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

## Instructions For Use

CE

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REF 43140-020 (20 tests)

### TRADE NAME AND INTENDED USE

**The MP Diagnostics ASSURE® 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 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[1]. Although most human coronavirus infections are mild, the epidemics of the two betacoronaviruses, severe acute respiratory syndrome coronavirus (SARS-CoV)[2–4] and Middle East respiratory syndrome coronavirus (MERS-CoV)[5,6], 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[7,8].

Coronavirus Disease 2019 (COVID-19) is a newly emerged disease that causes pneumonia[9-11]. 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[12], 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[13]. 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® SARS-CoV-2 IgG/IgM Rapid Test** is a immunochromatographic test which uses immobilized mouse anti-human IgG and IgM antibodies for capturing IgG and IgM antibodies in the human serum, plasma 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® 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 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 (serum, plasma 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 | IVD | In vitro diagnostic medical device |
| EC REP | Authorized representative in the European Community | | MP Diagnostics ASSURE® SARS-CoV-2 IgG/IgM Rapid Test has received Provisional Authorisation from the Health Sciences Authority in Singapore |
| LOT | Batch code<br>*Synonyms for this are:*<br>*Lot Number*<br>*Batch Number* | REF | Catalogue Number<br>*Synonyms for this are:*<br>*Reference Number*<br>*Reorder Number* |
| | Temperature Limitation | | Caution |
| | Manufacturer | | Consult Instructions for Use |
| Σ | Contains sufficient for <n> tests | | Do not reuse |

### KIT COMPONENTS

| | | |
|---|---|---|
| DEVICE | **MP Diagnostics ASSURE® SARS-CoV-2 IgG/IgM Rapid Test**<br>Incorporated with anti-human antibodies.<br>Packed in individually sealed pouch with a desiccant.<br>Store at 2°C - 28°C | 20 devices |
| APPLICATOR | CAPILLARY PIPETTE<br>With marking of 10µl and 20µl.<br>  | 20 pieces |
| BUFFER | CHASE BUFFER<br>contains sodium azide as preservative.<br>Store at 2°C - 28°C | 1 bottle (5ml) |
| | INSTRUCTIONS FOR USE | 1 copy |

### HEALTH AND SAFETY INFORMATION

1. In case of an accident or contact with eyes, rinse immediately with plenty of water and seek medical advice.

2. 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.
3. Wipe any spills of sera, plasma or blood promptly with 1% sodium hypochlorite solution.
4. 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.<br>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:**

1. The sample applicator is for single use only. DO NOT re-use the sample applicator.
2. Each sealed test device is for single use only. DO NOT re-use the test device.
3. For *in vitro* diagnostic use only.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
5. 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.
6. 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.
7. Do not interchange reagents between kit lots.
8. Do not use kit components beyond the expiry date printed on the kit box.
9. 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.
10. Reagents supplied should not present a hazard to health if used in accordance to the instructions stated.
11. For best results, allow all reagents and samples to reach room temperature (25°C ± 3°C) before use.
12. Humidity and temperature can adversely affect results.
13. DO NOT use the test device if the seal of the pouch is broken.
14. DO NOT use the test device if the pull tab is not fully inserted, i.e. pre-pulled.

## STORAGE

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

## MATERIAL REQUIRED BUT NOT PROVIDED

1. Timer
2. 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:**

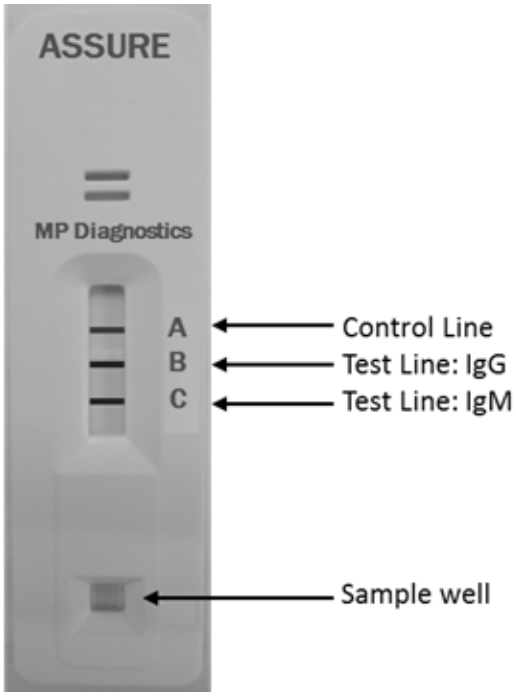
- Allow the kit to warm to room temperature (25°C ± 3°C) before running the assay.
- For best results, conduct the assay at room temperature (25°C ± 3°C).

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

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

1. Bring all kit components to room temperature (25°C ± 3°C) prior to testing.
2. Remove the test device from pouch, place it on a flat and dry surface.
3. With a capillary pipette, add 10µl (indicated by the first line on the pipette) of serum / plasma / whole blood into the sample well.
3. Add 3 drops of chase buffer into the sample well.
4. As the test begins to work, dark red color will move across the result window in the center of the test device.
5. Interpret test results at 15 minutes.

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

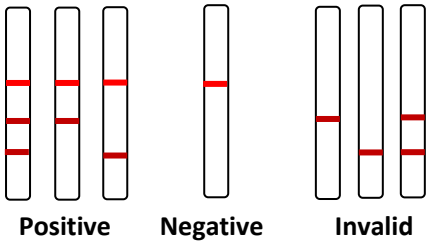



## QUALITY CONTROL

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 serum, plasma 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=6) | 100% (6/6) | 54.07% to 100% |
| Specificity (n=170) | 99.41% (169/170) | 96.77% to 99.99% |
| Accuracy (n=176) | 99.43% (175/176) | 96.88% to 99.99% |
| Positive Predictive Value | 85.71% | 45.95% to 97.69% |
| 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 | % |
| 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 |
| **Total** | | **63** | **63/63** | **100.0** |
| 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 |
| **Total Specificity Performance** | | **107** | **106/107** | **99.07** |

List of potentially cross-reactive and interference specimens

| Sample | No. of samples | Non-Reactive | Reactive |
|---|---|---|---|
| **Cross-Reactive samples** | | | |
| **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 |
| **Total** | 25 | 24 | 1 |
| **Specificity** | 96.0% (24/25) | | |
| **Potential interference samples** | | | |
| **Antinuclear Antibodies (ANA)** | 5 | 5 | 0 |
| **Rheumatoid Factor (RF)** | 5 | 5 | 0 |
| **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)** | | |

External Evaluation Study

Based on the test result from 32 positive samples collected at two sites in Singapore, the current sensitivity of MP Diagnostics ASSURE® SARS-CoV-2 IgG/IgM Rapid Test is 31/32 (97%). The test results from 10 negative controls were all negative for both IgM and IgG, indicating that the current specificity of MP Diagnostics ASSURE® SARS-CoV-2 IgG/IgM Rapid Test is 100%.

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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:

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

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