



PRODUCT MANUAL

Components

Test card

Diluent

Alcohol pad

Dropper

Bandage

Sterilized lancet

Bioscience

# 2019-ncov Antibody Diagnostic Kit (Colloidal Gold )

**PRODUCT NAME** 





Bioscience

Specification

1 test

150 µL

1 piece

1 piece

1 piece

1 piece

## belongs to Nestivirus, Coronaviridae, and divided into three genera: α, β, and γ. The alpha and beta gene are only pathogenic to mammals. The gamma gene mainly causes bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence that it can be transmitted through the fecal-oral route. There have been seven types of human coronavirus (HCoV - 229E, HCoVOC43, SARS - CoV, HCoV - NL63, HCoV - HKU1, MERS - CoV and 2019-nCoV), which are

PRODUCT MANUAL

## important pathogens of human respiratory tract infection. Among them, the new coronavirus (2019-nCoV) was found for 2019 cases of viral pneumonia in Wuhan. The clinical manifestations are systemic symptoms such as fever, fatigue, dry cough, dyspnea, which can quickly develop into severe pneumonia, respiratory failure, acute

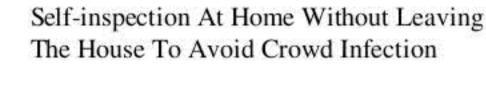
NTENDED USE

Respiratory distress syndrome, toxic shock, multiple organ failure, severe acid-base metabolism disorders and even life-threatening, 2019-nCoV Antibody Diagnostic Kit uses the principle of immunochromatographic method to qualitative detect the coronavirus (2019-nCoV) antibody in human whole blood, serum and plasma. It is used for clinical diagnosis of primary infection or secondary infection.

2019-nCoV diagnostic kit is used for the qualitative detection of new coronavirus (2019-nCoV) antibodies in human whole blood, serum or plasma. Coronavirus (CoV)

TEST PRINCIPLE This kit uses immunochromatography to perform the test, Add the sample to the test card, the sample moves forward along the test card under the capillary force. When it moves to the test zone, If there is 2019-nCoV antibody in the sample, it will bind with the recombinant protein which is labeled by colloidal gold, and this protein will be captured and formed a red line on the test zone; On the other hand, The colloidal gold-labeled biotin will be captured and formed a red line on control zone; In this case, there is two red line formed, which shows that a positive with 2019-nCoV-antibody.

Bioscience

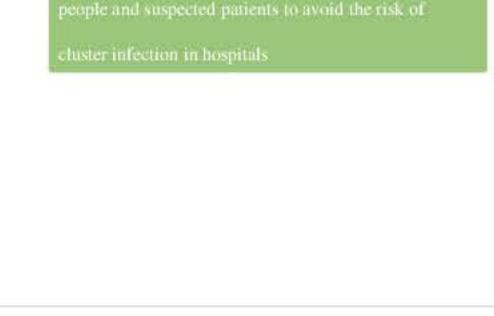


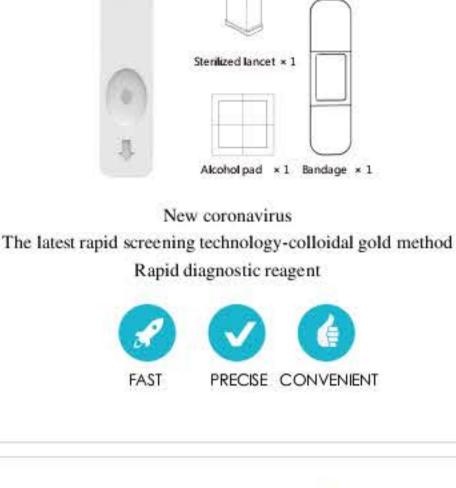


**CORE ADVANTAGES** 

Widely applicable to screening of asymptomatic

Easy sampling of fingertip blood without leaving home





Diluent × 1

Dropper × 1



[INTERPRETATION OF THE TEST RESULTS]

