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COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)
For in vitro diagnostic use only

【PRODUCT NAME】
COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold)
【PACKAGE AND SPECIFICATION】
Cassette : 20Test Kit/Box (1Test/Bag ×20 Bags) 、 40 Test /Box (1Test / Bag ×40 Bags)

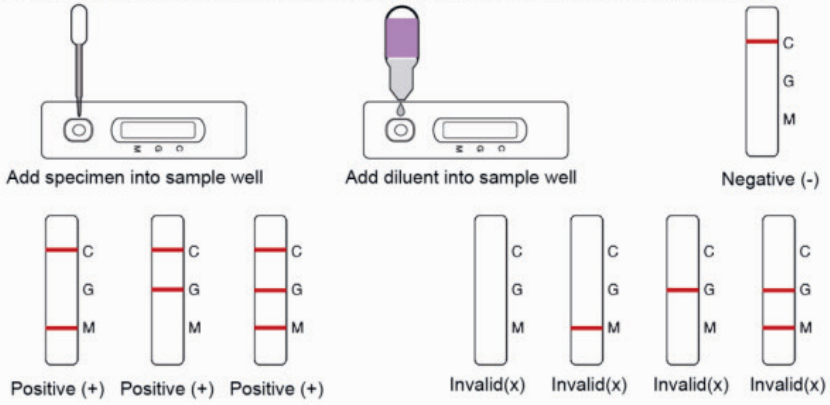
【INTENDED USE】
This product is used for in vitro qualitative detection of 2019-ncov (COVID-19) IgG/IgM antibodies in human whole blood, plasma and serum samples.This product is suitable for the auxiliary diagnosis of 2019-ncov (COVID-19) infection.2019-ncov (COVID-19) , mainly transmitted by inhalation and direct contact, is one of the main pathogens causing upper respiratory tract infection and lung diseases.It can cause the changes of the extrapulmonary system, which has aroused great concern.Timely and effective laboratory diagnosis of 2019-ncov (COVID-19) infection becomes particularly important

【PRINCIPLE】
This reagent uses immunochromatographic colloidal gold technique to detect 2019-ncov (COVID-19) IgG/IgM antibodies in samples.The detection card contains: 1) Recombinant COVID Antigen labeled colloidal gold .2) Cellulose Membrane fixed with three lines (G line and M line) and one quality control line (C line) .The M line was coated with mouse anti-human IgM antibody for detection of 2019-ncov (COVID-19) IGM antibody .The G line was coated with mouse anti-human IgG antibody for detection of 2019-ncov (COVID-19) IgM antibody. The C line was coated with sheep anti-chicken antibody.When specimen is added to sample well, capillary effect causes the fluid to flow to the NC membrane,COVID IgM (if present) will bind with mouse anti-human IgM and the M line will be visible., COVID IgG (if present) will bind with mouse anti-human IgG and the G line will be visible.No matter whether the specimen is positive or negative, the C line should be visible, otherwise the test is invalid.

【COMPONET】

COMPONENT	20Test Kit/Box	40Test Kit/Box	Main components
Test Kit	20Test Kit/Box (1Test/Bag ×20 Bags)	40Test Kit/Box (1Test/Bag ×40Bags)	The detection lines were coated with mouse anti-human IgM antibody and mouse anti-human IgG antibody, the quality control lines were coated with sheep anti-chicken antibody, and the colloidal gold pad contained recombinant COVID Antigen labeled colloidal gold .
Dryer	20Bags	40Bags	Silica Gel
Specimen Diluent	1Bottle(5mL)	1Bottle(8mL)	Solution of trimethylaminomethane hydrochloride(0.02M Tris-HCl)

2.Plasma and serum :Collect the specimen with a pipettor, Add 10μl plasma and serum into sample well,Add 1~2 drops diluent into sample well .Whole blood: Collect the specimen with a pipettor, Add 20μl whole blood into sample well,Add 1-2drop diluent into sample well .
3.Start timing .The result should be read at 15-20minutes.The result is invalid after 20 minutes.



