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2019-nCoV IgG / IgM Detection Kit(Colloidal Gold-Based) Instructions for Use (Version2.0)

PRODUCT NAME

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

CATALOG NUMBER & SIZE

C6603C-02: 50 tests / kit.

INTENDED USE

The 2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based) is an in vitro diagnostic test for the qualitative detection of IgG / IgM antibodies to the SARS-CoV-2 in human serum, plasma, whole blood (venipuncture or finger stick) samples collected in CLIA certified laboratories and by healthcare professionals for point-of-care testing.

The 2019-Novel coronavirus is a β coronavirus. The virus has an envelope, virions are round or oval, often polymorphic, with a diameter of 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 the bat SARS-like coronavirus (bat-SL-CoVZC45). After infection with 2019-nCoV, the common symptoms are fever, fatigue, dry cough, dyspnea etc. Some patients will develop severe symptoms including acute respiratory distress syndrome (ARDS), septic shock, metabolic acidosis, and coagulation disorders. Some patients will exhibit mild symptoms and/or symptoms with fever. Most patients have a good prognosis and full recovery while others can advance to a critical condition requiring intensive care.

Both IgM and IgG are immunoglobulins which are produced by the immune system in response to infection like that of 2019-nCoV. IgM antibody levels typically rise within 1 week of infection and achieve a peak at 2-3 weeks after the initial infection. IgG appears later than IgM (usually in 14 days after infection) and peak levels occur at about 5 weeks. IgM will become undetectable after about 4 to 5 weeks, while the IgG will be detectable for 6 months or even several years. The protective immunity period following SARS-CoV-2 infection is not currently known.

PRINCIPLE OF DETECTION

This product is based on immunochromatography with colloid gold recombinant antigen conjugates. The specimen (whole blood / serum / plasma with dilution buffer) flows through the blood separator through the conjugate release pad, and across the results window via capillary action. Human antibodies will be captured by anti-IgM and anti-IgG antibodies. Three reaction lines are present in the window: 1) The IgM line, 2) The IgG line, and 3) The C line (quality control) which indicates successful completion of the capillary flow on the test strip. Positive (red) results are generated by the capture of human anti-viral antibody / gold labeled viral antigen complex by the immobilized anti-IgM and IgG test lines.

MATERIALS PROVIDED

Component	Ingredients
Test Cassette	50 aluminum foil pouches with desiccant and test strip in a plastic cassette
Dilution Buffer	5 mL/bottle of sterile diluent
Dropper	50 droppers/pack
Instructions for	These printed instructions

Note: Do not interchange the components from different batches.

MATERIALS REQUIRED BUT NOT SUPPLIED

Lancet
Alcohol wipe
Timer

STORAGE & SHELF LIFE

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

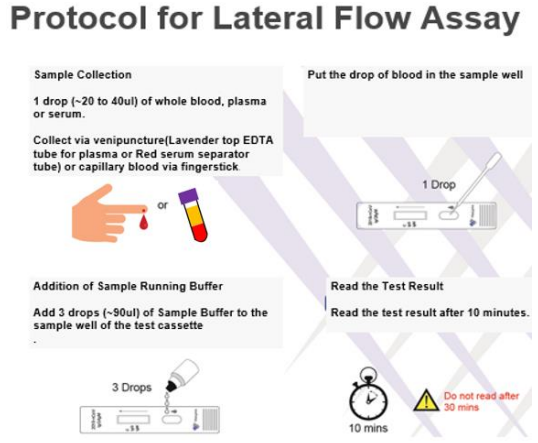
SAMPLING & HANDLING

1. Suitable specimen types: serum, plasma, and whole blood.
2. Sediment and suspended matter in the specimen may affect the test result. Specimens with sediment and/or particulate suspended matter should be removed by centrifugation at 3000 xg for 10 minutes.
3. Severe hematolytic, lipemic and turbid specimens should not be used.
4. 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 used immediately, please store following protocol:
   a. For whole blood specimens, store at 2°C~8°C for up to 3 days.
   b. For serum or plasma, store at 2°C~8°C for up to 7 days, or at < -20°C for up to 12 months.
5. Specimens must be fully brought to room temperature (18°C-28°C) before testing. Frozen samples should be thawed and mixed thoroughly before use.
6. Venous samples:
   a. For plasma collect in lavender top (EDTA) tubes and centrifuge for 10 minutes at 3000xg.
   b. For serum samples use red top or tiger-top tubes, allow clot formation and then centrifuge for 10 minutes at 3000xg.
7. Capillary (finger-stick) samples should follow the instructions as shown below:

