



# SARS-CoV2 Antigen Rapid Test Kit

Colloidal Gold Immunochromatography



## Product Feature



Non-invasive



Simple to use



Convenient, no devices required



Rapid, get result in 15 minutes



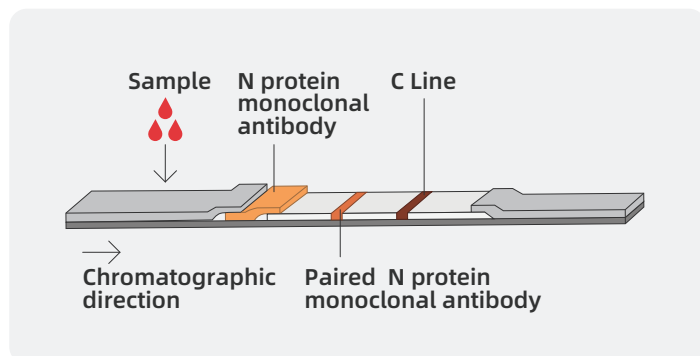
Stable, with high accuracy



Inexpensive, cost-efficiency

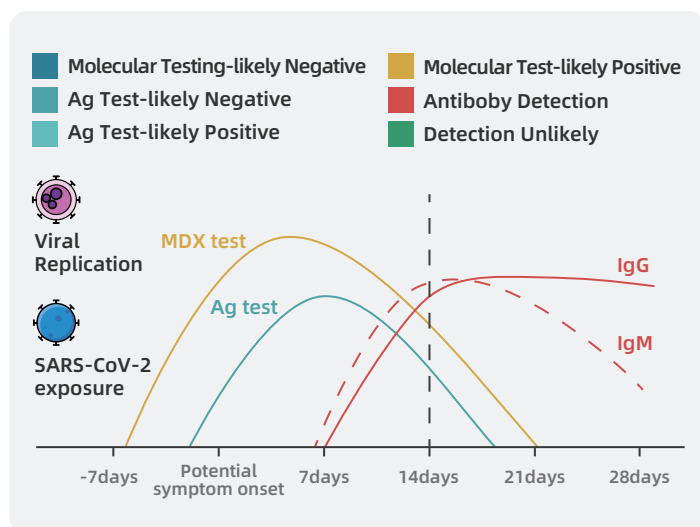


The test card contains a gold-labeled novel coronavirus N protein monoclonal antibody pre-coated on the binding pad and a paired novel coronavirus N protein monoclonal antibodies fixed in the test line (T) and corresponding antibodies in the quality control line (C).



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

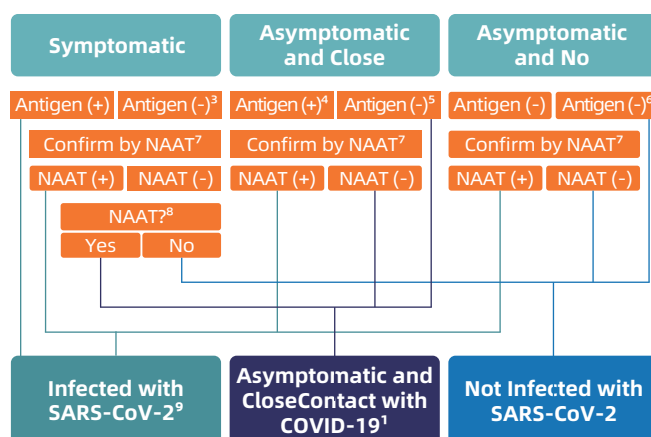
## Clinical Application of Antigen test kit

### ---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](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

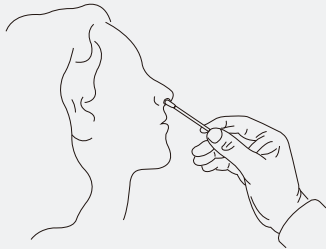
A total of 508 clinical specimens based on nucleic acid assay (PCR) were collected, including 243 positive specimens and 265 negative specimens. After comparing this product with nucleic acid assay (PCR) through the collected clinical samples, the results are summarized as follows:

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%)

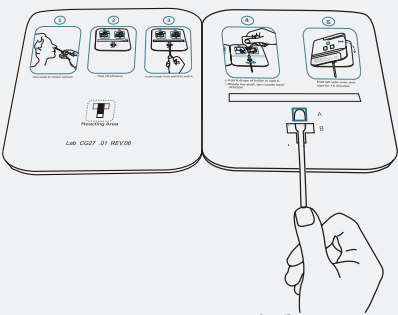
# Instruction



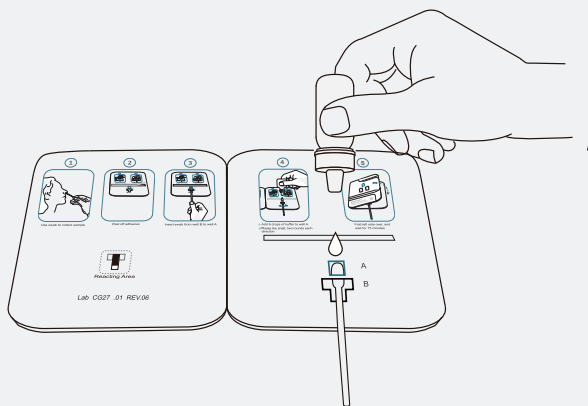
**Step 1:** Use swab to collect sample.



