LIMING BIO®

StrongStep®

System Device for SARS-CoV-2 & Influenza A/ B Combo Antigen Rapid Test

A Community of Shared Future for Mankind

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Introduction of Company

Nanjing Liming Bio-Products Co., Ltd.

It is a professional manufacturer of in vitro diagnostic reagents

2001
Time of establishment

40%
Percentage of master degree or above

100
Existing employees

3000 m^2
Purification area

StrongStep®

» Rapid Diagnostic Test
» 5 million Tests per Year

Limingbio Diagnostics are ASSURED

2001

The company was founded and became the distributor of BioMérieux and Abbott

2008

Transform to independent research, development and production of IVD, and obtain 6 class III registration certificates, 1 class II Registration Certificate and 5 class I registration certificates issued by the State Food and drug administration

2019

Successful construction of molecular detection technology platform

2020

Successfully developed a series of COVID-19 diagnostic test kits

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CE

REF:500220

20 Tests/Kit

Specimens: Nasal / Oropharyngeal swab

CONTENTS

- Individually Packed Test Devices : 20
- Package insert : 1
- Workstation : 1
- packs of swabs : 20（2 swabs/pack）

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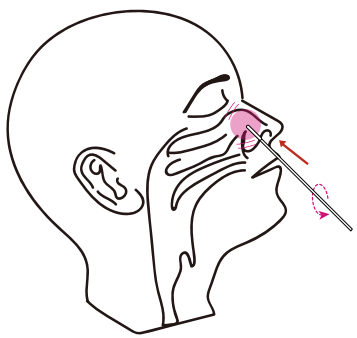
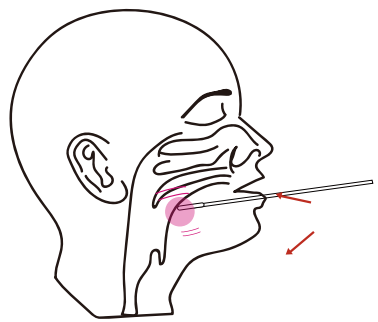
What is the Rapid Antigen Test ?

COVID-19 and influenza A/B antigens were detected by latex immunochromatography in the nasal swabs and Oropharyngeal swabs.

Sampling illustration



Nasal Swab Sample



Oropharyngeal Swab Sample

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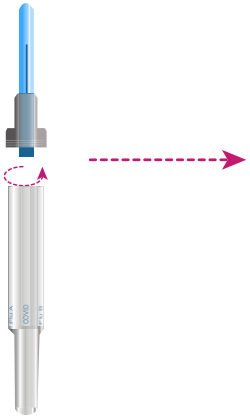
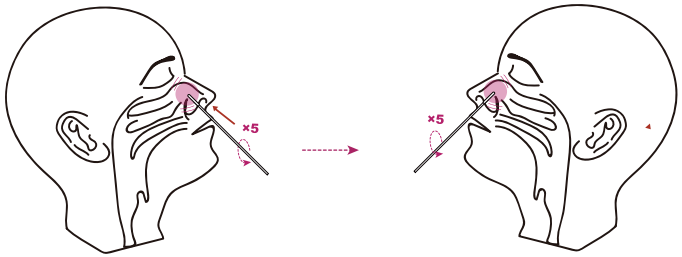
Nasal swab

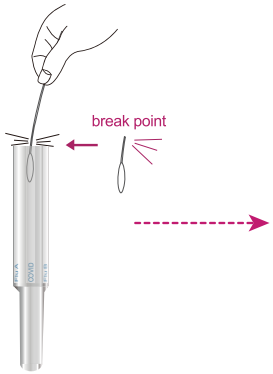
Unscrew the cover of the device



Insert one swab into one nostril of the patient.
Roll the swab 5 times along the mucosa inside the nostril.
Use the same swab, repeat this process for the other nostril .

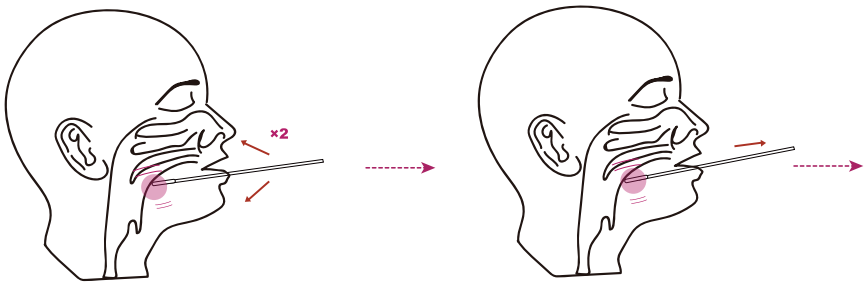


Withdraw the swab from the nasal cavity and put the swab front end into extraction tube , against the tube and break off the swab at the break point, let the swab tip fall into the tube.

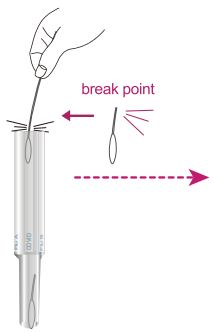


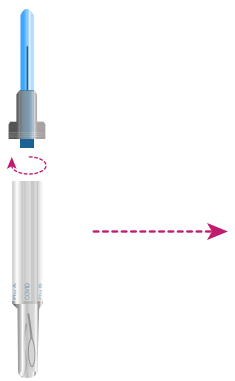
Oropharyngeal swab

Ask patient to open mouth and press tongue with tongue depressor if necessary.
Use another swab into the oropharynx and scrap left and right side pharynx mucous membrane 2 times.



Treat another swab with the same method above.





