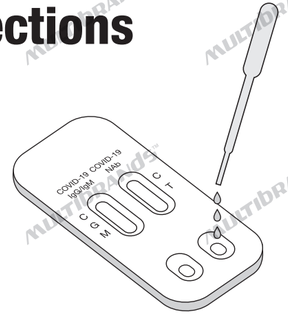
Panodyne® **COVID19**

SARS-CoV-2 Combined
(IgM/IgG/Neutralising antibody)
RAPID TEST (Colloidal Gold)

For professional use only

Directions



Before you start

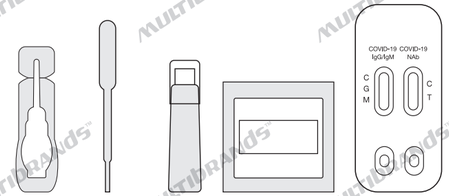
Read Instructions carefully.

Wash Hands thoroughly using soap and warm water.

Prepare and clean a dry flat surface to perform the test.

Test Kit Contents

Open the pack and check the contents



Test Solution | Pipette Dropper | Sterile Lancet | Alcohol Wipe | Test Cassette

Method

Take out the test cassette from the aluminium foil bag, mark the sample, and place it on a horizontal work surface.

Coronavirus (COVID-19) IgM/IgG antibody detection

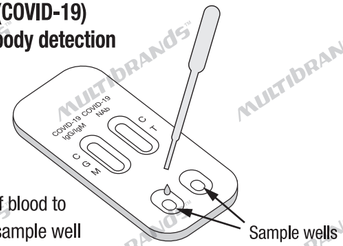
Take 10μL of serum, plasma or 20μL of whole blood sample directly into the sample well or the sample point at the lower end of the indicator arrow, and then add 100μL of sample diluent (3 drops)

Coronavirus (COVID-19) Neutralising Antibody Test

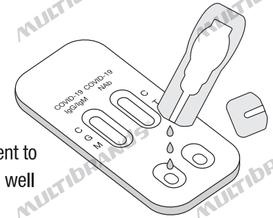
Take 40μL of serum, plasma or 60μL of whole blood sample directly into the sample well or the sample point at the lower end of the indicator arrow, and then drop 60μL of sample diluent (2 drops)

Interpret the result within 13-15 minutes, the test result is invalid after 15 minutes.

Coronavirus (COVID-19) IgM/IgG antibody detection

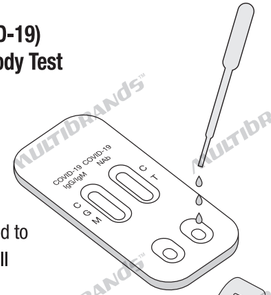


Add 1 drop of blood to the Igm/IgG sample well

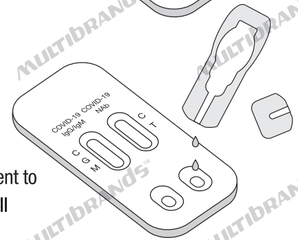


Add 3 drops of diluent to the Igm/IgG sample well

Coronavirus (COVID-19) Neutralising Antibody Test

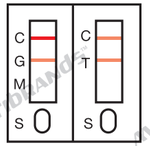


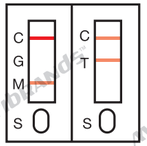
Add 3 drops of blood to the NAb sample well

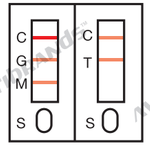


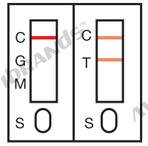
Add 2 drops of diluent to the NAb sample well

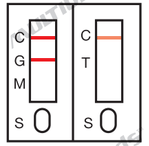
Interpret the result within 13-15 minutes, the test result is invalid after 15 minutes.

