597473

2019 nCov Ab Test (Colloidal Gold)

Instructions

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INNOVITA

2019 nCoV Ab Test (Colloidal Gold)

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

Instructions

Please read instruction manual carefully before performing and evaluating the test.
This test in intended for evaluation by health care professionals only and is not for home use.

A. 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.

B. 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.

B. 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).

• Content of this kit

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.

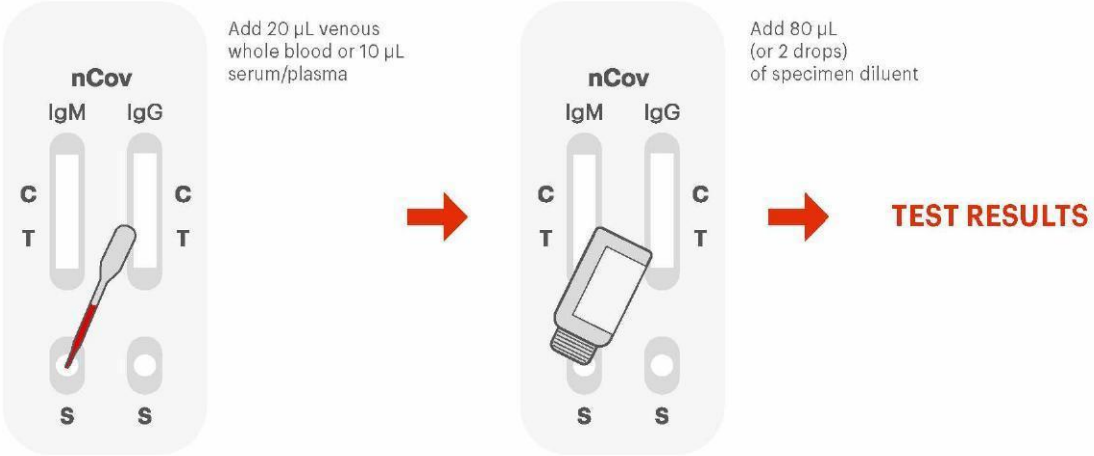
• Specimen collection and handling

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

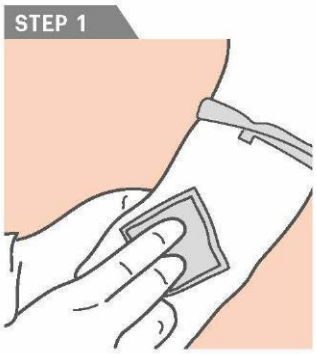
1. The kit is intended for test only in serum/plasma/venous whole blood specimens.
2. Specimens should be collected by standard protocol.
3. The venous whole blood specimens could be stored at 2°C - 8°C (36°F - 46°F) for up to 3 days, and it couldn't be frozen. Venous whole blood specimens can be anti-coagulated with routine dosage of heparin (9.8 - 28IU/mL), sodium citrate (3.8%, equivalent to 129 mmol/L), ethylenediaminetetraacetic acid (EDTA) (4.55 mmoL / mL ± 0.85 mmol/mL).
4. The serum or plasma specimen s 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°C 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

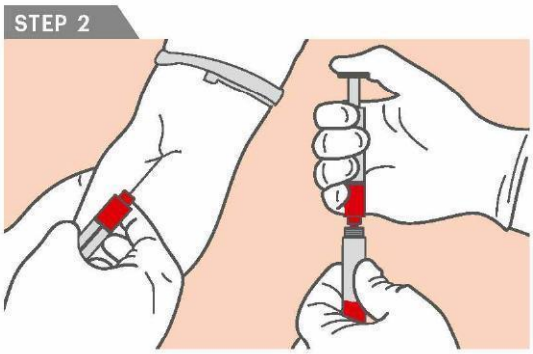
1. Allow the test, specimen diluent and/or controls to reach room temperature 10°C - 30°C (50°F - 86°F) prior to testing.
2. Remove the test device from the sealed pouch and use it as soon as possible.
3. Place the test device on a clean and level surface.
4. **FROM THE TOP OF THE SPECIMEN WELL:** Add 20 µL venous whole blood or 10 µL serum/plasma specimen into each specimen well.
5. **FROM THE BOTTOM OF THE SPECIMEN WELL:** Add 80 µL 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**.



