# RAPID 2019-NCOV IGG/IGM COMBO TEST CARD

FOR THE QUALITATIVE ASSESSMENT OF IGG AND IGM ANTIBODIES TO 2019 NOVEL CORONAVIRUS IN HUMAN SERUM, PLASMA, OR WHOLE BLOOD

Catalog Number: 1N38C2

***For In Vitro Diagnostic Use Only***

## INTENDED USE

Rapid 2019-nCoV IgG/IgM Combo Test Card is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of IgG and IgM antibodies to 2019 novel coronavirus (2019-nCoV, SARS-CoV-2) in human serum, plasma, or whole blood. Rapid 2019-nCoV IgG/IgM Combo Test Card is a supplement detection for COVID-19 suspected infected patients besides nucleic acid test, which could greatly raise the accuracy of the detection for COVID-19.

## 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 people can also be an infectious source. 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.

## PRINCIPLE

Rapid 2019-nCoV IgG/IgM Combo Test Card utilizes the principle of immuno-chromatography. Mouse anti-human IgM and mouse anti-human IgG antibodies are immobilized on the nitrocellulose membrane respectively, as two individual test lines (IgM line and IgG line) in the test window of the test device. The IgM line in the test window is closer to the sample well followed by IgG line. As the test sample flows through the membrane within the test device, the colored 2019-nCoV recombinant antigen-colloidal gold conjugate forms complexes with specific antibodies (IgM and/or IgG) to 2019 novel coronavirus, if present in the sample. This complex moves further on the membrane to the test region where it is captured by the mouse anti-human IgM and/or mouse anti-human IgG antibodies coated on the membrane leading to formation of a colored band, which indicates positive test results. Absence of this colored band in the test window indicates a negative test result. A built-in control line will always appear in the test window when the test is performed properly, regardless of the presence or absence of anti-2019 novel coronavirus antibodies in the specimen.

## MATERIALS PROVIDED

1. Rapid 2019-nCoV IgG/IgM Combo Test Card
2. Sample buffer
3. 2 μL capillary pipet
4. Instructions for Use

## MATERIALS REQUIRED BUT NOT SUPPLIED

Clock or timer, safety lancets, alcohol prep-pad, specimen collection container, centrifuge, biohazard waste container. disposable gloves, disinfectant.

## STORAGE

1. Store the test device at 4 to 30°C in the original sealed pouch. Do Not Freeze.
2. The expiration date indicated on the pouch was established under these storage conditions.
3. The test device should remain in its original sealed pouch until ready for use. After opening, the test device should be used immediately. Do not reuse the device.

## PRECAUTIONS

1. For **professional *in vitro*** diagnostic use only.
2. The product is strictly for medical professional use only and not intended for personal use.
3. Do not use the product beyond the expiration date.
4. Do not use the product if the pouch is damaged or the seal is broken.
5. Handle all specimens as potentially infectious.
6. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infectious material. When the assay procedure is completed, dispose specimens after autoclaving at 121°C for at least 20 min or treating with 0.5% Sodium Hypochlorite for 1-2 hours.

## SPECIMEN COLLECTION AND PREPARATION

1. The serum, plasma or whole blood specimen should be collected under standard laboratory conditions.
2. Heat inactivation of specimens, which may cause hemolysis and protein denaturation, should be avoided.
3. The test works best on fresh whole blood / serum / plasma samples. If testing cannot be performed immediately, serum / plasma may be stored at 2-8°C up to 3 days in case of delay in testing. For long-term storage, serum / plasma specimens can be frozen at -20°C for 3 months or -70°C for longer period. Avoid repeated freezing/thawing cycles.
4. Sodium azide can be added as a preservative up to 0.1% without affecting the test results.

