Temperature Limitation		Caution
	Manufacturer		Consult Instructions for Use
	Contains sufficient for <n> tests		Do not reuse

### KIT COMPONENTS


	<b>MP Diagnostics ASSURE<sup>®</sup> SARS-CoV-2 IgG/IgM Rapid Test</b>	20 devices
	Incorporated with anti-human antibodies. Packed in individually sealed pouch with a desiccant. Store at 2°C - 28°C	
	<b>CAPILLARY PIPETTE</b> With marking of 10µl	20 pieces
		
	<b>CHASE BUFFER</b> Contains 0.02% thimerosal and 0.01% Triton-X 100. Store at 2°C - 28°C	1 bottle (5ml)
	<b>INSTRUCTIONS FOR USE</b>	1 copy

### HEALTH AND SAFETY INFORMATION

- In case of an accident or contact with eyes, rinse immediately with plenty of water and seek medical advice.
- Consult a physician immediately in the event that contaminated materials are ingested or come in contact with open lacerations, or other breaks in the skin.

- Wipe any spills of sera, plasma or blood promptly with 1% sodium hypochlorite solution.
- Autoclave all used and contaminated materials at 121°C, 15 p.s.i. for 30 minutes before disposal. Alternatively, decontaminate materials in 5% sodium hypochlorite solution for 30-60 minutes before disposal in biohazard waste-bags.

Pursuant to EC regulation 1272/2008 (CLP), hazardous components as classified and labelled as follows:

Component:	Chase Buffer
Signal Word:	Warning
Pictogram:	
Hazard Statements:	H319 Causes serious eye irritation.
Precautionary Statements:	P264 Wash hands thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection/face protection.
Supplemental Statements:	EUH 210 Safety Data Sheet is available on request
Contains:	1% Triton X-100

#### ANALYTICAL PRECAUTIONS:

- The sample applicator is for single use only. DO NOT re-use the sample applicator.
- Each sealed test device is for single use only. DO NOT re-use the test device.
- For *in vitro* diagnostic use only.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
- Handle all samples as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
- Optimal assay performance requires **STRICT ADHERENCE** to the assay procedure described in this Instruction For Use. Deviations from the procedure may lead to aberrant results.
- Do not interchange reagents between kit lots.
- Do not use kit components beyond the expiry date printed on the kit box.
- The chase buffer reagent contains sodium azide as a preservative. Handle reagent carefully to avoid spills on work surface. Clean up spills with absorbent paper and water.
- Reagents supplied should not present a hazard to health if used in accordance to the instructions stated.
- For best results, allow all reagents and samples to reach room temperature (25°C ± 3°C) before use.
- Humidity and temperature can adversely affect results.
- DO NOT use the test device if the seal of the pouch is broken.
- DO NOT use the test device if the pull tab is not fully inserted, i.e. pre-pulled.

#### STORAGE

- Store the kit and its components at 2°C - 28°C.
- Do not freeze the kit and its components.
- The test device must remain in the sealed pouch until use.
- Do not use after the expiry date printed on the pouch.

#### MATERIAL REQUIRED BUT NOT PROVIDED

- Timer
- Alcohol swabs

#### ASSAY PROCEDURE

**IMPORTANT:** Strict adherence to the assay procedure will ensure optimal performance. Deviations from the procedure may lead to aberrant results.

#### Note:

- Allow the kit to warm to room temperature (25°C ± 3°C) before running the assay.

- For best results, conduct the assay at room temperature (25°C ± 3°C).

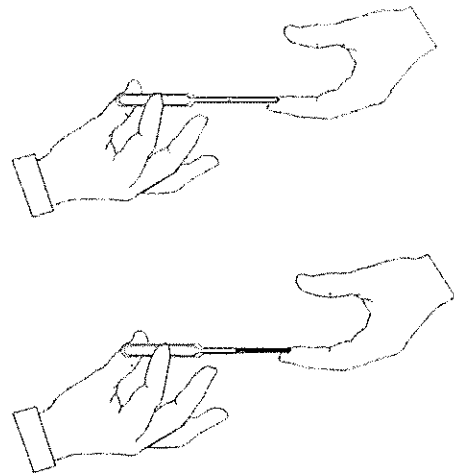
- Remove the cassette from the pouch and use it as soon as possible.
- Conduct the test immediately after removing the cassette from the pouch.
- Proceed with the assay procedures as shown in the diagrams below.

