The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette is only for use under the Food and Drug Administration's Emergency Use Authorization. In vitro diagnostic use only. Do not use after expiration date.

**INTENDED USE**

The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette is a lateral flow chromatographic immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human venous whole blood (sodium heparin, EDTA, and sodium citrate), serum or plasma. The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette 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 an individual can test positive. Even if the presence of antibodies confers protective immunity, The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C 263a, that meet the requirements to perform moderate or high complexity tests.

Results are for the detection of SARS-CoV-2 antibodies. The IgG and IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of detectable antibodies is present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

**SUMMARY**

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected individuals may also be infectious. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette is a lateral flow immunochromatographic assay for the detection of SARS-CoV-2 antibodies in venous whole blood, serum or plasma. For prescription use only. For in vitro diagnostic use only.

**PRINCIPLE**

The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette is a lateral flow immunochromatographic assay for the detection of SARS-CoV-2 antibodies in venous whole blood, serum or plasma. This test uses anti-human IgM antibody (test line IgM), anti-human IgG (test line IgG) and goat anti-mouse IgG (control line C) immobilized on a nitrocellulose strip. The conjugate pad contains recombiant SARS-CoV-2 antigen (Spike protein RBD domain main antigens of SARS-COV-2) conjugated with colloidal gold.

During testing, the specimen binds with SARS-CoV-2 antigen conjugated gold colloidal coated particles in the test cassette. When a specimen followed by assay buffer is added to the sample well, IgG and/or IgM antibodies if present, will bind to COVID-19 conjugates making antigen antibodies complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the corresponding immobilized antibody (anti-human IgM and/or anti-human IgG) the complex is trapped forming a colored line where color reaction test result. Absence of a colored line in the test region indicates a non-reactive test result.

To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

**WARNINGS AND PRECAUTIONS**

- For prescription use only. For in vitro diagnostic use only. Do not use after expiration date.
- This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA to perform moderate or high complexity tests.
- This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens; and this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Wash all specimen containers as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used tests, specimens and potentially contaminated material should be discarded in accordance with state, local or federal regulations (such as 42 CFR 493.1256) or accrediting organizations. The SARS-COV-2 IgG/IgM External Control Kit can be purchased separately. Please contact Hangzhou Biotest Biotech or your distributor for information on purchasing these controls.

**STORAGE AND STABILITY**

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE; Do not use beyond the expiration date.

**SPECIMEN COLLECTION AND PREPARATION**

Whole blood or plasma could be collected with tube containing Heparin or Citrate.

Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolysed specimens.

- Testing should be performed immediately after specimen collection. Do not leave the specimen at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture 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.

- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

**MATERIALS**

<table>
<thead>
<tr>
<th>Kit components</th>
<th>Format 1</th>
<th>Format 2</th>
<th>Format 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test cassettes:</td>
<td>20 cassettes</td>
<td>20 cassettes</td>
<td>25 cassettes</td>
</tr>
<tr>
<td>Buffer:</td>
<td>20 vials per kit</td>
<td>1 vial per kit</td>
<td>1 vial per kit</td>
</tr>
<tr>
<td>Drippers or capillaries</td>
<td>20 drippers/capillaries per kit</td>
<td>20 drippers/capillaries per kit</td>
<td>25 drippers/capillaries per kit</td>
</tr>
</tbody>
</table>

**DIRECTIONS FOR USE**

Allow the test cassette, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the test cassette on a clean and level surface.
3. To use a micropipette: Pipette and dispense 10µl of specimen to the specimen well (S) of the test cassette, then add 2 drops of buffer (approximately 80µl) to the buffer well (B) and start the timer. Avoid trapping air bubbles in the specimen well.
   - For Serum or Plasma: Do not mix.

4. To use a dropper: Hold the dropper vertically, draw the specimen up to the Fill Line (approximately 10µl), and transfer the specimen well of the test cassette, then add 2 drops of buffer (approximately 80µl) to the buffer well (B) and start the timer.
5. Wait for the colored line(s) to appear. The test result should be read at 10 minutes. Do not interpret the result after 20 minutes.

**INTERPRETATION OF RESULTS**

(See below for the interpretation of SARS-CoV-2 IgG/IgM results)

**IGG AND IGM POSITIVE**: Three lines appear. One colored line should be in the control line region (C), and two-colored lines should appear in IgG test line region and IgM test line region. The color intensities of the lines do not have to match.

