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Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method)

* 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

- **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 goat anti-chicken IgY antibody ("C" control line) (Figure 1). Two free colloidal gold-labeled antibodies, mouse anti-human IgM (mIgM) and chicken IgY, are in the release pad section (S). Once diluted serum or whole blood is applied to the release pad section, the mIgM 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 mIgM will not bind to the test line (T) and no color will develop. The free chicken IgY 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
Color Reference		1 card / kit	

The components of the Detection Cassette are:

1. Novel coronavirus N protein (fixed on porous capillary membrane)
2. Goat anti-chicken IgY antibody (fixed on porous capillary membrane)
3. Colloidal gold-labeled mouse anti-human IgM antibody (on the release pad)
4. Colloidal gold-labeled chicken IgY 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 or whole blood 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 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. Add 25µl of sample to the Sample Diluent and mix thoroughly. Add 2-3 drops to the release pad section (S) of the Detection Cassette.

b. 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 2019-nCoV: Both the test line (T) and the quality control line (C) are colored dark pink.
b. Negative for 2019-nCoV: The test line (T) does not develop color, or a faint gray band may be visible, but the quality control line (C) is colored.
c. Suspect: A light pink band is an inconclusive result. The sample requires an alternate testing method (such as RT-qPCR) to determine positivity.
d. 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.

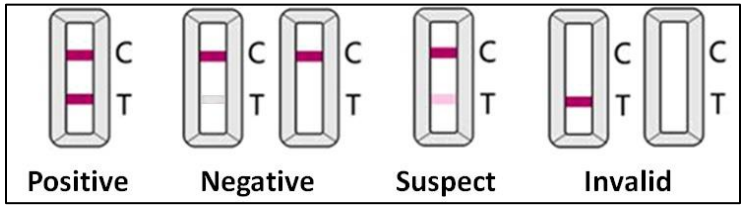

Figure 1: Representative schematic of possible lateral flow device results.
Note: If the color saturation on the test line (T) is darker than that shown for the "suspect" band, it should be judged as a positive result.

• 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 has not been determined (FluA, FluB, HCV, HBV, RSV, etc).
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. Our initial study of positive patients with China CDC found a sensitivity to positive COV2 patients of 93%, and a specificity of negative patients at 91%.

• 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.

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Product Code: CG-CVO-IgM

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