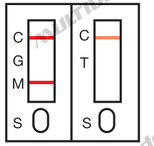

IgG+ IgM- NAb-

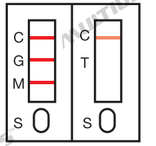

IgG- IgM+ NAb-

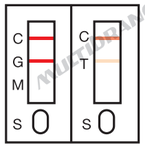

IgG+ IgM+ NAb-

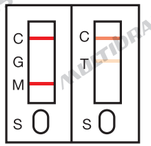

IgG- IgM- NAb-

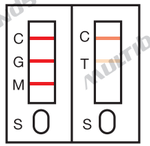

IgG+ IgM- NAb+

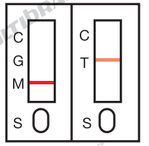

IgG- IgM+ NAb+


IgG+ IgM+ NAb+


IgG+ IgM- NAb+


IgG- IgM+ NAb+


IgG+ IgM+ NAb+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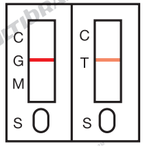
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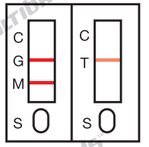
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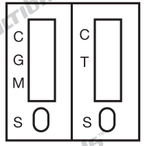
Invalid

Interpret the result within 13-15 minutes, the test result is invalid after 15 minutes.

For a video guide of these test instructions / procedures please visit:

www.panodyne.eu.com

Panodyne®

COVID19

SARS-CoV-2 Combined (IgM/IgG/Neutralising antibody) RAPID TEST (Colloidal Gold)

For professional use only

Intended use

The product is used for the qualitative detection of human veins in whole blood, serum or plasma samples of Corona Virus (COVID-19) IgM/IgG/neutralising antibody. It is only used as a supplementary test for the nucleic acid test of novel coronavirus or in cooperation with nucleic acid test in suspected cases. It cannot be used as a basis for the diagnosis and exclusion of pneumonia caused by novel coronavirus infection, and is not suitable for general screening. For medical institution use only, and biosecurity protection should be done in laboratory when testing of novel coronavirus. The results of this kit are only for clinical reference. If the test result is positive, further confirmation is needed. If the test result is negative, the possibility of infection cannot be excluded. Comprehensive analysis of the patient's condition should be carried out in combination with clinical symptoms and other laboratory tests.

Test principle

The rapid test is based on the principle of capture and colloidal gold immunochromatography, the nitrocellulose membrane Test M Zone of card1 is pre-coated with mouse anti-human IgM monoclonal antibody, Test G Zone is pre-coated with mouse anti-human IgG monoclonal antibody, the Control Zone is pre-coated with rabbit anti COVID-19 polyclonal antibody, the gold conjugation pad is pre-coated with colloidal gold labeled COVID-19 recombinant antigen; the nitrocellulose membrane Test Zone of card2 is pre-coated with COVID-19 recombinant antigen, the Control Zone is pre-coated with rabbit anti ACE2 polyclonal antibody, the gold conjugation pad is pre-coated with colloidal gold labeled ACE2 recombinant antigen; When a positive sample is added to the card 1 sample well, COVID-19 Antibodies (IgM/IgG) in the sample will be combined with colloidal gold (Au) labeled COVID-19 recombinant antigen and form into immune complexes (Au-COVID-19 recombinant antigen-[COVID-19- (IgM/IgG)]), the complexes will move forward inside the nitrocellulose membrane by chromatography effect. When reaching Test Zone, the complexes will be combined with mouse anti-human IgM monoclonal antibody and mouse anti-human IgG monoclonal antibody, and form into "(Au- COVID-19 recombinant antigen-[COVID-19-(IgM/IgG)])-[mouse anti-human IgM monoclonal antibody/mouse anti-human IgG monoclonal antibody]", thus agglutination color appears; The residual colloidal gold labeled COVID-19 recombinant antigen will be combined with rabbit anti COVID-19 polyclonal antibody at the Control Zone, and produce color under agglutination. When testing negative samples, there's no COVID-19 IgM or IgG in the samples, no immune complexes will be formed and color only appears in the Control line; When a positive sample is added to the card 2 ACE2 recombinant antigen, and the mixture will move forward inside the nitrocellulose membrane by chromatography effect. When reaching Test Zone, COVID-19 neutralising antibodies would compete with Au-labeled human ACE2 recombinant antigen to bind Test Zone of card2 which is pre-coated with COVID-19 recombinant antigen, Inhibit the formation of immune complexes (Au-ACE2 recombinant antigen-[COVID-19 recombinant antigen]) resulting in weakened agglutination color development.; The residual colloidal gold labeled ACE2 recombinant antigen will be combined with rabbit anti ACE2 polyclonal antibody at the Control Zone, and produce color under agglutination. When testing negative samples, there's no COVID-19 neutralising antibodies in the sample, does not inhibit the formation of immune complexes, thus color not only appears in the Control line, but also appears in the test line.

