RAPIT COVID-19 IgM/IgG Test Kit

CATALOG NO.: RUOCL0100NS0
FOR RESEARCH USE ONLY (RUO)

INTENDED USE

RAPIT COVID-19 IgM/IgG Test Kit is a lateral flow chromatography immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies against SARS-CoV-2 in human plasma with anti-coagulants (EDTA, sodium citrate and lithium heparin), serum, finger pricked whole blood or whole blood.

RAPIT COVID-19 IgM/IgG Test Kit is intended for research use only in detecting COVID-19 blood by detecting SARS-CoV-2 antibodies in the blood. IgM antibodies against SARS-CoV-2 are generally detectable in blood several days after initial infection but the levels over the course of infection are not well characterized. IgG antibodies against SARS-CoV-2 become detectable later following infection. Positive results for both IgG and IgM could occur after infection and can be indicative of acute or recent infection[1].

Negative results do not preclude SARS-CoV-2 infection. False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

INTRODUCTION

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)[2]. The disease was first identified in December 2019, and has since spread globally, resulting in the ongoing pandemic[3,4]. Majority of the cases result in mild symptoms, however some progress to pneumonia and multi-organ failure[3,5]. The overall mortality rate for this disease was up to 4.6% (ranging from 0.2% to 15% according to age group and other health problems)[6].

Current available method for COVID-19 is by reverse transcription polymerase chain reaction (RT-PCR) from a nasopharyngeal swab[7].

RAPIT COVID-19 IgM/IgG Test Kit is intended for the qualitative detection of antibodies indicative of SARS-CoV-2 infection and is to be used as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

PRINCIPLE OF THE PROCEDURE

RAPIT COVID-19 IgM/IgG Test Kit contains (1) mixed recombinant SARS-CoV-2 antigens labeled and quality control protein labeled conjugates and (2) two test lines (M and G, pre-coated with anti-human IgM and IgG antibody, respectively) and a control line (pre-coated with an antibody against quality control protein). When the sample is applied to the test strip, the gold-labeled recombinant SARS-CoV-2 proteins will bind with SARS-CoV-2 IgM and/or IgG antibodies present in sample and form antigen-antibody complexes. The antibody-antigen complexes are subsequently immobilised by the anti-human IgM and IgG and detected by SARS-CoV-2 recombinant proteins conjugates carried by sample diluent that flows downward giving a purplish red color. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working.

MATERIALS PROVIDED

The amount of reagents/components is sufficient for 25 optimal runs.

Label	Constituents	Quantity
DEVICE	RAPIT COVID-19 IgM/IgG Test Device immobilised with anti-human antibodies. Packed in individually sealed pouch with a desiccant. Store at 2°C - 28°C.	25 devices
SAMPLE DILUENT	Tris buffer, detergent, preservative. Store at 2°C - 28°C.	1 bottle (5 mL)
	INSTRUCTION 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 device.
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.

PRECAUTIONS

1. **RAPIT** COVID-19 IgM/IgG Test Kit is for Research Use Only.
2. Each sealed test device is for single use only. DO NOT re-use the test device.
3. Wear personal protective equipment (PPE) such as laboratory coats, disposable gloves and eye protection when samples are assayed
4. 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.
5. 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.
6. Do not interchange reagents between kit lots.
7. Do not use kit components beyond the expiry date printed on the kit box.
8. The sample diluent reagent contains preservative. Handle reagent carefully to avoid spills with absorbent paper and water.
9. Reagents supplied should not present a hazard to health if used in accordance to the instructions stated.
10. For best results, allow all reagents and samples to reach room temperature (25 ± 3 °C) before use.
11. Humidity and temperature can adversely affect results.
12. DO NOT use the test device if the seal of the pouch is broken.

ADDITIONAL MATERIALS REQUIRED

1. Sterile safety Lancet
2. Disposable 20µL Transfer Pipet
3. 20µL-, 50µL-, 100µL- micro-pipets and tips
4. Timer (up to 30 minutes)
5. Alcohol swabs
6. Bandages
7. Disposable gloves, Biohazard disposal container, Collection devices (for venous whole blood, serum, plasma)

STORAGE

1. The test device is sensitive to humidity and as well as to heat.
2. All kits and its components shall be stored at 2 ~ 30°C.
3. Do not freeze the kit and its components.
4. Do not store the test kit in direct sunlight.
5. The test device must remain in the sealed pouch until use. Perform the test immediately after removing the test device from a foil pouch.
6. Do not use after the expiry date printed on the box outer label.

