## BASIC INFORMATION

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## MEDICAL DEVICE REGISTRATION CERTIFCATE NO./PRODUCT TECHNICAL REQUREMENT NO.

GXZZ 20203400239

## APPROVAL DATE & MODIFICATION DATE OF INSTRUCTIONS FOR USE

March 8, 2022

## Symbols

| | |
|---|---|
| EC REP | Authorized Representative In the European Community |
| IVD | *In vitro* diagnostic medical device |
| -15°C / -30°C | Temperature limit 4 ~ 30°C |
| | Date of manufacture |

| | |
|---|---|
| Σ | Contains sufficient for <*n*> tests |
| REF | Catalogue number |
| LOT | Batch Code |

| | |
|---|---|
| | Manufacturer |
| | Use-by date |
| | Consult instructions for use |
| CE | CE Mark |

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IVD CE

EC REP
**Shanghai International Holding Corp. GmbH (Europe)**
Eiffestrasse 80, 20537 Hamburg, Germany



# 2019-nCoV IgG/IgM Detection Kit (Colloidal Gold-Based) Instructions for Use

## PRODUCT NAME

Generic Name: 2019-nCoV IgG/IgM Detection Kit (Colloidal Gold-Based)

## SPECIFICATION

10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 40 tests/kit, 50 tests/kit

## INTENDED USE

This test kit is suitable for in vitro qualitative detection of 2019-novel coronavirus (2019-nCoV) IgM/IgG antibodies in human serum or plasma. This test kit is only used as a supplementary detection marker for suspected cases with negative 2019-nCoV nucleic acid test result, or for diagnosis of suspected cases in conjunction with nucleic acid test. The test result of this kit should not be used as a basis for diagnosis and elimination of COVID-19. This test kit is not suitable for screening of general population.
The product can only be used by medical institutions.
Positive test results need further confirmation. Negative test results cannot rule out the possibility of 2019-nCoV infection.
The test kit is limited to clinical use and emergency stockpiles. It cannot be used in clinic as routine in vitro diagnostic reagent.
The test result of this kit is for clinical reference only. It is suggested that the patients' clinical manifestations and other laboratory tests should be combined to make a comprehensive analysis of patients.

## PRINCIPLE OF DETECTION

This product is based on capture and solid-phase immunochromatography methods for detection. The specimen (serum/plasma) flows from the specimen addition end through to the conjugate release pad (which causes the conjugation reaction between 2019-nCoV IgM/IgG antibodies in the specimen and the antigen colloidal gold of 2019-nCoV to form a complex of IgM/IgG antibody and colloidal gold-labeled antigen) due to capillary action. It then migrates to a capture zone of nitrocellulose membrane-immobilized antibody (mouse-anti-human IgM antibody, T1 line) to form an immune complex of colloidal gold-labeled antigen, IgM antibody and mouse-anti-human IgM antibody, thereby generating a T1 red line. The uncaptured colloidal gold conjugate complex continues to flow upward and will be captured by the mouse-anti-human IgG antibodies (T2 line) to form an immune complex of colloidal gold-labeled antigen, IgG antibody and mouse-anti-human IgG antibody, thereby generating a T2 red line. The remaining uncaptured colloidal gold conjugate complex moves upward, combining with C line (quality control line) to indicate the completion of this reaction.

## MAIN COMPONENTS PROVIDED IN THIS KIT

| Component | Main Ingredients |
|---|---|
| Test Cassette | Aluminum foil pouch, desiccant, test strip and plastic card. Test strip composing blotting paper, nitrocellulose membrane, specimen pad, colloidal gold-labeled pad and PVC plate. Nitrocellulose membrane T1 line (Test line) coating 1.0 mg/mL mouse-anti-human IgM antibody. Nitrocellulose membrane T2 line (Test line) coating 1.0 mg/mL mouse-anti-human IgG antibody. C line (quality control line) coating 1.0 mg/mL actin protein C. Conjugate release pad containing 40OD 2019-nCoV antigen-colloidal gold conjugate complex. |
| Specimen Dilution | HEPES Buffer containing casein (0.1 M), 5 mL/bottle. |
| Dropper | According to different specifications, 10 droppers/pack, 20 droppers/pack, 25 droppers/pack, 30 droppers/pack, 40 droppers/pack, 50 droppers/pack. |

Note: DO NOT interchange the components from different batches.

