LIMING BIO

V2022.1

It is a professional manufacturer of in vitro diagnostic reagents

Complete diagnostics program on COVID-19

SARS-CoV-2

Specialized In Manufacturing Rapid Tests For

Sexually Transmitted Diseases

Gastroenteritic Diseases

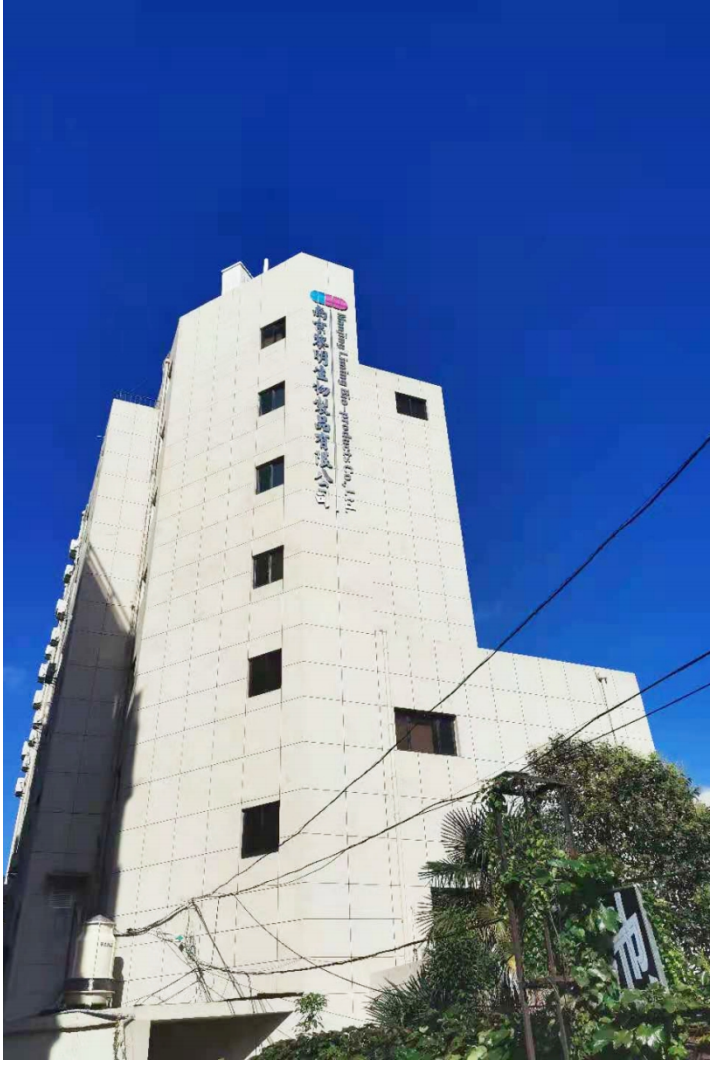
Fertility & Others

For more information,please visit our website **http://www.limingbio.com**

A Community of Shared Future for Mankind

Scan code and pay attention to us

www.limingbio.com



Company Profile

Nanjing Liming Bio-Products Co., Ltd. (Liming Bio) develops, manufactures and markets a series of rapid tests for Sexually Transmitted Diseases (STDs), Gastroenteritic diseases and Fertility. Founded in June, 2001, we have abundant experience in the field of diagnostics, especially for STDs.

LIMING BIO Diagnostics are ASSURED

Our technical team has begun application research on dyed latex immuno-chromatographic assay from 2002 and gained some breakthrough achievements, such as HSV 1/2 antigen rapid test, HPV antigen rapid test, Gonorrhoeae/Chlamydia combo rapid test, Trichomonas/Candida combo rapid test and so on.

Outstanding performance has been proved compared with other methods(including PCR or culture) which are time-consuming and costly.Using our rapid tests, either patient or healthcare professional can save a lot of time for waiting because it just needs 15 minutes or so.

