

NOTIFICATION FOR COVID-19 ANTIBODY TESTS

1. This test has not been reviewed by the FDA.
2. 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.
3. 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.
4. 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.
5. Not for the screening of donated blood.
6. This kit is only for in vitro diagnosis and is not intended for at home testing.

PRECAUTIONS AND WARNINGS

1. This test kit is intended to be used by suitably qualified healthcare practitioners only. Read the instructions carefully before use and conduct the test strictly in accordance with the kit instructions.
2. In order to reduce the risk of transmission, use appropriate PPE when collecting and handling specimens per the current CDC guidance for COVID-19 infection control precautions.
3. Samples and controls should always be treated as if infectious and biohazardous in accordance with safe laboratory procedures.
4. Follow the necessary precautions when handling specimens. Use personal protective equipment (PPE) consistent with current guidelines for the handling of potentially infectious samples.
5. Dispose of waste in compliance with local, state, and federal regulations.
6. Safety Data Sheets are available upon request.
7. Laboratories and health care facilities are required to report all positive results to the appropriate public health authorities.
8. Do not use if the product is expired or damaged.
9. Only use the diluent in the kit package. Other diluents may result in poor performance of the product.
10. Cassettes are intended to be for single use. Do not reuse.
11. After opening the inner packaging and/specimen dilution, follow the storage instructions as outlined in this IFU.
12. Proper specimen collection, storage, and transport are critical to the performance of this test. Inadequacy can result in a false result.
13. Retest if any results are invalid (control line is not visible).

REFERENCES

1. Hui DS, et al. (2020). The continuing 2019-nCoV epidemic threat of novel coronaviruses to global health-The latest 2019 novel coronavirus outbreak in Wuhan, China. International Journal of Infectious Diseases, 91, 264-266.
2. Templeton KE, et al. (2004). Rapid and sensitive method using multiplex real-time PCR for diagnosis of infections by influenza A and influenza B viruses, respiratory syncytial virus, and parainfluenza viruses 1, 2, 3 and 4. Journal of clinical microbiology 42(4): 1564-1569.
3. Smith AB, et al. (2003). Rapid detection of influenza A and B viruses in clinical specimens by Light Cycler real time RT-PCR. Journal of Clinical Virology 28(1):51-58.

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DATE OF APPROVAL AND MODIFICATION OF INSTRUCTION

April 1st, 2020

DATE OF MANUFACTURE AND EXPIRATION

See packaging.

Symbols

	Conformity of European		Tests per kit		Manufacturer
	For in vitro diagnostic use only		Catalog #		Expire Date
	Store between 4-30°C		Lot Number		Consult instructions for use



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

Instruction for Use (Version 1.0)

Rapid detection within **10 min.**
No testing equipments required.

2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based) Instruction for Use (Version 1.0)

PRODUCT NAME

2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based).

CATALOG NUMBER & SIZE

C6603C: 50 tests / kit.

INTENDED USE

This product is intended for the detection of 2019-Novel Coronavirus (2019-nCoV). It is an in vitro diagnostic test for the qualitative detection of IgG / IgM antibodies to the SARS-CoV-2 in human serum, plasma, and whole blood (venipuncture) samples collected by healthcare professionals at the point-of-care.

BACKGROUND

2019-Novel Coronavirus belongs to the new coronavirus of the genus β , which has an envelope, the particles are round or oval, often polymorphic, and the diameter is 60-140nm. Its genetic characteristics are significantly different from SARS-CoV and MERS-CoV. Current research shows that it has more than 85% homology with bat SARS-like coronavirus (bat-SL-CoVZC45). After infection with 2019-nCoV, the common symptoms are fever, fatigue, dry cough, dyspnea etc. Some patients present with more severe symptoms including, acute respiratory distress syndrome, septic shock, metabolic acidosis that is difficult to correct, and coagulation disorders. Some patients have mild symptoms and no fever. Most patients have a good prognosis, while a few are in critical condition or even die.

