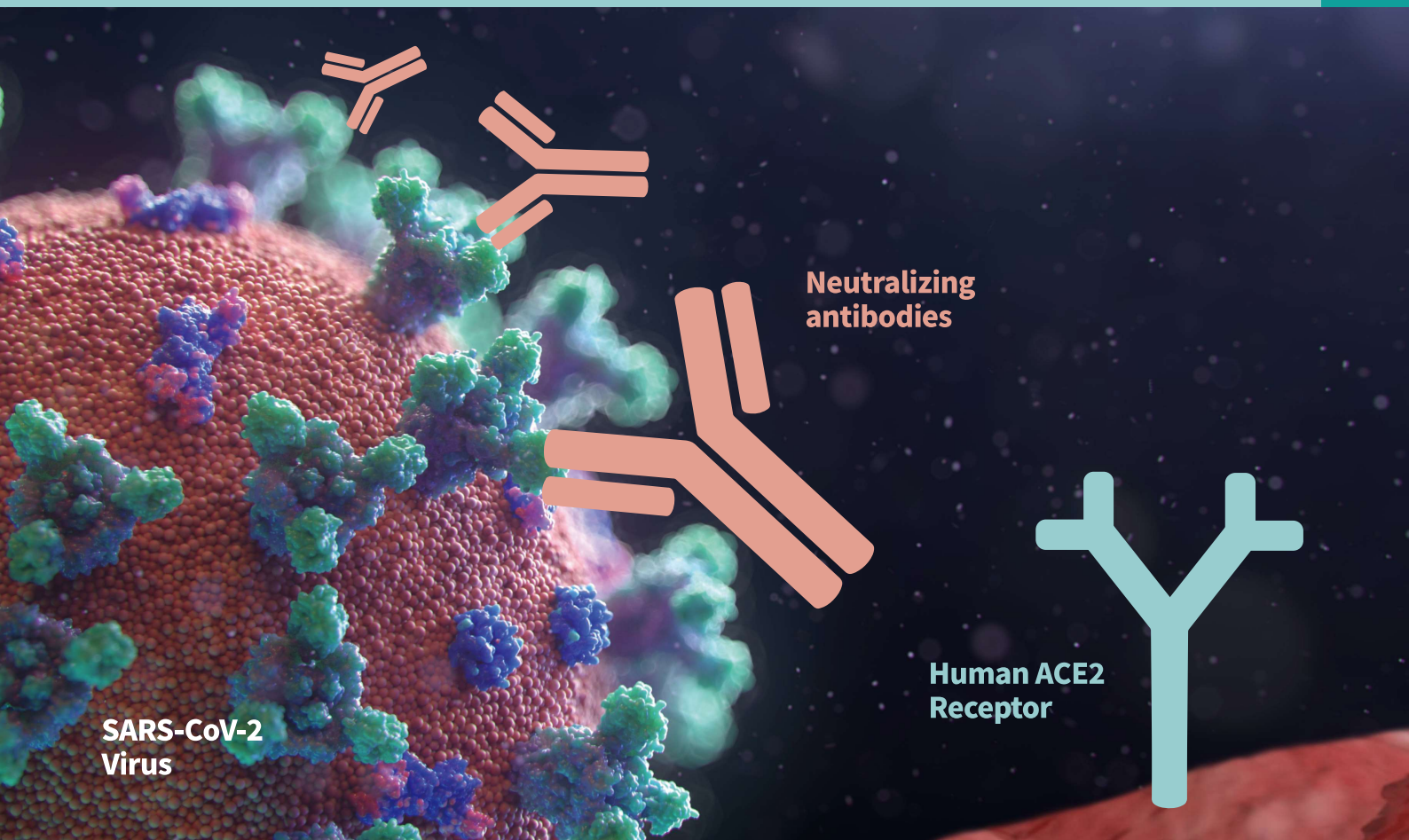


COVID-19 IgG neutralizing Antibody Rapid Test kit

Check COVID-19 Neutralizing antibodies After vaccination



PROTAN COVID-19 IgG Type 2 is intended for the detection of neutralizing antibodies (IgG) against COVID-19 SP RBD (spike protein receptor binding domain) in human whole blood after vaccination

TEST PROCEDURE

- STEP 1. Sample prepare
- STEP 2. Sample collect
- STEP 3. Read and interpret



15min

Do not read after 15 minutes. Not reliable.

POSITIVE



NEGATIVE



INVALID



COVID-19 IgG neutralizing Antibody Rapid Test kit

Check COVID-19 Neutralizing antibodies After vaccination

Background

As Vaccine programs are rolled out, restrictions are being eased with the “effective immune” time of SARS- CoV-2 Vaccinations. The ability to test for the presence of IgG Neutralizing Antibodies, after a Vaccination, has become more critical in the fight against re infection, the spread of the virus and the mass management of potential additional vaccinations.