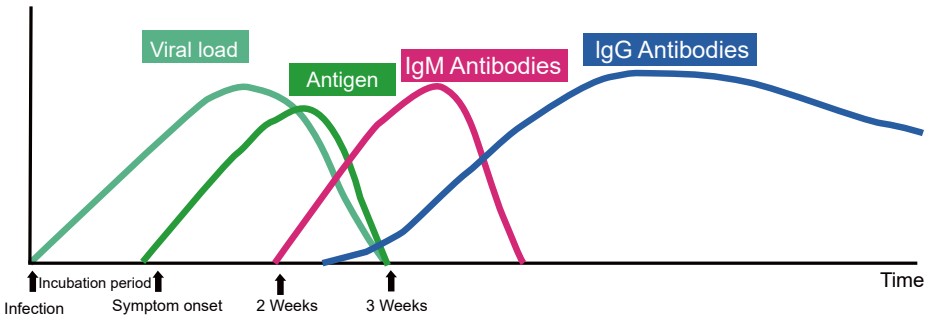
For many years, we are dedicated to our mission that: provide rapid,accurate and cost-effective STDs diagnostic tests through ceaseless efforts on the diagnostic research and development.

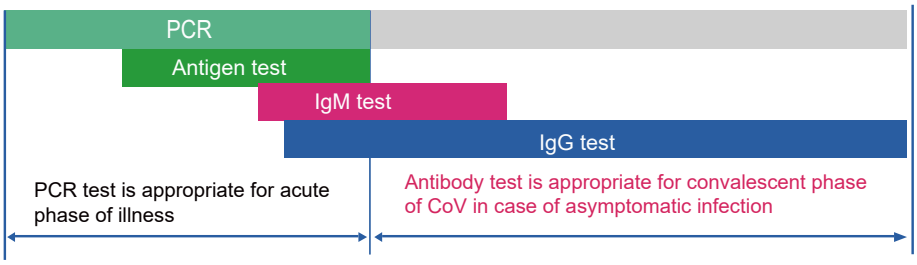
Current clinical symptoms screening methods (cough and fever, etc) fail to find the viral infections during the incubation period. To fully combat COVID-19, **LimingBio has developed complementarily eight types of diagnostic tests:**

Products Catalog

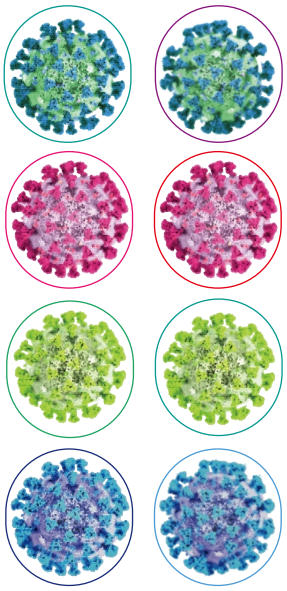
Cat	Product	Detection		Specimens	Specification
		SARS-CoV-2			
502090	SARS-CoV-2 IgM/IgG Antibody Rapid Test	Antibody		Whole Blood / Serum / Plasma	CE
500200	SARS-CoV-2 Antigen Rapid Test	Antigen	HOT	Nasal /Oropharyngeal swab/Saliva	CE
500210	System Device for SARS-CoV-2 Antigen Rapid Test	Antigen	HOT	Nasal /Oropharyngeal swab	CE
500190	Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit	RNA	HOT	Nasal / Nasopharyngeal swab	CE
510010	SARS-CoV-2 & Influenza A/B Multiplex Real-Time PCR Kit	RNA	NEW	Nasal / Nasopharyngeal swab	CE
500220	System Device for SARS-CoV-2 & Influenza A/B Combo Antigen Rapid Test	Antigen	HOT	Oropharyngeal / Nasal / Nasopharynx swab	CE
502130	SARS-CoV-2 Neutralization Antibody Rapid Test	Antibody	NEW	Venous whole blood / Fingerstick whole blood / Serum or plasma	
500210S	System Device for SARS-CoV-2 Antigen Rapid Test	Antigen	NEW	Saliva	

For more information,please visit our website **http://www.limingbio.com**





COVID-19



StrongStep®

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

REF:500220

20 Tests/Kit

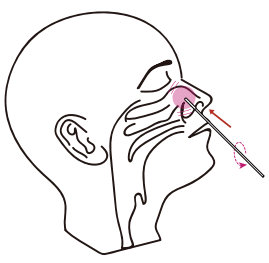
CONTENTS **22.5×18×7.5CM**

- Individually Packed Test Devices : 20
- Package insert : 1
- Workstation : 1
- Packs of swabs : 20（2 swabs/pack）
- Positive control swab : 1 (on request only)

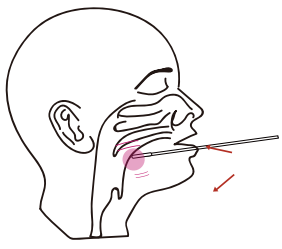
What is the Rapid Antigen Test ?