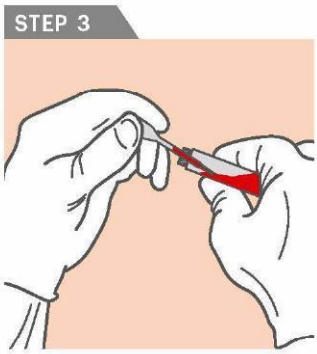
• Quick reference guide



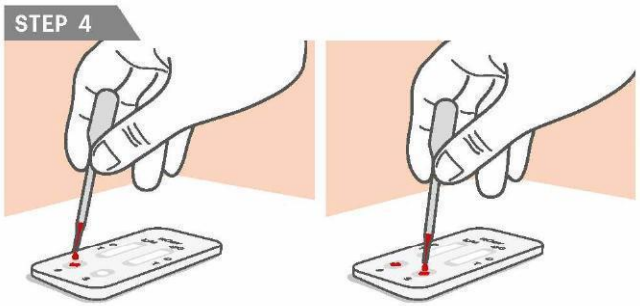
1. Clean the collection area with the provided alcohol wipe.



2. Collect blood sample according to instructions.



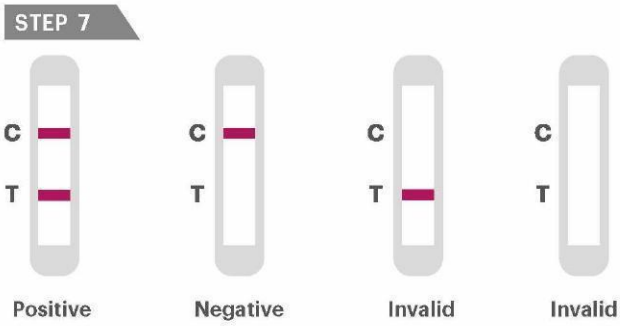
3. Use a pipette to collect the serum or plasma or venous whole blood specimen.



4. Add one drop (10μL) of serum or two drops (20μL) of blood into each specimen well (S) from the top of the specimen well.

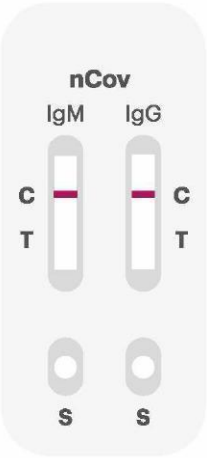
5. Add 2 drops (80μL) of specimen diluent into each specimen well.

6. Wait for 15 minutes.



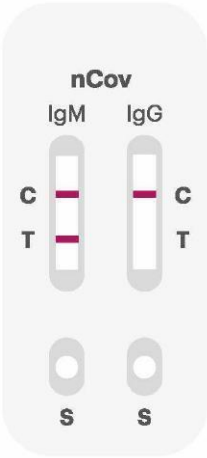
7. Read the results.
DO NOT read the results after 15 minutes.

• Results explained



[Negative result]

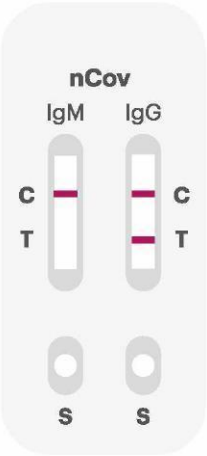
Or
Patient is infected and is in window period of infection - epidemiological history or clinical symptom should be evaluated. If not present then infection can be excluded.



[Positive result]

Probably in the early stage of infection, but no IgG is produced or the IgG concentration does not reach the lowest limit of detection. Negative nucleic acid test result might appear if patient is in the acute page of infection.

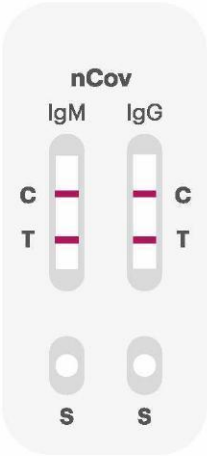
Or
Patient is not infected but has rheumatoid factor positive that can lead to false positive IgM indication. Clinical evaluation of patient for rheumatoid arthritis is recommended.



[Positive result]

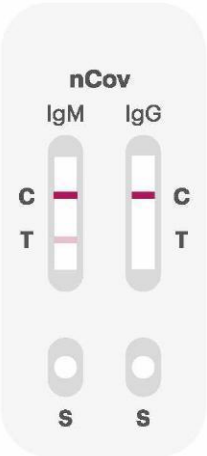
Probably in the advanced stage of infection or recurrent infection.

