COVID-19 IgG/IgM Immunodetection Kit

NBP2-89106

For detection of COVID-19 antibodies in Human Serum, Plasma or Whole Blood.

For research use only.

Not for diagnostic or therapeutic procedures.
INTENDED USE
COVID-19 IgG/IgM Immunodetection kit is a chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum, or plasma.

BACKGROUND
COVID-19 (Corona Virus Disease) is an infectious disease caused by the most recently discovered coronavirus, SARS-COV-2. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019. Coronaviruses are enveloped positive-sense RNA viruses. Prior to the appearance of SARS-CoV-2, six coronaviruses were known to cause human infection. Sars-CoV-2 is highly infectious and causes a potentially fatal atypical pneumonia, named Coronavirus disease 2019 (COVID-19) by the World Health Organization (WHO).

Serological assays are commonly used in research for detection of antibody responses caused by viral infection. In an immune response, IgM antibodies appear in the early stage, followed by the appearance of IgG during the mid to late disease stages. However, antibodies may be undetectable during the initial stages of viral infection.

DETECTION PRINCIPLE
COVID-19 IgG/IgM Immunodetection kit is a lateral flow immunoassay (FLA) that utilizes a combination of COVID-19 antigen coated colored particles for the detection of IgG and IgM antibodies to COVID-19 in human whole blood, serum, or plasma. The cassette has two test lines, an IgG line and an IgM line. Anti-human IgG is coated in the IgG test line and anti-human IgM is coated in IgM test line.

During testing, the sample is exposed to COVID-19 antigen-coated particles in the cassette. The mixture then migrates upward on the membrane due to capillary action. If the sample contains IgG antibodies to COVID-19, it will react with the anti-human IgG antibodies and a colored line will appear in the IgG test line. If the sample contains IgM antibodies to COVID-19, it will react with the anti-human IgM antibodies and a colored line will appear in the IgM test line.

If the sample does not contain antibodies to COVID-19, no colored line will appear in either of the test lines. A colored line will appear in the quality control line, indicating that the proper volume of sample has been added and membrane wicking has occurred.

REAGENTS
The test cassette contains antigen conjugated gold colloid particles and anti-human IgM antibodies, anti-human IgG antibodies coated on the membrane.
PRECAUTIONS
1. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where samples or kits are handled.
3. Handle all samples cautiously as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of samples.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
5. The used tests, samples and potentially contaminated should be discarded according to the local regulation.
6. Humidity and temperature can adversely affect results.

KIT STORAGE AND STABILITY
The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable before the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use after the expiration date.

SAMPLE STORAGE
Serum and plasma samples may be stored at 2-8°C for up to 3 days. For long-term storage, samples should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood samples.

MATERIALS
Materials supplied
* Test cassettes: 40T/Kit
* Buffer (7 mL)
* Droppers: 40D/Kit
* Desiccant

Materials required but not provided
* Samples: Serum, Plasma, or Whole Blood
* Centrifuge (for plasma only)
* Micropipette (if preferred over droppers)
* Timer

PROCEDURE
1. 1 drop (~20 μL) of serum/plasma/whole blood
2. 1 drop (~40 μL) of buffer for serum/plasma or 3 drops (~100 μL) for whole blood
* Bring donor samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.

* Keep the test cassette, sample, buffer, and/or controls to room temperature (15-30°C) prior to testing. The results will be affected by high or low temperature

* Bring the pouch to room temperature before opening. Take the test cassette from the sealed pouch and use it within one hour.

* Place the test cassette on a clean and level surface.

**For Serum or Plasma Samples**

* To use a dropper: Hold the dropper vertically, draw the sample and transfer the sample to the sample well of the test cassette (one drop/approximately 20 μL), then add 1 drop of buffer (approximately 40 μL) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

* To use a micropipette: Pipette and dispense 20 μL of sample to the sample well of the test cassette, then add 40 μL of buffer to the sample well and start the timer.

**For Whole Blood Samples**

* To use a dropper: Hold the dropper vertically, draw the sample and transfer the sample to the sample well of the test cassette (1 drop/approximately 20 μL), then add 3 drops of buffer (approximately 100 μL) to the sample well and start the timer. Avoid trapping air bubbles in the sample well.

* To use a micropipette: Pipette and dispense 20 μL of sample to the sample well of the test cassette, then add 100 μL of buffer to the sample well and start the timer.

* Wait for the colored line(s) to appear. The test result should be read in 10 minutes. The result is valid within 20 minutes.

**PRODUCT DESCRIPTION**

1. **IgG and IgM POSITIVE: Three lines appear.**
   One colored line should be in the control line (C) and a colored line should appear in both the IgG test line and the IgM test line. NOTE: Any shade of color in the IgG and/or IgM test line should be considered positive. The color intensities of the lines do not have to match.

2. **IgG POSITIVE: Two lines appear.**
   One colored line should be in the control line (C) and a colored line appears in the IgG test line.

3. **IgM POSITIVE: Two lines appear.**
   One colored line should be in the control line (C) and a colored line appears in the IgM test line.

4. **IgG and IgM NEGATIVE: One colored line should be in the control line (C). No lines appear in IgG and IgM test line.**

5. **INVALID: Quality control line fails to appear.**
   Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new cassette. If the problem persists, discontinue using the kit immediately and contact your local distributor.
TEST PROCEDURE

1. Cross-reactivity
This immunoassay does not detect parainfluenza virus, influenza A virus, influenza B virus, Chlamydia pneumoniae, Mycoplasma pneumoniae, adenovirus, respiratory syncytial virus, hepatitis B surface, type C Hepatitis virus, Treponema pallidum, human immunodeficiency virus, EB virus, measles virus, cytomegalovirus, enterovirus 71, mumps virus, HKU1 virus, OC43 virus, NL63 virus, 229E virus and chicken pox-zoster virus.

2. Non-interfering substances
≤250 μmol/L Bilirubin, ≤9 g/L hemoglobin, ≤15 mmol/L triglyceride, ≤80IU/mL rheumatoid factor, and ≤ 1: 240 the antinuclear antibody (ANA), ≤80U/mL anti-mitochondrial antibody (AMA), and ≤1000μg/mL mouse IgG, Histamine hydrochloride, alpha-interferon, zanamivir, ribavirin, oseltamivir, peramivir, lopinavir, ritonavir, abidol, levofloxacin, azithromycin, Ceftriaxone, meropenem, and tobramycin.

3. Sensitivity
1 U/mL for IgM and 0.5 U/mL for IgG

ADDITIONAL INFORMATION

LIMITATIONS

1. COVID-19 IgG/IgM Immunodetection kit should only be used for the detection of COVID-19 antibodies in serum, plasma or whole blood samples. Neither the quantitative value nor the rate of increase in COVID-19 antibody concentrations can be determined by this qualitative kit.

2. COVID-19 IgG/IgM Immunodetection kit will only indicate the presence of COVID-19 antibodies in the sample and should not be used for the diagnosis of a COVID-19 infection.