Storage conditions and expiry date

1. 2~30ºC dry, keep away from light, valid for 12 months.
2. The product should be stored in dry condition under 2~30ºC and kept away from light. Under the condition of 18 ~ 30ºC, the humidity is below 60%, use within 1 hour after opening. Humidity above 60%, it should be used immediately.
3. Production date and validity period are shown in the label.

Sample requirements

1. The whole blood should be venous blood. Serum samples can be collected by vein in a conventional manner. The plasma samples can be treated with heparin, sodium citrate and EDTA. Above samples can be placed under 2~8ºC for 5 days. Samples under-20ºC can be stored for at least 3months.
2. Samples should avoid hemolysis or repeated freezing-thawing. If the sample is turbid or has precipitation, it should be centrifuged or filtered to clarify before testing.

Test procedure

This package insert must be read completely before performing the test. Please restore the test card, sample diluent and sample to 18~30ºC before inspection.

Test procedure is as follows:

1. Remove the test card from the aluminum foil bag, mark the sample and put it on the horizontal worktable.

2. Sample Test

2.1 Corona Virus (COVID-19) IgM/IgG antibody Detection

Take 10 μL serum, plasma samples or 20μL whole blood to be directly added to the add hole or the bottom of the indicator arrow, and then add the sample diluent 60 μL (about 1-2 drops).

2.2 Corona Virus (COVID-19) Neutralising antibody

Take 40 μL serum, plasma samples or 60μL whole blood to be directly added to the add hole or the bottom of the indicator arrow, and then add the sample diluent 60 μL (about 1-2 drops).

3. Result should be read at 13-15minutes, negative results must be confirmed at the end of15minutes.

Interpretation of assay result

1. Test M Line Positive: red appears at M line and C line. It indicates that COVID-19 IgM antibody are detected in the sample, the patient may be in early stage of infection or currently infected. The final confirmation should be combined with clinical symptoms.
2. Test G Line Positive: red appears at M line and C line. It indicates that COVID-19 IgG antibody is detected in the sample, the patient may be currently infected or had previous infection. The final confirmation should be combined with clinical symptoms.
3. The intensity of T line color less than C line, simultaneous IgM or IgG Positive. It indicates that neutralising antibody is detected in the sample, or negative.
4. Test T Line Positive: only a red line appears in the position of the C line. It indicates that neutralising antibody is detected in the sample.
5. Negative result: only a red line appears in the position of the card 1 control line; red appears at card 2 T line and C line. It indicates that no COVID-19 IgM, IgG or neutralising antibody is detected in the sample.
6. Invalid results: The control line has no red stripe. The invalid results should resume experiment again, and the test should be in strict accordance with the instructions operation, if the test result is still invalid, please contact local suppliers or customer service with our company for technical consultation. The neutralisation antibody test results of this kit are not used as a basis for the effectiveness of the vaccine, but as a method of rapid initial screening in the field.

