



INNOVITA⁺®

Instructions for 2019-nCoV Ab Test (Colloidal Gold)

INNOVITA (Tangshan) Biological Technology Co., Ltd.

Product Name

2019-nCoV Ab Test (Colloidal Gold)

Intended Use

The kit is intended for the qualitative detection of IgM and IgG antibodies against 2019 Novel Coronavirus (2019-nCoV) in human serum/plasma/venous whole blood specimen. It is only used as a supplementary detection indicator for suspected nucleic acid negative results or in conjunction with nucleic acid detection in the diagnosis of suspected cases. It cannot be used as a basis for the diagnosis and exclusion of COVID-19. It is not suitable for general screening.

A positive test result requires further confirmation. A negative test result does not rule out the possibility of infection.

This product is limited to clinical use and emergency reserve during the COVID-19 epidemic outbreak since December 2019, and cannot be used in the clinic as a conventional in vitro diagnostic reagent. The test results of this kit are for clinical reference only. It is recommended to conduct a comprehensive analysis of the condition based on the patient's clinical manifestations and other laboratory tests.

Laboratory testing of 2019-nCoV should meet the requirements of the "Technical Guidelines for Laboratory Testing of COVID-19 Infection" to do a better biosafety job.

Summary

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). 2019-nCoV is a new strain that has not been previously identified in humans.

Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.

Standard recommendations to prevent infection spread include regular hand washing, covering mouth and nose when coughing and sneezing, thoroughly cooking meat and eggs. Avoid close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing.

Current estimates of the incubation period range from 1-12.5 days with median estimates of 5-6 days. These estimates will be refined as more data becomes available. Based on information from other coronavirus diseases, such as MERS and SARS, the incubation period of 2019-nCoV could be up to 14 days. WHO recommends that the follow-up of contacts of confirmed cases is 14 days.

Principle

The kit detects 2019-nCoV IgM and IgG antibodies by immuno-capture method. The nitrocellulose membrane is coated by mouse-anti human monoclonal IgM antibodies, mouse-anti human monoclonal IgG antibodies, and goat-anti-mouse IgG antibodies. The recombinant 2019-nCoV antigen and mouse IgG antibodies are labeled with colloidal gold as a tracer. After addition of the specimens, if 2019-nCoV IgM antibodies are present, the antibodies will bind to colloidal gold-coated 2019-nCoV antigens to form compounds, which are further captured by pre-coated mouse-anti human IgM antibodies to form new compounds, and generate purple line (T). If 2019-nCoV

IgG antibodies are present in specimen, the antibodies will bind to colloidal gold-labeled 2019-nCoV antigens to form compounds, and further form new compounds by binding to pre-coated mouse-anti human monoclonal IgG antibodies, which give rise to purple line (T). The binding of colloidal gold-labeled mouse IgG antibodies with goat-anti-mouse IgG antibodies will present purple line, which is used as the control line(C).

Composition

1. Sealed foil pouches each containing:
 - a. One cassette device
 - b. One desiccant
2. Specimen diluent
3. Instructions for use

Storage and Stability

1. Store at 4°C~30°C (39.2°F~86°F).
2. Use the test within 1 hour after opening the pouch under 60% humidity.
3. See production date and expiration date on label.