#### Assay Procedures for ASSURE® SARS-CoV-2 IgG/IgM Rapid Test

- Bring all kit components to room temperature (25°C ± 3°C) prior to testing.
- Remove the test device from pouch, place it on a flat and dry surface.
- For finger pricked whole blood

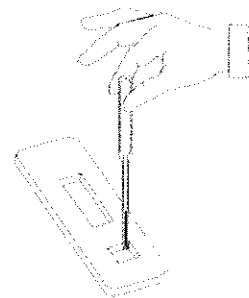
#### Step 1:

Hold the capillary pipette horizontally (without pressing any part of the pipette), avoid covering the vent holes on the bulb of the pipette. Place the tip of the pipette on the blood drop. Blood sample will automatically be drawn into the tube and stopped at the indicated line.



#### Step 2:

To release the blood sample, squeeze the bulb of the pipette into the sample well of test device.

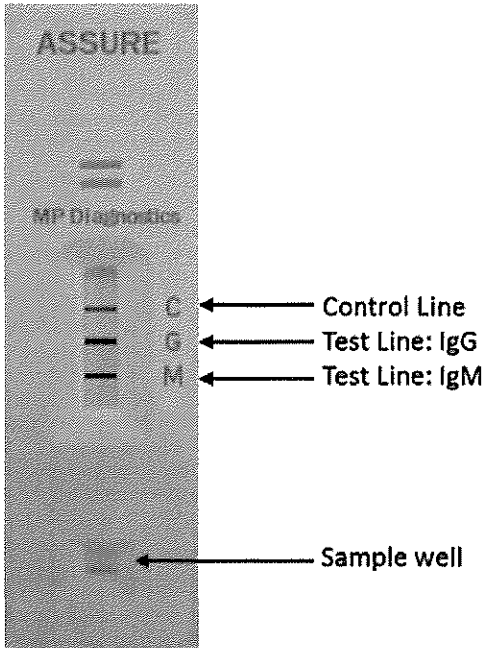


#### For serum/plasma/venous whole blood with anti-coagulants

Use a laboratory pipette to transfer 10µl of serum / plasma / whole blood with anti-coagulants into the sample well.

- Add 3 drops of chase buffer into the sample well.
- As the test begins to work, dark red color will move across the result window in the center of the test device.
- Interpret test results at 15 minutes.

**Caution:** Do not read test results after 15 minutes. Reading after 15 minutes may give false result.

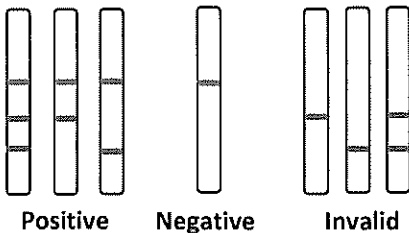


### QUALITY CONTROL

The control line is an internal procedure control. Absence of control line indicates incorrect assay technique used or faulty device. The assay procedure should be reviewed before repeating with a new device.

Positive and negative controls are not provided with this kit. However, it is recommended that controls are used as good laboratory practice to verify proper assay technique and performance.

### INTERPRETATION OF RESULTS



#### 1. Positive for COVID-19

A test is COVID-19 positive if Control Line (C) appears with any visible test lines (IgG/ IgM).

#### 2. Negative for COVID-19

A test is negative if Control line (C) appears with no visible test line(s). Retest in 3-5 days if SARS-CoV-2 infection is suspected.

#### 3. Invalid

A test is invalid if Control Line (C) is absent. The assay should be repeated using a new device.