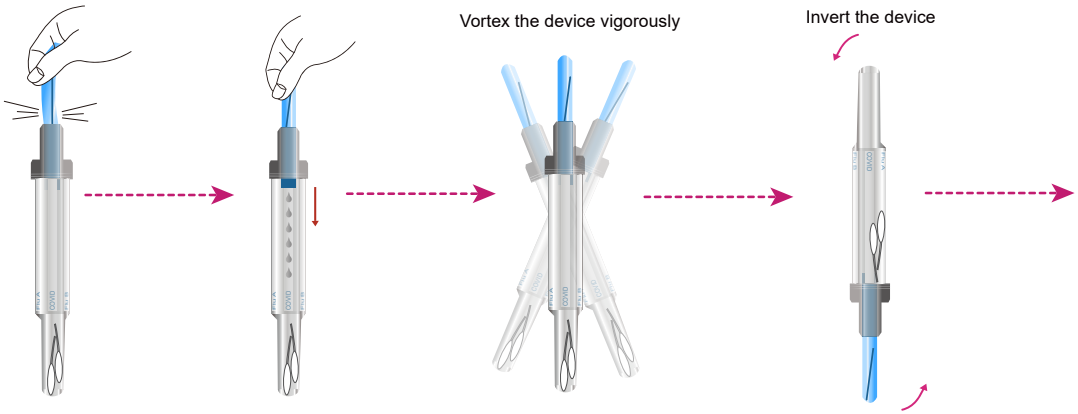
Screw the cover of the device

Break the stick in the buffer tube.

FIRMLY squeeze the buffer tube, make sure all the liquid fall into the lower tube.

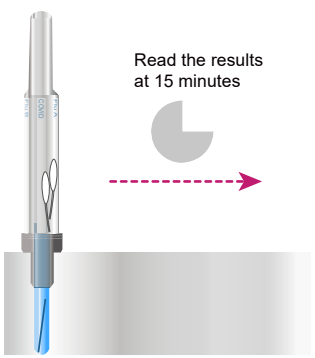
Vortex the device vigorously

Invert the device

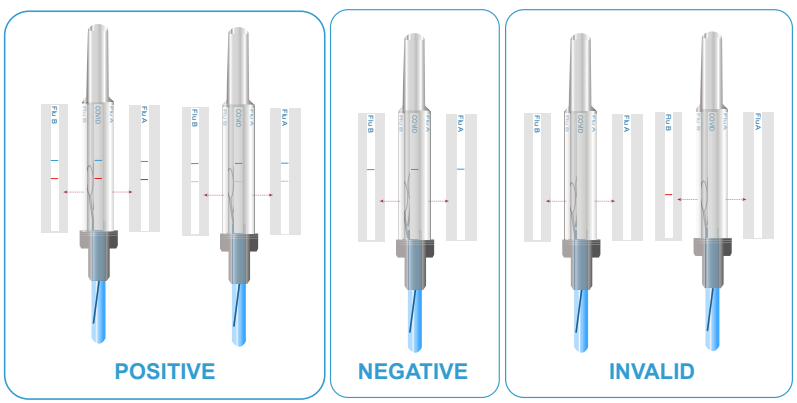


put the device into the workstation, let the sample buffer migrate onto the test strip.

Read the results at 15 minutes



RESULT



Advantages of system device

- Double biosafety protection design to protect operator and Lab
- Three types of severe respiratory viruses were detected simultaneously
- Independent Packaging
- Can be used for home self-testing

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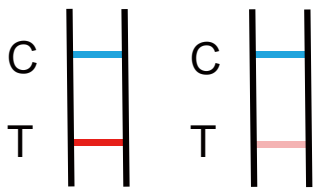
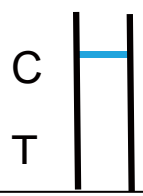
INTERPRETATION OF RESULTS

POSITIVE RESULT: 	Two colored bands appear within 15minutes. One blue band appears in the Control Zone (C) and another red band appears in the Test Zone (T). The test result is positive and valid. No matter how faint the red band appears in the Test Zone (T),the test result should be considered as positive result.
NEGATIVE RESULT: 	One blue band appears in the Control Zone (C) within 15 minutes. No red band appears in the Test Zone (T). The test result is negative and valid.
INVALID RESULT: 	No blue band appears in the Control Zone (C) within 15 minutes. The test result is invalid. Repeat the test with a new test device.

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Performance

	PCR Comparator		
SARS-CoV-2 Antigen Test	Positive	Negative	Total
Positive	36	2	38
Negative	3	71	74
Total	39	73	112

Positive Percent Agreement:
(PPA)=92.31% (79.13%～98.38%)
Negative Percent Agreement:
(NPA)=97.26% (90.45%～99.67%)

	PCR Comparator		
Influenza type A Antigen Test	Positive	Negative	Total
Positive	29	5	34
Negative	7	137	144
Total	36	142	178

Positive Percent Agreement:
(PPA)=80.56% (63.98%～91.81%)
Negative Percent Agreement:
(NPA)=96.48% (91.97%～98.85%)

	PCR Comparator		
Influenza type B Antigen Test	Positive	Negative	Total
Positive	17	2	19
Negative	6	153	159
Total	13	155	178

Positive Percent Agreement:
(PPA)=73.91% (51.59%～89.77%)
Negative Percent Agreement:
(NPA)=98.71% (95.42%～99.84%)

Clinical significance

1、The antigen test is positive and has the diagnostic value. It can be confirmed again by PCR.

2、If the antigen is negative, the possibility of virus infection cannot be completely ruled out.

3、It can be combined with the results of antibody test (blood sample) for comprehensive judgment.


One world One fight
LIMING BIO
THANKS