Limitations of the test method

1. The product is only used for the detection of whole blood, serum or plasma.
2. This product inspection result is only for clinical reference, should not serve as the only basis for clinical diagnosis and treatment. The clinical management of patients should be combined with its symptoms or signs, other medical history and laboratory examination, treatment response and epidemiological information such as the comprehensive consideration.
3. A negative test does not rule out the possibility of viral infection.
4. The target detection object of this product is the antibody of the target virus, which does not directly reflect the presence or absence of the virus in the sample.
5. Because the concentration level at which neutralising antibodies are protective is unknown, a positive neutralising antibody test does not imply the ability to protect individuals from Corona Virus (COVID-19) infection.

Product performance indicator

1. Smooth appearance, solid material attachment, complete contents, complete packaging no damage, clearly identifiable signs, no impurities were found in the sample extract.
2. Test Strip width conform to 3.5±0.2mm.
3. The moving speed of sample diluent≥10mm per minute.
4. Compliance rate of positive quality control products: inspection 10 positive quality control products, P1~P3 Corona Virus (COVID-19) IgM is required to be positive, IgG and neutralising antibody are required to be negative: P4~P8 Corona Virus (COVID-19) IgG is required to be positive, IgM and neutralising antibody are required to be negative; P9~P10 Corona Virus (COVID-19) neutralising antibody is required to be positive, IgM and IgG are required to be negative; the positive internal quality control compliance rate should be 10/10(+/+).
5. Compliance rate of negative quality control products: inspection 10 negative quality control products, N1~N10 Influenza A/B/Corona Virus (COVID-19) Antigen are required to be negative, the negative internal quality control compliance rate should be 10/10(-/-).
6. Minimum detection limit: the minimum detection limit of quality control products S1-S5, S1~S4 Corona Virus (COVID-19) IgM/IgG/neutralising antibody test results should be positive, S5 Corona Virus (COVID-19) IgM/IgG/neutralising antibody test results should be negative.
7. Repeatability: test 3 internal repeatability quality control products, each test for 10 times, test results should be positive.
8. Analysis capability:

(1) The COVID-19 IgM/IgG sensitivity was 94% and specificity was 97% respectively after evaluation.

(2) This reagent detects new coronavirus neutralising antibodies with a titre of not less than 1:8 in the serum of a cured patient or the serum of a healthy human after vaccination, as determined by the PRINT method, and the detection rate is greater than 87.5%.

Cautions

1. The operation shouldn't be done if the condition of kit and samples are not restored to 18 ~ 30ºC in case it will affect the accuracy of the results.
2. The positive samples obtained by the rapid test should be confirmed by other methods.
3. The rapid test should be sealed and kept in dry place. The test bar should be tested as soon as possible after being removed from the packaging, avoid placing it in the air for too long, causing the damp.
4. The deepness of the test line color is not necessarily associated with the titer of the antigen in the sample, and the results of the interpretation after 15 minutes are invalid.
5. When COVID-19 IgM/IgG/neutralising antibody content in the sample is very high, the c-line zone may be weakened, which is a normal phenomenon.
6. The results of rapid test are only for clinical reference and should not be the only basis for clinical diagnosis and treatment.
7. Waste samples and test should be treated as potential infectious agents.
8. The appearing time of the Control Line should not be taken as the time basis for judging the results of test line. The color rendering results should be observed and judged within a time limit of 13-15 minutes.
9. This product must be operated by professionally trained personnel, such as medical staff with clinical experience.
10. The rapid test is only used for in vitro diagnosis.

Index of Symbol

	Do not reuse	IVD	For in vitro diagnostic use only
2°C 30°C	Store between 2 - 30ºC		Consult instructions for use
	Use by	LOT	Lot number
	Do not use if package is damaged	Σ	Contains sufficient for <n> tests
	Keep away from sunlight		Keep dry
	Manufacturing date		Manufacturer
EC REP	Authorized representative in the European Community		

Manufactured by:
Multibrands Trading (Suzhou) Co. Ltd.
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E-mail: Peter@lotusnl.com

To report a serious adverse event in USA,
Contact: 1-315-636-4687

PDNVAT-U

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