sample should avoid repeated freezing and thawing, and the samples contaminated with bacteria

4. Should not be used for testing, so as not to affecting the test results. The samples should be stored at 4 °C and shall be balanced to room temperature before use.

5. Beware of moisture on the test strips. It should be used as soon as possible within 30 minutes after opening the inner packing. The test card should not be used after moisture.

13.REFERENCES

1. Chinese Biological Products Regulation

2. Guidelines for Preparation of Instructions for In Vitro Diagnostic Reagents

3. Bao Ying, Lei Chunlian. Advances in Corona Virus Disease (COVID-19) Research [J]. Shaanxi Medical Journal, 2002, 31 (10): 898901.

4. Daxboeck F, Krause R, Wenisch C. Laboratory diagnosis of Mycoplasma pneumoniae infection[J]. Clin BlicrobiolInfect,2003,9(6): 263-273.

14.SYMBOLS AND EXPLANATIONS

IVD				
In Vitro Diagnostic use	*See Instruction for Use*	*Don't use if the package damaged*	*Temperature Limit*	*Do not reuse*
				LOT
Keep away from Sunlight	*Manufacturer*	*Manufacturing Date*	*Expiry Date*	*Lot Number*
CE	EC REP	Σ		REF
European Conformity	*Authorized Representative*	*Tests per kit*	*Keep dry*	*Catalog*

TOPMEDLAB®

Manufacturer: Suzhou Topmedlab Medical Science and Technology Co.,Ltd.
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EC REP

MedPath GmbH
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rofi.

CE

Instruction Manual for Corona Virus Disease 2019

COVID-19 IgG/IgM RAPID TEST KIT

Dyed Microspheres

1. PRODUCT NAME

Common name: Corona Virus Disease 2019 (COVID-19) IgG/IgM Antibody Test Kits (Dyed microspheres)

2. PACKING SPECIFICATION

Card type: 25 pcs/box

3. INTENDED USAGE

This product is used for in vitro qualitative detection of COVID-19 IgG/IgM antibodies in human whole blood, plasma and serum samples.

This product is suitable for auxiliary diagnosis of COVID-19 infection.
The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Timely and effective laboratory diagnosis of COVID-19 infection has become particularly important.

4. TESTING PRINCIPLE

This product is used for detection of COVID-19 IgG/IgM antibodies in samples by immunochromatographic dyed microspheres technique.
The test reagent contains: Dyed microspheres-labeled recombinant COVID-19 antigens and dyed microspheres markers of quality control antibodies.

Cellulose membrane has two fixed testing lines (line G and line M) and one quality control line (line C). The test line G coated with mouse-anti-human-IgG antibodies is used to test COVID-19 IgG

antibodies. The test line M coated with mouse-anti-human-IgM antibodies is used to test COVID-19 IgM antibodies. Quality control line (line C) is wrapped with rabbit IgG.

The dyed microspheres pad contains dyed microspheres -labeled goat-anti-rabbit IgG antibodies.
When testing, if the sample contains COVID-19 IgG antibodies, the antibodies in the sample will first react with recombinant COVID-19 antigens on the dyed microspheres pad to form an antibody-cdyed microspheres labeled antigen complex. When the NC membrane carries out the chromatography to the line G, it will form an antibody-antibody-dyed microsphere -labeled antigen complex with mouse-anti-human IgG antibodies and display color bands in the line G.

If the sample contains COVID-19 IgM antibodies, the antibodies in the sample will first react with recombinant COVID-19 antigens on the dyed microspheres pad to form an antibody-dyed microsphere labeled antigen complex. When the NC membrane carries out the chromatography to the line M, it will form an antibody-antibody-dyed microsphere-labeled antigen complex with mouse-anti-human IgM antibodies and display color bands in the line M. If there is no COVID-19 IgG/IgM antibody in the sample, the complex cannot be formed and no color bands appear in the line G and line M.

The dyed microspheres-labeled goat-anti-rabbit IgG antibodies bonded to the quality control line C coated with the rabbit IgG show color bands. Color bands shall appear in the line C when testing samples, otherwise the test is invalid.