**IGG POSITIVE& IGM POSITIVE**: Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgG test line region. The result is positive for SARS-CoV-2 virus specific-IgG.

**IGM POSITIVE**: Two lines appear. One colored line should be in the control line region (C), and a colored line appears in IgM test line region. The result is positive for SARS-CoV-2 virus specific-IgM.

*NOTE: The intensity of the color in the IgG and/or IgM test line region(s) will vary depending on the concentration of SARS-CoV-2 antibodies in the specimen. Therefore, any shade of color intensity may be present for either IgG or IgM.*

**NEGATIVE**: One colored line should be in the control line region (C). No line appears in IgG and IgM test line region(s).

**QUALITY CONTROL**

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control, it confirming adequate membrane wicking. 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.
[LIMITATIONS]
For use under an Emergency Use Authorization Only
1. Use of the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette is limited to laboratory personnel who have been trained. Not for home use.
2. The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette is for in vitro diagnostic use only. The test should be used for the detection of SARS-COV-2 antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in SARS-COV-2 antibody concentration can be determined by this qualitative test.
3. The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of SARS-COV-2 virus specific antibodies in the serum, plasma or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
4. Reading test results earlier than 10 minutes after the addition of Buffer may yield erroneous results. Do not interpret the result after 20 minutes.
5. The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette will only indicate the presence of SARS-COV-2 antibodies in the specimen and should not be used as the sole criteria for the diagnosis of SARS-COV-2.
6. In the early onset of symptoms, anti-SARS-COV-2 IgM and IgG antibody concentrations may be below detectable levels.
7. The test may have lower sensitivity for IgG detection in symptomatic individuals prior to 14 days since symptom onset.
8. Results from immunosuppressed patients should be interpreted with caution.
9. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
10. A negative result for individual subject indicates absence of detectable anti-SARS-COV-2 antibodies. Negative results do not preclude SARS-COV-2 infection as the sole basis for patient management decisions. IgM antibodies may not be detected in the first few days of infection; the sensitivity of the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette early after infection is unknown. False positive results for IgG and IgM antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Samples with positive results should be confirmed with alternative testing methods and clinical findings before a diagnostic determination is made. A negative result can occur if the quantity of the anti-SARS-COV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the period of disease in which a sample is collected.
11. Some specimens containing unusually high titer of rheumatoid factor may affect expected results.
12. Positive results may be due to past or present infection with non-SARS-COV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
13. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-COV-2 infection or to inform infection status.
15. There may be false positive risk with the plasma in EDTA tube after 24hours.
16. The sensitivity of the test is impacted after being open for one hour-the intensity of the T line becomes weak. Testing must be performed within one hour after opening the pouch.

【Conditions of Authorization for the Laboratory】
The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and the authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-declaration#19I1.
Authorized laboratories using the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette (your product in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:
1. Authorized laboratories* using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
2. Authorized laboratories using your product will use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized clinical test types, antibody concentrations, ancillary reagents and authorized materials required to use your product are not permitted.
3. Authorized laboratories that receive your patient will notify the relevant public health authority of their intent to run your product prior to initiating testing.
4. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. All laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Hongzhou Biotest Biotech Co., Ltd (info.usa@biotests.com.cn) any suspected occurrence of false negative or false non-reaction results and significant deviations from the established performance characteristics of your product of which they become aware.
6. All laboratory personnel using your product must be appropriately trained in immunoassay techniques and given appropriate laboratory and personal protective equipment when handing this kit and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.
7. Authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

*The letter of authorization refers to, “Laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate or high complexity tests” as “authorized laboratories.”

【PERFORMANCE CHARACTERISTICS】

POSITIVE AGREEMENT:
Positive agreement was evaluated using specimens collected from symptomatic subjects. All subjects were confirmed positive for SARS-COV-2 by RT-PCR. The positive population consisted of the following subjects:
- Living in Site A during the COVID-19 pandemic.
- Living in Site B-1 during the COVID-19 pandemic.
- Living in Site B-2 during the COVID-19 pandemic.

SEROCONVERSION:
The sensitivity and specificity of the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette was evaluated on samples from individuals residing in Site C for Diagnosis and Treatment of Infectious Disease. The sensitivity was evaluated on 104 samples from 30 hospitalized patients. All the studied cases are confirmed by RT-PCR. Of these objectives, seven subjects were both IgM and IgG positive at the first test sample, twenty subjects seroconverted during observation and three subjects never seroconverted. The sensitivity was 90% (27/30) for the subjects tested.