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

Sampling illustration



Nasal Swab Sample



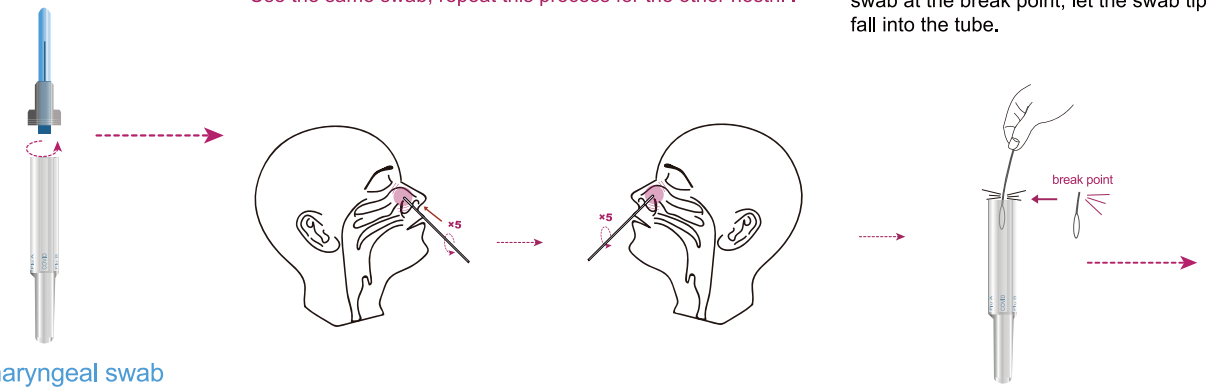
Oropharyngeal Swab Sample

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.

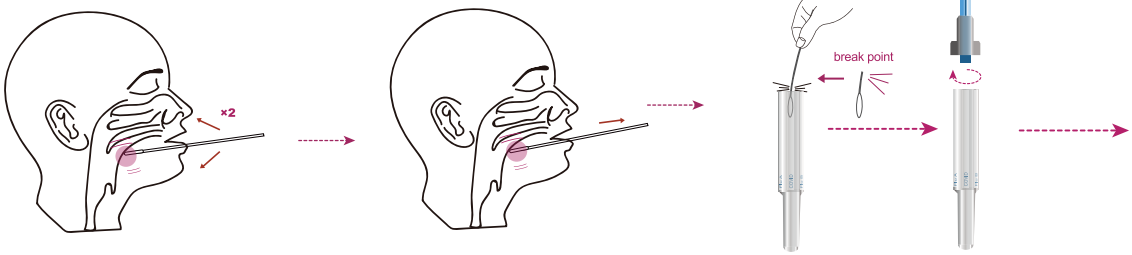


Oropharyngeal swab

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



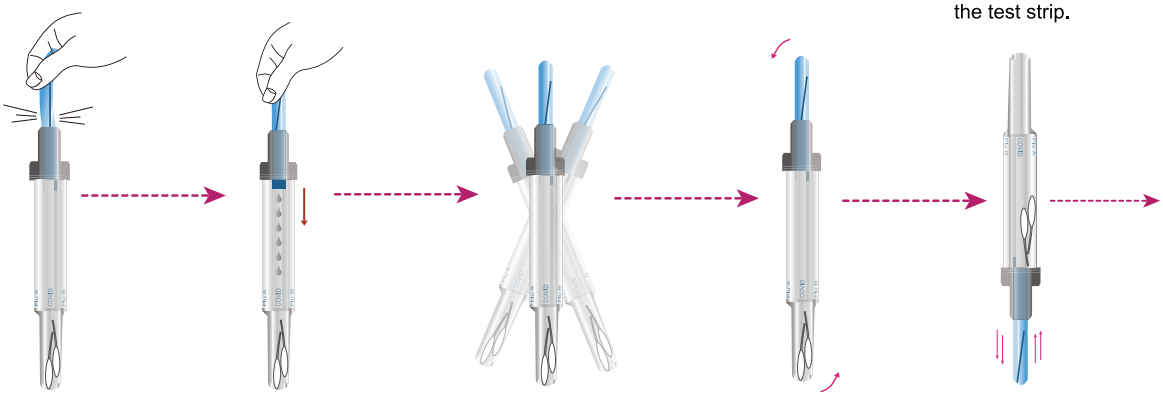
Break the stick in the buffer tube.