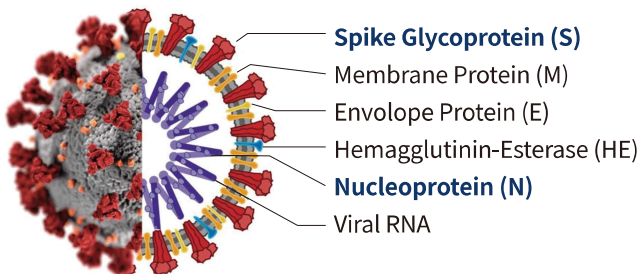
Currently, antibody tests detect antibodies targeting two different proteins of the SARS-CoV-2 virus; the Nucleocapsid Protein; the Spike Protein. Immunologically, antibodies to the Nucleocapsid protein are necessary, but in the full context of the pandemic, IgG Neutralizing Antibodies to Spike Protein hold the key.

A positive test with other types of antibody tests can confirm prior infection with SARS-CoV-2, however, a positive result with a Neutralizing Antibody rapid test that detects the presence of neutralizing antibodies to the SARS-CoV-2 spike protein holds more significance. This owing to their infection neutralizing capabilities.

Short history

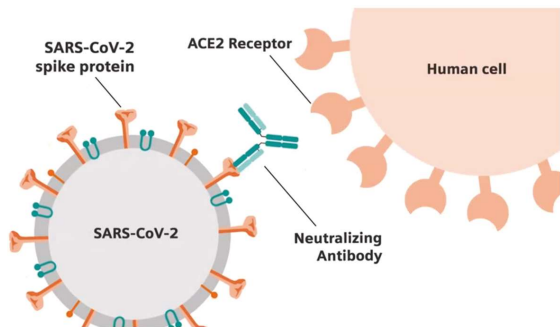
- The first outbreak started in Wuhan, Hubei, China in late 2019
- On 11 February 2020, the World Health Organization (WHO) named the disease “COVID-19”, which is short for coronavirus disease 2019

SARS CoV-2 Structure



S and N are target proteins for diagnostics and therapeutics

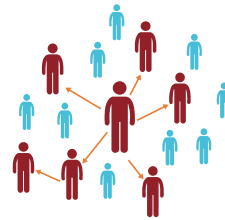
The role of Neutralizing Antibody



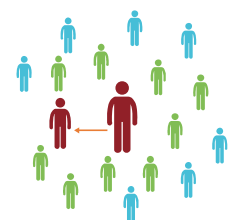
- RBD domain of Spike protein(S) recognize ACE2 receptor in human cells
- COVID-19 virus enter human cells via binding of RBD to ACE2
- Neutralizing Antibody bind to RBD domain of S protein so that COVID-19 Virus cannot interact with human cells

Neutralizing Antibody formation

Natural infection



After Vaccination



- Susceptible
- Infected
- Vaccinated

Vaccination builds protection
It's safer than getting the disease
Vaccination will help stop the pandemic

Kit performance (Clinical data)

		Vaccinated	Not Vaccinated	
PROTAN COVID-19 Type2	Positive	102	1	103
	Negative	4	28	32
	Total	106	29	135

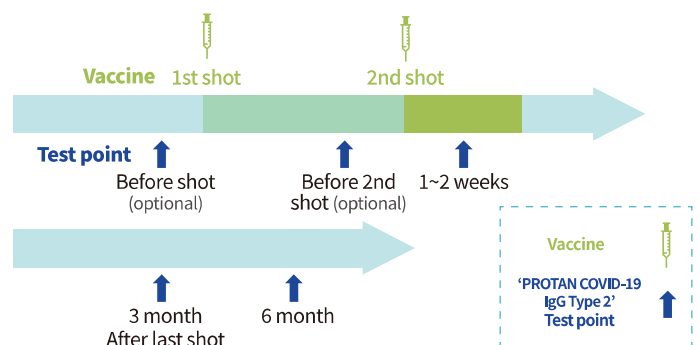
- **Clinical sensitivity : 96.23%** (102/106) (95% CI)
- **Clinical specificity : 96.55%** (28/29) (95% CI)
- PPV : 99.03% (102/103) (95% CI)
- NPV : 87.5% (28/32) (95% CI)

Moderna Vaccine Efficacy 94.5 % = similar to Type2 Positivity in Vaccinated 96.2%

Table 9. Interim Analysis* for Primary Efficacy Endpoint, COVID-19 Starting 14 Days After the 2nd Dose, Per-Protocol Set

Primary Endpoint: COVID-19 (per adjudication committee assessment)	Vaccine Group N=13934 Cases n (%) (Incidence rate per 1,000 person-years)	Placebo Group N=13883 Cases n (%) (Incidence rate per 1,000 person-years)	Vaccine Efficacy (VE) % (95% CI)*	Met Predefined Success Criterion**
All participants	5 (<0.1) 1.840	90 (0.6) 33.365	94.5% (86.5%, 97.8%)	Yes
18 to <65	5 / 10407 (<0.1) 2.504	75 / 10384 (0.7) 37.788	93.4% (83.7%, 97.3%)	NA
65 and older	0 / 3527	15 / 3499 (0.4) 21.046	100%	NA

Recommended Test schedule



Positive for test : checking 3 month, 6 month after last shot
Negative for test : Recommend for another shot