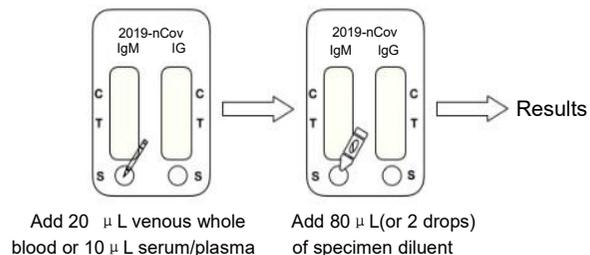
Specimen Collection and Handling

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

1. The kit is intended for test only in serum/plasma/venous whole blood specimens.
2. Specimens should be collected by standard protocol.
3. The venous whole blood specimens could be stored at 2°C~8°C (36°F~46°F) for up to 3 days, and it couldn't be frozen. Venous whole blood specimens can be anti-coagulated with routine dosage of heparin (9.8-28IU/mL), sodium citrate (3.8%, equivalent to 129mmol/L), ethylenediaminetetraacetic acid (EDTA) (4.55mmol/L / mL ± 0.85 mmol/mL).
4. The serum or plasma specimens could be stored at 2°C~8°C (36°F~46°F) for up to 7 days, and could be frozen at -20°C (-4°F) for 6 months. The specimens are repeatedly frozen and thawed no more than 8 times; it should be the best to test the sample after collection immediately.
5. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

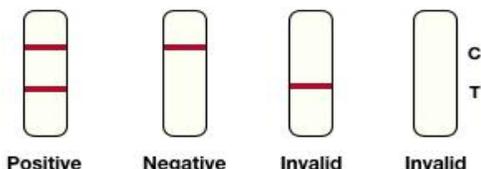
Test Procedure

1. Allow the test, specimen diluent and/or controls to reach room temperature 10°C~30°C (50°F~86°F) prior to testing.
2. Remove the test device from the sealed pouch and use it as soon as possible.
3. Place the test device on a clean and level surface.
4. **FROM THE TOP OF THE SPECIMEN WELL:** Add 20µL venous whole blood or 10µL serum/plasma specimen into each specimen well.
5. **FROM THE BOTTOM OF THE SPECIMEN WELL:** Add 80µL or 2 drops of specimen diluent into each specimen well.
6. Wait for the colored line(s) to appear. Read results within 15 minutes. Do not read the result after 15 minutes.



Results Interpretation

- IgM Positive:** The presence of two purple bands (T and C) within the IgM result window indicates positive for 2019-nCoV IgM antibody.
- IgG Positive:** The presence of two purple bands (T and C) within the IgG result window indicates positive for 2019-nCoV IgG antibody.
- Negative:** Only one purple band appearing at the control line (C) indicates negative result.
- Invalid:** If control line (C) fails to appear, no matter whether the T line is visible or not, the test is invalid. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, you should immediately stop using the kit with the same LOT No. and contact your local distributor.



Performance Characteristics

- Use the national or enterprise reference controls for testing, and the results meet the detection requirements of national or enterprise reference controls.
- Test the samples with a titer of 1:320 at the original concentrations with the 2019-nCoV IgM antibody and 2019-nCoV IgG antibody. No hook effect was observed.
- The clinical trial of this product is based on the clear diagnosis / exclusion criteria of the disease identified in the "COVID-19 Diagnosis and Treatment Program". Clinical research was conducted in 5 institutions and the total cases were 447. Using this kit, 110 cases out of 126 clinically confirmed cases are positive, with the sensitivity of 87.3% (95% CI: 80.40% to 92.0%); 62 cases of clinically excluded cases are totally negative with the specificity of 100% (95% CI: 94.20% to 100%).
- Avoid using special samples: red background may appear in the hyperlipemia (triglyceride concentration higher than 25mg/ml), icteric samples (Bilirubin concentration higher than 0.2mg/mL) and hemolytic specimen (hemoglobin concentration more than 5.0mg/mL), which may affect the test result.

- The 2019-nCoV IgM test was also evaluated with samples that are IgM positive for other diseases as listed in the following table. No cross reactivity was observed.

| | |
|--|---------------------------------|
| Coronavirus HKU1-IgM | Coronavirus OC43-IgM |
| Coronavirus NL63-IgM | Coronavirus 229E-IgM |
| Influenza A virus H1N1 (new type influenza A virus H1N1 2009, seasonal influenza virus H1N1) IgM | H3N2-IgM |
| H5N1-IgM | H7N9-IgM |
| Influenza B virus IgM | Respiratory Syncytial Virus IgM |
| Adenovirus IgM | Rhinovirus IgM |
| Enterovirus A-IgM | EB virus IgM |
| Measles virus IgM | Cytomegalovirus IgM |
| Rotavirus IgM | Mumps IgM |
| Varicella-zoster virus IgM | Parainfluenza virus IgM |
| Mycoplasma pneumoniae IgM | Chlamydia pneumoniae IgM |
| Coxsackievirus group B IgM | |