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

Vortex the device vigorously by vortex or hand.

Quickly invert the device.

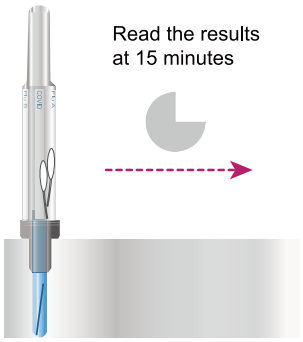
Knock the blue tube on the operation table surface if necessary to make sure all the liquid flow down , let the sample buffer migrate onto the test strip.



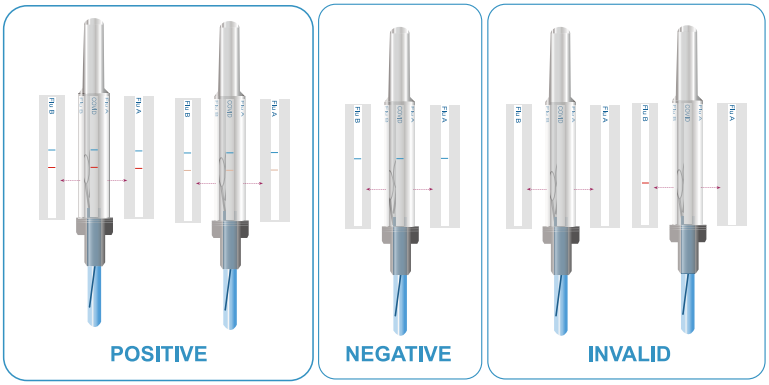
IMPORTANT: Do not invert the device again or else the liquid will flood onto the strip which lead to the failure of the testing.

Put the device into the workstation.

Read the results at 15 minutes



RESULT



Note: Result after 15 minutes may not be accurate.

StrongStep®

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
- No drop off in sensitivity when compared with the wild type with respect to the following variants - VOC1 Kent, UK, B.1.1.7 and VOC2 South Africa, B.1.351.

Performance

	PCR Comparator			
		Positive	Negative	Total
StrongStep® SARS-CoV-2 Antigen Rapid Test	Positive	101	3	104
	Negative	4	402	406
	Total	105	405	510

Positive Percent Agreement:
(PPA)= 96.19% (90.53%～98.95%)*
Negative Percent Agreement:
(NPA)= 99.26% (97.85%～99.85%)*
Kappa: 0.9579（0.9269～0.9889.highly consistent)*
*95% Confidence Interval

	PCR Comparator			
		Positive	Negative	Total
Influenza type A Antigen Test	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			
		Positive	Negative	Total
Influenza type B Antigen Test	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.