SPECIMEN COLLECTION

1. Sample should be human serum, plasma and fingerstick whole blood, venous whole blood only. Other body fluid samples are not tested and may cause incorrect or inaccurate results.

   Fingerstick Whole Blood Collection
   a. Clean the finger of the tested person with an antiseptic wipe. Allow the finger to dry thoroughly.
   b. Using a sterile lancet, puncture the skin just off the center of the finger. Avoid squeezing the fingertip to accelerate bleeding as this may dilute the blood with excess tissue fluid.
   c. Collect the sample by laying the disposable 20µl Transfer Pipet against the drop of blood until the Pipet is full.
   d. Fingerstick specimens must be tested immediately after collection.

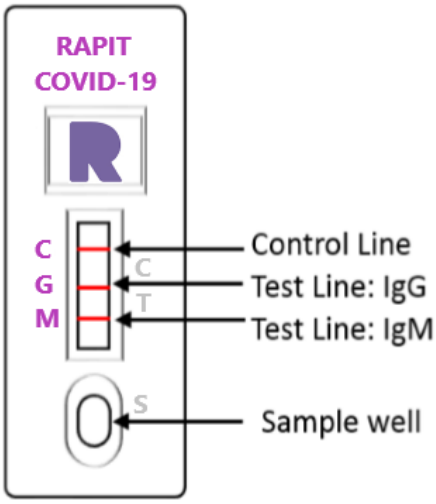
   Venous whole blood, serum or plasma collection
   a. Collect specimens using standard procedures.
   b. Follow the instructions provided with your collection device for use and processing of the sample.
   c. Samples should be thoroughly separated from all cellular material. Failure to do so may lead to erroneous result.
2. Collect whole blood specimens in anti-coagulant containing tubes and used as outlined in the assay procedure immediately. All serum / plasma collected should be tested immediately.
3. Handle all blood samples as if of infectious nature.
4. Restalyst only warrants optimal performance if samples are freshly collected that are clear, non-haemolysed, non-lipemic and non-icteric.
5. Lipemic, icteric or contaminated (particulate or bacterial) samples should be filtered (0.45µm) or centrifuged before testing.
6. Repeated freeze-thawing of the sample is not recommended. It may give erroneous results.

PROCEDURE OF TEST

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

1. Allow the kit to warm to room temperature (18 to 25 °C) before running the assay. For best result, conduct the assay at room temperature.
2. Remove the test device from the foil pouch and use it as soon as possible, and place it on a flat and dry surface.
3. **For Serum/Plasma sample,**
   With a pipette or with transfer pipet, add 10µl of serum/plasma into the sample well.
   For Whole Blood samples,
   With a pipette or with transfer pipet, add 20µl of serum/plasma into the sample well.
4. Add 2 drops (60µl) of sample diluent into the sample well immediately.
5. As the test begins to work purplish red color will move across the result window in the center of the test device.
6. Read the results at 10 to 15 minutes.

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

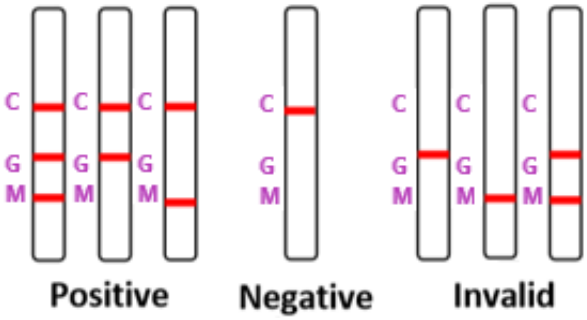


QUALITY CONTROL

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 control 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 (M / G)

2. Negative for COVID-19
   A test is negative if Control line (C) appears with no visible test line(s). Retest in 3-5days 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

1. The test does not determine the quantitative value of SARS-CoV-2 antibodies and not for prognosis of disease.
2. 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.
3. The product has not been tested with samples positive for SARS-CoV and MERS-CoV antibodies.

LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer makes no express warranty other than that the test kit will function as *in-vitro* assay for research use only within the specifications and limitations described in this Instruction Manual when used in accordance within 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.

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TECHNINCAL 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 Restalyst office or your local distributor.

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RESEARCH USE ONLY

EFFECTIVE DATE: 01/12/2020

