PROTAN
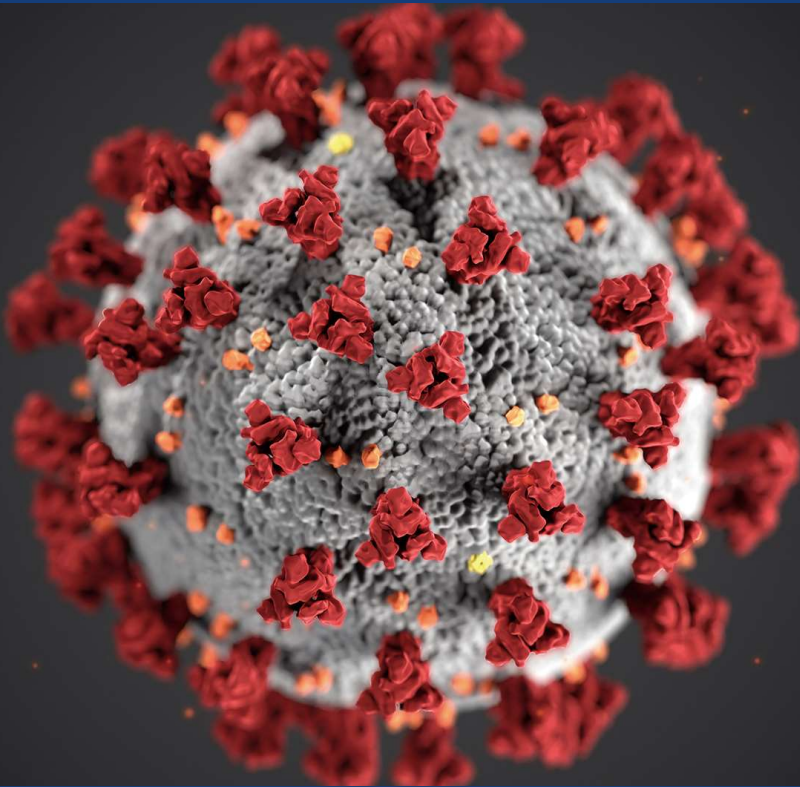# COVID-19 IgM/IgG Rapid Test

(Model name : PB-RDH015)

CE-IVD   EN ISO 13485

CORONAVIRUS
COVID-19
ANTIBODY TESTING

PROTAN COVID-19 IgM/IgG Rapid Test is a gold nanoparticle-based immuno-chromatographic test kit for qualitative determination of the both of COVID-19's IgM and IgG antibodies in human whole blood, serum or plasma.
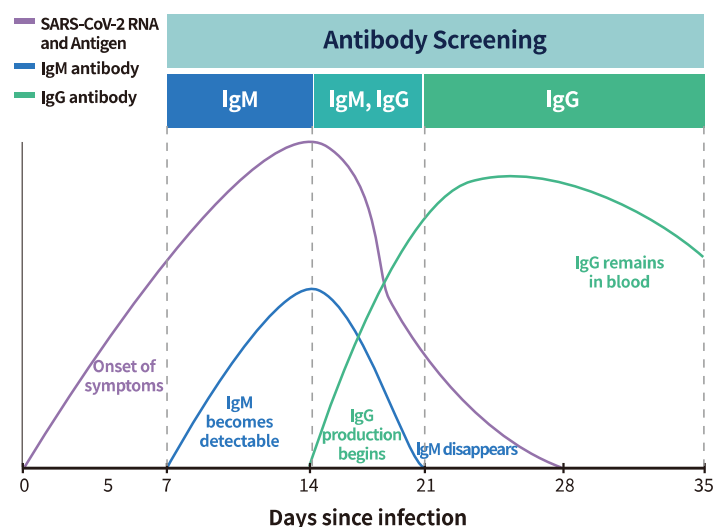
Explanation of the test

The results can be observed with the naked eye within 15 minutes. The test checks the presence of antibodies made in response to infections. Antibodies can be found in the blood after infection. The antibodies detected by this test indicate that a person has had an immune response to COVID-19. Antibody test results are important in detecting infections with few or no symptoms.

A lot of people don't have symptoms. Because of that, quick diagnostics are very important. PROTAN COVID-19 IgM/IgG enables to help for community to identify infection and isolate people without symptoms but suspected COVID-19.

Why antibody tests are useful

Answering the question of whether someone has had the virus before

Providing data and a greater understanding on the spread of the virus

Figure. Theoretical Variation of the Levels of SARS-CoV-2 RNA/Antigen, IgM and IgG after infection.

This Figure is based on the current knowledge about the rise and fall of SARS-CoV-2 RNA and antigen, IgM antibody and IgG antibody.
*Disclaimer: this chart is for illustrative purposes only

PROTANBIO Inc.