## STORAGE CONDITIONS & SHELF LIFE

The shelf life of this kit is 11 months at 4~30°C.
Once the package of the Test Cassette is opened (4~30°C, humidity < 65%), it must be used within 1 hour. The period of validity of specimen diluent is one month after opening.
See labels for production date and expiration date.

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## SPECIMEN REQUIREMENTS

1. Applicable specimen types are serum and plasma.
2. Sediment and suspended matter in the specimen may affect the test result. Those should be removed by centrifugation at 3000 g for 10 minutes.
3. Severe hematolytic, lipemic and turbid specimens should not be used.
4. Plasma specimens can be treated with heparin sodium or EDTA anticoagulant. After specimen collection, the test should be completed within the same day. If not, please store the specimens using as the following protocol: for Serum/plasma specimens, store at 2~8°C for 7 days, or at < -20°C for 5 months.
5. Specimens must be fully restored to room temperature (18°C-28°C) before testing. Freeze-preserved specimens should be completely melted, reheated and mixed thoroughly before use.

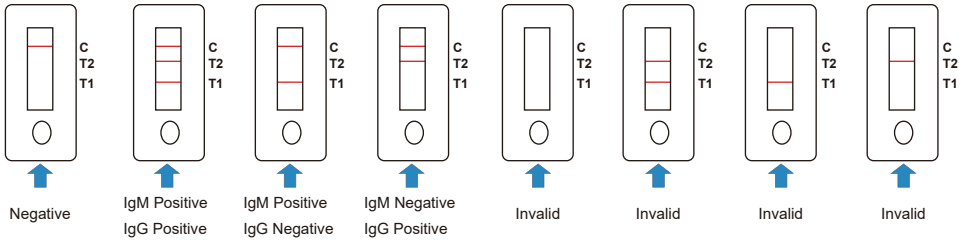
## TEST METHODS

**Read the instructions for use carefully before use.**

1. The test cassette must be at room temperature before use, and the test must be operated at room temperature.
2. Remove the test cassette from the foil pouch and place on a flat, dry table.
3. Using the dropper provided, add 1 drop (about 20 μL) of the serum, or plasma specimens to the specimen addition port. Then add 3 drops of dilution buffer (about 60 μL) to the specimen. Begin timing.
4. Read the results after 10 minutes. The result is invalid after 15 minutes.

## INTERPRETING TEST RESULTS

The test results are interpreted as follows:




(The pattern is for reference only, and the specific is subject to the real object)

1. Negative result: Only one red quality control line (C line) appears in the detection area.
2. IgM positive, IgG positive results: Three clear red lines appear in the detection area, one is the quality control line (C line), one is T2 detection line, and the other is T1 detection line.
3. IgM positive, IgG negative results: Two clear red lines appear in the detection area, one is the quality control line (C line) and another is T1 detection line.
4. IgM negative, IgG positive results: Two clear red lines appear in the detection area, one is the quality control line (C line) and another is T2 detection line.
5. Invalid result: No red quality control line (C line) appears in the detection area (e.g. without any red lines or only test lines (T1, T2 line)), indicating that the test error or the test result is invalid, and the test should be retested.

## LIMITATIONS OF TEST METHODS

1. The test results of this product are only for clinical reference and should not be used as the only basis for clinical diagnosis and treatment. The final diagnosis result should be made by the doctor after integrating all the test indicators and clinical symptoms. The clinical management of patients should be considered in combination with their signs/symptoms, medical history, other laboratory tests and treatment reactions and epidemiology. It is recommended to repeat the test for suspicious specimens at intervals.
2. The accuracy of detection is affected by the specimen collection process. Improper specimen collection and storage process will affect the test results and should avoid high temperature and direct sunlight.
3. This reagent provides a qualitative detection for the 2019-nCoV IgM antibody and IgG antibody in the specimen, but not quantified detection.
4. Due to the limitation of the testing methodologies, it cannot rule out the possibility of a 2019-nCoV infection based on negative results. It is recommended to combine other test results and clinical symptoms to make an accurate diagnosis.



