COVID-19 IgM and IgG Dual Antibody Rapid Test Kit for Finger Prick Samples
Catalog # CG-CoV-IgM/IgG-FP

*** This test has not been reviewed by the FDA ***

For in vitro diagnostics and following FDA policy for the public health emergency

• PRODUCT NAME

Generic name: COVID-19 IgM and IgG Antibody Detection Kit (Colloidal Gold Method) for Finger Prick Samples.

• PRODUCT SPECIFICATIONS

20 tests/box

• EXPECTED USAGE

This kit is suitable for the qualitative detection of novel coronavirus (SARS-CoV-2) IgM and IgG antibodies in human whole blood from a finger prick. Common signs of a person infected with a coronavirus include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome (SARS), kidney failure, and even death. Coronavirus can be excreted through respiratory secretions or transmitted through oral fluids, sneezing, physical contact, and through air droplets.

• DETECTION PRINCIPLES

The detection kit uses the principle of immunochromatography: 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. Each cassette is a dry medium that has been coated separately with novel coronavirus N protein ("T" test line) and anti-mouse antibody ("C" control line) (Figure 2). Free colloidal gold-labeled anti-human IgG are in the release pad section (S). Once diluted serum or whole blood is applied to the release pad section, the anti-human IgM and IgG antibody will bind to coronavirus IgM and IgG antibodies if they are present, forming an Ig-IgM or Ig-IgG complex. The sample and antibodies will then move across the cassette's medium via capillary action. If coronavirus IgM or IgG antibodies are present in the sample, the test line (T) will be bound by the Ig-IgM or Ig-IgG complex and develop color. If there is no coronavirus IgM or IgG antibody in the sample, free anti-human IgM or free anti-human IgG will not bind to the test line (T) and no color will develop. The free anti-human antibodies will bind to the control lines (C); these control lines should be visible after the detection step as this confirms that the kit is working properly.

• KIT COMPONENTS

Component	Specification	Quantity	Ingredients
Detection Cassette	1 unit / bag	20 bags per kit	Test cassette, desiccant
Pipette Dropper		20 per kit	
Sample Diluent	245 µl / tube	20 tubes per kit	Sample diluent, liquid
Lancet	20 units / bag	20 lancets per kit	Lancet device
Bandage	20 unit / box	20 units per kit	Bandage
Alcohol pad	20 unit / box	20 units per kit	Alcohol pad

The components of the Detection Cassette are:

1. Novel coronavirus N protein (fixed on porous capillary membrane)
2. Anti-mouse antibody (fixed on porous capillary membrane)
3. Colloidal gold-labeled anti-human IgG antibody (on the release pad)

Note: The components in different batches cannot be used interchangeably.

• STORAGE AND EXPIRATION

Keep kits in a cool and dry place at 2 – 30°C. Do not freeze the individual kits and/or box. Correctly stored kits are valid for 18 months (see the kit box for expiration information).

• REQUIRED INSTRUMENTS

None

• SAMPLE PREPARATION FOR TEST

Assay is for use with human whole blood from a finger prick as indicated below:

a. Wash your hands with warm water
b. Select the finger pad you are going to prick and choose a puncture site off center of the fingertip
c. Massage and/or shake to stimulate blood flow towards the collection area
d. Clean the collection area and the pipet provided in cartridge bag with an alcohol swab (provided in kit)
e. Place the finger with chosen collection site on a flat surface facing up
f. Twist the cap off the Lancet (provided in kit) and press firmly against the collection site to puncture the finger.
g. Create a large drop of blood by applying pressure at the base of the finger and massaging upward
h. Squeeze the pipet bulb to expel air. Draw fingertip blood into the pipet by gently releasing the bulb. The pipet should be filled just up to the indicated line (refer to the Figure 1 below). Take care to avoid bubbles.
i. Expel the drawn up blood into the Sample Diluent vial and mix thoroughly by squeezing pipet 2-3 times. The sample is now ready to test.

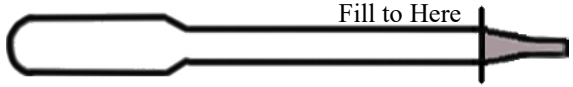

Figure 1: Representative pipette and amount of blood to draw up for test (indicated in gray).