Negative result: one red line; Only one red line appears in the control zone

with no other line; This indicates that no 2019-nCoV antibody was detected

and the result was negative, as shown in the following figure (a);

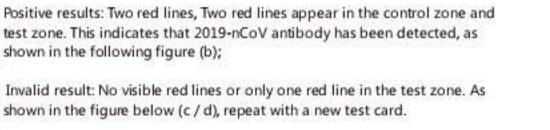
shown in the following figure (b);

C Line

T Line







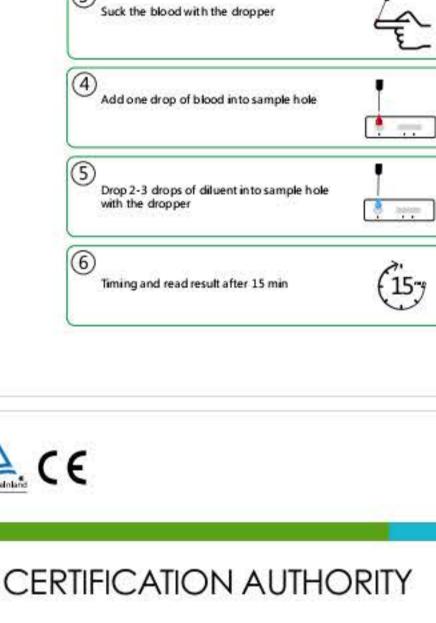
SAMPLING DETECTION PROCESS

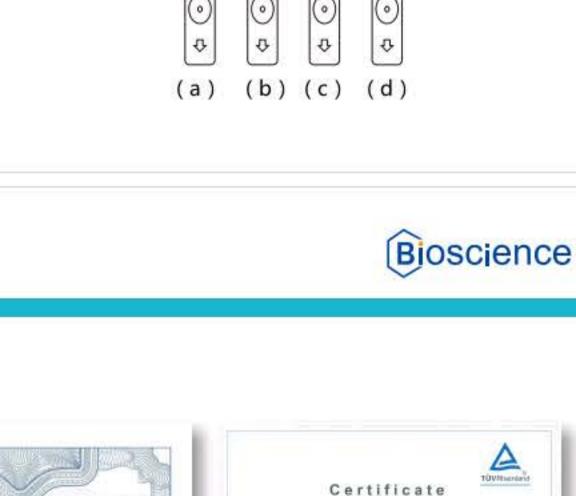
Before blood collection, please wash your hands

carefully and disinfect the finger with alcohol pad

Place the sterilized finger on the table and puncture

the finger with sterilized lancet







QUALITY

CERTIFICATION

Bioscience novel coronavirus

(2019-nCoV) antibody

diagnostic kit has passed EU

quality management system

certification

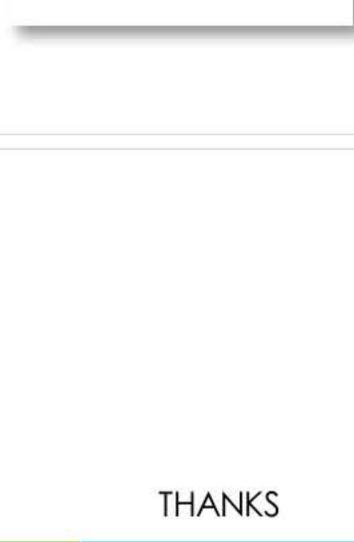
Bioscience receives ISO13485 quality manage-

ment system certificate from

TUV Rheinland LGA Products GmbH

POWEFUL BRAND





Declaration of Conformity

Bogds Development Area, Tamps, Clean

CUVID-19 Actibody Disgressing Kir (Collected Gold)

COVID-19 tgG Antholy Oxymetic Kit (CLIA)

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COVID-075/M Ambody Disarrent: Kit (College) Gold-

payments of the Council Directive 98/79/DC on at vitro diagnostic medical devices. All supporting

EN 190 (1485-2012)

nestwire Welfing Ltd

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Building No. 15 Japanese and Medical Equipment Enhanced Park, Loging Book



