



LEPU MEDICAL

INTERNATIONAL

Training: SARS-CoV-2 Antigen Rapid Test Kit | IMSD Karry

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Introduction



LEPU Test Kit



Abbott Test Kit



Q&A and Discussion



Introduction of Antigen test



SARS-COV-2 Tests Methods

RT-PCR test: --test virus RNA

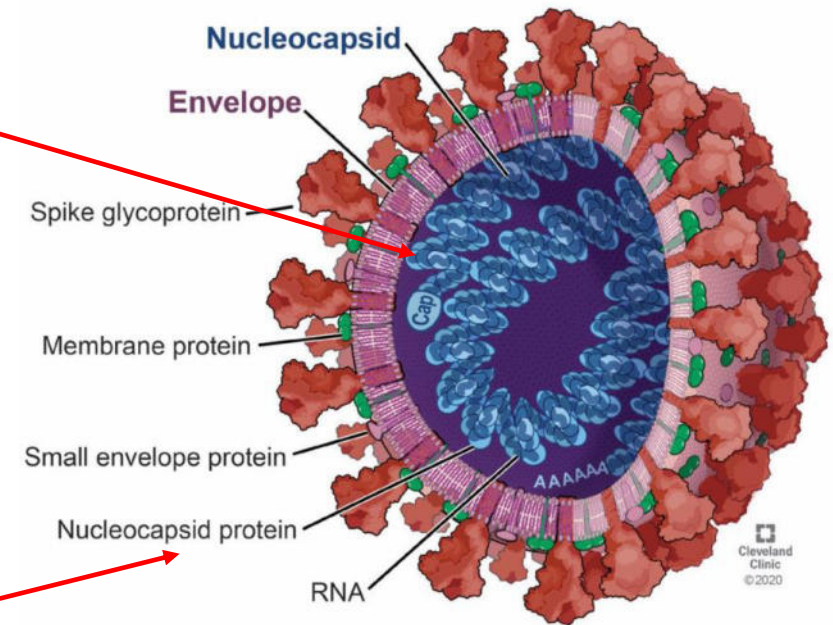
A method of polymerase-chain-reaction amplification of nucleic acid sequences that uses RNA as the template for transcribing the corresponding DNA using reverse transcriptase.

Antibody test: --test antibody from patients's blood

Antibody tests involve analyzing a patient's sample (usually blood) for the presence or absence of a particular antibody

Antigen test: --test Antigen of virus

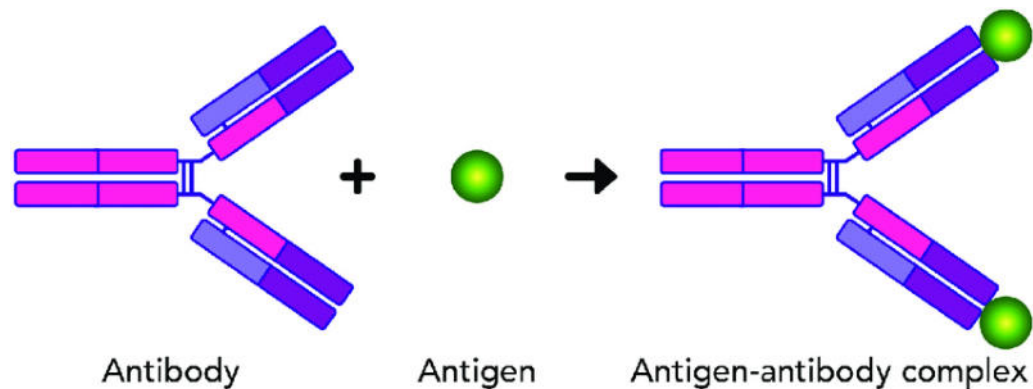
Antigen test basically looks for those fragments of antigens within a person's body to see if they're infected with the virus.