• SAMPLE PRESERVATION

Samples should be run as soon as possible after collection per the instructions above.

• TESTING METHOD

Read the instructions carefully before use. Bring the Detection Cassette, Sample Diluent, and sample to room temperature before testing.

a. Add 2-3 drops of the prepared sample to each of the 2 release pad sections (S) of the Detection Cassette.
b. The results can be interpreted in 8-10 minutes. Results measured after 20 minutes are invalid and should be discarded.

• INTERPRETATION OF TEST RESULTS

a. Positive for coronavirus: For either the IgM or IgG side or both: Both the test line (T) and the quality control line (C) are colored.
b. Negative for coronavirus: For both the IgM and IgG sides: The test line (T) does not develop color, but the quality control line (C) is colored.
c. Invalid: There is no colored control line (C) band. The results are invalid regardless of whether a red band appears on the test line (T); repeat testing is required.

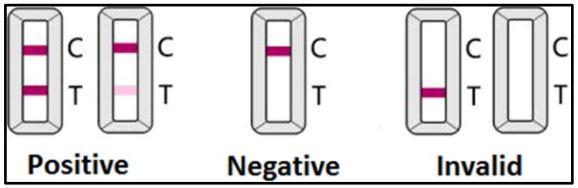

Figure 2: Representative schematic of possible lateral flow device results.

Note: Regardless of the color saturation present of the band on the test line (T), even a very weak band should be judged as a positive result.

• LIMITATION OF DETECTION METHOD

a. The product is designed only for use with human whole blood finger prick samples for the qualitative detection of novel coronavirus (SARS-CoV-2).
b. 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.
c. 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.
d. 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.
e. Coronavirus may not be detected even though coronavirus antibodies are present in the sample, leading to a false negative. This may occur if the amount of coronavirus antibodies is below the detection level of the kit.
f. If the product gets wet prior to use, or is stored improperly, it may cause incorrect results.

• PRODUCT PERFORMANCE INDEX

a. Confirmation of Positive Reference samples per batch: 3 individual positive references samples were tested, and the result should identify all as positive samples. Results found 3 of 3 to be a positive and valid result.
b. Confirmation of Negative Reference samples per batch: 20 negative reference samples and products were tested, and the results should find all samples as negative. Results found 20 of 20 samples to show a negative and valid result.
c. Minimum detection limit: 3 samples at different concentrations of antibodies were tested, whereby a correct dilution (L3) and a lower dilution (L2) should be positive, while a too far diluted sample (L1), should be negative. Results confirmed L3, and L2 as positive, while L1 was negative.
d. Repeatability: 10 Detection Cassettes for the sample positive sample across 2 different lots of Detection Cassettes were probed simultaneously. All 10 showed a positive and valid result.
e. The sensitivity to positive COV2 cases was 80.4% with IgM alone (~ >6 days post infection) and 84.1% with running of IgM and IgG detection kits.
f. The specificity of the test was 93.4% with IgM alone, and 92.3% with both IgM and IgG detection kits.

• PRECAUTIONS

a. This test has not been reviewed by the FDA.
b. This product is for in vitro diagnostic use only, following FDA guidance “Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency”.
c. The assay should be performed as outlined in this manual, and in accordance with all instructions.
d. Do not use expired or damaged products.
e. Only use the matching diluent in the kit package. Diluents from different kit lots cannot be mixed.
f. Do not use tap water, purified water or distilled water as negative controls.
g. 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.
h. If there is no movement of the liquid after 30 seconds of beginning the test, 1 additional drop of sample solution should be added.
i. Take care to prevent the possibility of virus infection when collecting samples. Wear disposable gloves, masks, etc., and wash your hands afterwards.
j. 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 national regulations.

Version: V1.0 **Date: 2020 – APR-16**

Product Code: CG-CoV-IgM/IgG-FP

For ordering information or other inquires, contact:

RayBiotech
Empowering your proteomics
3607 Parkway Lane, Suite 200
Norcross, GA 30092
1-888-494-8555
Email: info@raybiotech.com
Visit us on the web at www.RayBiotech.com

IVD