SARS-CoV-2 Neutralizing Antibody Rapid Test Kit

Latex Immunochromatography- Blocking Sandwich Method

1 test/ 5 tests/ 25 tests

Available in two formats: CE-marked and For Research Use Only



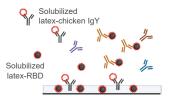
SARS-CoV-2 Neutralizing Antibody Rapid Test Kit is a lateral flow immunoassay for the qualitative detection of neutralizing antibodies against the receptor binding domain (RBD) protein of the SARS-CoV-2 virus in serum, plasma and whole blood samples.





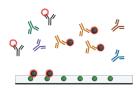


II. PRINCIPLE



Immobilizedlatex-RBD and latex-chicken IgY

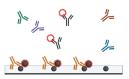
Sample pad is pre-coated with latex-RBD and latex-chicken IgY. When a sample is added, they solubilize. If SARS-CoV-2 neutralizing antibodies are present in the sample, they bind to the solubilized latex-RBD to form the neutralizing antibody-latex-RBD complex.



Immobilized ACE2

The sample flows over the ACE2-coated pad.Unbound latex-RBD molecules interact with the ACE2 protein and are trapped at this region. Non-specific antibodies, the neutralizing antibody-latex-RBD complex, and the latex-chicken lgY fail to bind with the immobilized ACE2.

A visible red line (T-line) is generated



Immobilized RBD

The sample flows over the RBD-coated test Test pad (T). The neutralizing antibody-latex-RBD complex interacts with the coated RBD and accumulates at this region forming a visible red line (T line). A visible red line (C-line) is generated



Immobilized anti-chicken IgY antibody

The remaining samples flows through the Control pad (C) coated with the anti-chicken IgY antibody. Here, the latex-chicken IgY interacts with the anti-chicken IgY antibody and accumulates forming a visible red line (C line).

1











ACE2

RBD



Neutralizing antibody-latex-RBD



RBD-Neutralizing antibody-latex-RBD



Solubilized latex-chicken IgY



Immobilized anti-chicken IgY antibody



III. TEST PROCEDURE







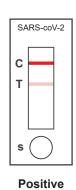


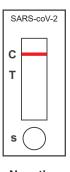


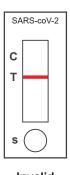


VI. INTERPRETATION OF RESULTS











Positive

Negative

Invalid

Invalid

Positive (+): Two distinct colored lines appear. One red-colored shows on C line and another shows on T line. That indicates SARS-CoV-2 Nab positive result.

Negative (-): One red-colored line shows on C line indicates a negative result. The negative results indicate that there may be no neutralizing antibody in the sample or too low of a concentration.

Invalid: If the control region (C line) is not visible, the result is invalid.

V. CLINICAL PERFORMANCE

Samples from a cohort of patients were tested using the SARS-CoV-2 Neutralizing Antibody Rapid Test Kit. The combined cohort consisted of samples from normal healthy people (n= 25) and samples from confirmed SARS-CoV-2 positive patients (n=25) based on plaque reduction neutralization test (PRNT) results.

Plaque Reduction Neutralization Test (PRNT)		Positive (n=25)	Negative (n=25)
SARS-CoV-2 Neutralizing Antibody Rapid Test Kit	Positive	25	1
	Negative	0	24
	Sensitivity	100.0% (95% CI 86.7-100%)	
	Specificity		96.0% (95% CI 80.5-99.3%)