Antigen test

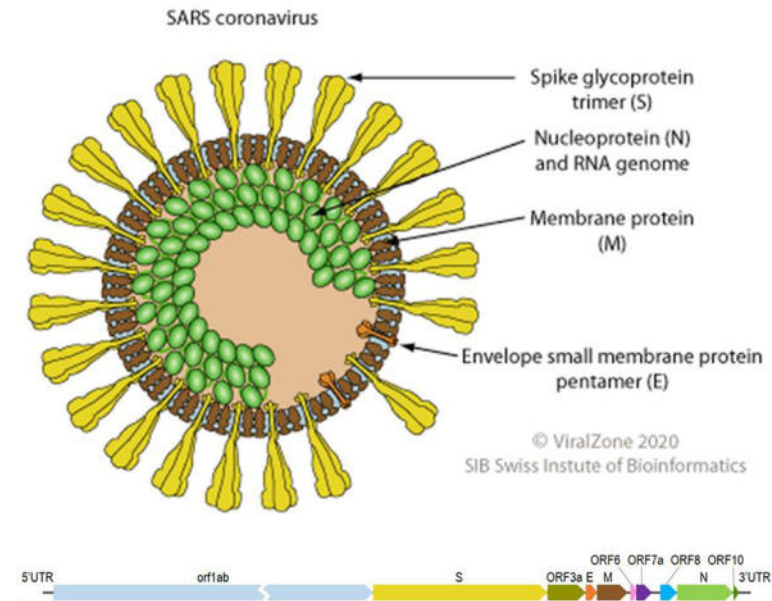
Antigen test:

- Antigen tests are immunoassays that detect the presence of a specific viral antigen, which implies current viral infection.



SARS-CoV-2 antigen:

- N-protein antigen conserved protein, can be used as a tool for the diagnosis of coronaviruses



Tests Methods comparison

Antigen test:

- Relatively inexpensive
- Reliable results in approximately 15 minutes
- No device required
- “Gold standard” for clinical diagnostic detection of SARS-CoV-2 remains RT-PCR.

Table 2. Summary of Some Differences between RT-PCR Tests and Antigen Tests

	RT-PCR Tests	Antigen Tests
Intended Use	Detect current infection	Detect current infection
Analyte Detected	Viral RNA	Viral Antigens
Specimen Type(s)	Nasal Swab, Sputum, Saliva	Nasal Swab
Sensitivity	High	Moderate
Specificity	High	High
Test Complexity	Varies	Relatively easy to use
Authorized for Use at the Point-of-Care	Most devices are not, some devices are	Yes
Turnaround Time	Ranges from 15 minutes to >2 days	Approximately 15 minutes
Cost/Test	Moderate	Low

Traditional Antigen test kit

Traditional Antigen Test Kit:

Description

- *nasal swab/ throat swab
- *noninvasive
- ***can detect virus in early stage of infection**

Market Players:

Beijing Savant Biotechnology,
Coris BioConcept,
Fuji Rebio Inc,
RapiGEN Inc,
Shenzhen Bioeasy.



Test Procedure



Advanced Antigen Test Kit

Advanced Antigen Test Kit:

Advantages

- *Lower cost
- *Easy sample handling procedure
- *app with pass

Market Players:

Abbott
Lepu Medical





Lepu SARS-CoV-2 Antigen Rapid Test Kits

LEPU SARS-CoV-2 Antigen Rapid Test Kit

Lepu advanced Product :

Lepu SARS-CoV-2 Antigen Rapid Test Kit (colloidal gold immunochromatography)

Principle:

Based on the specific antibody-antigen reaction and immunoanalysis technology. detection of nucleocapsid protein (N-protein) antigen from SARS-CoV-2.

Product Composition:

- The product consists of test cards/buffers in box
- App



SARS-CoV-2 Antigen Rapid Test Kit



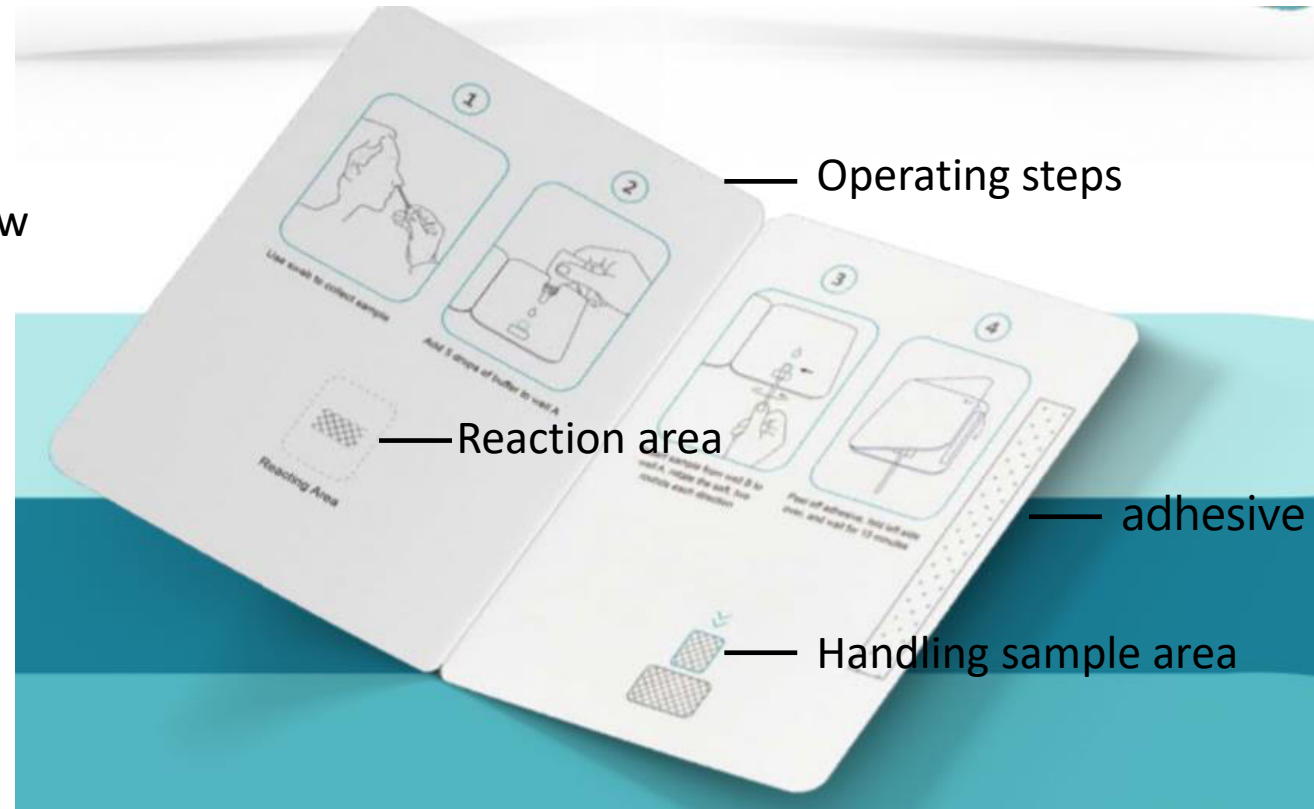
App for users and doctor

SARS-CoV-2 Antigen Rapid Test Kit

SARS-CoV-2 Antigen Rapid Test Kit Construction:



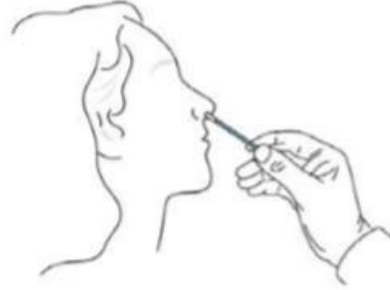
Unique QR code for each kit, can only be scanned on our app



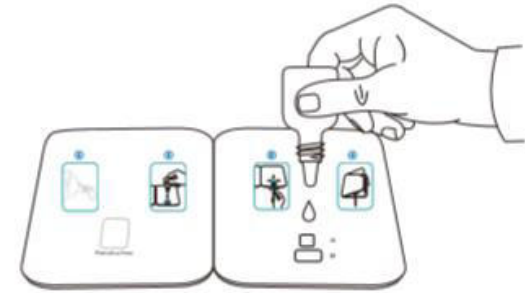
Operating Steps

Four Operating Steps:

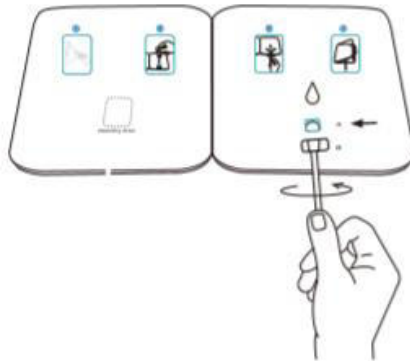
- Collect samples : Less impurities, easy to collect samples
- Add reaction buffers to well A. Lay it flat!! 5 drops!!
- Insert the swab through well B to well A: Rotate swab shaft 2 times CLOCKWISE (to the right). Keep the card flat
- Peel off the adhesive, fold the left side over, and wait for 15 minutes.



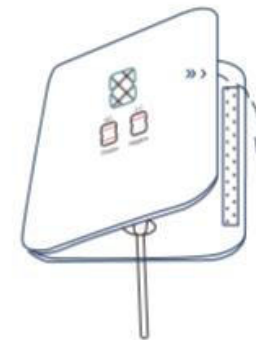
Step 1: Use swab to collect sample.



Step 2: Add 5 drops of buffer to well A.



Step 3: Insert the sample through well B to well A, rotate the shaft clockwise first and counterclockwise, twice each.



Step 4: Peel off the adhesive, fold the left side over, and wait for 15 minutes.

Result Interpretation

➤ Positive (+):

It will appear purple stripes in both quality control area (C) and either test area (T)

➤ Negative (-):

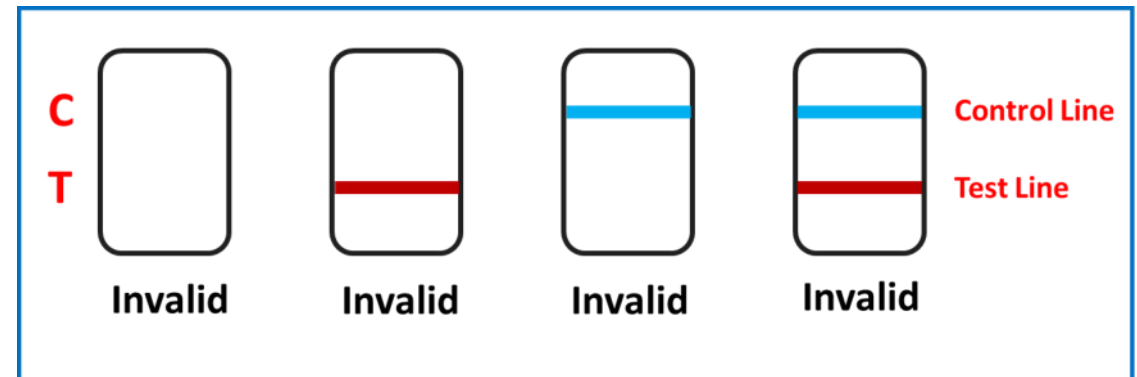
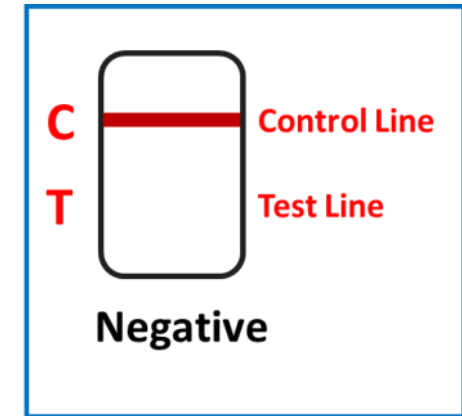
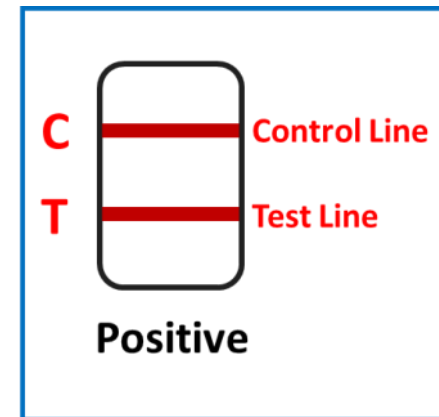
There is only one purple stripe in C area , and without purple stripe in either test area (T)

