COVID-19 Vaccine IgG Rapid Test (Colloidal Gold)

【Catalog Number】

REF CoV19-RBD

【Package Size】

☐ 1 Test/pack ☐ 20 Tests/box

【Intended Use】

The COVID-19 Vaccine IgG Rapid Test is a lateral flow immunoassay test intended for the qualitative, in vitro, detection of antibodies for the Receptor Binding Domain (RBD) of the of the SARS-CoV-2 virus spike protein or antibodies present after COVID-19 vaccination in human serum, plasma or whole blood. The kit is intended to help to identify individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, or to assess the immune response of individuals previously immunized with a COVID-19 vaccine. At this time, it is unknown for how long the antibodies persist following the infection or vaccination, or if the presence of antibodies confers protective immunity of the individual. This product is recommended only for use at the medical institutions (not for the home use).

【Test Principle】

1. The COVID-19 Vaccine IgG Rapid Test is a lateral flow immunoassay test to detect the antibodies (IgG) to the Receptor Binding Domain (RBD) of the of the SARS-CoV-2 virus spike protein or antibodies to the COVID-19 vaccine in collected samples. The test cassette contains colloidal gold-labeled SARS-CoV-2 recombinant RBD protein that binds to SARS-CoV-2 RBD IgG antibodies forming a complex.
2. T-line (IgG detection line) is coated with mouse anti-human IgG that captures the SARS-CoV-2 RBD IgG positive complex, developing the red purple line. This indicates that the sample is SARS-CoV-2 RBD IgG positive. If the line is not visible the sample is SARS-CoV-2 RBD IgG negative or below the limit of detection.
3. C-line (control line) is a built-in control feature that captures control substrates generating a red purple line. This indicates the procedure was run correctly.

【Contents of the Kit】

1. Materials for the kit contains:

Content	1 Test/pack	20 Tests/box
Cassette	1×1	1×20
Sample Dilution	1×300uL	20×300uL
Pipette Dropper	1×1	1×20
Package Insert (IFU)	1×1	1×1

2. Materials not provided but required:
   Lancet | Alcohol wipes | Gloves | Timer

【Storage and Handling】

1. Store at 2-30°C in a dry place, avoid direct sunlight. Do not freeze.
2. Use the test cassette within one hour after opening the pouch. Failure to do so might result in erroneous results or a test failure due to the environmental humidity.

【Sample Requirements】

1. Suitable for human serum, plasma and whole blood samples;
2. Blood serum or plasma samples are obtained via conventional methods (venipuncture) and centrifugation. Suitable anticoagulants include sodium heparin, EDTA or sodium citrate;
3. It is recommended to use the samples immediately after collection. If storage is needed, serum or plasma samples can be stored at 2-8°C for up to 5 days or at -20°C for longer periods. Avoid repeated freeze-thaw cycles of the samples.
4. Lipemic, hemolytic or turbid samples should be avoided.

【Test Method】

Before use, the kit components should be warmed up to the room temperature (25°C±5°C).

1. Remove the test strip from the pouch, mark with ID and place on testing table;

2. Transfer 10μL of the sample using the pipette into the sample well following with 2 drops of sample dilution (approximately 100μL) immediately;
3. Let the sample to soak into the cassette, read the result within 10-15 minutes.

Note: Do not interpret the results after 15 minutes. If more time is needed for interpretation, please take photos after the test is done.

【Quality Control】

1. Each test cassette has a built-in control feature included. Red colored line should be visible in the detection window at the Control line level (C).
2. The Control line will appear if the test procedure has been performed correctly. If the Control line is not present after the test, the test is invalid.

【Interpretation of Results】

Two visible lines are possible in the detection window. The control (C) line appears after the sample migrated through the cassette.

1. Negative Result

If only the control line (C) appears and the test line T (T) is not visible, then no SARS-CoV-2 RBD antibody has not been detected and the result is negative.

2.

If both, the control line (C) and the test line (T) are visible, the SARS-CoV-2 RBD IgG antibody has been detected and the result is positive.

3. Invalid Result

If the control line (C) is not visible, results are invalid and a re-test is warranted.

Note: The color intensity of the lines is related to the concentration of test substrates and does not affect the results of the test.

【Performance Characteristics】

Specificity & Sensitivity Study

A total of 500 clinical samples were tested by the COVID-19 Vaccine IgG Rapid Test and compared with the SARS CoV-2 Virus Neutralization Test (VNT). The whole blood samples used for the test were collected from the finger punctures.

Table1. Specificity and Sensitivity Test Results

COVID-19 Vaccine IgG Test Results	SARS-CoV-2 VNT Results		Total
	Positive	Negative	
Positive	98	0	97
Negative	2	400	403
Total	100	400	500

Positive Percent Agreement (PPA): 98% (98/100)
Negative Percent Agreement (NPA): 100% (400/400)
The results for the COVID-19 Vaccine IgG Rapid Test demonstrate a specificity of 100% (400/400), and a sensitivity of 98% (98/100).