Table 1. IgM PPA (Per site and sites combined):

<table>
<thead>
<tr>
<th>Site</th>
<th>Days post symptom onset</th>
<th># PCR positive at any time</th>
<th>RightSign™ COVID-19 IgG/IgM Rapid Test Cassette</th>
</tr>
</thead>
<tbody>
<tr>
<td>A &amp; B-2 plasma</td>
<td>8-14</td>
<td>83</td>
<td>77 (%)</td>
</tr>
<tr>
<td></td>
<td>≥15</td>
<td>158</td>
<td>150 (%)</td>
</tr>
</tbody>
</table>

Table 2. IgG PPA (Per site and sites combined):

<table>
<thead>
<tr>
<th>Site</th>
<th>Days post symptom onset</th>
<th># PCR positive at any time</th>
<th>RightSign™ COVID-19 IgG/IgM Rapid Test Cassette</th>
</tr>
</thead>
<tbody>
<tr>
<td>A &amp; B-2 (Serum)</td>
<td>6-14</td>
<td>83</td>
<td>76 (%)</td>
</tr>
<tr>
<td></td>
<td>≥15</td>
<td>158</td>
<td>152 (%)</td>
</tr>
</tbody>
</table>

Table 3. IgM NPA (Per site and sites combined):

<table>
<thead>
<tr>
<th>Site</th>
<th># PCR negative</th>
<th>RightSign™ COVID-19 IgG/IgM Rapid Test Cassette</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site C</td>
<td>149%</td>
<td>95% CI</td>
</tr>
</tbody>
</table>

Table 4. IgG NPA (Per site and sites combined):

<table>
<thead>
<tr>
<th>Site</th>
<th># PCR negative</th>
<th>RightSign™ COVID-19 IgG/IgM Rapid Test Cassette</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site C</td>
<td>149%</td>
<td>95% CI</td>
</tr>
</tbody>
</table>

Table 5. IgM PPA (Site C):

<table>
<thead>
<tr>
<th>Site</th>
<th>Days post symptom onset</th>
<th># PCR positive at any time</th>
<th>RightSign™ COVID-19 IgG/IgM Rapid Test Cassette</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8-14</td>
<td>27</td>
<td>14 (%)</td>
</tr>
<tr>
<td></td>
<td>≥15</td>
<td>45</td>
<td>43 (%)</td>
</tr>
</tbody>
</table>

Table 6. IgG PPA (Site C):

<table>
<thead>
<tr>
<th>Site</th>
<th>Days post symptom onset</th>
<th># PCR positive at any time</th>
<th>RightSign™ COVID-19 IgG/IgM Rapid Test Cassette</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8-14</td>
<td>27</td>
<td>14 (%)</td>
</tr>
<tr>
<td></td>
<td>≥15</td>
<td>45</td>
<td>43 (%)</td>
</tr>
</tbody>
</table>

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Independent Clinical Agreement Validation

The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette was tested on 2020-04-21 at the Federation National Laboratory for Cancer Research (FNLCR) sponsored by the National Cancer Institute (NCI). The test was validated against a panel of previously frozen samples consisting of 30 SARS-CoV-2 antibody-positive serum samples and 80 antibody-negative serum and plasma samples. Each of the 30 antibody-positive samples was confirmed with a nucleic acid amplification test (NAAT) and both IgM and IgG antibodies were confirmed to be present in all 30 samples. The presence of antibodies in the samples was confirmed by several orthogonal methods prior to testing with the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette. The presence of IgM and IgG antibodies specifically was confirmed by one or more comparator methods. Antibody-positive samples were selected at different antibody titers. All antibody-negative samples were collected prior to 2020 and include; i) Seventy (70) samples selected without regard to clinical status, “Negatives” and ii) Ten (10) samples selected from banked serum from HIV+ patients, “HIV+.” Testing was performed by one operator using one lot of the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette. Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2004).

For evaluation of cross-reactivity with HIV+, it was evaluated whether an increased false positive rate among antibody-negative samples with HIV+ was statistically higher than the false positive rate among antibody-negative samples without HIV (for this, a confidence interval for the difference in false positive rate was calculated per a score method described by Altman). The results and data analysis are shown below.

Table 8. Summary Statistics

Table 9. Summary Statistics

Table 10: Cross-reactive Study Data of RightSign™ COVID-19 IgG/IgM Rapid Test Cassette.

Table 11: Summary Statistics

Table 12: Cross-reactive Study Data of RightSign™ COVID-19 IgG/IgM Rapid Test Cassette.

