

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

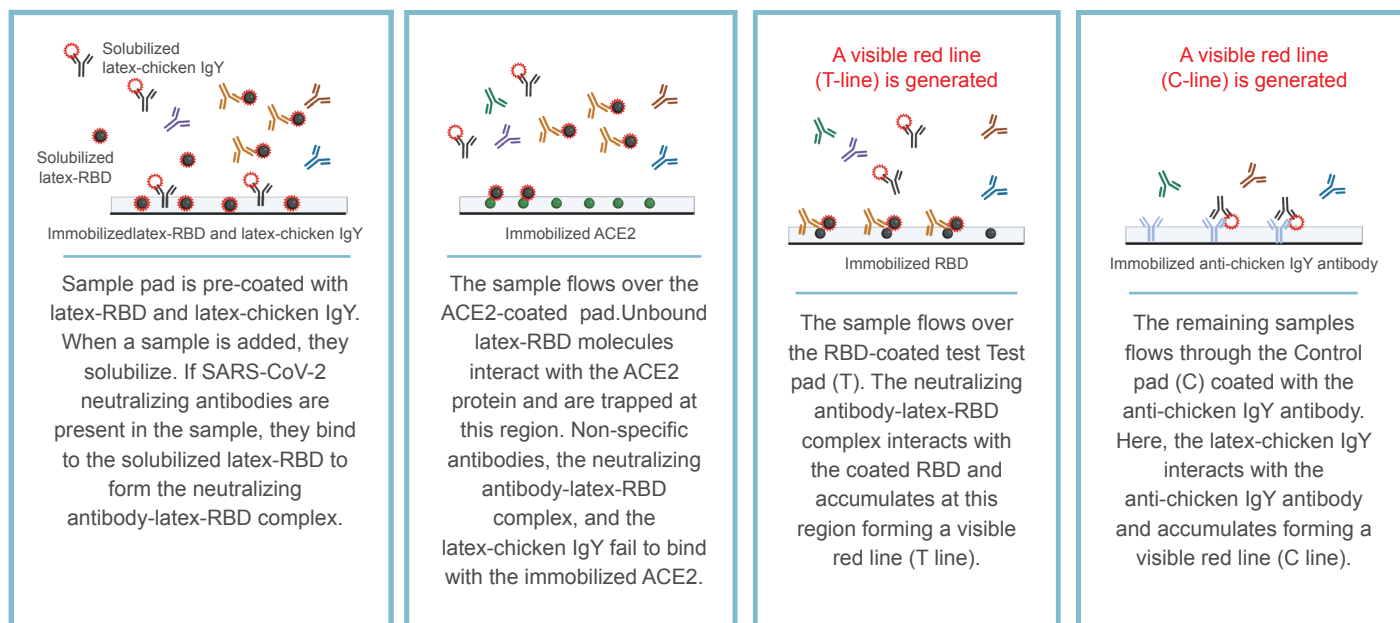


I. INTENDED USE

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



1

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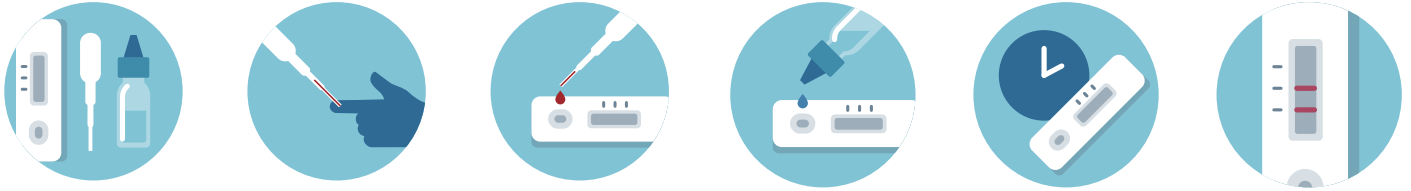
4

● Latex-RBD
● ACE2
● RBD

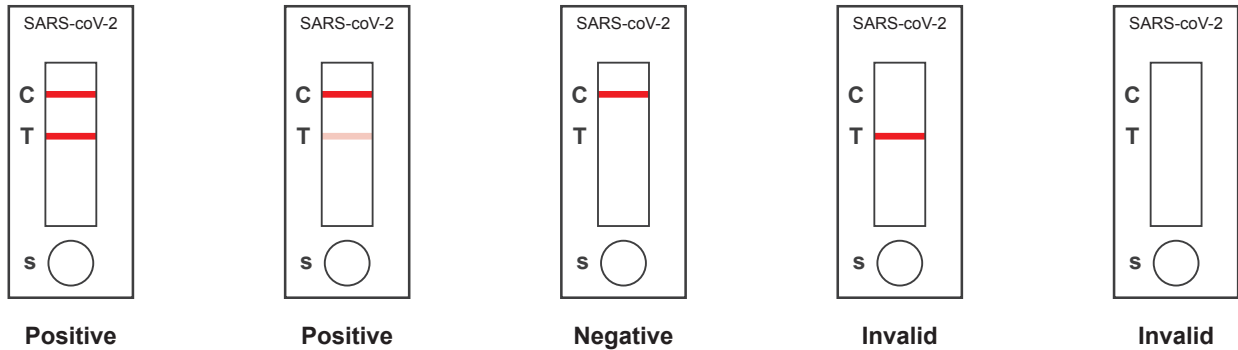
● Neutralizing antibody-latex-RBD
● RBD-Neutralizing antibody-latex-RBD

● Solubilized latex-chicken IgY
● Immobilized anti-chicken IgY antibody

III. TEST PROCEDURE



VI. INTERPRETATION OF RESULTS



Positive (+): 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%)