PathFlow® SARS-CoV-2 IgG rapid test (EN)

Instructions for Use
A rapid test for the qualitative detection of IgG antibodies to SARS-CoV-2 S-RBD and/or N protein in human whole blood, serum, or plasma specimen. For professional in vitro diagnostic use only.

INTENDED USE
The PathFlow® SARS-CoV-2 IgG rapid test is a lateral flow chromatographic immunoassay for the qualitative detection of IgG antibodies to SARS-CoV-2 spike (S) protein receptor binding domain (RBD) and/or Nucleocapsid (N) protein in human whole blood, serum, or plasma specimens. The PathFlow® SARS-CoV-2 IgG rapid test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2.

SUMMARY
SARS-CoV-2 belongs to the Coronaviridae family and is closely related to the SARS coronavirus that appeared in 2002/2003[1]. The virus was first identified in humans in Wuhan, China, at the end of 2019 and is transmissible from person to person[2]. The main route of transmission is droplet infection, but infections via aerosols and smear have also been described[3,4]. The incubation period is usually three to seven days, up to a maximum of fourteen days[5]. SARS-CoV-2 infected patients are often asymptomatic or experience only mild symptoms such as a dry cough, fever, and shortness of breath[6,7]. Some of the infected persons develop a severe pneumonia, which can lead to death.

PRINCIPLE
The PathFlow® SARS-CoV-2 IgG rapid test is a qualitative membrane-based immunochromatographic assay for the detection of IgG antibodies to SARS-CoV-2 in whole blood, serum, or plasma specimens. Anti-human IgG are coated within the test line region. During testing, the control line region, indicating that the proper volume of specimen has been served as a procedural control, a coloured line will always appear in the test line region system. The test cassette system is the detection reagent. A goat anti-mouse IgG is employed in the control line region. The PathFlow® SARS-CoV-2 IgG rapid test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2.

MATERIALS
• Test cassettes, package insert, extraction buffer, droppers,
• Anti-human IgG are coated within the test line region. During testing, the control line region, indicating that the proper volume of specimen has been served as a procedural control, a coloured line will always appear in the test line region system. The test cassette system is the detection reagent. A goat anti-mouse IgG is employed in the control line region. The PathFlow® SARS-CoV-2 IgG rapid test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2.

STORAGE AND STABILITY
• Store as packaged at room temperature or refrigerated (2-30°C).

SPECIMEN COLLECTION AND PREPARATION
• For Ve nous Whole Blood specimen:
• For Serum or Plasma specimens:

SERUM AND PLASMA SPECIMENS
• Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear non-haemolysed specimens.

WHOLE BLOOD SPECIMENS
• Whole blood collected by venepuncture or fingerstick, serum, or plasma.

SPECIMEN STORAGE
• Serum and plasma specimens may be stored at 2-8°C for up to 7 days. For long term storage, serum/plasma specimens should be kept below -20°C. Whole blood collected by venepuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

STORAGE AND STABILITY
• Do not freeze

INTERPRETATION OF RESULTS
• The intensity of the colour in the test line region (T) will vary according to the illustrations below.

Note: When adding specimen and buffer, add them to their specified wells only. Do not use the buffer beyond 6 months after opening the vial. For Venous Whole Blood Specimen, Serum or Plasma Specimen For Serum or Plasma specimens:

1. Use a dropper: Hold the dropper vertically, draw the specimen to the fill line (approximately 10µL), and add 2 drops of buffer (approximately 80µL) to Buffer well (B), and start the timer.

2. To use a pipette: Transfer 10µL of specimen to the Specimen well (S), then add 2 drops of buffer (approximately 80µL) to Buffer well (B) and start the timer.

3. For Venous Whole Blood specimen:
• Use a dropper: Hold the dropper vertically, draw the specimen about 1 cm above the fill line and transfer 1 full drop (approx. 20µL) of specimen to the Specimen well (S). Then add 2 drops of buffer (approximately 80µL) to Buffer well (B) and start the timer.

