LEPU MEDICAL

SARS-COV2 Antigen Rapid Test Kit

Colloidal Gold Immunochromatography

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Product Feature

Non-invasive

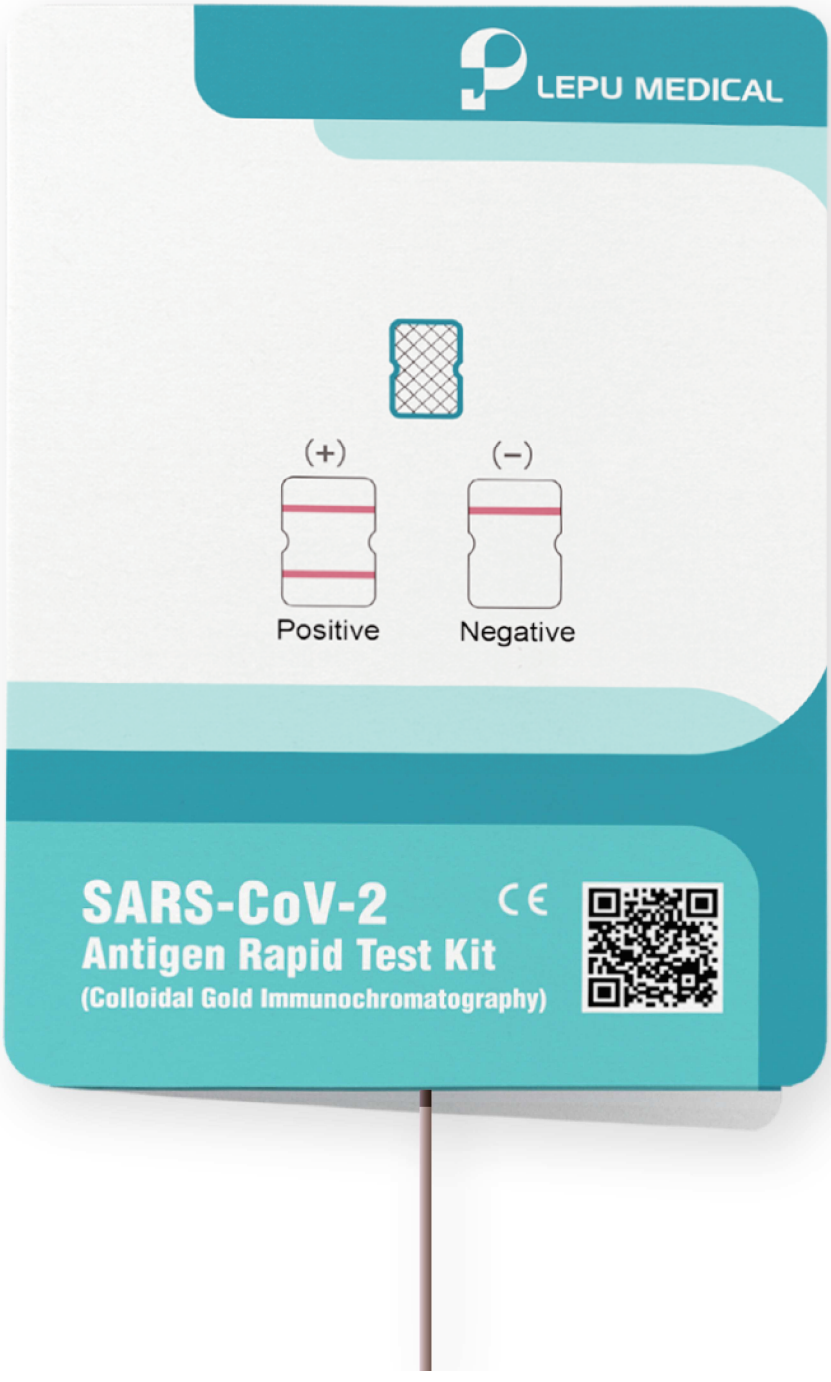
Simple to use

Convenient, no devices required

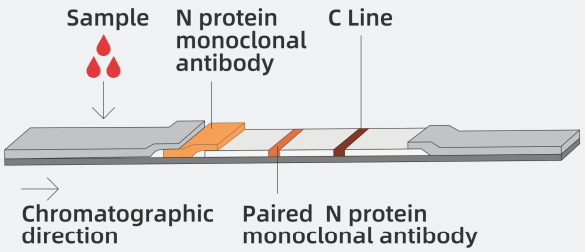
Rapid, get result in 15 minutes

Stable, with high accuracy

Inexpensive, cost-efficiency

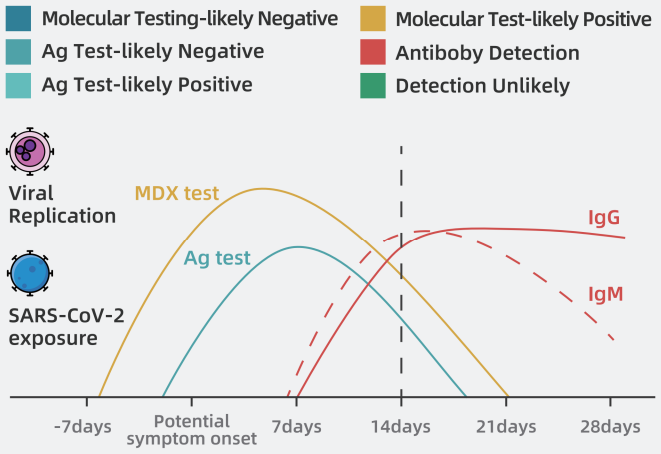


The test card contains a gold-labeled novel coronavirus N protein monoclonal antibody pre-coated on the binding pad and a paired novel coronavirus N protein monoclonal antibodies fixed in the test line (T) and corresponding antibodies in the quality control line (C).



SARS-COV2 Antigen Rapid Test Kit can detect the virus from first phase of infect (2-3 days before potential symptom onset) to last phase of infection (7-10 days after potential symptom onset).