PROTAN
COVID-19 IgM/IgG Rapid Test
(Model name : PB-RDH015)

PROTAN COVID-19 IgM/IgG Rapid Test is

☑ **No analyzer required**

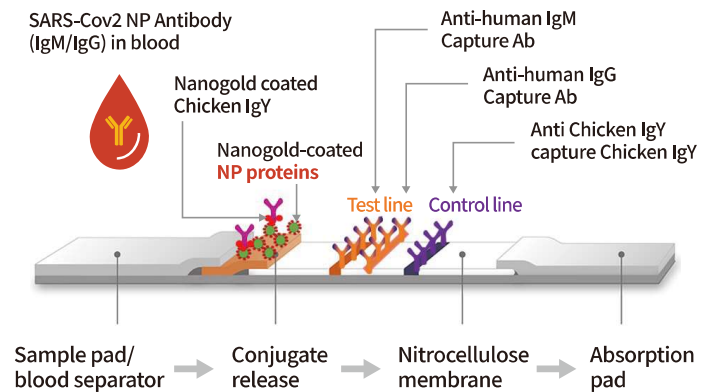☑ **Convenient**

☑ **Simple blood test**

☑ **Easy to use just with finger tip blood**

☑ **Check result in 15min.**

Kit Performance

Method		Clinical confirmation sample		Total
		Positive	Negative	
PROTAN COVID-19 IgM/IgG	Positive	70	8	78
	Negative	1	154	155
Total		71	162	233

- **Clinical sensitivity: 98.59%** (70/71)
- **Clinical specificity:95.06%** (154/162)
- **Positive predictive value (PPV): 89.74%** (70/78)
- **Negative predictive value (NPV): 99.35%** (154/155)

Lateral flow immunochromatographic assay

SARS-Cov2 NP Antibody (IgM/IgG) in blood

Nanogold coated Chicken IgY

Nanogold-coated NP proteins

Anti-human IgM Capture Ab

Anti-human IgG Capture Ab

Anti Chicken IgY capture Chicken IgY

Test line   Control line

Sample pad/ blood separator → Conjugate release → Nitrocellulose membrane → Absorption pad

COMPOSITION

- Full package for the whole test procedure, No need for additional tool/device

1. Test Cassettes
2. Assay Buffer
3. Tool for Specimen(dropper)

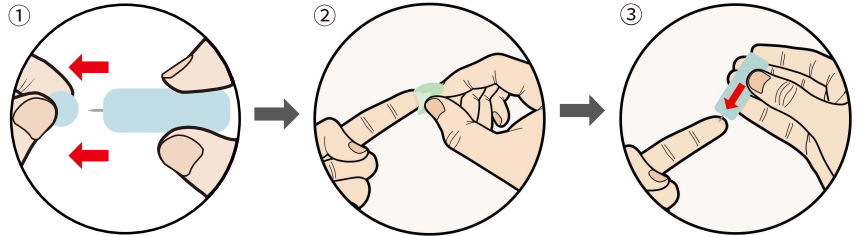4. Lancet & Alcohol Swab
5. Package Insert

*Package: 25 tests

PROTAN
COVID-19 IgM/IgG Rapid Test

(Model name : PB-RDH015)
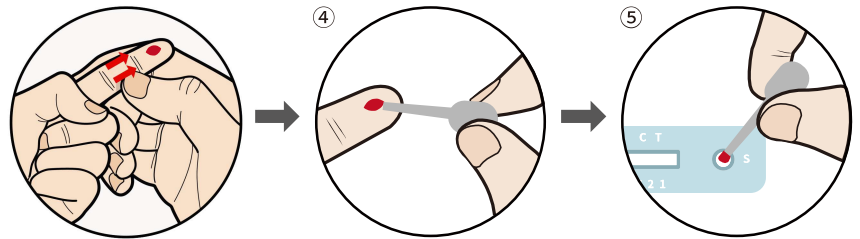
TEST PROCEDURE AND INTERPRETATION OF RESULT

1. Sample prepare

① Remove protective cap of the lancet
② Sterilize Finger using alcohol swab
③ Prick fingertip with the lancet
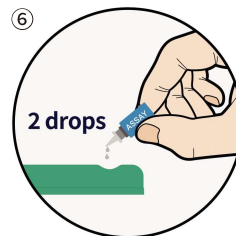*After use, dispose lancets in appropriate sharps container to avoid cross contamination.

2. Sample collect

④ Collect blood with specimen
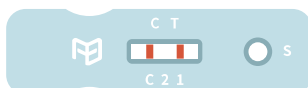⑤ Dispense the blood into sample well

*If there's blood already taken, you can use a pipette.

· Whole blood   20㎕

Add 20㎕ of whole blood to sample well using mini tip or micro pipette

3. Drop of Buffer

⑥ Add 2~ 3 drops(80 ㎕) of Assay Buffer to Blood in sample well

⑥

2 drops

4. Read at 15 min.

15min

⚠

Do not read after 15 minutes. Not reliable.

5. Interpret

POSITIVE

COVID-19 IgM Ab positive

COVID-19 IgG Ab positive

COVID-19 IgM/IgG Ab positive

NEGATIVE

INVALID