➤ Invalid:

- 1) No purple stripe in C area
- 2) Blue stripe in C area
- 3) Reasons: incorrect operating procedures or the test card has already deteriorated
- 4) Retest



View results right here through window



Lepu SARS-CoV-2 Antigen Rapid Test Kit

Advantages of our Test kit:

- Non-invasive
- Simple to use
- Convenient, no devices required
- Rapid, get result in 15 minutes
- Stable, with high accuracy
- Inexpensive, cost-efficiency



Lepu IVD App

The APP displays results from the 15-minute Lepu SARS-CoV-2 Antigen Rapid Test Kit.

For Patients:

- Easy to get results from APP
- Get LP IVD PASS if receive negative results

For doctors:

- Easy to use
- Send reports by online app



Lepu IVD App for patient



Lepu IVD App for doctors



3 different type QR code

LP IVD App operation steps



Step 1: Download and register your account;

Step 2: Create user's profile and generate QR code;

Step 3: Wait the doctor to scan QR code on both smart phone and card.

Step 4: After generating results, doctors scan the QR code on the card again to input the result.

Step 5: Get the results after the doctor upload the result and have A LEPU PASS.

Applications



Hospital



Test site



Airport



Hotel



Corporation



Mass screening

Three ways for Customer Interaction

1. With APP:

Patients download apps→registration→Scan QR code for collecting patients' data→Antigen test→Scan QR code to upload results→patients view results on app

2. With Bar code

Input the patients information in hospital's system→Generate barcode→Stick to test card→Antigen test→Doctors scan barcode to input test results

3. With nothing but kit

Sign up patients name on test card→Antigen test→Test results/report

	Hospital	Test site	Airport	Hotel	Corporation	Mass screening
Model	1\2\3	1\3	1\3	3	1\3	1\2\3



Compare with Abbott Test Kit



Abbott antigen test card

Abbott's product: BinaxNow COVID-19 Ag CARD

Usage: For the detection of nucleocapsid protein (**N-protein**) antigen from SARS-CoV-2. Same principle with our kits.

Operations steps of the test card:

1. 6 drops of extraction reagent.
2. Insert the sample swab and rotate it.
3. Securely seal the card and wait for 15 minutes.

Operations steps of the Navica app:

1. Create the patient's profile.
2. Use the Navica ID to get tested at a Navica-enabled test site.
3. Receive a Navica pass if the result is negative.



Abbott COVID-19 Ag Card/ Navica app

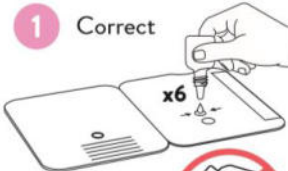
Similar with our Lepu SARS-CoV-2 Antigen Rapid Test Kit

Abbott antigen test card

INTRODUCING


Patient Samples require 6 drops of Extraction Reagent.

1 Correct

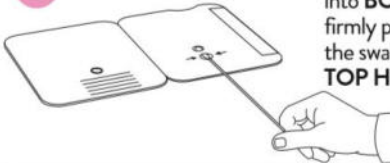


Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE**, slowly add 6 **DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.

Wrong

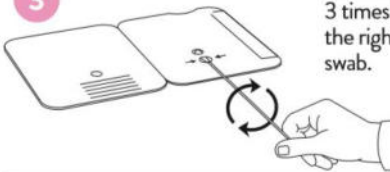


2



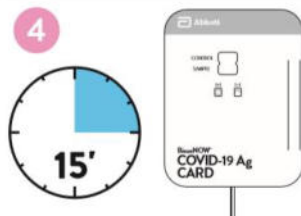
Insert sample or control swab into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE**.

3



Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). Do not remove swab.

4



Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read result in the window 15 minutes after closing the card. In order to ensure proper test performance, it is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes.