Both IgM and IgG are immunoglobulins which are produced by the immune system to provide protection against the 2019-nCoV. The level of IgM antibody begins to rise within 1 week and achieves the peak at 2-3 weeks after the initial infection. IgG appears later than IgM (usually in 14 days after infection) and achieves the peak at 5 weeks, lasting for 6 months or even several years.

PRINCIPLE OF DETECTION

This product is based on capture and solid-phase immunochromatography methods for determination. The specimen (whole blood / serum / plasma) flows from the blood separator through to the conjugate release pad (which occurs the conjugation reaction between IgG / IgM antibody in the specimen and the antigen colloidal gold of 2019-nCoV to form an immune complex of IgG / IgM antibody and colloidal gold-labeled antigen) due to capillary action. Then migrate 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 unreacted immune complex continues to flow upward, 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 immune complex moves upward, combining with C line (quality control line) to indicate the completion of this reaction.

Components

Components	Ingredients
Test Cassette	Aluminum foil pouch, desiccant, test strip and plastic card. Test strip composing blotting paper, nitrocellulose membrane, specimen separator, colloidal gold-labeled pad and PVC. IgM line (Test line) coating 1.0 mg/mL mouse-anti-human IgM antibody. IgG 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 40 OD 2019-nCoV antigen-colloidal gold conjugate complex.
Specimen Dilution	HEPES Buffer containing casein (0.1 M), 5 mL/bottle.
Dropper	50 droppers/pack.

Note: Do not interchange the components from different batches.

MATERIALS REQUIRED BUT NOT SUPPLIED

Clock or Timer

STORAGE & SHELF LIFE

This kit should be stored at 4°C~30°C for 18 months in a sealed condition. Once the inner packaging of strip is opened (4°C~30°C, humidity < 65%), it must be used in 1 hour. The opening specimen dilution buffer should be stored at 4°C, it is valid within 1 month. It is recommended to mark the opening date of the specimen dilution buffer.

SAMPLING & HANDLING

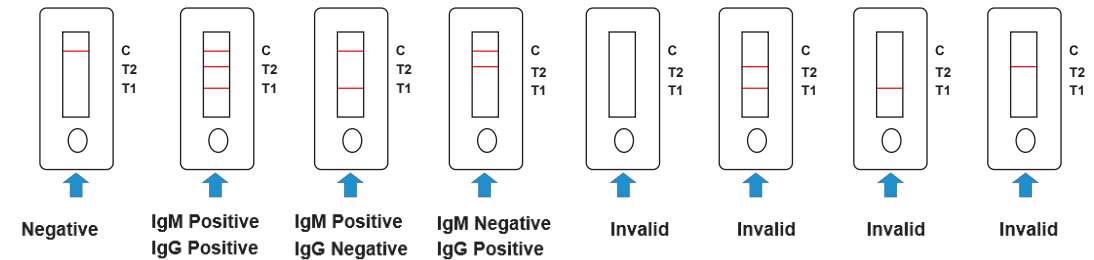
- Suitable specimen type: serum, plasma, and whole blood.
- Sediment and suspended matter in the specimen may affect the test result. It should be removed by centrifugation at 3000 g for 10 minutes.
- Severe hemolytic, lipemic and turbid specimens should not be used.
- Whole blood/plasma specimens can be treated with heparin sodium or EDTA anticoagulant. After specimen collection, the test should be completed within the same day. If not, please store it as the following protocol:
For whole blood specimens, store at 2°C~8°C for 3 days.
For Serum/plasma specimens, store at 2°C~8°C for 7 days, or at < -20°C for 12 months.
- 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.

Directions

Read the instructions carefully before use.

- The test strips must be at room temperature before use and the test must be operated at room temperature.
- Remove the test strips from the foil pouch and place on a flat, dry table.
- Using the dropper provided, add 1 drop (about 20 μ L) of the serum, plasma, or whole blood specimens to the oval sample slot. Then add 3 drops of dilution buffer (about 60 μ L) to the sample. Begin timing.
- Read the results after 10 minutes.