4. For Fingerstick Whole Blood specimen:
• Use alcohol pad to clean the fingertip of the middle finger or ring finger as the puncture site.
• Carefully rotate and pull off the lancet cap.
• Push the sterile lancet firmly into the fingertip of the middle finger.
• Wipe off the first drop of blood. To increase blood flow, use the thumb and forefinger to gently apply pressure around the puncture site.
• Hold the dropper vertically, draw the blood to 1cm above the fill line and transfer 1 full drop of blood (approximately 20µL) to the Specimen well (S), then add 2 drops of buffer (approximately 80µL) to the Buffer well (B) and start the timer.

5. Interpreting the result:
• Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS
POSITIVE: *Two distinct coloured lines appear. One coloured line should be present in the control line region (C) and another in the test region (T).

*NOTE: The intensity of the colour in the test line region (T) will vary depending on the concentration of IgG antibodies to SARS-CoV-2 present in the specimen. Any shade of colour in the test line region should be considered positive.
NEGATIVE: One coloured line appears in the control line region (C). No line appears in the test line region (T).

INVALID: Colour line (C) fails to appear. Insufficient specimen volume or incorrect procedural technique are the most likely reasons for control line failure. Review the procedure and repeat the test with a new cassette.

If the problem persists, discontinue using the cassette immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A coloured line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance [5].

LIMITATIONS

1. The test procedure and the interpretation of test result must be followed closely when testing for the presence of SARS-CoV-2 virus-specific antibodies. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.

2. The PathFlow® SARS-CoV-2 IgG rapid test is for in vitro diagnostic use only. Neither the quantitative value nor the rate of increase in the concentration of IgG antibodies to SARS-CoV-2 can be determined by this qualitative test.

3. The PathFlow® SARS-CoV-2 IgG rapid test will only indicate the presence of IgG antibodies to SARS-CoV-2 in the specimen.

4. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.

5. The haematocrit level of the whole blood can affect the test results. Haematocrit level needs to be between 25% and 65% for accurate results.

6. The test will show negative results under the following conditions: The titre of the novel coronavirus antibodies in the sample is lower than the minimum detection limit of the test, or the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody utilized in the test, or the novel coronavirus antibody has not appeared at the time of sample collection. It is recommended to re-sample the patient a few days later and test again.

7. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.

8. Results from immunosuppressed patients should be interpreted with caution.

9. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains or other interference factors.

10. Not for the screening of donated blood.

PERFORMANCE CHARACTERISTICS

The PathFlow® SARS-CoV-2 IgG rapid test was compared with RT-PCR/verification panel/CLIA results; the results are tabulated below.

Clinical study for immune response to previous SARS-CoV-2 infection:

<table>
<thead>
<tr>
<th>Method</th>
<th>PCR (n=350) &amp; Panel (n=111)</th>
<th>Total Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>PathFlow® SARS-CoV-2 IgG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>236</td>
<td>238</td>
</tr>
<tr>
<td>Negative</td>
<td>2</td>
<td>23</td>
</tr>
<tr>
<td>Total Result</td>
<td>242</td>
<td>219</td>
</tr>
<tr>
<td>Relative sensitivity: 98% (95%CI*: 92.0%~98.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relative specificity: 99% (95%CI*: 96.3%~99.9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accuracy: 98% (95%CI*: 95.6%~99.0%)</td>
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</tbody>
</table>

Clinical study for immune response to vaccination:

<table>
<thead>
<tr>
<th>Method</th>
<th>CLIA (n=80)</th>
<th>Total Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>PathFlow® SARS-CoV-2 IgG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>22</td>
<td>22</td>
</tr>
<tr>
<td>Negative</td>
<td>25</td>
<td>48</td>
</tr>
<tr>
<td>Total Result</td>
<td>23</td>
<td>55</td>
</tr>
<tr>
<td>Relative sensitivity: 96% (95%CI*: 78.1%~99.9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relative specificity: 100% (95%CI*: 86.3%~100%)</td>
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<td></td>
</tr>
<tr>
<td>Accuracy: 98% (95%CI*: 88.9%~99.9%)</td>
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INTERFERENCE SUBSTANCES

The following compounds have been tested using the PathFlow® SARS-CoV-2 IgG rapid test and no interference was observed.

Triglyceride: 100mg/dl
Bilirubin: 60mg/dl
Ascorbic Acid: 20mg/dl
Haemoglobin: 1000mg/dl

BIBLIOGRAPHY


TABLE OF SYMBOLS

This document applies to the following product codes: M598CE.