2019-nCoV IgM/IgG Antibody Colloidal Gold Assay Kit

Product Name

2019-nCoV IgM/IgG Antibody Colloidal Gold Assay Kit

Cat. No: EH4933

Pack Size: 1 Test per kit

Expected Usage

This kit is used to qualitatively detect 2019-nCov IgM/IgG antibody in human serum & plasma sample in vitro. It only can be used as a supplementary testing of 2019-nCov in suspected cases. It can't be used to make a definite diagnosis of 2019-nCov disease, still needs to work together with nucleic acid testing.

Product is for medical organization use only.

Positive result still needs further testing, negative result can't exclude the possibility of infection.

This kit can't be used as a routine clinical diagnostic reagent. The testing result is only for clinical diagnosis reference.

For safety reasons, the laboratory that performs the testing must have a relevant qualification.

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Principle of Detection

The product was detected by solid phase immunochromatography using capture method. The test sample (blood/plasma) diffuses upward by capillary force, when passes through the marker pad, the 2019-nCov IgM/IgG antibody will react with the 2019-nCoV antigen colloidal gold complex. The new formed colloidal gold labeled antigen-IgM complex and colloidal gold labeled antigen IgG complex will diffuse onto the nitrocellulose membrane together with sample, then react with the mouse anti-human IgM antibody which is coated on the T1 line (detection line), then T1 line turns red. The non-react colloidal gold immune complex continues to move up and is blocked by T2 line (detection line) which coated with the mouse anti-human IgG antibody, then T2 line turns red. Finally, the remaining un-intercepted colloidal gold conjugates continued to move up and combine with the C line (quality control line), indicating that the whole process is finished.

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Product Components

Components	Ingredient
Detection Card	Foil bag, Desiccant, Test Strip and plastic card. 1.0mg/ml mouse anti-human IgM antibody coated on T1 line 1.0mg/ml mouse anti-human IgG antibody coated on T2 line 1.0mg/ml internal reference protein C coated on C-line (qc line) The marker pad contain 40 OD recombinant 2019-nCov antigen-Colloidal Gold complex
Sample dilution	HEPES buffer containing Casein(0.1M), 200μl/tube
Dropper	1 piece per kit

P.S: You can’t mix components from different batches.

Storage

6 months at 4-30℃.

After the reagent card is opened (temperature 4-30℃, humidity less than 65%), the period of validity is 1h.The diluent is valid for 28 days after being opened.

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Sample collection

1. The sample is serum/plasma.
2. You need to remove the sediment and suspension of the sample by 3000gx10 min centrifugation.
3. Sample with severe hemolysis, lipohemia and turbidity can’ t be tested.
4. Collect plasma using EDTA-Na2 or heparin as an anticoagulant. After sample collection, the test should be completed on the same day. If the test cannot be completed on the same day, please store it as follows: the serum/plasma samples can be stored for 7 days at 2-8℃, and stored for 24 days at -20℃, without affecting the result.
5. The samples must be restored to room temperature before testing. The freeze-preserved samples should be completely melted and used after mixing. Avoid repeated freeze-thaw cycles.

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Protocol

Please read the instruction carefully before operation.

1. Testing is performed under room temperature, please restore the test card to room temperature before use.
2. Take the test card out of foil bag, place it on a flat and dry platform.
3. Adding one drop (20ul) sample by the dropper to the well of card, then add another 3 drops(60ul) sample dilution to the well. Start timing.
4. Observe the color at 10 minutes to get the result. The result is invalid after 15 minutes.

Results

The test results are determined as follows.

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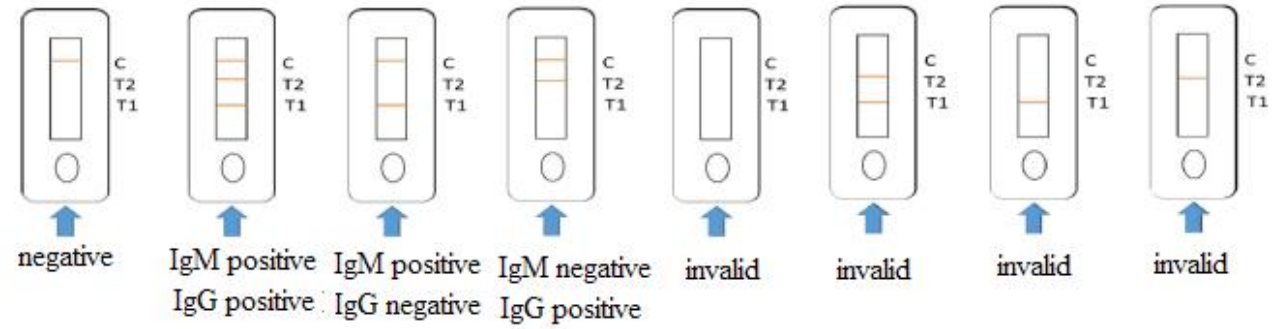

(Just for reference, please subject to your observation)

1. Negative: You can see a red quality line on C line.
2. IgM positive, IgG positive: You can see three red lines, one C line, one T2 line and one T1 line.
3. IgM positive, IgG negative: You can see two red lines, one C line and one T1 line.
4. IgM negative, IgG positive: You can see two red lines, one C line, one T2 line
5. Invalid: no any lines are observed. Then you need to re-test the sample again.

