NOVA Test® COVID-19 IgM/IgG Antibody Test (Colloidal Gold)

CE IVD

Cat.No.: nCov-497

1. INTENDED USE

The COVID-19 IgM/IgG Antibody Test (Colloidal Gold) is a lateral flow immunoassay for the simultaneous detection and differentiation of IgG and IgM antibodies of COVID-19 in human serum, plasma or whole blood. The COVID-19 IgM/IgG Antibody Test (Colloidal Gold) is an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. Results from the COVID-19 IgM/IgG Antibody Test (Colloidal Gold) should not be used as the sole basis for diagnosis.

Results are for the detection of SARS-CoV-2 antibodies. IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although levels over the course of infection are not well characterized. IgG antibodies to SARS-CoV-2 become detectable later following infection. Positive results for both IgG and IgM could occur after infection and can be indicative of acute or recent infection.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first few days of infection; the sensitivity of the qSARS-CoV-2 IgG/IgM Rapid Test early after infection is unknown.

False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

At this time, it is unknown for how long IgM or IgG antibodies may persist following infection.

For prescription use only. For in vitro diagnostic use only. For emergency use authorization use only.

2. SUMMARY AND PRINCIPLE OF THE ASSAY

Coronavirus (CoV) belongs to order Nidovirales, family Coronavirus, and is divided into α、β、γ three genera. The α、β genera is only pathogenic to mammals, while the γ genus mainly causes infection in birds. CoV is mainly transmitted by direct contact with secretions, by aerosol or droplet, and there is also evidence that it can be transmitted by fecal-oral route.

So far, there have been seven types of human coronavirus (HCoV) that cause respiratory diseases in humans: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and SARS-CoV-2 is an important pathogen of human respiratory tract infection. Among them, the SARS-CoV-2 by wuhan viral pneumonia cases were found, the clinical manifestation of systemic symptoms such as fever, fatigue, dry cough, dyspnea, etc., can rapidly develop severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock and multiple organ failure, severe alkali metabolic disorders, etc., and even life threatening.

The COVID-19 IgM/IgG Antibody Test (Colloidal Gold) is intended for qualitative detection of antibodies indicative of SARS-CoV-2 infection and is to be used as an aid for diagnosis of SARS-CoV-2 infection.

3. Test principle

The COVID-19 IgM/IgG Antibody Test (Colloidal Gold) is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing SARS-CoV-2 antigens conjugated with colloid gold (COVID-19 conjugates), 2) a nitrocellulose membrane strip containing two test bands (M and G bands) and a control band (C band). The M band is pre-coated with monoclonal anti-human IgM for the detection of SARS-CoV-2 IgM antibodies, G band is pre-coated with reagents for the detection of SARS-CoV-2 IgG antibodies, and the C band is pre-coated with quality control antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. SARS-CoV-2 IgM antibodies if present in the specimen will bind to the COVID-19 conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a burgundy colored M band, indicating a SARS-CoV-2 IgM positive test result.

SARS-CoV-2 IgG antibodies if present in the specimen will bind to the COVID-19 conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy colored G band, indicating a SARS-CoV-2 IgG positive test result.

Information regarding the immune response to SARS-CoV-2 is limited and still evolving. At this time, it is unknown how long IgM or IgG antibodies may persist following infection.

Absence of any test bands (M and G) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band regardless of the color development on any of the test bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

4. PACKAGE CONTENTS

1) Pouch contents: Test cassette, desiccant.

2) 10 μl capillary pipette

3) Sample buffer (5ml) per bottle for 20 tests

4) Test instruction.

5. MATERIAL PROVIDED

1) Lancet.

2) Alcohol wipe.

6. WARNINGS AND PRECAUTIONS

1) For professional in vitro diagnostic use only.

2) Do not reuse.

3) Do not use if the pouch seal or its packaging is compromised.

4) Do not use after the expiration date shown on the pouch.

5) Do not mix and interchange different specimens.

6) Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.

7) Wash hands thoroughly after finishing the tests.

8) Do not eat, drink or smoke in the area where the specimens or kits are handled.

9) Clean up spills thoroughly with appropriate disinfectants.

10) Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.

11) Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.

12) Keep out of children's reach.

7. SPECIMEN PREPARATION

1) Suitable for human serum, plasma or whole blood samples, including those prepared by clinical anticoagulants (EDTA, heparin, sodium citrate).