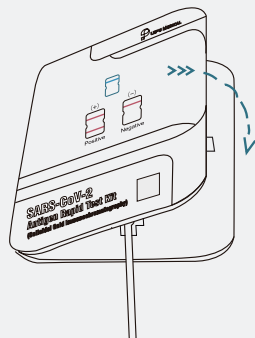
**Step 2:** Peel off adhesive.



**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.

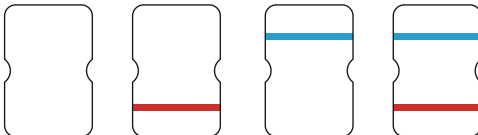
# Result Interpretation

(+)



(-)





Positive

Negative

Invalid

# Product specifications



1 Test



5 Tests



10 Tests



25 Tests



Hospital



Test Site



Airport



Station



Hotel



Corporation



Mass Screening

# EU Common List of COVID-19 Rapid Antigen Tests



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management  
**Health Security and Vaccination**

## EU health preparedness:

**A common list of COVID-19 rapid antigen tests,  
including those whose test results are mutually  
recognised, and a common standardised set of data to  
be included in COVID-19 test result certificates**

Agreed by the Health Security Committee  
on 17 February 2021

### III. Rapid antigen tests of which the test results are mutually recognised

As stipulated in point 15 of the Council Recommendation of 21 January 2021, Member States will agree on a selection of rapid antigen tests of which they will mutually recognise the test results for public health measures, based on the information included in the common list (see Annex I).

The Health Security Committee agrees that, for rapid antigen test results to be mutually recognised, at least three Member States should be using a rapid antigen tests in practice. Based on this criterion, Member States agree that the results of the following rapid antigen tests will be mutually recognised for public health measures:

- Abbott Rapid Diagnostics, Panbio™ COVID-19 Ag Rapid Test
- AMEDA Labordiagnostik GmbH, AMP Rapid Test SARS-CoV-2 Ag
- Becton Dickinson, BD Veritor System for Rapid Detection of SARS-CoV-2
- **Beijing Lepu Medical Technology, SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold immunochromatography)**
- BIOSYNEX SWISS SA, BIOSYNEX COVID-19 Ag BSS
- CerTest Biotect S.L., CerTest SARS-CoV-2 CARD TEST
- Hangzhou Clongene Biotech, Clungene COVID-19 Antigen Rapid Test Kit
- Healgen Scientific Limited, Coronavirus Ag Rapid Test Cassette (Swab)
- LumiraDX UK LTD, LumiraDx SARS-CoV-2 Ag Test
- nal von minden GmbH, NADAL COVID -19 Ag Test
- Quidel Corporation, Sofia 2 SARS Antigen FIA
- SD BIOSENSOR, Inc., STANDARD F COVID-19 Ag FIA
- SD BIOSENSOR, Inc., STANDARD Q COVID-19 Ag Test
- Siemens Healthineers, CLINITEST Rapid COVID-19 Antigen Test
- Xiamen Boson Biotech Co, Rapid SARS-CoV-2 Antigen Test card
- Zhejiang Orient Gene Biotech Co.,Ltd, Coronavirus Ag Rapid Test Cassette (Swab)

***Declaration of Conformity***

**Manufacture Address:** Beijing Lepu Medical Technology Co., Ltd.  
Building 7-1 No.37 Chaoqian Road, Changping District,  
Beijing, 102200, P.R. China

**European Representative:** Lepu Medical (Europe) Cooperatief U.A.  
Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, The  
Netherlands

**Product information:** SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold  
Immunochromatography)  
Model:  
1 test/kit; 5 tests/kit; 10 tests/kit; 25 tests/kit; 50 tests/kit

**Classification:** Others (not in List A and List B)

**Conformity Assessment Route:** Section 2 to 5 in annex III of IVDD 98/79/EC  
We herewith declare that the above mentioned products  
meet the provisions of the following EC Council Directives  
and Standards.  
All supporting documentations are retained under the  
premise of the manufacturer.

**General Applicable Directive:** DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT  
AND OF THE COUNCIL of 27 October 1998 on *in vitro*  
diagnostic medical devices

**Standards Applied:** All applicable harmonized standards (published in the  
official journal of the European Communities on 25<sup>th</sup> March  
2020).  
The applicable standards are listed in Annex 1.

**Place, date of issue** Beijing, P.R. China, 3<sup>th</sup>, Sept., 2020

**Signature of Management Representative** 

Beijing Lepu Medical Technology Co., Ltd.

Building 7-1 No.37 Chaoqian Road, Changping District, Beijing, 102200, P.R. China



## **Annex 1**

EN ISO 13485:2016 Medical devices – quality management systems - requirements for regulatory purposes

EN ISO 14971:2019 Medical devices – application of risk management to medical devices

EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices

EN ISO 18113-1:2011 In vitro diagnostic medical devices – information supplied by the manufacturer (labelling) – Part 1: terms, definitions and general requirements

EN ISO 18113-2:2011 In vitro diagnostic medical devices – information supplied by the manufacturer (labelling) – Part 2: in vitro diagnostic reagents for professional use

EN ISO 23640:2015 In vitro diagnostic medical devices – evaluation of stability of in vitro diagnostic reagents

EN 13612:2002/AC: 2002 Performance evaluation of in vitro diagnostic medical devices

IEC 62366-1:2015 Application of usability engineering to medical devices

**Revision history:**

<b>Version</b>	<b>Revision history</b>	<b>Author</b>	<b>Date</b>
1/0	First procedure	Wenna Li	3 <sup>th</sup> , Sept., 2020