## PRODUCT PERFORMANCE INDICATORS

1. Minimum Limit of Detection (LOD): Test with the in-house LOD references. S1 and S2 are positive for 2019-nCoV IgG antibody, negative for IgM antibody; S3 is negative for 2019-nCoV IgG/IgM antibodies; S4 and S5 are positive for 2019-nCoV IgM antibody, negative for IgG antibody; and S6 is negative for 2019-nCoV IgG/IgM antibodies.
2. Negative coincidence rate: Test with the in-house negative references and the results are all negative for 2019-nCoV IgG/IgM antibodies, with a coincidence rate of 100%.
3. Positive coincidence rate: Test with the in-house positive references. PC01-PC05 are all positive for 2019-nCoV IgM/IgG antibodies, with a coincidence of 100%; PC06-PC10 are all negative for 2019-nCoV IgG antibody and all positive for IgM antibody, with a coincidence rate of 100%; PC11-PC15 are all negative for 2019-nCoV IgM antibody, and all positive for IgG antibody, with a coincidence rate of 100%.
4. Precision:

Intra-batch difference: Test with the in-house repetitive references. CV1 and CV2 are positive for 2019-nCoV IgG antibody and negative for IgM antibody; CV3 and CV4 are negative for 2019-nCoV IgG antibody and positive for IgM antibody, with uniform color development.

Inter-batch difference: Test with the in-house repetitive references. The results of the kit of three batch numbers: CV1 and CV2 are positive for 2019-nCoV IgG antibody and negative for IgM antibody; CV3 and CV4 are negative for 2019-nCoV IgG antibody and positive for IgM antibody, with uniform color development.

5. Analytical specificity

5.1 Cross-reactivity: This product will not cross react with positive specimens of human coronavirus HKU1,OC43, 229E, influenza A H1N1 virus, seasonal H1N1 influenza virus, H3N2, H5N1, H7N9, influenza B Yamagata, Victoria, respiratory syncytial virus, parainfluenza virus, rhinovirus species A, B and C, adenovirus types 1, 2, 3, 4, 5, 7 and 55, coxsackievirus (enterovirus species B), enterovirus 71 (enterovirus species A), enterovirus 68 (EV-D68) (enterovirus species D), EB virus, measles virus, human cytomegalovirus, rotavirus, norovirus, mumps virus, varicella-zoster virus, mycoplasma pneumoniae, chlamydia pneumoniae IgG/IgM antibodies.

5.2 Interferents: When bilirubin ≤0.2 g/L, triglyceride ≤10 g/L, hemoglobin ≤5 g/L, rheumatoid factor ≤500 IU/mL, antinuclear antibody titer ≤1:240, anti-mitochondrial antibody titer ≤1:160, HAMA ≤20 ng/mL, total IgG ≤50 mg/L and total IgM ≤5 mg/L, they will not interfere with the test results. Oseltamivir, levofloxacin, ceftriaxone, zanamivir, interferon alpha (IFN-α), ribavirin, peramivir, lopinavir, ritonavir, arbidol, azithromycin, meropenem, tobramycin, histamine hydrochloride, phenylephrine, oxymetazoline, sodium chloride, beclomethasone, dexamethasone, flunisolide, triamcinolone acetonide, budesonide, mometasone and fluticasone have no effect on the test results.

6. Hook effect: Hook effect will occur at the concentration levels that exceed the lowest limit of detection of IgG antibody of this product by more than 1280 times and the lowest limit of detection of IgM antibody by more than 640 times. If 2019-nCoV infection is highly suspected but the antibody test result is negative, the specimen should be re-tested after dilution.
7. After the specific IgM positive specimen is destroyed, the IgM antibody test result is negative, and the IgG antibody test is not affected.
8. Heparin sodium and EDTA anticoagulants have no effect on the detection of this kit.
9. The precision test is conducted by different test personnel at a different time with this kit, and the results comply with product performance requirements.
10. For virus infection specimens from different regions, the lowest limit of detection and detection repeatability of the reagents comply with the requirements.
11. Clinical study: The clinical trial of this product was carried out at 5 sites. The enrolled cases were suspected cases of 2019-nCoV infection, and included 201 confirmed cases and 369 excluded cases, with 51 early cases in confirmed cases. Clinical sensitivity of this product: 91.54% (95% CI: 86.87%, 94.65%) and specificity: 97.02% (95% CI: 94.74%, 98.33%). The specimen types for clinical evaluation were serum and plasma. After a preliminary evaluation, it was confirmed that the clinical performance of the product meets the emergency needs of the COVID-19 epidemic. The clinical data for the product after marketing will be further collected to confirm the clinical performance of the product.

## PRECAUTIONS

1. This test kit is only for in-vitro diagnosis.
2. This test kit is intended to be used by testing personnel after professional training only. Read the instructions for use carefully before use and conduct the test strictly in accordance with the kit instructions for use.
3. Specimens should always be treated as if infectious and treatment of reagents and specimens shall be in accordance with infectious disease laboratory procedures. Pay attention to biosafety operation. All used specimens and reagents shall be handled as medical waste.