StrongStep®
SARS-CoV-2 & Influenza A/B Multiplex Real-Time PCR Kit

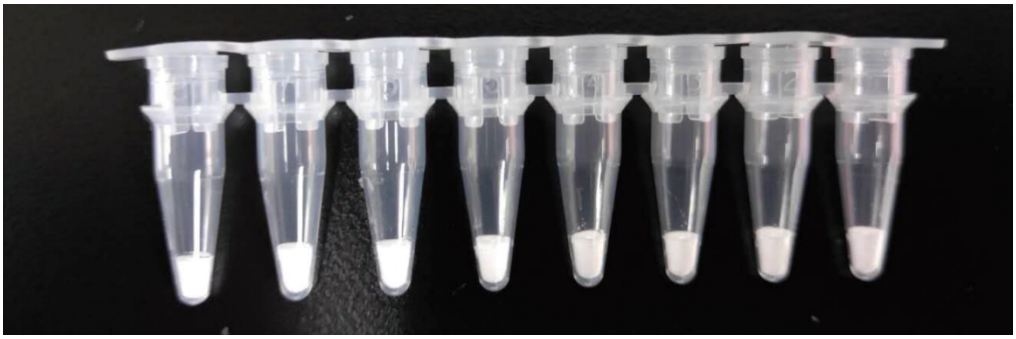
REF:510100

96 Tests/Kit

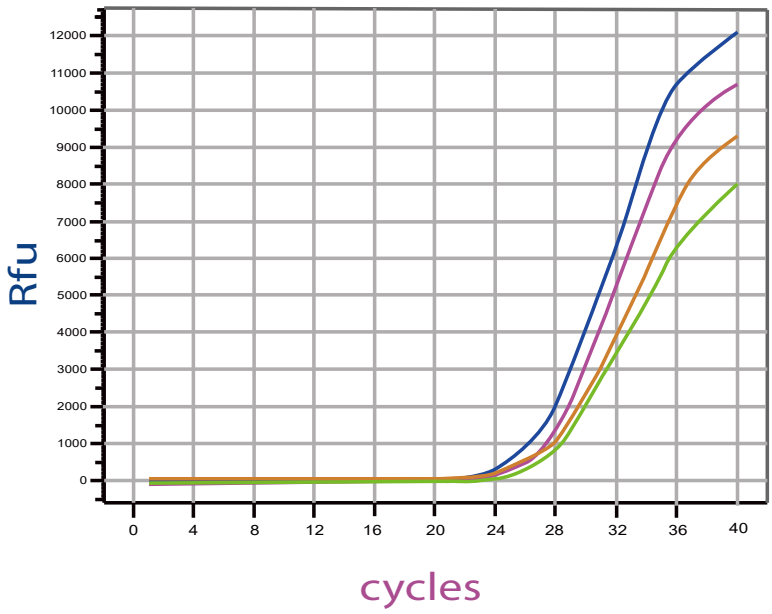
16cm×11cm×5.5cm

Specimens: nasal / nasopharyngeal swab / oropharyngeal swab

Results come out in 2 hours, satisfactory performance done by clinical trials. room-temperature transportation .



Kit Components	Contents	Amount & Package
SARS-CoV-2 and influenza A/B rt-qPCR reagents	Lyophilized ready-to-use PCR beads in 8-Strip Tubes: containing Reverse transcriptase, Taq DNA polymerase, Primers & probes, dNTPs, $MgCl_2$, KCl	12 X vacuum seal bags
	New 8-Strip Caps	
Positive control	Lyophilized Armored RNA containing target gene.	1 X 2.0 ml tube
Instructions for Use		1



- This kit provides multiplex detections of SARS-CoV-2's ORF1ab gene、 Influenza A's M gene and Influenza B's NS1 gene in a single tube.
- An internal Control (IC) amplifying human RNase P gene was used to evaluate extraction of RNA and detect PCR inhibition in PCR.
- The kit is supplied as lyophilized PCR BEADS, which contains nucleic acid amplification enzyme, reaction buffer, specific primers and probes. The kit can be directly put into qPCR instrument after adding sample and water.

1 Quadruple detections in a singletube

Detection of conserved region of SARS-CoV-2's ORF1ab gene、 Influenza A's M gene and Influenza B's NS1 gene, respectively.An internal Control (IC) amplifying human RNase P gene was used to identify possible PCR inhibition, to measure extraction purity and to confirm the integrity of the PCR run.

2 Ready to use

The kit is supplied as ready-to-use lyophilized PCR beads, After adding water and purified template, it can be tested on the machine.

3 Very strong thermal stability

The reagents are freeze-dried and sealed in vacuum bags. The kit can be stable at room temperature. After accelerating at 56 ° C for 9 weeks, he reagent form and performance remained unchanged.

4 Ambient temperature storage and transportation

No need for cold chain, no need to store at low temperature before opening to fully free up cold storage space.

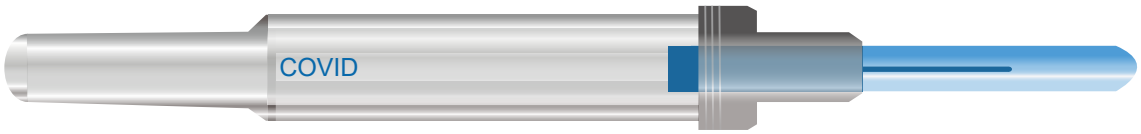
StrongStep® Dual Biosafety System Device for SARS-CoV-2 Antigen Rapid Test

REF:500210

20 Tests/Kit

CONTENTS

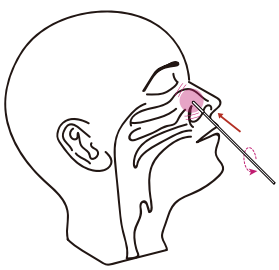
- Individually Packed Test Devices : 20
- Package insert : 1
- Workstation : 1
- Packs of swabs : 20（2 swabs/pack）
- Positive control swab : 1 (on request only)



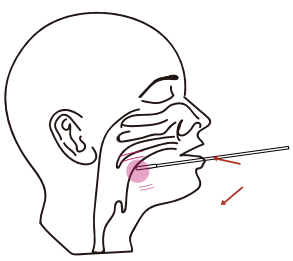
What is the Rapid Antigen Test ?