Cross-reactivity

The RightSign™ COVID-19 IgG/IgM Rapid Test Cassette presents the following potentially cross-reactive substances.

Interfering Substances

The following potentially interfering substances were added to COVID-19 negative and spiked

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positive specimens.

Table 11: Interference Study Data of RightSign™ COVID-19 IgG/IgM Rapid Test Cassette.

<table>
<thead>
<tr>
<th>Analytes</th>
<th>Concentration</th>
<th>Negative Specimen</th>
<th>Spiked with Positive Specimen</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>IgG line</td>
<td>IgM line</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>20 mg/dL</td>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>Caffeine</td>
<td>20 mg/dL</td>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>Albumin</td>
<td>2 g/dL</td>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>Acetylsalicylic Acid</td>
<td>20 mg/dL</td>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>Mercuric Acid</td>
<td>20 mg/dL</td>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>Ethanol</td>
<td>1%</td>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td>2g/dL</td>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>Cystine</td>
<td>5000 mg/dL</td>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>1mg/dL</td>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>1000 mg/dL</td>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>Oxalic Acid</td>
<td>60 mg/dL</td>
<td>Negative</td>
<td>Negative</td>
</tr>
<tr>
<td>Uric acid</td>
<td>20 mg/ml</td>
<td>Negative</td>
<td>Negative</td>
</tr>
</tbody>
</table>

None of the substances at the concentration tested interfered in the assay.

[BIBLIOGRAPHY]


Manufactured by: Hangzhou Biotest Biotech Co., Ltd.
No.17, Futai Road, Zhongtai Street, Yuhang District, Hangzhou, P.R. China

Revision: RP5801141
Effective Date: TBD
**Instruction for use of RightSign™ SARS-COV-2 IgG/IgM External Control Kit**

For Emergency Use Authorization only
For prescription use only
For in vitro diagnostic use only.

**INTENDED USE**

The RightSign™ SARS-COV-2 IgG/IgM External Control Kit is intended to use as quality controls for the performance of RightSign™ COVID-19 IgG/IgM Rapid Test Cassette. The performance of RightSign™ SARS-COV-2 IgG/IgM External Control Kit has not been established for any other assays or instrument platforms.

**MATERIALS**

Materials Provided:

1. vial of SARS-COV-2 Negative Control
2. vial of SARS-COV-2 Positive Control

**PRECAUTIONS**

1. For Emergency Use Authorization only
2. For in vitro diagnostic use only
3. This product has not been FDA cleared or approved;
4. This product has been authorized by FDA under an EUA for use by laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests;
5. This product has been authorized for use with the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens;
6. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
7. The controls are intended for professional use only
8. Please read through the whole package insert before performing the test. Failure of following the insert will give inaccurate test results. If the result is not as expected, do not proceed the testing and contact manufacturer immediately.
9. Do not use after expiration date.
10. This product contains human source and or potential infectious ingredients. Use the Centers for Disease Control (CDC) recommended universal precautions for handling this product and human blood. Do not pipette by mouth; do not eat or drink in areas where specimens are being handled. Treat the controls as potential biological hazardous materials.
11. Wear protective clothing and disposable gloves while handling the control reagents.
12. Wash hands thoroughly after performing the test.

**STORAGE**

UNOPENED RightSign™ SARS-COV-2 IgG/IgM External Control Kit can be stored at -20°C until expiration date. Once opened, the RightSign™ SARS-COV-2 IgG/IgM External Control Kit is stable at 2-8°C for 30 days or by the expiration date, whichever comes first. Avoid freeze-thaw cycles. Do not use after expiration date.

**PROCEDURE**

Follow the test procedure as stated in the package inserts of the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette:

1. Allow the controls to reach room temperature prior to use. Mix gently before use.
2. Add 10 ul of negative or positive control into specimen well (S).
3. Transfer 2 drops (approximately 80ul) of buffer to the buffer well (B).
4. Record results at 10 minutes. Do not interpret the result after 20 minutes.
5. Return controls to refrigerated storage immediately after use.
6. SARS-COV-2 Negative Control should yield a negative result.
7. SARS-COV-2 Positive Control should yield an IgG and IgM positive result.

**LIMITATION**

The RightSign™ SARS-COV-2 IgG/IgM External Control Kit is designed for use only with the RightSign™ COVID-19 IgG/IgM Rapid Test Cassette. The validity of the reaction produced in another rapid test cannot be guaranteed. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

**BIBLIOGRAPHY**