Or
Patient is not infected though probably has been previously infected, has recovered or the virus has been cleared. IgG produced by the immune response maintains for a long time and is still detectable in blood.



[Positive result]

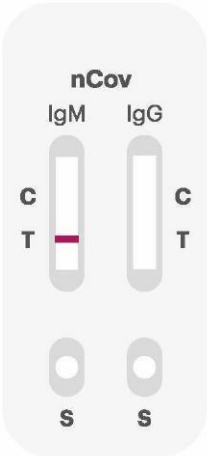
Active phase of infection.
But the human body has developed immunity with persistent IgG antibody being produced. If combined with a negative nucleic acid test the result might also indicate that patient has recently been infected and is in the recovery phase. The virus in the body has been cleared and IgM has not been reduced to the lowest limit of detection; It can also mean that the nucleic acid test result is false negative and the patient is in active phase of infection.



[Positive result]

Initial infection with very low virus load at early stage. In this case nucleic acid test might appear negative. When the viral load is lower than the lowest detection limit of nucleic acid, a small amount of IgM was produced, and no IgG was produced.

Or
Patient is not infected but has rheumatoid factor positive that can lead to false positive IgM indication. Clinical evaluation of patient for rheumatoid arthritis is recommended.



[Invalid]

If control line **(C)** fails to appear, no matter whether the **(T)** line is visible or not, the test is invalid.

• Results interpretation

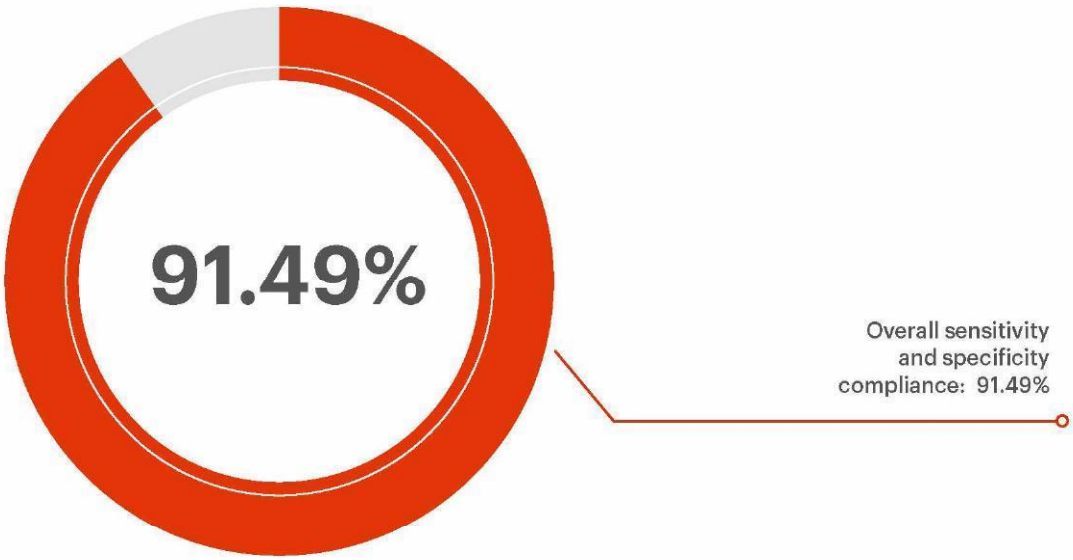
1. **IgM Positive:**
   The presence of two purple bands (T and C) within the IgM result window indicates positive for 2019-nCoV IgM antibody.
2. **IgG Positive:**
   The presence of two purple bands (T and C) within the IgG result window indicates positive for 2019-nCoV IgG antibody.
3. **Negative:**
   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.

• Test result reference with nucleic acid test

Nucleic acid	IgM	IgG	Nucleic acid and antibody test results reference
Positive	-	-	Probably in "window period" of infection.
	+	-	Probably in the early stage of infection, but no IgG is produced or the IgG concentration does not reach the lowest limit of detection.
	-	+	Probably in the advanced stage of infection or recurrent infection.
	+	+	Active phase of infection. But the human body has developed immunity with persistent IgG antibody being produced.
Negative	+	-	Highly probably in the acute stage of infection. At this time, it is necessary to consider cases where the nucleic acid test result is suspect or the patient has other diseases. Rheumatoid factor has been found to result in weak positive or positive in IgM.
	-	+	Probably previous infection. But the body has recovered or the virus has been cleared. IgG produced by the immune response maintains for a long time and is still detectable in blood.
	±	-	Initial infection with very low virus load at early stage; When the viral load is lower than the lowest detection limit of nucleic acid, a small amount of IgM was produced, and no IgG was produced; Or rheumatoid factor positive of the patient resulted in IgM false positive.
	+	+	The patient has recently been infected and is in the recovery phase. The virus in the body has been cleared and IgM has not been reduced to the lowest limit of detection; Or the nucleic acid test result is false negative and the patient is in active phase of infection.