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Explanation

1. The testing result can only be reference for clinical diagnosis, shouldn’ t be the sole basis of clinical diagnosis.
2. The accuracy of testing will be affected by sample collection and sample storage.
3. The kit can only qualitatively detect 2019-nCov IgM/IgG antibody of sample. You can’ t use it to do any quantitative detection.
4. Due to the limitation of detection reagent methodology, the negative result cannot exclude the possibility of novel coronavirus infection, so it is recommended to combine with nucleic acid testing or virus culture and clinical comprehensive diagnosis.

Product Performance

1. Detection limit: Detect commercialized detection limit control, S1, S2 have positive result of 2019-nCov IgG antibody, negative result of 2019-nCov IgM

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antibody; S3 have negative result of 2019-nCov IgM/IgG antibody; S4, S5 have positive result of 2019-nCov IgM antibody, negative result of 2019-nCov IgG antibody; S6 have negative result of 2019-nCov IgM/IgG antibody.

2. Negative control: Detect commercialized negative control, 100% result are negative for IgM/IgG antibody.

3. Positive control: Detect commercialized positive control, PC01-PC05 100% have positive result of 019-nCov IgM/IgG antibody; PC06-PC10 100% have negative result of 2019-nCov IgG antibody, positive result of 2019-nCov IgM antibody; PC11-PC15 100% have negative result of 2019-nCov IgM antibody, positive result of 2019-nCov IgG antibody.

4. Precision:

   Intra-Assay: Detect commercialized repeated control, CV1, CV2 have positive result of 2019-nCov IgG antibody, negative result of 2019-nCov IgM antibody; CV3, CV4 positive result of 2019-nCov IgM antibody, negative result of 2019-nCov IgG antibody

   Inter-Assay: Detect commercialized repeated control, all the samples from 3 different batch CV1, CV2 have positive result of 2019-nCov IgG antibody,

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negative result of 2019-nCov IgM antibody; CV3, CV4 positive result of 2019-nCov IgM antibody, negative result of 2019-nCov IgG antibody.

5. Specification:

5.1 Cross reactivity: The kits have no cross reactivity with HKU1, OC43,229E, H1N1, H3N2, H5N1MH7N9,Yamagata, Victoria, RSV, Parainfluenza virus, rhinovirus A/B/C, Adenovirus 1/2/3/4/5/7/22, enterovirus B, enterovirus A, EV-D68, EB virus, measles virus, HCMV, rotavirus, Norovirus, Mumps virus, varicella-zoster, Mycoplasma pneumonia and Chlamydia pneumonia IgG antibody and IgM antibody.

5.2 Interference: ilirubin<0.2 g/L, triglyceride<10 glL, hemoglobin<5 g/L, rheumatoid factor<500 IU/ml, HAMA<20 ng/ml, Total IgG<50 mg/L, Total IgM<5 mg/L, Below medicine like Oseltamivir, levofloxacin, ceftriaxone, Zanamivir, Interferon-α, ribavirin, peramivir, lopinavir, Ritonavir, Arbidol, azithromycin, Meropenem, Tobramycin, Histamine dihydrochloride , phenylephrine, Nacl, Beclomethasone...have no effect on test results.

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6. Hook Effect: When the IgG antibody concentration excess 1280 times than detection limit, IgM antibody concentration excess 640 times than detection limit, hook effect will happen. Pls dilute the sample before testing.
7. When IgM antibody positive sample is invalid, IgM antibody result will change to negative, but the IgG antibody detection will not be effected.
8. Heparin and EDTA anticoagulants have no effect on the detection of this kit。
9. Detect different people at different time, the precision of result is acceptable.
10. Detect different infected samples from different territory, the repeatable and detection limit of kits are acceptable.
11. Clinical research: Detect infected suspected cases from 5 organization(201 confirmed cases, 369 excluded cases), it conclude the kit sensitivity on clinical is 91.54%(95%CI:86.87%, 94.65%) and the specificity is 97.02%(95%CI: 94.74%, 98.33%). Sample type is serum/plasma. After preliminary evaluation, it is basically confirmed that the clinical performance of the product can meet the

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emergency needs of epidemic situation.

Remark

1. The kit is only for in vitro diagnosis.
2. Please read the instruction carefully before the operation; please operate the test strictly according to the instruction. The operator must be qualified and trained.
3. Samples are infective, please pay important attention on biological safety operation. Pls throw away the waste as medical waste.

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