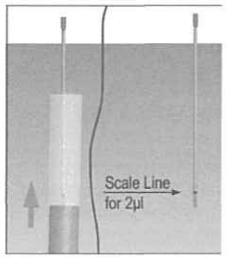
## QUALITY CONTROL

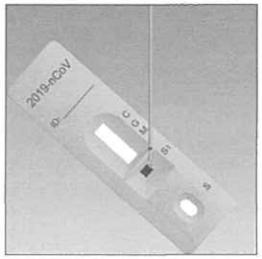
1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which are not provided with this test kit are commercially available.

## PROCEDURE

| | |
|---|---|
| 1 | Bring the kit components to room temperature before testing. |
| 2 | Open the pouch and remove the Card. Once opened, the test card must be used immediately. |
| 3 | Label the test card with patient identity. |

**4**



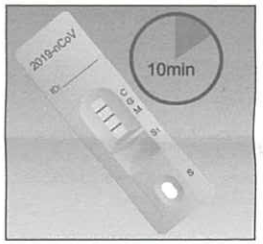




Withdraw the blood specimen with the capillary pipet provided, gently squeeze out the extra specimen to leave 2 μL in the pipet as marked with the scale line. Apply 2 μL of blood specimen to the "S1" area as marked.

**5**


Add 2 drops of sample buffer (approximately 80-100 μL) to well marked as "**S**".

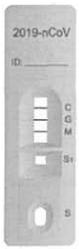
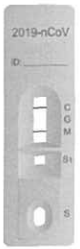
**6**




Read the result at 10 minutes. A strong positive sample may show result earlier.

***Note: Results after 15 minutes may not be accurate.***

## INTERPRETATION OF RESULTS

| POSITIVE | | |
|---|---|---|
|  |  |  |
| **Both IgG/IgM Positive** | **IgG Negative IgM Positive** | **IgG Positive IgM Negative** |
| Control line and both test lines appear. | Both control line and the M test line appear. | Both control line and the G test line appear. |





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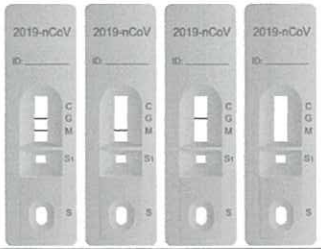
| NEGATIVE | |
|---|---|
|  | Only control line appears. |

| INVALID | |
|---|---|
|  | The test result is invalid if a colored band does not form in the control region. The sample must be re-tested, using a new test device. |

**PERFORMANCE CHARACTERISTICS**

**Accuracy**

A total of 323 specimens from COVID-19 confirmed patients were tested, the results showed that 306 specimens were IgM positive and/or IgG positive, and the clinical sensitivity was 94.74% (95% CI: 92.30% - 97.17%). A total of 306 specimens from COVID-19 excluded patients were tested, the results showed that 297 specimens were both IgM and IgG negative, and the clinical specificity was 97.06% (95% CI: 95.17% - 98.95%). The accuracy was 95.87% (95% CI: 94.31% - 97.42%).

A total of 323 specimens from COVID-19 confirmed patients were tested, the results showed that 228 specimens were IgM positive, and the IgM clinical sensitivity was 70.59% (95% CI: 65.62% - 75.56%). A total of 306 specimens from COVID-19 excluded patients were tested, the results showed that 305 specimens were IgM negative, and the IgM clinical specificity was 99.67% (95% CI: 99.03% - 100%). The accuracy was 84.74% (95% CI: 81.93% - 87.55%).

A total of 323 specimens from COVID-19 confirmed patients were tested, the results showed that 292 specimens were IgG positive, and the IgG clinical sensitivity was 90.40% (95% CI: 87.19% - 93.61%). A total of 306 specimens from COVID-19 excluded patients were tested, the results showed that 298 specimens were IgG negative, and the IgG clinical specificity was 97.39% (95% CI: 95.60% - 99.17%). The accuracy was 93.80% (95% CI: 91.91% - 95.68%).

A total of 323 specimens from COVID-19 confirmed patients were tested, including 85 early stage, 123 middle stage, and 115 late-stage / recovery period cases. Based on the test results for specimens with different disease progress, the clinical sensitivity was relatively low for early stage cases (82.35%), which significantly increased for middle stage and late stage specimens (98.37% and 100% respectively).