Bioscience (Tianjin) Diagnostic Technology Co., Ltd. No. 201.10 SWNI Road, Dongli District 300300 Tianjin

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EN ISO 13485:2016

## There have been seven types of human coronavirus (HCoV - 229E、HCoVOC43、SARS - CoV、HCoV - NL63、HCoV - HKU1、MERS - CoV and 2019-nCoV), which are important pathogens of human respiratory tract infection. Among them, the new coronavirus (2019-nCoV) was found for 2019 cases of viral pneumonia in Wuhan. The clinical manifestations are systemic symptoms such as fever, fatigue, dry cough, dyspnea, which can quickly develop into severe pneumonia, respiratory failure, acute Respiratory distress syndrome, toxic shock, multiple organ failure, severe acid-base metabolism disorders and even life-threatening. 2019-nCoV Antibody Diagnostic Kit uses the principle of immunochromatographic method to qualitative detect the coronavirus (2019-nCoV) antibody in human whole blood, serum and plasma.

It is used for clinical diagnosis of primary infection or secondary infection.

Components

Test card

Diluent

Dropper

Bandage

Alcohol pad

Sterilized lancet

serum and plasma can be inactivated in a water bath or oven at 56°C for 30 minutes before useing).

1.The whole blood should be kept at 2 ~ 8°C and be tested within 24 hours after collection.

Generic Name: 2019-nCoV Antibody Diagnostic Kit (Colloidal Gold ) Manual

Registrant / Manufacturer: Bioscience (Tianjin) Diagnostic Technology Co., Ltd

After-sales service company: Bioscience (Tianjin) Diagnostic Technology Co.,Ltd

Tel/Fax:022-84849080

Website: www.bioscience-tj.com

[PRODUCT NAME]

[INTENDED USE]

[TEST PRINCIPLE]

that a positive with 2019-nCoV-antibody.

[MATERIALS PROVIDED]

5 tests/box

[PACKING SPECIFICATION]

Address: Building 14, International Medical Equipment Park, Liujing Road, Dongli District, Tianjin, China

2019-nCoV Antibody Diagnostic Kit (Colloidal Gold Method )Home User

User Manual

2019-nCoV diagnostic kit is used for the qualitative detection of new coronavirus (2019-nCoV) antibodies in human whole blood, serum or plasma. Coronavirus (CoV) belongs to Nestivirus, Coronaviridae, and divided into three genera: α, β, and γ. The alpha and beta gene are

This kit uses immunochromatography to perform the test; Add the sample to the test card, the sample moves forward along the test card under the capillary force. When it moves to the test zone, If there is 2019-nCoV antibody in the sample, it will bind with the recombinant protein which is labeled by colloidal gold, and this protein will be captured and formed a red line on the test zone; On the other hand, The colloidal gold-labeled biotin will be captured and formed a red line on control zone; In this case, there is two red line formed, which shows

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secretions or through aerosols and droplets. There is also evidence that it can be transmitted through the fecal-oral route.

Production license No.: Tianjin food and drug administration machinery production 20100309

[MAIN INGREDIENTS]

Sample collection and preparation:

kindly re-collect the sample and test again;

[STORAGE CONDITIONS AND VALIDITY] Storage at 2 ~ 30 °C, the shelf life is 18 months. The test card should be used within 1 hour after the opening of the foil bag; The working buffer should be capped immediately after opening, and keep cooling to avoid direct sunlight. Production date and use period please refers to the test card label. [SAMPLE REQUIREMENTS]

Applicable sample types: Fresh whole blood, serum or plasma.

Components of kit with different Lot cannot be used interchangeably.

1. Hyperlipidemia samples (triglycerides > 10 mg / mL), bilirubin content > 0.2 mg / mL, hemoglobin content > 5 mg / mL, rheumatoid factor (RF) concentration > 1500 IU / mL in the sample, which may affect Measured value. The effect of microbially contaminated samples on the results has not been determined, but the use of such samples should be avoided.

