FOR RESEARCH USE ONLY!

Coronavirus IgM/IgG Antibody Detection Card

rev 04/20

(Catalog # K1463-25, -50, -100; 25, 50 or 100 Tests; Store at 4°C)

I. Introduction:

Coronavirus (SARS-CoV-2) IgM/IgG Antibody Detection Card is used for the qualitative, *in vitro* detection of IgM and IgG antibodies against the novel Coronavirus (Sars-Cov-2) in human serum, plasma, whole blood or fingertip blood. The detection is based on the colloidal gold immune-technology for detecting novel Coronavirus nucleoprotein (N)/spike glycoprotein (S) IgM or IgG antibodies. The Test Card contains a **nitrocellulose membrane** and a **combination card**. The detection area of the nitrocellulose membrane is coated with mouse anti-human IgG and mouse anti-human IgM antibodies to detect the novel Coronavirus nucleoprotein (N)/spike glycoprotein (S) antibodies and the control area is coated with rabbit anti-chicken IgY. The combination card comprises of sprayed colloidal gold labeled recombinant novel Coronavirus nucleoprotein (N)/spike glycoprotein (S) antigen and chicken IgY, sample pad, absorbent pad and a PVC soleplate.

If the sample contains the novel Coronavirus nucleoprotein (N)/spike glycoprotein (S) IgM or IgG antibodies, these antibodies will bind to the gold labeled virus antigen. The binding of antibodies in the sample to the antigen forms a sandwich immune complex with the coated anti-human IgM and IgG monoclonal antibodies, which develops a purplish red color indicating that the novel Coronavirus nucleoprotein (N)/spike glycoprotein (S) antibodies are present in the sample. We offer the **IgM/IgG Antibody Detection Card** for researchers to quickly detect Coronavirus in samples and aid in research on Coronavirus.

II. Application:

- A rapid tool to detect Coronavirus nucleoprotein (N)/spike glycoprotein (S) IgG and IgM antibodies

III. Key Features:

- Rapid, easy and convenient
- **Obtain results in 3-15 min**
- **High sensitivity and specificity**
- Direct observation without any instruments

IV. Sample Types:

- Human serum, plasma, whole blood or fingertip blood

V. Contents:

Components	K1463-25 (25 Tests)	K1463-50 (50 Tests)	K1463-100 (100 Tests)	Part Number
Test Card	25	50	100	K1463-XX-1
Sample Diluent	25 X 450 µl	50 X 450 µl	100 X 450 µl	K1463-XX-2
Dessicant bag	1	1	1	K1463-XX-3

VI. User Supplied Reagents and Equipment:

- Pipettes
- Pipette tips

VII. Shipping and Storage Conditions:

The kit should be stored at 4°C. The components will be stable for 6 months if stored properly. The test strip should be used within 20 min once the foil pouch is opened.

VIII. Reagent Preparation and Storage Conditions:

Before proceeding with the test, please bring the sample diluent buffer and the test card to room temperature (RT) by incubating for more than 30 min. Damaged test strips or package should not be used for the test.

IX. Detection Protocol:

1. Assay Principle:

a. The antibodies IgG and IgM are the most commonly used markers of infectious diseases. IgM is produced first during infection and is usually used as a marker of acute infection. IgM gradually decreases and disappears after the appearance of IgG. IgG usually exists in the body for a longer time, even after the virus has been completely eliminated. A **Positive Result** can be used as an indicator of a current or previous infection of Coronavirus.

b. The Coronovirus Detection Card is based on the colloidal gold immune-technology to detect novel Coronavirus IgM and IgG antibodies. The **Test Card** contains a **nitrocellulose membrane** and a **combination card**. The detection area of the **nitrocellulose membrane** is coated with mouse anti-human IgG and mouse anti-human IgM antibodies and the control area is coated with rabbit anti-chicken IgY. The **combination card** comprises of sprayed colloidal gold labeled recombinant novel Coronavirus nucleoprotein (N)/spike glycoprotein (S) antigen and chicken IgY, sample pad, absorbent pad and a PVC soleplate.