A novel coronavirus antigen was detected by latex immunochromatography in the nasal swabs and Oropharyngeal swabs.

Sampling illustration



Nasal Swab Sample

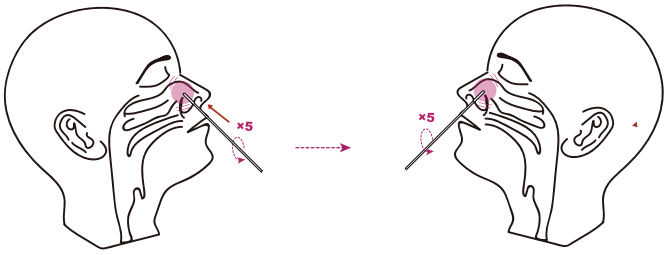


Oropharyngeal Swab Sample

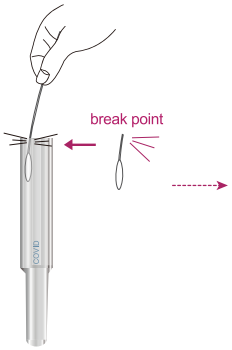
Unscrew the cover of the device.

Nasal swab

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 .

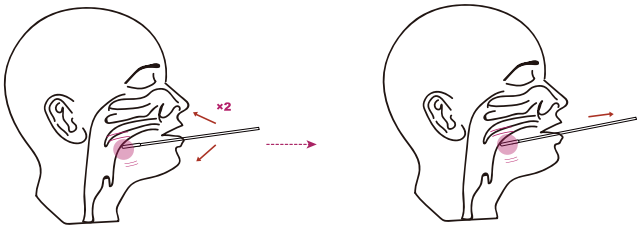


Withdraw the swab from the nasal cavity and put the swab front end into extraction tube , against the tube and break off the swab at the break point, let the swab tip fall into the tube.



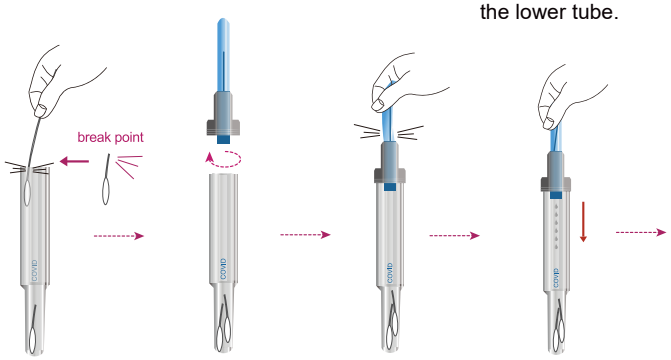
Oropharyngeal swab

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.



Screw the cover of the device.

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



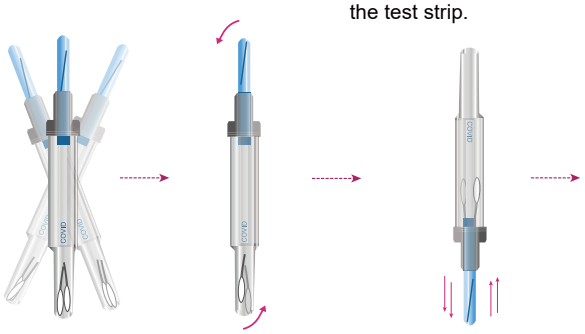
Treat another swab with the same method above.

Break the stick in the buffer tube.

Vortex the device vigorously by vortex or hand.

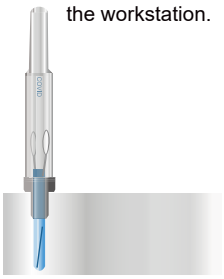
Quickly invert the device.

Knock the blue tube on the operation table surface if necessary to make sure all the liquid flow down , let the sample buffer migrate onto the test strip.



IMPORTANT: Do not invert the device again or else the liquid will flood onto the strip which lead to the failure of the testing.

Put the device into the workstation.



Read the results at 15 minutes.

Note: Result after 15 minutes may not be accurate.

Advantages of system device

1、Double biosafety protection design to protect operator and Lab

2、Independent Packaging

3、Can be sold in supermarket or drugstores，can be used for home self-testing

4、No drop off in sensitivity when compared with the wild type with respect to the following variants - VOC1 Kent, UK, B.1.1.7 and VOC2 South Africa, B.1.351.