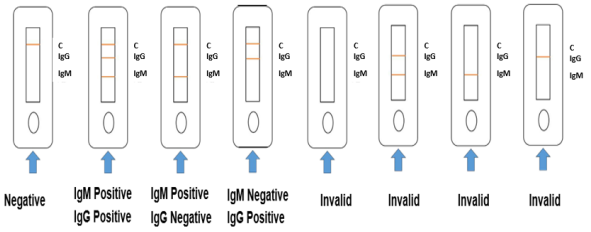
DIRECTIONS

Read the instructions carefully before use.

1. The test strips must be at room temperature before use and the test must be operated at room temperature
2. Remove the test strips 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, plasma, or whole blood specimens to the oval sample slot. Then add 2-3 drops of dilution buffer (about 60 µL) to the sample. Begin timing.
4. Read the results after 10 minutes.



INTERPRETING TEST RESULTS



The test results are analyzed as follows:

1. Negative result: Only one red quality control line (C line) appears in the detection area.
2. IgM positive, IgG positive result: Three red lines appear in the detection area, one is quality control line (C line), one is IgM detection line, and the other is IgG detection line.
3. IgM positive, IgG negative result: Two clear red line appear in the detection area, one is quality control line (C line) and another is IgM detection line.
4. IgM negative, IgG positive result: Two clear red line appear in the detection area, one is quality control line (C line) and another is IgG detection line.

5,6,7,8. Invalid results: No red quality control line (C line) appears. Test error and test should be repeated.

CLINICAL INTERPRETATION

1. IgM and IgG Negative
   a. Patient may be in the window period of infection – consider antigen (molecular) test if 2019-nCoV is suspected and/or follow up IgM/IgG test at a later time.
   b. Patient may not have exposure to 2019-nCoV.
2. IgM Positive, IgG Negative – Patient may be in the early stage of infection.
3. IgM Positive, IgG Positive – Patient may be in the active phase of infection.
4. IgM Negative, IgG Positive
   a. Patient may be in the late or recurrent stage of infection.
   b. Patient may have had a past infection and has recovered.

LIMITATIONS OF THE TEST METHOD

1. A negative test result does not rule out the possibility of infection with 2019-nCoV. It is recommended to combine other test results and clinical symptoms to make an accurate diagnosis.
2. The clinical management of patients should be considered in combination with their signs / symptoms, medical history, treatment reactions, epidemiology and other laboratory tests. It is recommended to repeat the test for suspicious samples at intervals.
3. The sample collection process can affect test results. Improper storage will affect the test results. Elevated temperature, freezing and direct sunlight exposure should be avoided.
4. This is a qualitative test for the novel coronavirus IgM antibody and IgG antibody in the sample. The intensity of the test lines does not correlate with the antibody titer of the specimen.
5. The test should not be used with patients that have received vaccination to 2019-nCoV or have been treated with antibodies (convalescent serum / plasma treatment).
6. The performance of the test has been validated with the recommended volumes. Excessive loading of the specimen could lead to false positive results.
7. Unusually high titer of IgG or IgM (present in certain cancers such as Multiple Myeloma) or rheumatoid factor present in some specimens may affect results.

PRODUCT PERFORMANCE CHARACTERISTICS

1. In-House Control Sample Quality Controls
   a. Two samples positive for IgG and negative for IgM
   b. Two samples positive for IgM and negative for IgG
   c. One sample positive for both IgG and IgM
   d. One sample negative for both IgG and IgM
2. Negative coincidence rate: In-house negative reference samples are all negative for 2019-nCoV IgG/IgM antibodies with a coincidence rate of 100%.
3. Positive coincidence rate:
   a. Five In-house positive samples for 2019-nCoV IgG and IgM are all positive with a coincidence rate of 100%.

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b. Five In-house positive samples for 2019-nCoV IgG and negative for IgM are all positive for IgG and negative for IgM with a coincidence rate of 100%.
c. Five In-house positive samples for 2019-nCoV IgM and negative for IgG are all positive for IgM and negative for IgG with a coincidence rate of 100%.

4. Inter-batch reproducibility: Each lot of test kits are subjected to validation with in-house reference samples and demonstrate uniform color development and positive and negative coincidence rates of 100%.