2) Test specimens as soon as possible after collecting. Store specimens at 2°C to 8°C if not tested immediately. Store serum and plasma specimens at 2°C to 8°C up to 5 days. The specimens should be frozen at -20°C for longer storage. Avoid multiple freeze-thaw cycles. Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.

3) 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.

4) Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference on result interpretation.

8. ASSAY PROCEDURE

1) Bring the specimen and test components to room temperature（15～30 ℃） if refrigerated or frozen. Mix the specimen well prior to assay once thawed.

2) When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

3) Be sure to label the device with specimen's ID number.

4) Fill the pipette dropper with the specimen. Holding the dropper vertically, dispense 10 μL of specimen into the sample well making sure that there are no air bubbles.

5) Then add 2 drops (about 70-100 μL) of Sample Diluent immediately.

10 μL of specimen　　2 drops of sample diluent

6) Set up timer. Results can be read in 15 minutes.

Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

9. RESULT INTERPRETATIONS

Negative

If only the C band is present, the absence of any burgundy color in the both test bands (M and G) indicates that no SARS-CoV-2 antibody is detected in the specimen. The result is negative.

Positive

In addition to the presence of C band, if only M band is developed, the test indicates for the presence of SARS-CoV-2 IgM antibody. The result is positive.

In addition to the presence of C band, if only G band is developed, the test indicates for the presence of SARS-CoV-2 IgG antibody. The result is positive.

In addition to the presence of C band, both M and G bands are developed, the test indicates for the presence of both IgG and IgM SARS-CoV-2. The result is also positive.

Invalid

If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands as indicated below. Repeat the assay with a new device.

Negative results do not rule out SARS-CoV-2 infection, particularly for patients who have been in contact with known infected persons or in areas with high prevalence of active infection. Follow-up testing with a molecular diagnostic test is necessary to rule out infection in these individuals.

Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.

False positive results may occur due to cross-reacting antibodies from previous infections, such as other coronaviruses, or from other causes

Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.

10. STORAGE AND STABILITY

1) Store in a dry place at 2 ~ 30°C away from light.

2) After opening the inner package, the test cassette will fail due to moisture absorption. Please use it within 1 hour.

3)Valid for 18 months.

4) The test results were valid within at least 4 hours after the reagent was opened.

11. LIMITATIONS

1) The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to SARS-CoV-2 in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.

2) The sample should be tested in the laboratory with certain conditions. All samples and materials in the testing process shall be handled in accordance with the laboratory practice for infectious diseases.

3) The COVID-19 IgM/IgG Antibody Test (Colloidal Gold) is limited to the qualitative detection of antibodies to SARS-CoV-2 in human serum, plasma or whole blood.

4) A negative result can occur if the quantity of SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.

5) Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.

6) The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical

12. PERFORMANCE CHARACTERISTICS

Diagnostic Sensitivity and Specificity

300 samples were collected from selected subjects, all samples were tested with COVID-19 IgM/IgG Antibody Test (Colloidal Gold) and the COVID-19 nucleic acid detection kit (by fluorescent PCR method) produced by Shanghai ZJ Bio-Tech Co., Ltd. Calculated the specificity and sensitivity, in which COVID-19 IgM/IgG Antibody Test (Colloidal Gold) are all positive regardless of IgM positive or IgG positive, the results are as follows:

ShangHai ZJ	COVID-19 IgM/IgG Antibody Test (Colloidal Gold)		Total
	POS	NEG	
POS	160	3	163
NEG	8	129	137
Total	168	132	300

Diagnostic Sensitivity: 160/(3+160)×100%=98.2% (95% CI: 94.7%-99.4%)

Diagnostic Specificity: 129/(8+129)×100%=94.2% (95% CI: 89.1%-97.1%)

Overall Agreement: (160+129)/300×100%=96.3% (95% CI: 93.6%-98.0%)

300 samples were collected from selected subjects, all samples were tested with COVID-19 IgM/IgG Antibody Test (Colloidal Gold) and COVID-19 antibody detection reagent (by immunochromatography) produced by Guangzhou Wondfo Biotechnology Co., Ltd. Calculated the specificity and sensitivity, the results are as follows:

IgG of GuangZhou Wondfo	IgG of COVID-19 IgM/IgG Antibody Test (Colloidal Gold)		Total
	POS	NEG	
POS	137	6	143
NEG	5	152	157
Total	142	158	300

Diagnostic Sensitivity: 137/(6+137)×100%=95.8% (95% CI: 91.1%-98.0%)

Diagnostic Specificity: 152/(5+152)×100%=96.8% (95% CI: 92.8%-98.6%)