INTERPRETING TEST RESULTS



The test results are analyzed as follows:

- Negative result: Only one red quality control line (C line) appears in the detection area.
- IgM positive, IgG positive result: 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.
- IgM positive, IgG negative result: Two clear red lines appear in the detection area, one is the quality control line (C line) and another is T1 detection line.
- IgM negative, IgG positive result: Two clear red lines appear in the detection area, one is the quality control line (C line) and another is T2 detection line.
- 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

- 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 clinical management of patients should be considered in combination with their signs / symptoms, medical history, treatment reactions and epidemiology and other laboratory tests. It is recommended to repeat the test for suspicious samples at intervals.
- The accuracy of detection is affected by the sample collection process. Improper sample collection and storage process will affect the test results and should avoid high temperature and direct sunlight.
- This production provides a qualitative test for the novel coronavirus IgM antibody and IgG antibody in the sample, but not quantified detection.
- Due to the limitation of the testing methodologies, it cannot rule out the possibility of the novel coronavirus infection based on negative results. It is recommended to combine other test results and clinical symptom to make an accurate diagnosis.

PRODUCT PERFORMANCE INDICATOR

- Lowest limit of detection
Test with the in-house LOD references. S1 and S2 are positive for novel coronavirus IgG antibody, negative for IgM antibody; S3 is negative for novel coronavirus IgG/IgM antibodies; S4 and S5 are positive for novel coronavirus IgM antibody, negative for IgG antibody; and S6 is negative for novel coronavirus IgG/IgM antibodies.
- Negative coincidence rate
Test with the in-house negative references, and the results are all negative for novel coronavirus IgG/IgM antibodies, with a coincidence rate of 100%.
- Positive coincidence rate
Test with the in-house positive references. PC01-PC05 are all positive for novel coronavirus IgG/IgM antibodies, with a coincidence of 100%; PC06-PC10 are all negative for novel coronavirus IgG antibody, and all positive for IgM antibody, with a coincidence rate of 100%; PC11-PC15 are all negative for novel coronavirus IgM antibody, and all positive for IgG antibody, with a coincidence rate of 100%.
- Precision
Intra-batch difference: Test with the in-house repetitive references. CV1 and CV2 are positive for novel coronavirus IgG antibody and negative for IgM antibody; CV3 and CV4 are negative for novel coronavirus 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 are shown as follows: CV1 and CV2 are positive for novel coronavirus IgG antibody and negative for IgM antibody; CV3 and CV4 are negative for novel coronavirus IgG antibody and positive for IgM antibody, with uniform color development.
- Analytical specificity:
5.1 Cross-reactivity Specificity
This product will not cross react with positive samples of human coronavirus HKU1, NL63, 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 Class Specificity

There is no cross reaction between 2019-nCoV specific IgG antibody and specific IgM antibody under high concentration.

5.3 Interferents

When bilirubin \leq 0.2 g/L, triglyceride \leq 10 g/L, hemoglobin \leq 5 g/L, rheumatoid factor \leq 500 IU/mL, antinuclear antibody titer \leq 1:240, anti-mitochondrial antibody titer \leq 1:160, HAMA \leq 20 ng/mL, total IgG \leq 50 mg/L and total IgM \leq 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 novel coronavirus pneumonia is highly suspected but the antibody test result is negative, the sample should be re-tested after dilution.

7. After the specific IgM positive sample 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 different time with this kit, and the results comply with the requirements of product performance.

10. For virus infection samples from different regions, the lowest limit of detection and detection repeatability of the reagent comply with the requirements.

11. Clinical study

The clinical trial of this product was carried out in 5 sites based on the criteria for disease confirmation/exclusion specified in the Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia. The enrolled cases were suspected cases of novel coronavirus infection, including 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 sample types for clinical evaluation were serum, plasma and whole blood. After preliminary evaluation, it is basically confirmed that the clinical performance of the product can meet the emergency needs of the epidemic. The clinical data for the product after marketing will be further collected to confirm the clinical performance of the product.