Cross-Reactivity Study

No cross reaction with other coronaviruses or other viruses has been found. In particular human coronavirus (hku1, OC43, nl63 and 229E), SARS and MERS coronaviruses; H1N1 (new H1N1 influenza virus (2009), seasonal H1N1 influenza virus), H3N2, H5N1, h7n9, influenza B Yamagata, Victoria, respiratory syncytial virus A, B, parainfluenza virus 1, 2, 3, rhinovirus a, B, C, adenovirus 1, 2, 3, 4, 5, 7, 55, enterovirus a, B, C, D, human lung virus, human partial lung virus, EB virus, measles Virus, human cytomegalovirus, rotavirus, norovirus, mumps virus, varicella zoster virus. No cross reaction with bacterial cells as Mycoplasma pneumoniae

and Chlamydia pneumonia was detected.

【Limitations】

1. This product can only be used for detection of the IgG antibodies to the Receptor Binding Domain (RBD) of the of the SARS-CoV-2 virus spike protein or antibodies present after COVID-19 vaccination. Whole blood, serum, or plasma can be used. No other bodily fluids or secretions are usable.
2. This product is designated only for qualitative testing. If quantitative results are needed, tests for quantitative assessments should be used.
3. Negative results may be caused by low concentrations of SARS-CoV-2 RBD IgG antibody in the sample, and cannot completely rule out the possibility of infection or vaccination.

【Warnings and Precautions】

1. This product is a single use, in vitro diagnostic device that should be used strictly in accordance with this user manual. Test should not be reused, or used when damaged or expired.
2. Test should be used immediately after removal from the pouch. Moisture present in the environment might cause erroneous results, or test failure.
3. Using fresh samples is highly recommended.
4. Wearing the protective gear (clothing, gloves, mask) for sample collection and testing is warranted.
5. Desiccants present in aluminum pouch should not be taken orally.

【Disposal of the device】

The test samples should be considered potentially infectious and should be handled in accordance with local rules and regulations for infectious materials, especially considering biosafety regulations. Non used samples, used kits and material should be discarded as potentially infectious material following corresponding local rules and regulations.

【Contact Information】

CE

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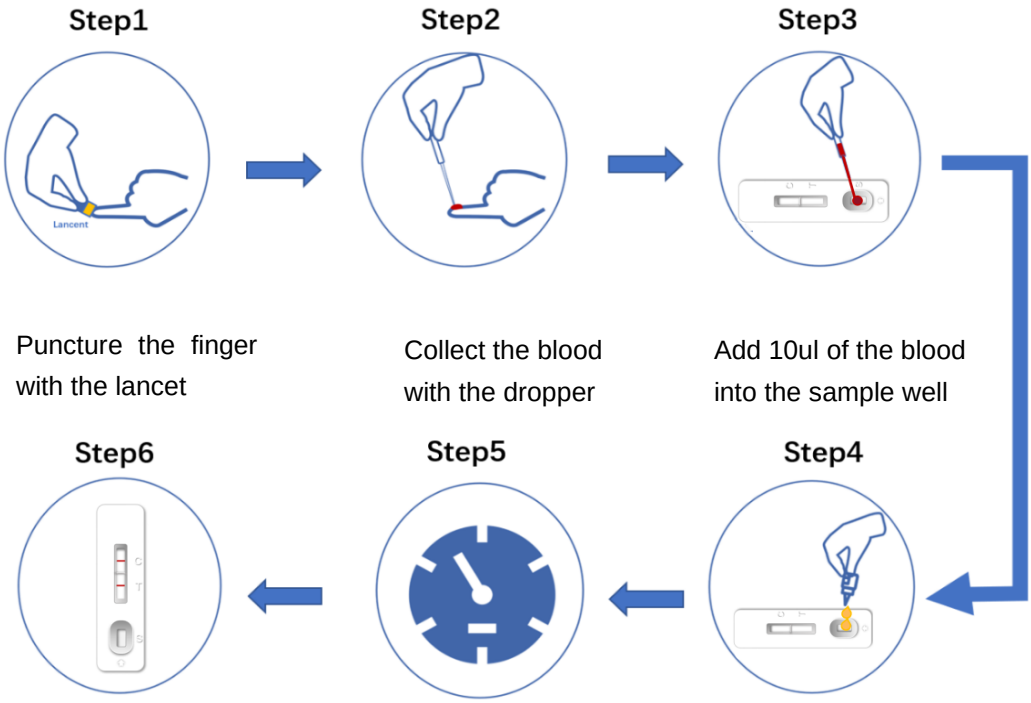
	Manufacturer
EC REP	Authorized EU Representative
	Date of Manufacture
	Use-by date
LOT	Batch Code
REF	Catalogue Number
	Consult Instructions for use
IVD	In Vitro Diagnostic Medical Device
	Do not re-use
	Temperature limit

Finger Prick Sampling and Testing Procedure



Testing Procedure Using Blood Serum/Plasma