

## Novel Coronavirus (SARS-CoV-2) IgG Antibody Detection Kit (Colloidal Gold Method) Manual Catalog #: CG-CoV-IgG

### • PRODUCT NAME

Generic name: Novel Coronavirus (SARS-CoV-2) IgG 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) IgG antibodies in human serum, plasma, 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 IgG (mIgG) and chicken IgY, are in the release pad section (S). Once diluted serum, plasma, or whole blood is applied to the release pad section, the mIgG antibody will bind to coronavirus IgG antibodies if they are present, forming an IgG-IgG complex. The sample and antibodies will then move across the cassette's medium via capillary action. If coronavirus IgG antibody is present in the sample, the test line (T) will be bound by the IgG-IgG complex and develop color. If there is no coronavirus IgG antibody in the sample, free mIgG 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 per kit	Test card, dropper, desiccant
Sample Diluent	250 µl / tube	20 tubes per kit	Sample diluent, liquid

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 IgG 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 kit box for expiration information).

### • REQUIRED INSTRUMENTS

None

### • SAMPLE REQUIREMENTS

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

- a. Whole blood collection: Collection of whole blood requires a tube with anticoagulant. After anticoagulated blood is collected, shake the tube well to mix.
- b. Serum and plasma collection: Serum and plasma should be separated as soon as possible after blood collection to avoid hemolysis.
- c. Samples should be collected via venous draw and should not be hemolyzed. During sample processing disposable pipettes or pipette tips are required, and care must be taken to prevent cross-contamination..

### • SAMPLE PRESERVATION

Samples should be run as soon as possible after collection and kept at or below 8 °C at all times. Samples can be stored at 2-8°C for 7 days if not run immediately. 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.

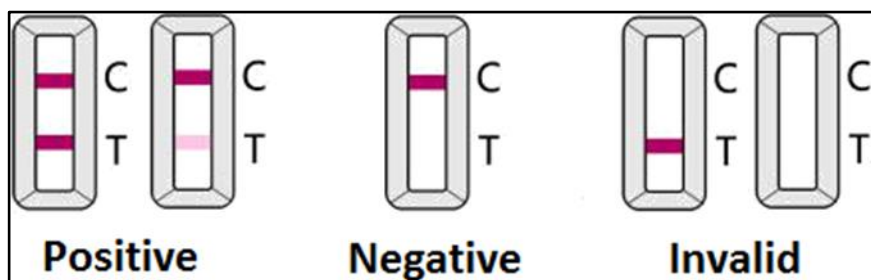
## • TESTING METHOD

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

- 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.
- The results can be interpreted is 8-10 minutes. Results measured after 20 minutes are invalid and should be discarded.

## INTERPRETATION OF TEST RESULTS

- Positive for coronavirus: Both the test line (T) and the quality control line (C) are colored.
- Negative for coronavirus: The test line (T) does not develop color, but the quality control line (C) is colored.
- 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:** 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

- The product is designed only for use with human serum, plasma, whole blood samples for the qualitative detection of novel coronavirus (SARS-CoV-2).
- This product test results are for reference only and should not be the sole basis for diagnosis and treatment. Use of this kit should be combined with clinical symptoms and should be confirmed by other conventional detection methods.
- 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).
- If the product gets wet prior to use, or is stored improperly, it may cause incorrect results.

## • PRODUCT PERFORMANCE INDEX

- 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.
- 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.
- 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.
- 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.

## • PRECAUTIONS

- This product is for research use only.
- The assay should be performed as outlined in this manual, and in accordance with all instructions.
- Do not use expired or damaged products.
- Only use the matching diluent in the kit package. Diluents from different kit lots cannot be mixed.
- Do not use tap water, purified water or distilled water as negative controls.
- 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.
- If there is no movement of the liquid after 30 seconds of beginning the test, 1 additional drop of sample solution should be added.
- Take care to prevent the possibility of virus infection when collecting samples. Wear disposable gloves, masks, etc., and wash your hands afterwards.
- 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.

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**Product Code: CG-CoV-IgG**

For ordering information, or other inquiries



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