- The 2019-nCoV IgG test was also evaluated with samples that are IgG positive for other diseases as listed in the following table. No cross reactivity was observed.

| | |
|--|---------------------------------|
| Coronavirus HKU1-IgG | Coronavirus OC43-IgG |
| Coronavirus NL63-IgG | Coronavirus 229E-IgG |
| Influenza A virus H1N1 (new type influenza A virus H1N1 2009, seasonal influenza virus H1N1) IgG | H3N2-IgG |
| H5N1-IgG | H7N9-IgG |
| Influenza B virus IgG | Respiratory Syncytial Virus IgG |
| Adenovirus IgG | Rhinovirus IgG |
| Enterovirus A-IgG | EB virus IgG |
| Measles virus IgG | Cytomegalovirus IgG |
| Rotavirus IgG | Mumps IgG |
| Varicella-zoster virus IgG | Parainfluenza virus IgG |
| Mycoplasma pneumoniae IgG | Chlamydia pneumoniae IgG |
| Coxsackievirus group B IgG | |

- RF, ANA and AMA don't exhibit cross reactivity with the test.
- Common antivirals such like Epistine hydrochloride ($\leq 4\text{mg/L}$), Ribavirin ($\leq 40\text{mg/L}$), Interferon ($\leq 200\text{mg/L}$), Oseltamivir ($\leq 30\text{mg/L}$), Abidol ($\leq 40\text{mg/L}$), Levofloxacin ($\leq 200\text{mg/L}$), Azithromycin ($\leq 10\text{mg/L}$), Ceftriaxone ($\leq 400\text{mg/L}$), Meropenem ($\leq 200\text{mg/L}$) have no interference effect on the detection of this kit.
- Systemic lupus erythematosus has no interference effect on the detection of this kit.
- Non-specific IgM antibody ($\leq 0.8\text{mg/mL}$) and non-specific IgG antibody ($\leq 4\text{mg/mL}$) have no interference effect on the detection of this kit.
- Heparin, sodium citrate, EDTA and other anticoagulants have no interference effect on the detection of this kit.
- The precision experiments were carried out by different experimenters, at different times and at different places, and the results met the product performance requirements.
- After the specific IgM positive sample was destroyed by β -mercaptoethanol, the IgM test result was negative.
- After preliminary evaluation, it is basically confirmed that the clinical performance of the product can meet the emergency needs of the epidemic. The product will further collect clinical data to confirm the clinical performance of the product after it is marketed.

Limitations

- The kit is for qualitative detection and auxiliary diagnosis use only.
- In the early phase of infection, no IgM or IgG antibody will be produced, or the titer will be very low, thus, negative result will occur. Re-testing will be conducted in 7-14 days, and the sample that is collected last time will be detected in parallel during re-testing to confirm whether the serology turns positive or the titer increases significantly.
- The reference value of serological antibody detection is limited for the immune-compromised patients or patients who receive immunosuppressive therapy.
- IgM antibody positive will occur not only in primary infection, but also in secondary infection.
- IgG antibody positive indicates previous infection or secondary infection.
- The confirmation or exclusion of infection will be combined with the patient's clinical manifestations or other further methods.

Precaution

- Use fresh specimens whenever possible.
- Results after 15 minutes are considered invalid.
- The product should be used as soon as possible once the foil pouch is open, in case of long-term exposure to environment.
- Follow standard biosafety guidelines for handling and disposal of potential infective material.

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|--|---|--|-----------------------------------|
| | Do not reuse | | For in vitro diagnostic use only |
| | Stored between 4-30°C | | Consult instruction for use |
| | Caution | | Lot number |
| | Use by | | Contains sufficient for <n> tests |
| | Keep away from sunlight | | Keep dry |
| | Manufacturer | | Do not use if package is damaged |
| | Authorized Representative in the European Community | | |
| | CE Mark | | |

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