Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit for Serum, Whole blood, or Finger Prick Samples

*** This test has not been reviewed by the FDA ***
For in vitro diagnostics and following FDA policy for the public health emergency
Catalog #: CG-CoV-IgM; CG-CoV-IgM-FP

- **PRODUCT NAME**

Generic name: Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method).

- **PRODUCT SPECIFICATIONS**

20 tests/box

- **EXPECTED USAGE**

This kit is suitable for the qualitative detection of novel coronavirus (SARS-CoV-2) IgM antibodies in human serum and whole blood. 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 1). Free colloidal gold-labeled anti-human IgM are in the release pad section (S). Once diluted serum or whole blood is applied to the release pad section, the anti-human IgM antibody will bind to coronavirus IgM antibodies if they are present, forming an IgM-IgM complex. The sample and antibodies will then move across the cassette's medium via capillary action. If coronavirus IgM antibody is present in the sample, the test line (T) will be bound by the IgM-IgM complex and develop color. If there is no coronavirus IgM antibody in the sample, free anti-human IgM will not bind to the test line (T) and no color will develop. The free anti-human IgM antibody 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.

- **KIT COMPONENTS**

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

**items only included in the CG-CoV-IgM-FP kit

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 IgM 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 box for expiration date).

- **REQUIRED INSTRUMENTS**

None

- **SAMPLE REQUIREMENTS**

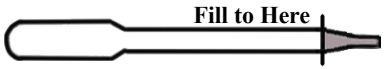
Assay is suitable for human serum, whole blood, or finger prick samples. Samples should be used as soon as possible after collection.

a. Whole blood collection: Any non-anticoagulated whole blood, including finger prick blood may be used, but the test must be processed immediately as per the "TESTING METHOD" section. These samples cannot be stored.
b. Serum collection: Samples should be collected via venous draw and should not be hemolyzed. Serum should be separated as soon as possible after blood collection to avoid hemolysis.
c. During sample processing disposable pipettes or pipette tips are required, and care must be taken to prevent cross-contamination.

- **SAMPLE PREPARATION FOR TEST**

a. If serum is used, no additional sample preparation is required.
b. If human whole blood from a finger prick is used, please prepare samples as follows:
    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 2 below). Take care to avoid bubbles.

Figure 2: Representative pipette and amount of blood to draw up (indicated in gray).



- **SAMPLE PRESERVATION**

Non-anticoagulated samples have to be run immediately. Other samples should be run as soon as possible after collection and kept at or below 8 °C at all times. If long-term storage is required, please store at -20 °C for periods less than 3 months, or store at -80 °C for periods longer than 3 months. Avoid repeated freezing and thawing.

- **TESTING METHOD**

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

a. If using serum as a sample: add 25µl to the Sample Diluent and mix thoroughly. Add 2-3 drops to the release pad section (S) of the Detection Cassette.
b. If using whole blood: Expel the drawn-up blood (see Figure 2) into the Sample Diluent vial and mix thoroughly by squeezing the pipet 2-3 times. Mixing thoroughly will prevent coagulation. Add 2-3 drops to the release pad section (S) of the Detection Cassette.
c. The results can be interpreted is 8-10 minutes. Results measured after 20 minutes are invalid and should be discarded.

INTERPRETATION OF TEST RESULTS

a. Positive for coronavirus: Both the test line (T) and the quality control line (C) are colored.
b. Negative for coronavirus: 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); additional testing is required.

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.

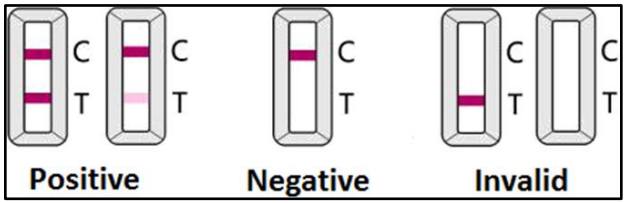


Figure 1: Representative schematic of possible lateral flow device results.

NOTE: When using whole blood, the sample front can wick into the test window from the release pad after some time (Figure 3). It is best to read the results for these samples at 5-8 minutes, before the sample front obscures the test window. If the sample front obscures the test window prior to 5 minutes, re-test with less blood in the sample diluent (25µl minimum) and/or less blood-diluent mixture to the release pad (e.g. 2 drops instead of 3 drops).

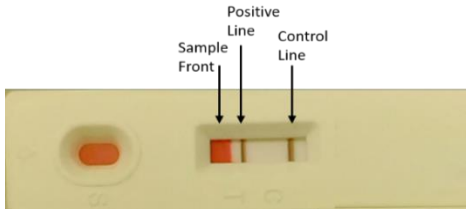


Figure 3: Example test image taken after 8 minutes showing the sample front in the test window, a positive test line, and the control line.

LIMITATION OF DETECTION METHOD

a. 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.
b. 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.
c. 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.
d. Cross reactivity to other viral antibodies was not seen against the following (<10%): CMV, FluA, FluB, HCV, HBV, HSV, RSV, PIV, RUB, Syphilis, Toxo, nor was cross reactivity seen in ANA+ patients
e. The product is designed only for use with human serum or whole blood samples for the qualitative detection of novel coronavirus (SARS-CoV-2).
f. 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. To decrease the chance of obtaining a false negative, it is recommended that both coronavirus IgG and IgM are tested (catalog #CG-CoV-IgG, # CG-CoV-IgM).
g. If the product gets wet prior to use, or is stored improperly, it may cause incorrect results.
h. Not for the screening of donated blood.

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 is 90.44% (123/136, 95%CI: 84.21-94.81%) in IgM and IgG tests combined against reference standard in an overall study population.
f. The specificity of the test was 93.4% with IgM alone, and 98.31% (1044/1062, 95%CI: 97.33-98.99%) in IgM and IgG tests combined against reference standard in an overall study population.

PRECAUTIONS

a. This test has not been reviewed by the FDA.
b. This product is for in vitro diagnostic use only, both CE approved and 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.