### LIMITATIONS OF THE PROCEDURE

The MP Diagnostics ASSURE® SARS-CoV-2 IgG/IgM Rapid Test is a qualitative in vitro immunochromatographic test to detect and differentiate IgM/IgG antibodies against SARS-CoV-2 in human serum, plasma, finger pricked whole blood or whole blood with anti-coagulants. This test is not for determining the quantitative value of SARS-CoV-2 antibodies and not for prognosis of disease. Optimal assay performance requires the strict adherence to the assay procedure described. Deviation from the procedure may lead to aberrant results. A POSITIVE result may indicate infection with SARS-

CoV-2. The positive results should be further confirmed by more specific supplemental tests. A NEGATIVE result does not exclude the possibility of infection with SARS-CoV-2.

The product has not been tested with samples positive for other human coronavirus antibodies.

### PERFORMANCE CHARACTERISTICS

Total Diagnostic Performance (In-house study)

Diagnostic Parameter	Performance of ASSURE SARS-CoV-2 IgG/IgM Rapid Test	95% Confidence Interval
Sensitivity (n=17)	100% (17/17)	80.49% to 100.00%
Specificity (n=170)	99.41% (169/170)	96.77% to 99.99%
Accuracy	99.47%	97.06% to 99.99%
Positive Predictive Value	94.44%	70.66% to 99.17%
Negative Predictive Value	100%	

Specificity performance of ASSURE SARS-CoV-2 IgG/IgM Rapid Test in healthy donors and various clinical conditions (n=170)

Sample Profile	Source	Sample size (n)	ASSURE SARS-CoV-2 IgG/IgM Rapid Test Performance	
			Performance	%
Normal Human Donor	PromedDx LLC	25	25/25	100.0
	Various sources	13	13/13	100.0
	German Red Cross Blood Donor Service Baden-Wuerttemberg-Hessen	25	25/25	100.0
<b>Total</b>		<b>63</b>	<b>63/63</b>	<b>100.0</b>
Cross-reactivity	Various sources	25	24/25	96.0
Interference	Various sources	40	40/40	100.0
Hospitalized	PromedDx LLC	32	32/32	100.0
Pregnancy	PromedDx LLC	10	10/10	100.0
<b>Total Specificity Performance</b>		<b>107</b>	<b>106/107</b>	<b>99.07</b>

List of potentially cross-reactive and interference specimens

Sample	No. of samples	Non-Reactive	Reactive
<b>Cross-Reactive samples</b>			
HIV 1/2	3	3	0
HTLV I/II	3	2	1
HCV	3	3	0
Measle IgG	5	5	0
Tuberculosis (TB)	3	3	0
Dengue	3	3	0
Mycoplasma pneumoniae	2	2	0
Chlamydia pneumoniae	3	3	0
<b>Total</b>	<b>25</b>	<b>24</b>	<b>1</b>
<b>Specificity</b>		<b>96.0% (24/25)</b>	
<b>Potential interference samples</b>			
Antinuclear Antibodies (ANA)	5	5	0
Rheumatoid Factor (RF)	5	5	0

Sample	No. of samples	Non-Reactive	Reactive
Lipemic	5	5	0
Icteric	5	5	0
Haemolysed	5	5	0
Triglyceride	5	5	0
Total protein	5	5	0
Total bilirubin	5	5	0
Total	40	40	0
Specificity	100.0% (40/40)		
Overall analytical specificity	98.46% (64/65)		

#### Overall Performance

Based on internal evaluation and clinical study report, the sensitivity of 99% to 100% (total N=166) is established using samples from recovered donors, convalescent patients and samples from day 15 to day 60 post symptoms.

The specificity of 95% to 99.41% (total N=368) is established using samples from in-house and external site.

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#### LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer makes no express warranty other than that the test kit will function as an *in vitro* diagnostic assay within the specifications and limitations described in the product Instruction Manual when used in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied, including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any other purposes. The manufacturer is limited to either replacement of the product or refund of the purchase price of the product. The manufacturer shall not be liable to the purchaser or third parties for any damage, injury or economic loss howsoever caused by the product in the use or in the application thereof.

#### TECHNICAL PROBLEMS / COMPLAINTS

Should there be a technical problem / complaint, please do the following:

- Note the kit lot number and the expiry date.
- Retain the kits and the results that were obtained.
- Contact the nearest MP Biomedicals office or your local distributor.



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