5. MAIN INGREDIENTS

Test kit composition :25 pcs/box
Main ingredients: 25 test cards (1pcs/bag×25 bags)

The testing line is coated with mouse-anti-human IgM antibodies and mouse-anti-human IgG antibodies, and the quality control line is coated with rabbit IgG, the dyed microspheres pad contains dyed microspheres-labeled recombinant COVID-19 antigens.

Diluent: 1 bottle (5mL/bottle)

6. STORAGE CONDITIONS AND VALID TERM

It is stored in a cool and dark place at 4-30°C, with a valid term of 12 months. The testing reagent will fail after opening the inner packing due to moisture absorption. Therefore, it needs to be used up within 30 minutes.

7. SAMPLE REQUIREMENTS

7.1 It can be used to test the whole blood, plasma and serum samples.

7.2 The samples can be collected by vein as usual.

7.3 The samples measured within 5 days can be stored at 4°C, and the plasma and serum samples tested over 5 days need to be refrigerated at - 20°C. The test shall be carried out within 6 times of freezing and thawing at - 20°C. Do not freeze and thaw the sample repeatedly.

7.4 The whole blood, plasma and serum should be collected and preserved under sterile conditions, and the sample hemolysis should be avoided. Samples with bacterial contamination cannot be used for testing.

8.METHODS OF TEST

8.1 Balance the test reagent and sample to room temperature, tear the aluminum foil bag, take out a test strip/paper, and lay it flatly.

8.2 Take the sample with a pipette, add about 25μl of serum or plasma or whole blood at the sample adding place of the test paper, and add 1 drops of sample diluent. The timer is used for timekeeping. The experimental results shall be observed within 8-20 minutes, and the observations are invalid beyond 20 minutes.

9.EXPLANATION OF THE TEST RESULT

9.1 Negative: There is only a quality control line (line C). Both testing lines (line G and line M) do not appear.

9.2 Positive:
a: There are two lines: quality control line (line C) and testing line (line G).
b: There are two lines: quality control line (line C) and testing line (line M).
c: There are three lines: quality control line (Cline C) and testing lines (line G and line M).

9.3 Invalidation: The test result is invalid if there is no quality control line (line C), and it should be retested.

10.METHODS OF TEST

10.1 In the early stage of infection, if the IgG/IgM is not produced or the titer is very low, it may have a negative result. The patient is suggested to be rechecked within 7-14 days. When retesting,

10.2 the samples collected last time shall be tested in parallel to confirm whether there is a serological positive conversion or significant increase in titer.

10.3 If the patients with impaired immune function or receiving immunosuppressive therapy, the reference value of serological antibody detection will be limited.

10.4 IgG/IgM antibody positive occurs in the primary infection, and IgM may also turn up in the secondary infection.

11.PRODUCT PERFORMANCE INDEX

1. Negative reference coincidence rate: Enterprise negative reference coincidence rate 10/10.

2. Positive reference coincidence rate: Enterprise positive reference coincidence rate 10/10.

3. Minimum detection amount: Enterprise minimum detection limit reference L1 should be negative, L2、L3 should be positive.

4. Precision :2 enterprise repetitive reference products for testing, each repeated test 10 times, should be positive.

5. Stability : 37 °C after 14 days of placement for should meet the above requirements.

6. Cross reaction: It is basically no cross reaction in the positive samples with mycoplasma pneumoniae (MP) - IgM, chlamydia pneumoniae (CP) - IgM, respiratory syncytial virus (RSV), IgM, influenza virus (FluV), mycobacterium tuberculosis (TB) antibody, hepatitis C virus (HCV), treponema pallidum (TP), hepatitis B surface antigen (HBsAg), human immunodeficiency virus (HIV), rheumatoid factor (RF) and antinuclear antibody (ANA).

7. Interference: There is no interference in the contrast detection with the samples containing 15mg/ml of triglyceride, 6mg/ml of hemoglobin and 0.2mg/ml of bilirubin, respectively.

12.PRECAUTIONS

1. Please operate in strict accordance with the instructions and strictly control the reaction time.

2. The kit is disposable, only for in vitro diagnosis. The test results should be in combination with other test indicators and medical characteristics for comprehensive judgement.

3. The test of samples must be carried out in a given environment. The blood samples in contact during the test should be handled according to the laboratory procedures for infectious diseases. The small cup containing serum must be clean and not reusable to avoid contamination. The test