2019-nCoV IgG Antibody Determination Kit
(Immunochromatographic Assay)

PRODUCT NAME
Product Name: 2019-nCoV IgG Antibody Determination Kit
(Immunochromatographic Assay)

PACKAGE
10 Test/Box; 25 Test/Box; 50 Test/Box; 100 Test/Box.

INTENDED USE
It is used for the qualitative detection of novel coronavirus IgG antibody in human serum, plasma or whole blood in vitro. The product is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.

Coronavirus is a large family that exists widely in nature. It is susceptible to humans and many animals. It is named for its corona-like fibroids on the surface of its virus particles. The typical clinical symptoms of the new coronavirus (2019-nCoV) infection are fever, fatigue, muscle soreness, and dry cough, which can progress to severe pneumonia, respiratory failure, and even life-threatening.

Current evidence indicates that the new coronavirus is transmitted mainly through droplets, aerosols, and direct contact with secretions. After humans are infected with the new coronavirus (2019-nCoV), the human immune system will generate an immune response against the virus, producing specific antibodies. Detection of relevant antibodies can be used to screen for infection with the new coronavirus. Therefore, it is of great clinical significance to establish a simple, safe and reliable new method for laboratory diagnosis of coronavirus.

PRINCIPLE
After an appropriate amount of sample is added to the detection well, the sample moves under the action of capillaries. The new coronavirus IgG antibody in the sample will be combined with fluorescent microsphere-labeled sheep anti-human IgG FC antibody to form a microsphere-antibody-antibody complex. The complex is then chromatographed along the nitrocellulose membrane to the detection zone (T), which binds to the pre-coated 2019-nCoV virus antigen, and its fluorescence intensity is directly proportional to the anti-IgG content in the sample; chicken IgY fluorescent antibody particle is chromatographed to the quality control area (C), combined with pre-coated sheep anti-chicken IgY

STORAGE AND STABILITY
The strip is stable for 18 months (while sealed in an aluminum foil pouch) if stored at 2 - 30 °C. The kit is effective in 1 hour after moving from aluminum foil pouch. The date of manufacture is detailed in the label.

<table>
<thead>
<tr>
<th>Name</th>
<th>Composition</th>
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<tbody>
<tr>
<td>Strip</td>
<td>It consists of a cartridge and a detection strip. The detection strip includes a sample pad, glass fiber (coated with fluorescent microspheres- antibody conjugate, fluorescent microspheres- IgY conjugate), and nitrocellulose membrane (The detection area T is coated with 2019-nCoV antigen, quality control area is coated with sheep anti-chicken IgY antibody), absorbent paper, PVC board</td>
</tr>
<tr>
<td>Buffer</td>
<td>Main component is phosphate buffered saline (PBS) One test/tube</td>
</tr>
<tr>
<td>Magcard</td>
<td>Have Calibration curve information of this batch reagents.</td>
</tr>
</tbody>
</table>

Note: Components of different batches can’t be mixed.

SAMPLE REQUIREMENTS
- Clinical fresh non-hemolyzed serum, plasma or whole blood (EDTA anticoagulation) samples.
- After sampling, the sample should be tested within 24h at room temperature. The sample should be stored for no more than 5 days in cold condition of 2-8°C and should be stored for no more than one month in cryopreservation condition of -18°C. The whole blood sample should be stored for no more than five days at 2-8°C if it can’t be tested within two hours after sampling.
- The sample needs to be restored to room temperature before testing. Cryopreserved samples need to be completely melted, rewarmed, mixed evenly before use, avoid freezing and thawing repeatedly.

TEST PROCEDURE
1. Please read the manuals of the kit, analyzer and incubator before using. The test should be carried out at room temperature.
2. Reading card: Read the calibration information from Magcard and select the calibration curve for the corresponding sample type.
3. If the sample is stored refrigerated or frozen, please allow the sample to fully melt at room temperature (20-30 °C) and mix it upside down before use.
4. Before starting the test, remove the test strip from the aluminum foil bag, lay it flat on the table, and mark the sample number.

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5. Sampling: Serum/plasma/whole blood sample. To take 10 ul sample to buffer to shake and mix in 5-10s. Use a pipette to take 80 ul of the mixed sample and add it to the sample well of the strip.

6. Test: After the sample is added, the strip is put aside for 15 minutes, and then the test strip is placed in the Time-Resolved Immunofluorescence analyzer to read the data. Please strictly control the time for 15 min.

7. The Time-Resolved Immunofluorescence analyzer measures and analyzes the optical signal to quantify the concentration of the substance to be tested.

**INTERPRETATION OF TEST RESULTS**

1. The test result is the relative content of the 2019-nCoV IgG antibody.

2. If the test result is less than 1 U/L, it is negative; otherwise, the test result is more than or equal to 1 U/L, which is positive.

**PRODUCT PERFORMANCE**

- Appearance: The appearance of the reagent should be neat and tidy, and the test symbol should be clearly marked. There is no leakage. The test strip is intact.

- Film strip width: should not be less than 2.5mm.

- Liquid migration speed: should not be lower than 10mm/min.

- Repeatability (Precision): Repeated testing (1±0.2) U/L samples for ten times, the result coefficient of variation CV≤15%.

- Accuracy: The positive and negative conformity rate and precision of this product meet the requirements of quality standards, and the product quality is stable during the validity period.

**LIMITATIONS OF THE TEST**

- This reagent is used for the detection of human whole blood, serum or plasma samples. It cannot be used for the detection of saliva, urine or other body fluids.

- Diagnosis and treatment cannot rely solely on this test result. Please consider both clinical history and other laboratory test results.

- In early phase of the infection, high titers of virus-specific IgM antibodies may lead to negative results. If a viral infection is suspected, IgM antibodies should also be tested.

- The interpretation of positive results should be further determined in conjunction with clinical symptoms and other etiological methods (nucleic acid and sequencing, etc.).

- A negative result indicates that no new coronavirus IgG antibody is detected, but a negative result may also be obtained if the amount of new coronavirus IgG antibody in the sample is below the minimum detection limit of the kit.

The following shall appear in the test report with the result:

- This test has not been reviewed by the FDA.

- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.

- 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.

- Not for the screening of donated blood

**NOTES**

- This product is for in vitro diagnostic use only.

- The operation steps cannot be omitted or simplified.

- The positive samples detected by this kit need to be confirmed by other methods.

- Disinfect or treat all samples and reagents as potential sources of contamination in accordance with local regulations.

**INDEX OF SYMBOLS**

For technical assistance, please contact:

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