CE

Instructions for 2019-nCoV Ab Test (Colloidal Gold)

Product Name

Made in China

2019-nCoV Ab Test (Colloidal Gold)

Intended Use

SARS-CoV-2 (also known as 2019-nCoV) is the virus that causes COVID-19 disease. This kit is intended for the qualitative detection of IgM and IgG antibodies against 2019 Novel Coronavirus (2019-nCoV) in human serum/plasma/whole blood specimen.

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). A novel coronavirus (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, and avoiding close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing.

A novel coronavirus (CoV) is a new strain of coronavirus that has not been previously identified in humans. The new, or “novel” coronavirus, now called 2019-nCoV, had not been previously detected before the outbreak was reported in Wuhan, China in December 2019.

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.

To date, there is no specific medicine recommended to prevent or treat the novel coronavirus.

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 complexes, 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

Required but not supplied

a. alcohol swabs
b. finger lancets (if using capillary blood from finger sticks)
c. transfer pipettes.

Storage and Stability

1. Store at 4℃~ 30℃ (39.2℉~ 86℉)
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

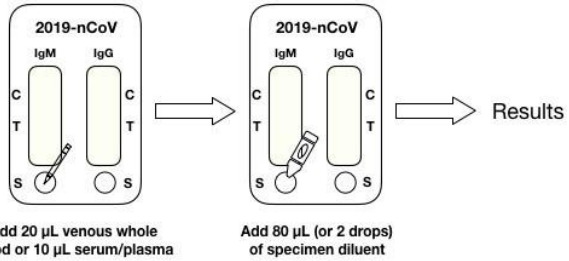
Consider any materials of human origin as infectious and handle them using standard bio-safety procedures, universal precautions and consider consulting your organizations policies and federal governmental guidance available from CDC and OSHA (Centers for Disease Control and Occupational Health and Safety Administration).

1. The kit is intended for test of only serum, plasma, or whole blood specimens.
2. Specimens should be collected by standard protocol.
3. The whole blood specimens may be stored at 2℃~8℃ (36℉~46℉) for up to 3 days but may not be frozen. Venous whole blood specimens can be anti-coagulated with routine dosage of heparin (9.8 - 28 IU/mL), sodium citrate (3.8%, equivalent to 129 mmol/L), ethylenediaminetetraacetic acid (EDTA) (4.55 mmoL/mL ± 0.85 mmol/mL).
4. The serum or plasma specimens may be stored at 2℃~ 8℃ (36℉~46℉) for up to 7 days, and may be frozen at -20℃ (-4℉) for 6 months. The specimens may be repeatedly frozen and thawed no more than 8 times, however, it is best to test the sample immediately after collection.
5. If user desires to use frozen specimens, then 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.

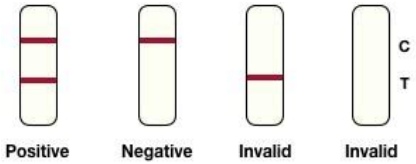
Test Procedure

1. Allow the test, specimen diluent and/or controls to reach room temperature 10℃~30℃ (50℉~86℉) prior to testing.
2. Remove the test device from the sealed pouch and use test device 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 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

1. **IgM Positive**: The presence of two purple bands (T and C) within the IgM result window indicates positivity for 2019-nCoV IgM antibody.
2. **IgG Positive**: The presence of two purple bands (T and C) within the IgG result window indicates positive for 2019-nCoV IgG antibody.
3. **Negative**: Only one purple band appearing at the control line (C) indicates negative result.
4. **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

1. Clinical research was conducted in 5 institutions. 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%).
2. Avoid using special samples: red background may appear in the hyperlipemia (triglyceride concentration higher than 25 mg/ml), icteric samples (Bilirubin concentration higher than 0.2 mg/mL) and hemolytic specimen (hemoglobin concentration more than 5.0 mg/mL). which may affect the test result.
3. 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	

4. 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
IInfluenza 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	

5. RF, ANA and AMA don't exhibit cross reactivity with the test.
6. Common antivirals such like Epistine hydrochloride (≤ 4mg/L), Ribavirin (≤ 40mg/L), Interferon (≤ 200mg/L), Oseltamivir (≤ 30mg/L), Abidol (≤40mg/L), Levofloxacin (≤ 200mg/L), Azithromycin (≤100mg/L), Ceftriaxone (≤ 400mg/L), Meropenem (≤ 200mg/L) have no interference effect on the detection of this kit.
7. Systemic lupus erythematosus has no interference effect on the detection of this kit.
8. Non-specific IgM antibody (≤0.8 mg/mL) and non-specific IgG antibody (≤4 mg/mL) have no interference effect on the detection of this kit.
9. Heparin, sodium citrate, EDTA and other anticoagulants have no interference effect on the detection of this kit.
10. The precision experiments were carried out by different experimenters, at different times and at different places, and the results met the product performance requirements.
11. After the specific IgM positive sample was destroyed by β-mercaptoethanol, the IgM test result was negative.

Limitations

1. The kit is for qualitative detection and aid in diagnosis use only.
2. In the early phase of infection, no IgG or IgM antibody will be produced, or the titer will be very low, thus, negative result will occur.

3. The detection of serological antibodies may be limited in immune-compromised patients or patients who receive immunosuppressive therapy.
4. IgM against SARS-CoV-2 may be detectable in both prior or current infection.
5. A positive test for IgG against SARS-CoV-2 may indicate prior or current infection.

Warnings

1. This test has not been reviewed by the FDA.
2. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
3. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
4. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.
5. Positive results are NOT an indication of immunity to SARS-CoV-2.
6. Not for the screening of donated blood.
7. The COVID-19 IgM/IgG Antibody (IgM/IgG) Combined Test is for professional *in vitro* diagnostic use only. This test is a qualitative assay. It is not designed to determine the quantitative concentration of SARS-CoV-2 antibodies.
8. The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage, or repeated freezing and thawing of the sample will affect the test result.
9. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
10. Use fresh specimens whenever possible.
11. Results read after 15 minutes are considered invalid.

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Importer/Distributer/Customer Support:
20/20 BioResponse, Inc.
9430 Key West Avenue
Rockville, MD 20850
Customer Service: (240) 453-6339
Website: http://coronachecktest.com/

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

No.: Manufacturers -1.0-05_20/20 BioResponse

Effective Date: April 2, 2020