Overall Agreement: (137+152)/300×100%=96.3% (95% CI: 93.6%-97.9%)

300 samples were collected from selected subjects, all samples were tested with COVID-19 IgM/IgG Antibody Test (Colloidal Gold) and COVID-19 IgM / IgG combined detection kit (by colloidal gold method) produced by Innovita (TangShan) Biological Technology Co.,Ltd. Calculated the specificity and sensitivity, the results are as follows:

IgM of Innovita	IgM of COVID-19 IgM/IgG Antibody Test (Colloidal Gold)		Total
	POS	NEG	
POS	130	5	135
NEG	4	161	165
Total	134	166	300

Diagnostic Sensitivity: 130/(5+130)×100%=96.3% (95% CI: 91.6%-98.4%)

Diagnostic Specificity: 161/(4+161)×100%=97.6% (95% CI: 93.9%-99.0%)

Overall Agreement: (130+161)/300×100%=97.0% (95% CI: 94.4%-98.4%)

IgG of Innovita	IgG of COVID-19 IgM/IgG Antibody Test (Colloidal Gold)		Total
	POS	NEG	
POS	136	6	142
NEG	6	152	158
Total	142	158	300

Diagnostic Sensitivity: 136/(6+136)×100%=95.8% (95% CI: 91.1%-98.0%)

Diagnostic Specificity: 152/(6+152)×100%=96.2% (95% CI: 92.0%-98.2%)

Overall Agreement: (136+152)/300×100%=96.0% (95% CI: 93.1%-97.7%)

Analysis of Sensitivity and Specificity

Inactive COVID-19 IgM/IgG sensitivity panel including 3 SARS-COV-2 IgM positive serum (Strong, medium and weak), 3 SARS-COV-2 IgG positive serum(Strong, medium and weak), and one negative serum was applied to validate the analysis sensitivity of COVID-19 IgM/IgG Antibody Test (Colloidal Gold) and parallelly refer with the testing results of CE approved commercial Wondfo SARS-COV-2 Antibody Test. COVID-19 IgM/IgG Antibody Test (Colloidal Gold) could identify all the positive samples and showed the similar sensitivity with reference CE approved commercial Wondfo SARS-COV-2 Antibody Test to COVID-19 IgM/IgG Sensitivity Panel. No false positive or negative results were observed.

COVID-19 IgM/IgG Antibody Test (Colloidal Gold) showed no cross reaction with seromarkers associated with unrelated medical conditions: CRP, RF, HIV, HBV serum markers (HBsAg, anti-HBc IgM/IgG), HCV, herpes simplex virus IgG (HSV), cytomegalovirus IgM/IgG, mycoplasma IgM, Dengue Virus IgM/IgG and negative samples also included 50 health serum from blood donors and 20 health whole blood samples from blood donors.

Repeatability and Reproducibility

Tests showed positive results with all positive samples and showed negative results with negative samples. There was no significant difference observed to the same sample when repeatedly testing 10 tests in the same batch. No appreciable intra and inter lot variation were observed among different tests for each lot, different lots for the same sample.

The results demonstrated that the repeatability and reproducibility of COVID-19 IgM/IgG Antibody Test (Colloidal Gold) are satisfactory.

Interfering Substances

The following compounds have been tested using the COVID-19 IgM/IgG Antibody Test (Colloidal Gold) and no interference was observed.

Acetaminophen	20 mg/dl	Atropine	20 mg/dl
Acetylsalicylic acid	20 mg/dl	Cannabinol	10 mg/dl
Ascorbic acid	20 mg/dl	Ethanol	1%
Caffeine	20 mg/dl	Methanol	1%
Gentesic acid	20 mg/dl	Albumin	2,000mg/dl
Phenylpropanolamine	20 mg/dl	Glucose	2,000mg/dl
Salicylic acid	20 mg/dl	Bilirubin	1,000mg/dl
EDTA	80 mg/dl	Hemoglobin	1,000mg/dl
Benzoylecgonine	10 mg/dl	Triglyceride	50 mg/dL
Total cholesterol	6mmol/L		

13. BIBLIOGRAPHY

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Index of Symbols

	Attention, see instructions for use
IVD	For In-Vitro Diagnostic Use only
	Store between 2 – 30 centigrade
	Do Not use if package is damaged
	Test per kit
	Use by
LOT	Lot Number
EC REP	Authorized Representative
	Do NOT Reuse
REF	Catalogue No
CE	CE Mark

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