c. The **nitrocellulose membrane** is coated with two test lines (M and G) and a control line (C). The M and G lines are coated with mouse anti-human IgM monoclonal antibodies and mouse anti-human IgG monoclonal antibodies respectively to detect the novel Coronavirus nucleoprotein (N)/spike glycoprotein (S) antibodies. The C line is coated with quality-control antibodies.

d. When the Coronavirus sample is added to the sample hole of the Test Card, the sample will move along the detection card by chromatography. If the sample contains novel Coronavirus nucleoprotein (N)/spike glycoprotein (S) IgM or IgG antibodies, the antibodies will bind to the gold labeled novel Coronavirus nucleoprotein (N)/spike glycoprotein (S) antigen. This binding to antigen forms an immune sandwich complex with the coated anti-human IgM or IgG monoclonal antibody at the M or G line. The immune complex develops a **purplish red color** at the M or G line which indicates the presence of novel Coronavirus nucleoprotein (N)/spike glycoprotein (S) IgM or IgG antibodies in the sample.

2. Sample Preparation:

a. The Coronovirus Detection Card can be used to detect Coronavirus in serum or EDTA, heparin and sodium citrate anticoagulant treated plasma or whole blood samples.

b. Immediately after specimen collection, shake up and down 5-10 times. Do not shake the specimen vigorously with force.

c. The samples should be detected immediately after collection. If samples cannot be detected immediately, they should be stored at low temperatures. Samples can be stored at 2-8°C for 48 hr and at -20°C for 3 months.

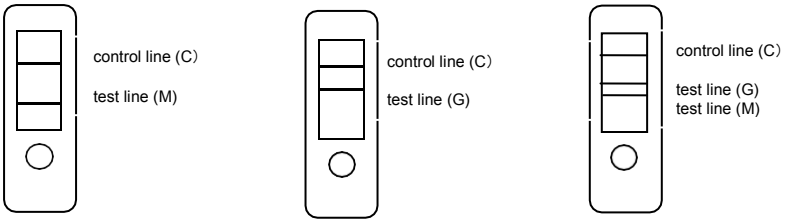
d. Samples with severe lipemia, turbidity, microbial contamination, repeated freeze-thaw and hemolytic samples should not be used.

3. Test Protocol:

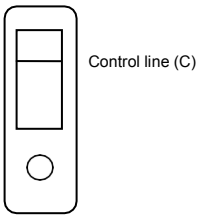
a. Equilibrate the **Test Card**, Sample and Sample Diluent at RT for 30 min (15°C-30°C) before testing.
b. Open the aluminum foil bag of the **Test Card**. Take out the Test Card and place it horizontally on the desktop.
c. Use a pipette to add 10 µl of the serum, plasma or 20 µl of the whole blood to the sample hole**.** Then add 60 µl of the **Sample Diluent** to the sample hole of the Test Card.
d. **Read** the test result within 15 min. The results read after 18 min are invalid.

4. Interpretation of Results:

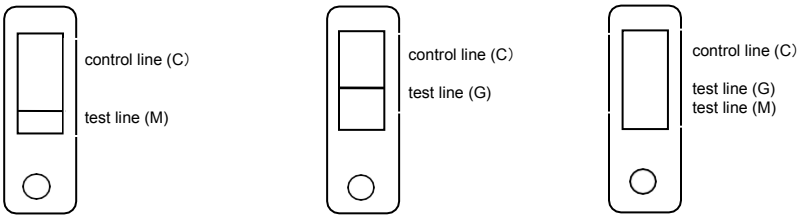
a. **Positive Result:** If both the test line (G) and the control line (C) show purple color bands, then the result is positive indicating the presence of IgG antibodies of novel Coronavirus nucleoprotein (N)/spike glycoprotein (S). If both the test line (M) and the control line (C) show purple color bands, then the result is positive indicating the presence of IgM antibodies of novel Coronavirus nucleoprotein (N)/spike glycoprotein (S). If all the test lines (M), (G) and control line (C) show color bands, then the result is positive indicating the presence of the novel Coronavirus nucleoprotein (N)/spike glycoproteins (S) IgM and IgG antibodies.



b. **Negative Result:** If only the control line C shows color, but the G and M test lines do not show color, the result is negative showing absence of IgM/IgG antibodies of novel Coronavirus nucleoprotein (N)/spike glycoprotein (S).



c. **Invalid Result:** Invalid result is confirmed if color does not develop at the control line, even if the test lines (G and M) show color.