Progression of infection



References:

Sethuraman N, Jeremiah SS, Ryo A. Interpreting Diagnostic Tests for SARS-CoV-2. JAMA. 2020 Jun 9;323(22):2249-2251. doi: 10.1001/jama.2020.8259. PMID: 32374370

Long QX, Liu BZ, Huang AL. Antibody responses to SARS-CoV-2 in patients with COVID-19. Nat Med. 2020 Jun;26(6):845-848. doi: 10.1038/s41591-020-0897-1. Epub 2020 Apr 29. PMID: 32350462.

"Both antigen tests and NAATs perform best when the person is tested when viral load is generally highest"
-Interim Guidance for Antigen Testing for SARS-CoV-2, Centers for Disease Control and Prevention

Swab

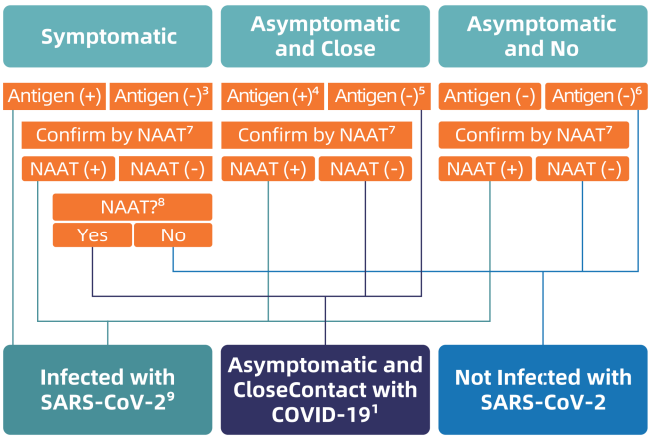
buffer

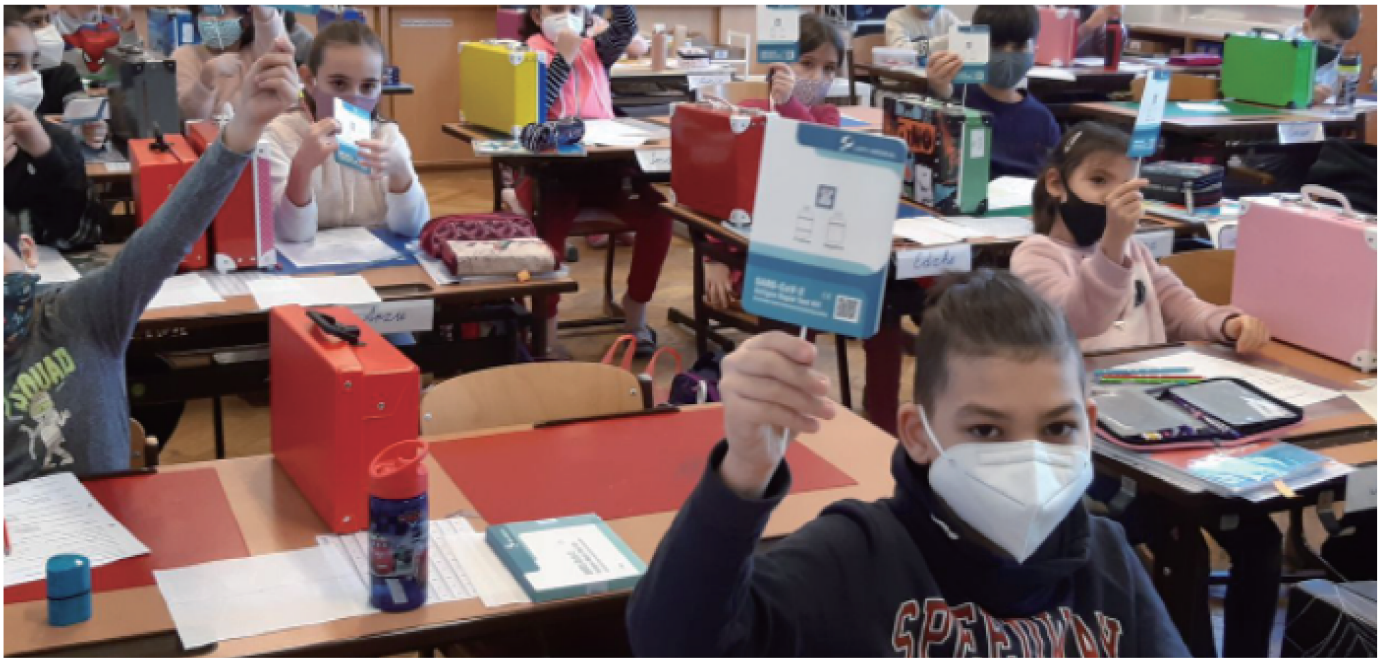
Clinical Application of Antigen test kit ---Antigen testing algorithm recommended by CDC