5. Analytical specificity

a. This product will not cross react with positive samples of

Hu-CoV HKU1	Hu-CoV-OC43	Hu-CoV-229E	Hu-CoV-NL63
Influenza A H3N2	Influenza A H5N1	Influenza A H7N9	Influenza B Victoria
Influenza B Yamagata	Epstein Barr Virus	Parainfluenza virus	Rhinovirus species A, B &C
Enterovirus 68 (EV-D68) (Enterovirus species D)	Respiratory Syncytial Virus	Chlamydia pneumoniae	Human cytomegalovirus
Mycoplasma pneumoniae	Measles Virus	Adenovirus types 1,2,3,4,5,7 and 55	Coxsackievirus (Enterovirus species B)
Rotavirus	Norovirus	Mumps virus	Influenza A H1N1

b. Class Specificity: There is no cross reaction between 2019-nCoV specific IgG antibodies and specific IgM antibodies at elevated concentration.

c. Interferents: The following have no effect on test results (for drugs when present at therapeutic dosages)

bilirubin ≤ 0.2 g/L	Triglyceride≤ 10g/L	Total IgG ≤ 50 mg/L	hemoglobin ≤ 5g/L
Ceftriaxone	Zanamivir	Interferon α (IFN-α)	Ribavirin
IgM ≤ 5 mg/L	Phenylephrine	Oxymetazoline	Sodium chloride
antinuclear antibody titer ≤ 1:240	anti-mitochondrial antibody titer≤ 1:160	Human anti-mouse antibody≤ 20 ng/mL	rheumatoid factor ≤ 500 IU/mL
Levofloxacin	Lopinavir	Ritonavir	Arbidol
Tobramycin	Histamine hydrochloride	Flunisolide	Triamcinolone acetonide
Meropenem	Mometasone	Fluticasone	Meropenem
Oseltamivir	Oseltamivir	Peramivir	Beclomethasone
Dexamethasone	Azithromycin	Budesonide	Tobramycin

6. Hook effect: The hook effect will occur at concentration levels that exceed the lowest limit of detection of IgG antibody by more than 1,280-fold and the lowest limit of detection of IgM antibody by more than 640-fold. If 2019-nCoV pneumonia is highly suspected but he antibody test result is negative, the sample should be diluted and retested.
7. Elimination of IgM from a positive sample will result in a negative IgM antibody test result and the IgG antibody test is not affected.
8. Sodium Heparin and EDTA anticoagulants have no effect on the antibody detection with this kit.
9. Inter-operator and inter-lot variability have been tested with this kit and the results comply with the requirements of product performance.
10. For samples from different regions, the LOD (limit of detection) and detection repeatability of the test are in compliance with requirements.
11. Clinical Study: The clinical trial for this product was carried out at 5 sites based on the criteria for disease confirmation or exclusion as specified in the Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia.
Enrollment was based on suspicion of 2019-CoV infection including:
a. 201 Confirmed cases (including 51 early cases)
b. 369 Excluded cases
Clinical Sensitivity of this product: 91.54% (95% Confidence Interval, CI 86.87% to 94.65%)
Clinical Specificity of this product: 97.02% (95% Confidence Interval CI 94.74% to 98.33%)
The sample types for clinical evaluation were using serum and plasma. The clinical study confirmed that the clinical performance of the product addresses the emergency needs associated with the epidemic. Additional clinical data for the product will continue after marketing.

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. Not for the screening of donated blood.
5. This kit is only for in vitro diagnosis.

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. Positive and negative controls should be run on a regular basis to verify operator and test performance.
5. Follow the necessary precautions when handling specimens. Use personal protective equipment (PPE) consistent with current guidelines for the handling of potentially infectious samples.
6. Do not use tap water, purified water or distilled water as negative controls.
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 buffer, follow the storage instructions as outlined in these Instructions for Use.
12. Proper specimen collection, storage, and transport are critical to the performance of this test. Improper handling can result in a false result.
13. Retest if any results are invalid (control line is not visible).
14. Material Safety Data Sheet (MSDS) are available at www.vazyme.com

REFERENCES

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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.

DISTRIBUTED BY

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DATE OF APPROVAL AND MODIFICATION OF INSTRUCTION
April 9, 2020

DATE OF MANUFACTURE AND EXPIRATION
See packaging.

SYMBOLS

CE	Conformity of European
IVD	For in vitro diagnostic use only
4 °C – 30°C	Store between 4-30°C

Σ	Tests per kit		Manufacturer
REF	Catalog #		Expire Date
LOT	Lot Number		Consult instructions for use