[TESTING METHOD]

3. Mark the sample ID on the test card;

that there is no air bubble during the operation.

detected, as shown in the following figure (b);

[SAMPLING DETECTION PROCESS]

(INTERPRETATION OF THE TEST RESULTS)

Experimental Process

Sample Storage

Interference:

1. If it is a refrigerated or frozen sample, put it at room temperature at least 30 minutes and ensure a thoughly mixting before testing;

1. Negative result: one red line; Only one red line appears in the control zone with no other line; This indicates that no 2019-nCoV

4. Add 10 µL sample to the sampling well of the test card, and then add 100 µL working buffer into the sampling well, please kindly ensure

2. Positive results: Two red lines, Two red lines appear in the control zone and test zone. This indicates that 2019-nCoV antibody has been

3. Invalid result: No visible red lines or only one red line in the test zone. As shown in the figure below (c / d), repeat with a new test card.

Add one drop of blood into sample,

CLine

TLine

When ready to test, open the aluminum foil bag and take the test card out, then lay it flat on a horizontal table;

4

Venous whole blood samples are collected (EDTA anticoagulant tube is recommended). (for the safety of the operator, the obtained

A Servely hemolyzed sample is not recommended, which may interfere with the test and lead to false results. Once this happens, please

Refrigerated and frozen samples must be kept at room temperature at least 30 minutes and ensure a thoughly mixting before testing.

Serum and plasma can be stored at 2 ~ 8°C for 7 days and at -20±4°C for 30 days, and avoid repeated freezing-thawing.

## 1 Before blood collection, please wash your hands carefully and disinfect the finger with alcohol pad;

1. Continuity of operation is required.

NUMBER]

from the aluminum foil bag, do not use the test card.

2 Place the sterilized finger on the Drop 2-3 drops of diluent into table and puncture the finger with sample hole with the dropper; sterilized lancet;

5. Time 15 minutes then read the result, the result will be invalid after 20 minutes.

antibody was detected and the result was negative, as shown in the following figure (a);

- (3) (6) Timing and read result after 15 min. Suck the blood with the dropper;
- Cautions

should be used within 1 hour. After using, please discard it and do not reuse it.

invalid or wrong results. This kit is only used for in vitro diagnosis, and should not be used for other purposes. • ProClin300 contained in this kit may cause allergic reactions. Avoid prolonged contact of the reagent with the skin, and wash your hands thoroughly after the reagent is processed. Due to the methodologies or antibody specificity of the detection of coronavirus (2019-nCoV) antibodies, the use of reagents from different manufacturers on the same sample may yield different results. Therefore, in the process of infection monitoring, the results obtained with different reagents should not be directly compared with each other, so as not to cause

erroneous medical interpretations; the test report sent to the clinician by the laboratory indicates the characteristics of the reagents used. • It is forbidden to use any components of the kit with visible damage, or any components with broken seals. If the desiccant is missing

• Dispose of used test tips, buffer bottles, and test cards in accordance with local bio-safety management procedures.

• Some patient samples contain possible sources of biological infection, so all patient samples should be treated as biohazard.

[MEDICAL DEVICE REGISTRATION CERTIFICATE NUMBER/PRODUCTTECHNICAL REQUIREMENT

. Operators need to carry out testing operations strictly in accordance with the kit and instrument instruction, otherwise it may lead to

2. The test card must be kept in a sealed aluminum foil bag unless it is ready for immediate use. Once the aluminum foil bag is opened, it

Address: Building 14, International Medical Equipment Park, Liujing Road, Dongli District, Tianjin, China Tel/Fax:022-84849080 After-sales service company: Bioscience (Tianjin) Diagnostic Technology Co.,Ltd Website: www.bioscience-tj.com Production license No.: Tianjin food and drug administration machinery production 20100309

[DATE OF SPECIFICATION APPROVAL AND MODIFICATION]

Registrant / Manufacturer: Bioscience (Tianjin) Diagnostic Technology Co.,Ltd