PROTAN COVID-19 IgG Type2
ONE STEP Rapid Test Kit

PROTANBIO Inc.

After Vaccination, what should we do… ?

The acute Global pandemic of Covid-19 has forced Governments in the world to implement unprecedented restrictive measures that are necessary to control and manage the spread of the SARS CoV-2 virus. These measures have created substantial and serious impact on the well-being of the public, business and government economies.

Whether a patient has been Asymptomatic, Symptomatic, Recovering or more importantly now **Vaccinated**, none of the aforementioned can guarantee an individual's immediate and or long-term immunity against Covid-19 re-infection. Therefore, the ability to spread the virus in the future amongst family and population remains a real possibility. Currently there are no approved devices with "optional" supportive technology that could provide this much needed and critical ability, and in particular one that also responds to the various types of Vaccines that are now applied against potential SARS CoV-2 and it's increasing prevalent mutations.

A significant solution to managing and controlling the spread of the virus, more importantly being able to factually determine how effective a vaccination and or vaccination program has been, lies in the ability to regularly and reliably test whether an individual has neutralizing IgG Antibodies present after Vaccination and if so, monitor how long that Antibody protection remains present and active in their immune system as the main and most effective defense against the spread of the Covid-19 virus.

Why needs PROTAN COVID-19 IgG Type2 ?

Several studies have demonstrated that antibodies produced against the receptor binding domain (RBD) of the spike protein are capable of viral neutralization. Neutralizing antibodies of RBD can efficiently stop the infection by blocking the interaction between the SARS-CoV-2 virus and the host cells. PROTAN COVID-19 IgG Type 2 is a a lateral flow chromatographic immunoassay intended for qualitative detection of the presence of **neutralizing IgG antibodies after a SARS-CoV-2 Vaccination** in human Serum, Plasma and Whole Blood. The PROTAN COVID-19 IgG Type 2 is designed to test the presence of protective antibodies (IgG) against COVID-19 after Vaccination. This may be a significant solution to managing and controlling the spread of the virus, more importantly being able to factually determine how effective a vaccination.

When to use this kit

• As an aid in the validation of COVID-19 vaccination.
• If you are concerned that you need more COVID-19 vaccination.

PROTAN COVID-19 IgG Type2

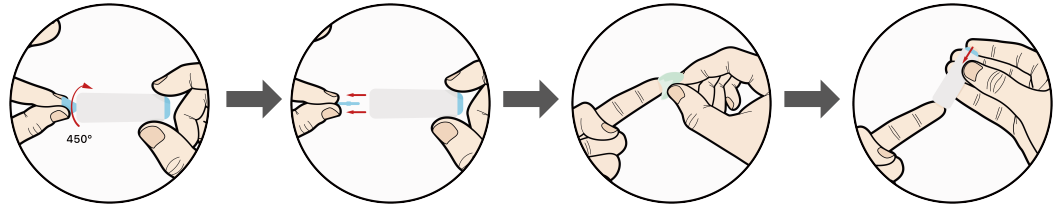| For Self-Test	For Point of Care Test(PoCT)

Reference
1. Ju, B. et al. Nature 584, 115–119 (2020).   2. Rogers, T. F. et al. Science 369, 956–963 (2020).   3. Liu, L. et al. Nature 584, 450–456 (2020).
4. Cao, Y. et al. Cell 182, 73–84 (2020).   5. Zost, S. J. et al. Nature 584, 443–449 (2020).   6. Jiang S, et al. Nat Biomed Eng. 4, 1134-1139, (2020).
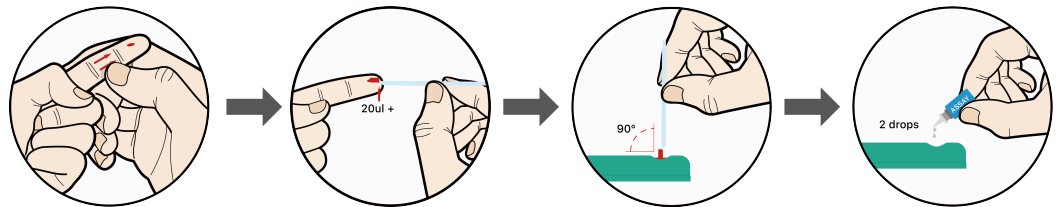
STEP 1. Prepare to sample collect

1. Remove the protective cap -Twist the cap 450° and pull straight out to remove
2. Sterilize Finger
3. Press lancet against side of fingertip and press button.
*After use, dispose lancets in appropriate sharps container to avoid cross contamination.

450°

STEP 2. sample collect

1. Squeeze Finger(Fresh Blood)
2. Draw the whole blood sample in through the end of the Mini-Tip
3. Set the sample collected at a right angle(90°) based on the diagnostic kit and dot the sample
4. Add 2-3 Drops of Assay buffer to Blood in Blood Well

20ul +   90°   2 drops

STEP 3. Read and Interpret

1. Wait 15 minutes.
2. Check the result and interpret

*Caution
All components are disposable medical devices.
Dispose of used products in a safe place. there is a risk of infection.
(Prohibit re-use)

15min
Do not read
after 15 minutes.
Not reliable.

POSITIVE

NEGATIVE

INVALID

Performance of PROTAN COVID-19 IgG Type2

- Clinical sensitivity: 96.23%(102/106) (95% CI : 0.92599 ~ 0.99854)
- Clinical specificity: 96.55%(28/29) (95% CI : 0.89911 ~ 1.03193)
- PPV: 99.03% (102/103) (95% CI : 0.97136 ~ 1.00923)
- NPV: 87.5% (28/32) (95% CI : 0.76041 ~ 0.98959)

Model name : PB-RDH017

	Vaccinated	Not Vaccinated	
Positive	102	1	103
Negative	4	28	32
Total	106	29	135