Performance

	PCR Comparator		
StrongStep® System Device for SARS-CoV-2 Antigen Rapid Test		Positive	Negative	Total
	Positive	101	3	104
	Negative	4	402	406
	Total	105	405	510

Positive Percent Agreement:
(PPA)= 96.19% (90.53%～98.95%)*
Negative Percent Agreement:
(NPA)= 99.26% (97.85%～99.85%)*
Kappa: 0.9579（0.9269～0.9889.highly consistent)*
*95% Confidence Interval

StrongStep® SARS-CoV-2 Antigen Rapid Test

CONTENTS

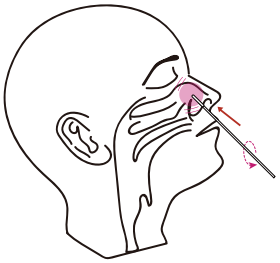
- Sealed foil pouch packed test devices : 25
- Dilution Buffer vials : (2*12ml/bottle) (optional)
- Dilution Buffer vials : (25*0.7mL / bottle) (optional)
- Extraction tube with pre-filled dilution buffer : 25 (optional)
- Extraction Tubes : 25 (optional)
- Packs of swab : 25 (optional)
- Saliva collection funnel : 25 (optional)
- Workstation : 1
- Package insert : 1

REF : 500200
225×180×65mm
25 Tests / Box
Specimens : Nasal / Oropharyngeal swab / Saliva

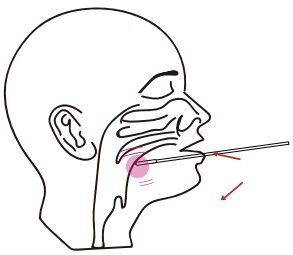
What is the Rapid Antigen Test ?

A novel coronavirus antigen was detected by latex immunochromatography in the nasal swabs / Oropharyngeal swabs/Saliva.

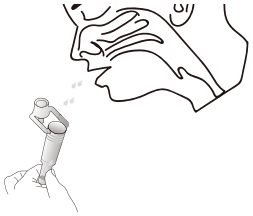
Sampling illustration



Nasal Swab Sample



Oropharyngeal Swab Sample



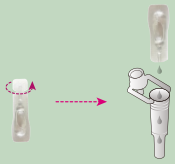
Saliva sample processing

For the detection of SARS-CoV-2 virus Nucleocapsid Protein antigen in human Nasal / Oropharyngeal swab or Saliva collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms.

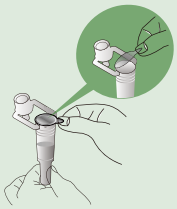
Method of operation of kit illustrated

For 12mL/bottle buffer,add 20 drops of Dilution Buffer into the extraction tube.

For 0.7mL/vial buffer,squeeze all the Dilution Buffer into the extraction tube.



For pre-filled buffer, remove the seal from the vial containing the liqutd.



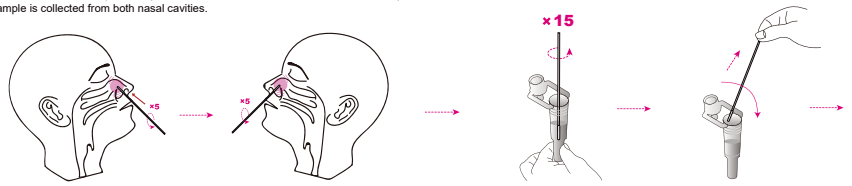
Swab sample processing

• Nasal Swab Sample

- Insert one swab into one nostril of the patient. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.
- Use the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.

Put the nasal swab into the tube and squeeze the tube while roll the swab against the side of tube for 15 times.

Squeeze the swab against the upper part of tube and discard the swab.

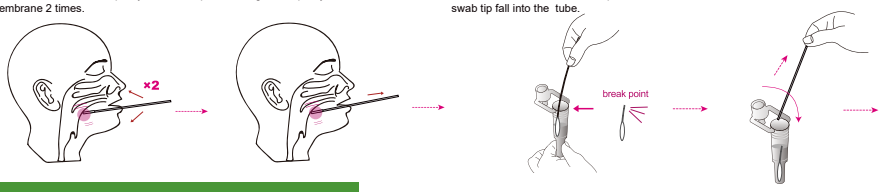


• Oropharyngeal Swab Sample:

- 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.

