COVID-19 IgM/IgG Antibody Detection Kit
(Colloidal Gold Immunochromatography) Manual

Catalog#  
YXI-CoV-1gM&IgG

PRODUCT SPECIFICATIONS
1 test / kit, 10 tests/box.

EXPECTED USAGE
This kit is suitable for the qualitative detection of COVID-19 by detecting SARS-CoV-2 IgM/IgG antibodies in human serum, plasma, or whole blood. Common signs of infection with SARS-CoV-2 include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death. SARS-CoV-2 can be excreted through respiratory secretions or transmitted through oral fluids, sneezing, physical contact, and through air droplets.

DETECTION PRINCIPLES
The principle of immunochromatography of this kit: the separation of components in a mixture through a medium using capillary force and the specific and rapid binding of an antibody to its antigen. This test consists of two cassettes, an IgG cassette and an IgM cassette. In the IgM cassette, is a dry medium that has been coated with a SARS-CoV-2 recombinant antigen (“T” test line) and a goat anti-mouse polyclonal antibodies (“C” control line). The colloidal gold-labeled antibodies, mouse anti-human IgM (mIgM) is in the release pad section. Once diluted serum, plasma, or whole blood is applied to the sample pad section(S), the mIgM antibody will bind to SARS-CoV-2 IgM antibodies if they are present, forming an mIgM-IgM complex. The mIgM-IgM complex will then move across the nitrocellulose filter(NC filter) via capillary action. If SARS-CoV-2 IgM antibody is present in the sample, free mIgM will not bind to the test line (T) and no color will develop. The free mIgM will bind to the control line (C); this control line should be visible after the detection step as this confirms that the kit is working properly.

Once diluted serum, plasma, or whole blood is applied to the sample pad section(S), the colloidal gold-labeled antibodies, SARS-CoV-2 recombinant antigen and chicken IgY antibody are in the release pad section. Once diluted serum, plasma, or whole blood is applied to the sample pad section(S), the colloidal gold-labeled antibodies, SARS-CoV-2 recombinant antigen will bind to SARS-CoV-2 IgG antibodies if they are present, forming an IgG-IgG complex. The IgG-IgG complex will then move across the nitrocellulose filter(NC filter) via capillary action. If SARS-CoV-2 IgG antibody is present in the sample, free IgG will bind to the test line (T) and no color will develop. The free IgG will bind to the control line (C); this control line should be visible after the detection step as this confirms that the kit is working properly.

INTERPRETATION OF TEST RESULTS
IgG POSITIVE:* Two lines appear. One coloured line should be in the control line region (C), and a coloured line appears in the IgG test line region. The result is positive for SARS-CoV-2 specific-IgG antibodies.

IgM POSITIVE:* Two lines appear. One coloured line should be in the control line region (C), and a coloured line appears in the IgM test line region. The result is positive for SARS-CoV-2 specific-IgM antibodies.

IgG and IgM POSITIVE:* Both the test line (T) and the quality control line (C) are colored in an IgG cassette and an IgM cassette.

*NOTE: The intensity of the colour in the test line regions will vary depending on the titre of SARS-CoV-2 antibodies present in the specimen. Therefore, any shade of colour in the test line region should be considered positive.
NEGATIVE: One coloured line appears in the control region (C). No apparent coloured line appears in the IgG or IgM test region (T).

INVALID: Control line fails to appear. Insufficient sample 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATION OF DETECTION METHOD
a. The product is designed only for use with human serum, plasma, whole blood samples for the qualitative detection of SARS-CoV-2 IgM and IgG antibody.
b. As in case of all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test but should rather be made after all the clinical findings have been evaluated and should be confirmed by other conventional detection methods.
c. A false negative may occur if the amount of SARS-CoV-2 IgM or IgG antibody is below the detection level of the kit.
d. If the product gets wet prior to use, or is stored improperly, it may cause incorrect results.
e. The test is for qualitative detection of SARS-CoV-2 IgM or IgG antibody in human serum, plasma or blood sample and does not indicate the quantity of the antibodies.

PRECAUTIONS
a. This product is for research use only.
b. The assay should be performed as outlined in this manual, and in accordance with all instructions.
c. Do not use expired or damaged products.
d. Only use the matching diluent in the kit package. Diluents from different kit lots cannot be mixed.
e. Do not use tap water, purified water or distilled water as negative controls.
f. The test should be used within 1 hour after opening. If the ambient temperature is higher than 30 °C, or the test environment is humid, the Detection Cassette should be used immediately.
g. If there is no movement of the liquid after 30 seconds of beginning the test, additional drop of sample solution should be added.
h. Take care to prevent the possibility of virus infection when collecting samples. Wear disposable gloves, masks, etc., and wash your hands afterwards.
i. This test card is designed for a single, one-time use. After use, the test card and samples should be regarded as medical waste with risk of biological infection and properly disposed of in accordance with relevant national regulations.

OPERATION DESCRIPTION (For self-test with peripheral blood)

To stimulate blood flow, massage the finger tip from which blood will be collected.

Wipe the finger tip with cotton alcohol towel and let it dry naturally.

WARNING:
- This test has not been reviewed by the FDA.
- 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.
- 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.
- 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.
- If required, please refer to SDS document at www.aurorabiomed.com