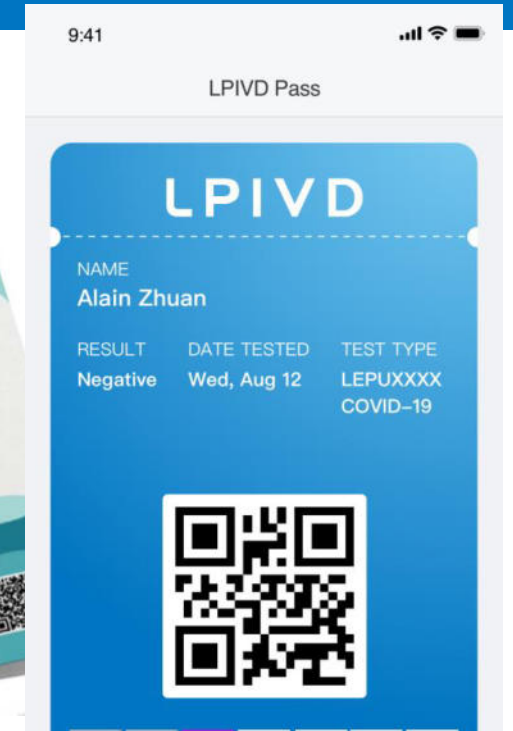
Used test cards should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.

Comparisons with Abbott

	Lepu	Abbott
Principle	Antigen-antibody reaction (N-protein)	Same
Testing period	15 mins	Same
Operation steps for apps and cards	Same	Same
Specificity and sensitivity	Under the test	97.1% sensitivity and 98.5% specificity.
Test Stripe	Not easy to fall off	
Card size	Unique larger size	Credit card size
Areas for handing samples	Square well (easier for reaction)	Round hole
Price	Same function. Lower price	\$5
Design	Better design	