(https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/Antigen_Testing_Algorithm_2020-12-14_v03_NO_DRAFT_SPW_508.pdf)

- Symptomatic
- Asymptomatic and Close Contact with Covid-19
- Asymptomatic and No Known Exposure

Antigen testing algorithm





Clinical performance

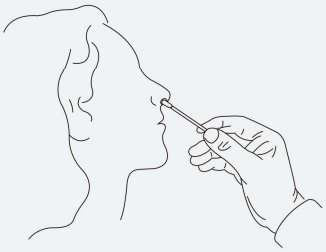
A total of 508 clinical specimens based on nucleic acid assay (PCR) were collected, including 243 positive specimens and 265 negative specimens. After comparing this product with nucleic acid assay (PCR) through the collected clinical samples, the results are summarized as follows:

SARS-COV2 Antigen Rapid Test Kit	Nucleic acid assay (PCR)	
	Positive	Negative
Positive	231	1
Negative	12	264
Analysis of sensitivity	95.06%（95%CI:91.57%~97.15%）	/
Analysis of specificity	/	99.62%（95%CI:97.89%~99.93%）

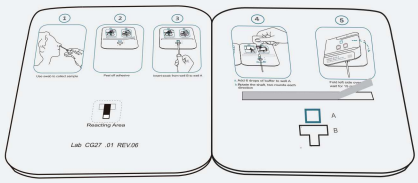
Performance against the Comparator Method-by Cycle Threshold Counts.

SARS-COV2 Antigen Rapid Test Kit	Nucleic acid assay (PCR)	
	Positive(Ct≤32)	Positive(Ct≤25)
Positive	227	202
Negative	8	3
sensitivity	96.60%（95%CI:93.43%~98.27%）	98.54%（95%CI:95.79%~99.50%）

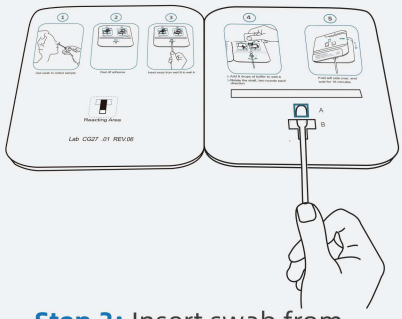
Instruction



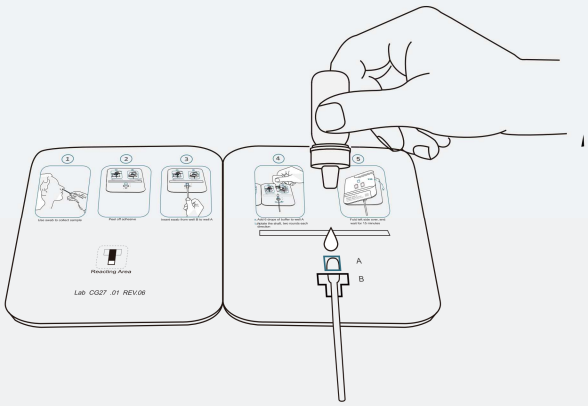
Step 1: Use swab to collect sample.



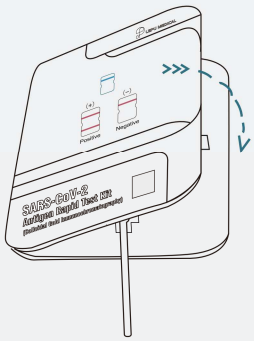
Step 2: Peel off adhesive.