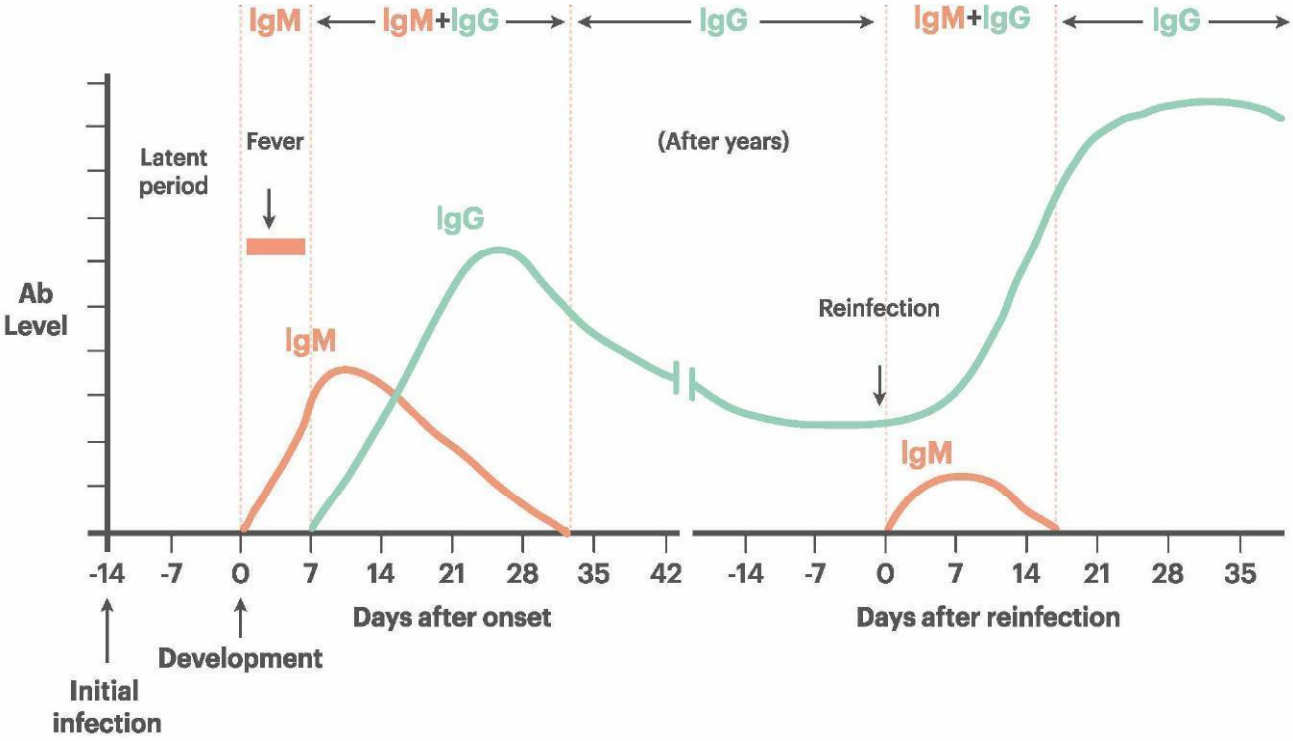
• Comparison analysis between diagnostic methods

	Nucleid Acid	Antibody Testing
Significance	RNA is the direct evidence of infection.	Antibody stimulated in the blood after infection is the indirect evidence of infection.
Limitations	· High requirement on lab condition and operator; · Complicated procedure, time-consuming, high infection risk to operator; · Result easily affected by specimen quality, testing condition and operation.	Reference to clinical diagnosis, but the confirmation or exclusion of infection will be combined with the patient's clinical manifestations or other further methods.



• Significance of IgM & IgG

The detection of IgM and IgG antibodies against 2019-nCoV is a fast and simple method. The results are of epidemiological significance, and it is an important means to understand the occurrence, development, prognosis and outcome of 2019-nCoV infection.