5. Analysis Specificity:

a. Cross Reactivity:

i. The reagent has no cross reactivity with the following pathogens: human Coronaviruses (hku1, OC43, nl63 and 229E), H1N1 (the new influenza A H1N1 virus (2019), seasonal H1N1), H3N2, H5N1, H7N9 influenza B Yamagata, Victoria, respiratory syncytial virus, rhinovirus A, B, C groups, adenovirus, 1, 2, 3, 4, 5, 7, 55, enterovirus group A, B, C, D, EB virus, measles virus, human cytomegalovirus, rotavirus, norovirus, mumps virus, varicella zoster virus, and mycoplasma pneumoniae samples.

b. Interfering Substances:

i. When the bilirubin concentration is ≤0.2 g/l, hemoglobin content is ≤5 g/l and triglyceride content is ≤10 g/ l, there is no interference with the test results.
ii. The test results are not affected by α-interferon, zanamivir, ribavirin, oseltamivir, ceftriaxone, meropenem, ritonavir, abidor, rheumatic factor, anti- nuclear antibody and anti-mitochondrial antibody.

6. Sensitivity and Clinical performance:

In vitro diagnostic reagents were compared with the clinical diagnostic criteria of novel Coronavirus pneumonia. The test results showed that the clinical sensitivity of the product was 88.12% (95% CI: 83.12%, 90.26%), and the specificity was 99.23% (95% CI: 96.19%, 99.92%). In addition, 257 patient's homologous serum/plasma and whole blood samples (including 45 positive and 25 negative) were selected for comparative tests. The results showed that with reference to the serum/plasma test results, the whole blood test results of the new Coronavirus IgG antibody positive coincidence rate was: 93.33% (95% CI: 87.21% ~95.12%), IgM antibody positive coincidence rate was: 97.78% (95% CI: 90.12% ~98.99%), negative coincidence rate was: 100.00% (95% CI: 96.12% ~98.0%) and total consistency rate was: 97.78% (95% CI: 93.12% ~98.05%).

7. Limitations:

a. The Coronavirus card is intended for research use only. Test results may be wrong due to technical reasons, operational errors and other sample factors.

b. Positive test results should be carefully analyzed in persons who have received blood transfusions or other blood products in recent months.
c. This product contains animal-derived substances. Although it is not contagious, it should be treated with care as a potential source of infection while handling. Users should take precautions to ensure their safety and that of others. After the test is completed, the used Test Cards, Sample Diluents, etc. should be treated as biomedical waste.
d. This product is a single-use reagent. Do not reuse it.

X. Related Products:

Product Name	Cat. No.	Sizes
Coronavirus (SARS-CoV-2) PCR Detection Kit	K1461	100 Rxns
Coronavirus Sample preparation Kit	M1461	250 Preps
ACE2 (Human) ELISA Kit	E4528	100 Assays
Angiotensin II Converting Enzyme (ACE2) Activity Assay Kit (Fluorometric)	K897	100 Assays
Human CellExp™ Coronavirus Spike Protein (SARS-CoV-2; S1), Recombinant	P1524	10 µg
Recombinant Coronavirus Envelope Protein (SARS-CoV ENV;1-76)	P1503	10 µg, 50 µg
Anti-SARS-CoV-2 Antibody	A2061	50 µg
Anti-SARS-CoV-2 Antibody (Clone# 6F10)	A2060	50 µg

FOR RESEARCH USE ONLY! Not to be used on humans.

UK & Rest of the World
184 Park Drive, Milton Park
Abingdon OX14 4SE, UK
T: +44 (0)1235 828 200
F: +44 (0) 1235 820 482

North America
1035 Cambridge Street,
Cambridge, MA 02141
T: +1 (617) 945-5033 or
T: +1 (800) 987-0985
F: +1 (617) 945-8218

Germany
Bockenheimer Landstr. 17/19
60325 Frankfurt/Main
T: +49 (0) 69 779099
F: +49 (0) 69 13376880

Switzerland
Centro Nord-Sud 2E
CH-6934 Bioggio-Lugano
T: +41(0) 91 604 55 22
F: +41(0) 91 605 17 85