【STORAGE AND STABILITY】
The kit can be stored at cool ,dark place. (4-30°C). Valid for 24 months.After opening the inner package, the detection reagent will lose its efficacy due to moisture absorption and should be used within 30 minutes.

【SPECIMEN REQUIRMENTS】
1.Can be used to detect whole blood, plasma and serum specimen.
2. Specimen were collected as general manner.
3. The Specimen which need to be test within 5 days can be stored at 4℃, and if the plasma and serum specimen which need to be test more than 5days should be frozen at -20℃.The test kit should be carried out freeze-thaw in -20℃ no more than 6 times .Do not freeze and thaw samples repeatedly.
4. Whole blood, plasma and serum shall be collected and stored in sterile conditions .Avoid sample hemolysis , Samples contaminated with bacteria cannot be used for testing.

【TEST PROCEDURE】
1.Remove test kit, specimen to room temperature .Tear off the foil pouch, take out the test strip/cassette and place the test kit on a clean and level surface.

【TEST METHOD】
1.In the early stage of infection, no IgG/IgM is produced or the titer is very low, which will lead to negative results. The patient should be prompted to review within 7-14 days.
2.In patients with impaired immune function or receiving immunosuppressive therapy, serological antibody detection is of limited reference value.
3.IgG/IgM antibody positivity occurs not only in primary infection but also in secondary infection.

【PRODUCT PERFORMANCE 】
The performance of the product was tested with the enterprise new coronavirus-igg /IgM antibody for Internal control blood test, meeting the following requirements:
1.Negative reference product compliance rate: 10 negative serums in the internal control blood liquidation were tested, and the compliance rate was 10/10.
2.Positive reference product Compliance rate: 10 positive serums in the internal control blood liquidation were tested, and the compliance rate was 10/10.
3.Minimum detection amount: the minimum detection amount of serum in the internal control blood liquidation test, L1 should be negative, L2 and L3 should be positive.
4.Precision: 10 detection reagents were tested in parallel with the precision serum of internal controlled blood liquidation, and the detection results were consistent and the chroma was uniform.
5.Stability: after being placed at 37℃ for 14 days, the test should meet the above requirements.
6.Cross reaction: with mycoplasma pneumoniae (MP) - IgM, chlamydia pneumonia (CP) - IgM, syncytial virus (RSV), influenza virus that the IgM (FluV) and mycobacterium tuberculosis (TB), hepatitis c virus (HCV), syphilis antibodies (TP), hepatitis b surface antigen (HBsAg), the AIDS virus (HIV), rheumatoid factor (RF) and antinuclear antibody (ANA) positive samples basic no cross reaction.
7.Interference: there was no interference when compared with the samples containing 15mg/mL triglyceride, 6mg/mL hemoglobin and 0.2mg/mL bilirubin, respectively.

【 WARNINGS AND PRECAUTIONS】
1.Please operate in strict accordance with this instruction and strictly control the reaction time.
2.This kit is a disposable product, which is only used for external diagnosis.The test results should be judged synthetically with other test indexes and medical characteristics.
3.The test of samples must be carried out in a specific environment. The blood samples in contact during the test should follow the laboratory test procedures for infectious diseases.
4.The small cup containing the serum must be clean and not reusable to avoid contamination.Test samples should be avoided from repeated freeze-thaw, and samples contaminated with bacteria should not be used for testing, so as not to affect the test results.Samples stored at 4℃ must be balanced to room temperature before use.
5.Guard against moisture in the test strip. Use the test kit within 30 minutes after opening the inner package.

【REFERRENCE 】
1. 《China biological product code》
2. 《Guidelines for preparation of in vitro diagnostic reagent specifications》
3.Daxboeck F, Krause R, Wenisch C. Laboratory diagnosis of Mycoplasma pneumoniae infection[J]. Clin Blicrobiol Infect, 2003, 9(6): 263-273.

【MANUFACTURE 】
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