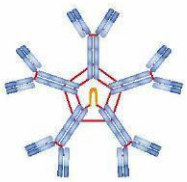


• Significance of IgM/IgG combined detection

1. Complementary to nucleic acid testing to help confirm the diagnosis of suspected patients.
2. Assist clinical diagnosis and monitor the development of disease cource.
3. Improve diagnostic efficiency and reduce infection risk.

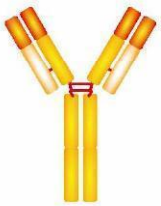
IgM

Serves as the first kind of defense, which means it is the first antibody to be immediately developed when any foreign particle is introduced, though its function is temporary.



IgG

Is a long term response for any disease and thus protect our body from viral and bacterial attacks.



• Performance characteristics

1. Use the national or enterprise reference controls for testing, and the results meet the detection requirements of national or enterprise reference controls.
2. 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.
3. 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%).
4. 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.
5. 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
Varicella-zoster virus IgM	Parainfluenza virus IgM
Mycoplasma pneumoniae IgM	Chlamydia pneumoniae IgM
Coxsackievirus group B IgM	

6. 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
Varicella-zoster virus IgG	Parainfluenza virus IgG
Mycoplasma pneumoniae IgG	Chlamydia pneumoniae IgG
Coxsackievirus group B IgG	

7. RF, ANA and AMA don't exhibit cross reactivity with the test.
8. Common antivirals such like Epistine hydrochloride (≤4 mg/L), Ribavirin (≤40 mg/L), Interferon (≤200 mg/L), Oseltamivir (≤30 mg/L), Abidol (≤40 mg/L), Levofloxacin (≤200 mg/L), Azithromycin (≤100 mg/L), Ceftriaxone (≤400 mg/L), Meropenem (≤200 mg/L) have no interference effect on the detection of this kit.
9. Systemic lupus erythematosus has no interference effect on the detection of this kit.
10. 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.
11. Heparin, sodium citrate, EDTA and other anticoagulants have no interference effect on the detection of this kit.
12. The precision experiments were carried out by different experimenters, at different times and at different places, and the results met the product performance requirements.
13. After the specific IgM positive sample was destroyed by β-mercaptoethanol, the IgM test result was negative.
14. 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

1. The kit is for qualitative detection and auxiliary diagnosis use only.
2. 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.
3. The reference value of serological antibody detection is limited for the immune-compromised patients or patients who receive immunosuppressive therapy.
4. IgM antibody positive will occur not only in primary infection, but also in secondary infection.
5. IgG antibody positive indicates previous infection or secondary infection.
6. The confirmation or exclusion of infection will be combined with the patient's clinical manifestations or other further methods.

• Precaution

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

• FAQ

1. **Is the result accurate after the required time for result interpretation?**
   The result is inaccurate and should be interpreted according to the time specified in the instruction manual. If the result is negative at the time of interpretation, but a faint line appears after the interpretation time, it may be caused by the continuous release of colored markers, but this result is invalid.

2. **What should be paid attention to when using specimens and products stored in the refrigerator?**
   If refrigerated, the specimen should be rewarmed under room temperature before testing. If the test is done without returning to room temperature, the test sensitivity may be reduced.

3. **Why may there be red vertical line in the result window?**
   - It may happen when the specimen flows on the membrane. This will not affect the test result, but the result will be read within the specified time based on a clear background;
   - The hemolytic specimen may be used. Retest with fresh specimen.

4. **The specimen moves particularly slow or doesn't move at all (No liquid flowing on the membrane in the result window).**
   - The package is damaged or the reagent is invalid: Retest;
   - The package is damaged or the reagent is invalid: Retest;
   - Improper assembly of test kit: Contact the supplier.

5. **C line doesn't appear at the specified time for reading result.**
   - Too much specimen is added, resulting in abnormal flow of liquid: Add correct specimen volume according to the instructions;
   - If the sample does not flow, there is a problem with the test kit: Contact the supplier.

6. **False positive**
   - Serum specimen contains special interfering substances: Use other methods to confirm the test results;
   - Read the results after the specified time: Do not read the results after the specified time in the manual .

7. **False negative**
   - The antibody concentration in the specimen is lower than the detection threshold: Confirm with other test methods;
   - In the early stage of infection, the antibody is not produced or the titer is very low, resulting in a negative result: Confirm with other test methods;
   - There are errors in the interpretation standards. Read the instructions carefully, and interpret in accordance with the specified method and time.

Together
we create the future
of personalized medicine.

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