Step 3: Insert swab from well B to well A.

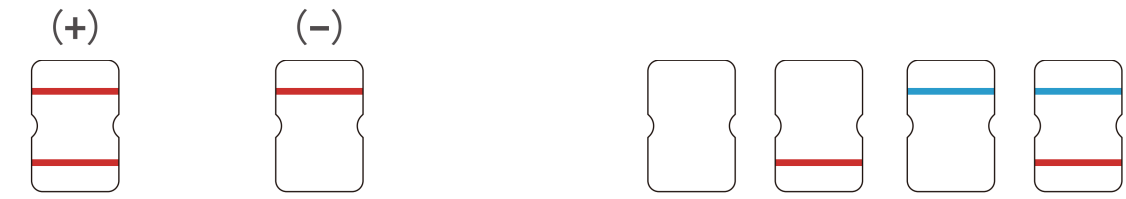


Step 4: a. Add 6 drops of buffer to well A
b. Rotate the shaft, two rounds each direction.



Step 5: Fold left side over, and wait for 15 minutes.

Result Interpretation

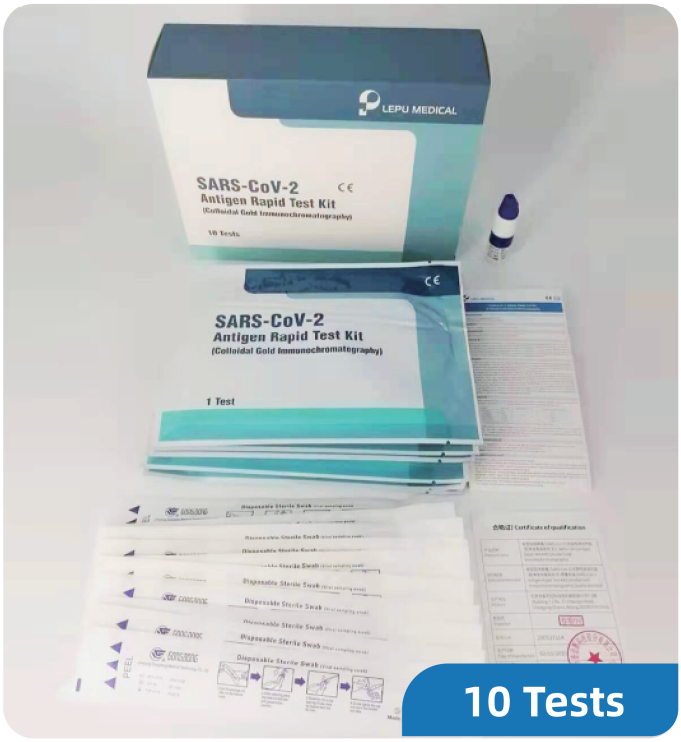


Positive **Negative** **Invalid**

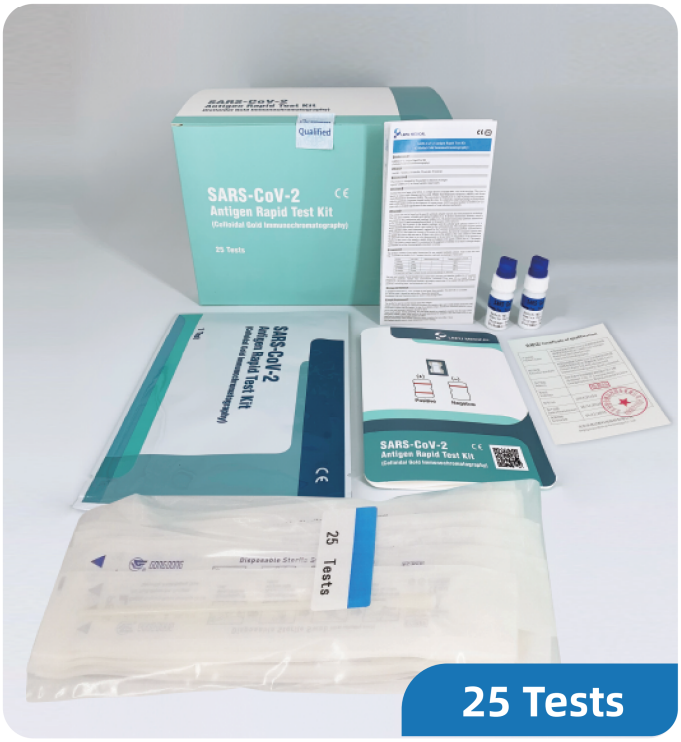
Product specifications

1 Test

5 Tests



10 Tests



25 Tests

Hospital | Test Site | Airport | Station | Hotel | Corporation | Mass Screening