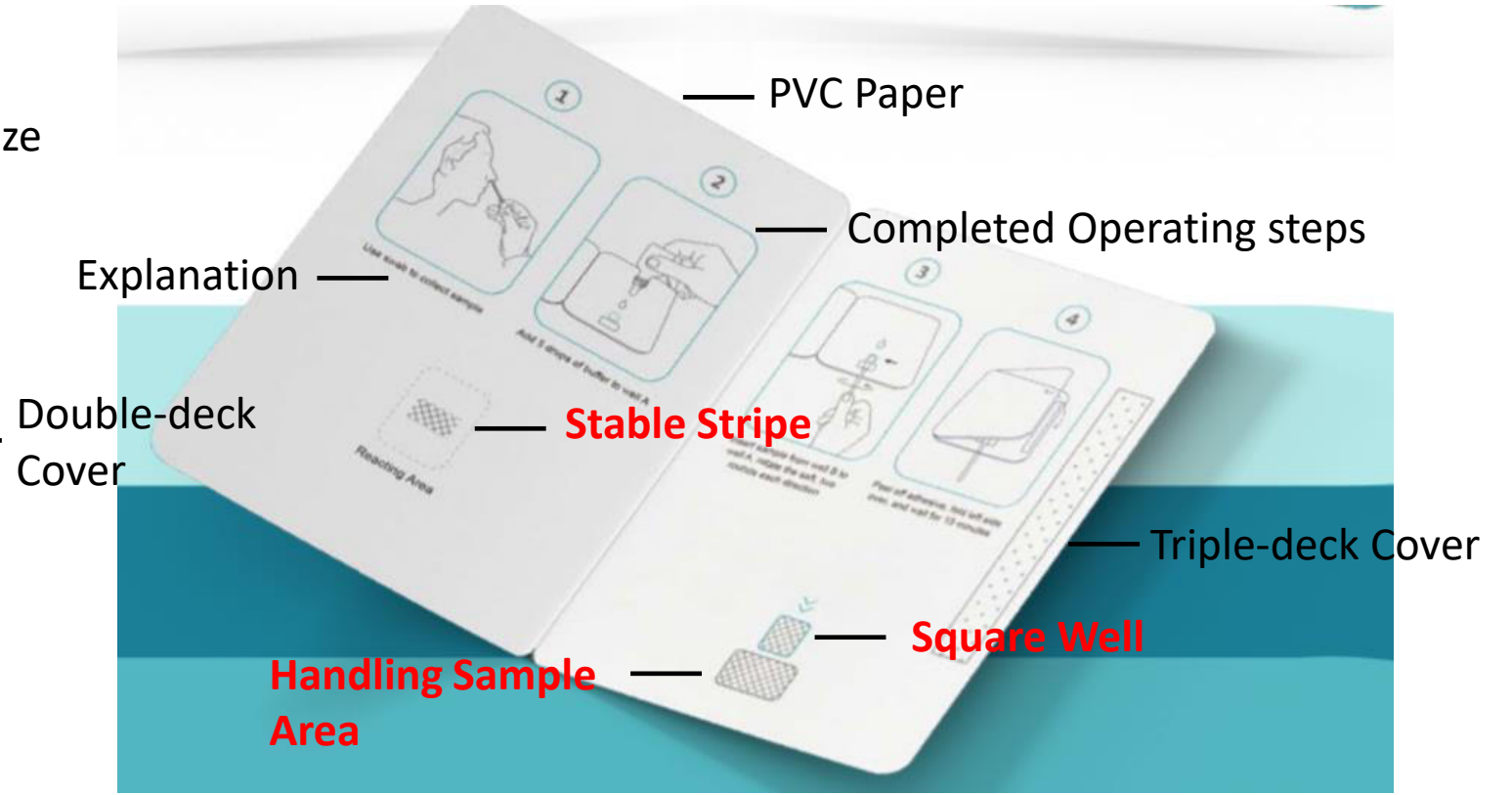
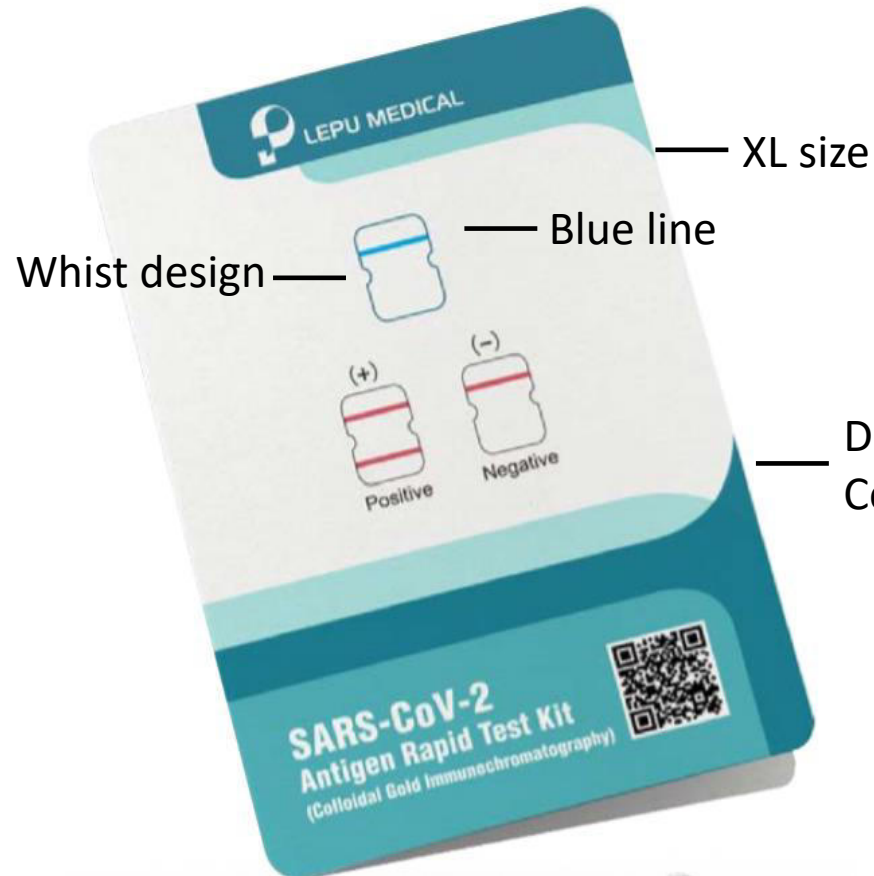
Competitive power

Same function
Lower price



The advantages in design

SARS-CoV-2 Antigen Rapid Test Kit Construction:





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