134 serum samples with their autologous plasma and whole blood samples were simultaneously tested. Test results were consistent, with 49 positive and 85 negative cases.

**Assay Specificity**

**1. Other diseases**

Rapid 2019-nCoV IgG/IgM Combo Test Card has tested samples that are positive for other diseases listed below: HBsAb, TP antibody, HCV antibody, HIV antibody, Influenza A virus antibody, Influenza B virus antibody, Respiratory syncytial virus antibody, Mycoplasma pneumoniae antibody, Chlamydia pneumonia antibody, Respiratory adenovirus antibody, Parainfluenza virus antibody, Legionella pneumophila antibody, Rheumatoid Factor (RF) and ANA. All the samples showed no effect on the specificity of the assay.

**2. Blood compounds**

Rapid 2019-nCoV IgG/IgM Combo Test Card has tested samples with high Bilirubin, Triglyceride and Hemoglobin. The results showed that these compounds had no effect on the specificity of the assay up to the listed concentration.

| | |
|---|---|
| Bilirubin | 342 μmol/L |
| Triglyceride | 37 mmol/L |
| Hemoglobin | 10 mg/mL |

**3. Common drugs**

Rapid 2019-nCoV IgG/IgM Combo Test Card has tested samples with common drugs. The results showed that these drugs had no affect on the specificity of the assay up to the listed concentration.

| | | | |
|---|---|---|---|
| Zanamivir | 426 ng/mL | Ribavirin | 6 mg/L |
| Oseltamivir | 46.9 mg/L | Peramivir | 132.7 μg/mL |
| Lopinavir | 3.2 mg/mL | Ritonavir | 159 μg/mL |
| Arbidol | 2.0 μg/mL | Levofloxacin | 9.2 mg/L |
| Azithromycin | 1.2 μg/mL | Ceftriaxone | 240 mg/L |
| Meropenem | 200 mg/L | Tobramycin | 12 mg/L |

**4. Precision**

To analyze within-run and between-run precision, three lots of Rapid 2019-nCoV IgG/IgM Combo Test Card were tested with controls by three lab technicians for 10 consecutive working days. The results showed 100% agreement.

**LIMITATIONS**

1. The test is limited to the qualitative detection of anti-2019-nCoV antibody levels in serum, plasma, or whole blood specimen. The exact concentration of anti-2019-nCoV antibody cannot be determined by this assay.
2. Although the test is very accurate in detecting anti-2019-nCoV antibody, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. In the early stage of infection, if IgM and IgG antibodies are not produced or the titer is very low, false negative results will occur. It is suggested that patients should collect samples again after 7-14 days, and test at the same time with the last collected samples to confirm whether there is serologically positive transfer or significant increase in titer. In the later stage of infection, IgM titer will decrease or even be negative, while IgG will continue to increase.
5. The negative results have to be carefully considered together with clinical presentations. Any positive result from this test should be confirmed with supplemental laboratory testing (e.g. RT-PCR).

**REFERENCES**

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2. Hoffman, T., Nissen, K., Krambrich, J., Rönnberg, B., Akaberi, D., Esmaeilzadeh, M., ... & Lundkvist, Å. (2020). Evaluation of a COVID-19 IgM and IgG rapid test; an efficient tool for assessment of past exposure to SARS-CoV-2. Infection Ecology & Epidemiology, 10(1), 1754538.

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***Xiamen Boson Biotech Co., Ltd***
90-94 Tianfeng Road, Jimei North Industrial Park,
Xiamen, Fujian, 361021, P.R.China

Tel: 86-592-3965101
Fax: 86-592-3965155
Email: info@bosonbio.com
www.bosonbio.com

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***Lotus NL B.V.***
Koningin Julianaplein 10, 1e Verd, 2595AA,
The Hague, Netherlands.

Tel: +31645171879(English), +31626669008(Dutch)
Email: peter@lotusnl.com



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