Put the swab front end into extraction tube , break off the swab at the break point, let the swab tip fall into the tube.

Discard the shank of the swab.

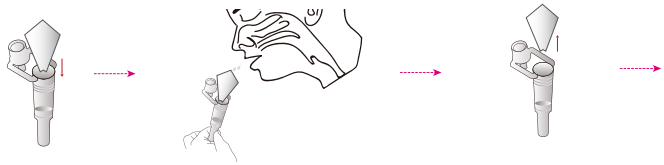


Saliva sample processing

Install the saliva collection funnel on the tube

Spit out the saliva into the tube through the saliva collection funnel

Then remove the saliva collection funnel



Test operation

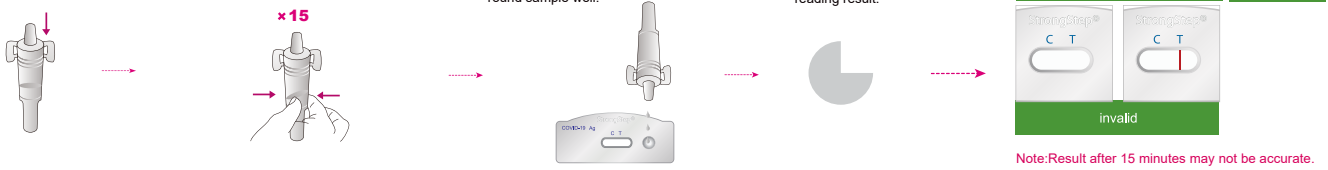
Cover the cap

Mix the solution by squeeze the tube forcefully for at least 15 times.
Allow the specimen to soak in the dilution buffer for one minute prior to the next step

Remove the test device from its sealed pouch.

Add 3 drops of specimen solution to round sample well.

Wait for 15 minutes reading result.



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Swabs	PCR Comparator		
StrongStep® SARS-CoV-2 Antigen Rapid Test		Positive	Negative	Total
	Positive	101	3	104
	Negative	4	402	406
	Total	105	405	501

Positive Percent Agreement: (PPA)= 96.19% (90.53%～98.95%)*
Negative Percent Agreement: (NPA)= 99.26% (97.85%～99.85%)*
Kappa: 0.9579（0.9269～0.9889.highly consistent)*
*95% Confidence Interval

Saliva	PCR Comparator		
StrongStep® SARS-CoV-2 Antigen Rapid Test		Positive	Negative	Total
	Positive	102	2	104
	Negative	4	173	177
	Total	106	175	281

Positive Percent Agreement: (PPA)=96.23% (90.62%～98.96%)*
Negative Percent Agreement: (NPA)=98.86% (95.93%～99.86%) *
Kappa: 0.9544（0.9183～0.9905）
*95% Confidence Interval

- After sampling, it can be tested on site immediately and the result will be given in 15 minutes
- No auxiliary equipment is required during operation
- The positive result is of diagnostic valuePoor quality of samples may result in false negative
- Therefore, novel coronavirus pneumonia is not completely excluded by negative results.
- The reagent shall be transported and stored under normal temperature
- No drop off in sensitivity when compared with the wild type with respect to the following variants - VOC1 Kent, UK, B.1.1.7 and VOC2 South Africa, B.1.351.

StrongStep®
Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit (detection for three genes)

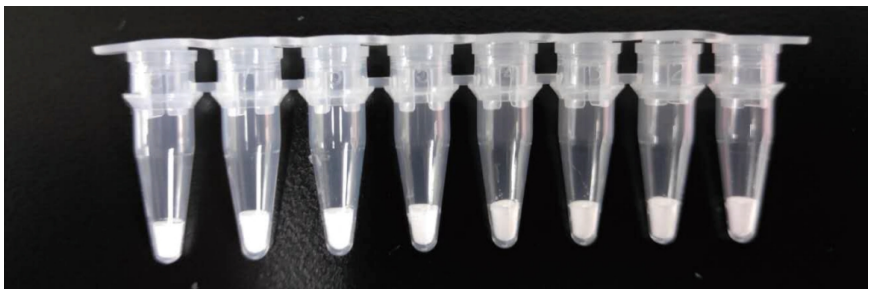
REF:500190

96 Tests/Kit

Specimens: Nasal
Nasopharyngeal swab

16cm×11cm×5.5cm

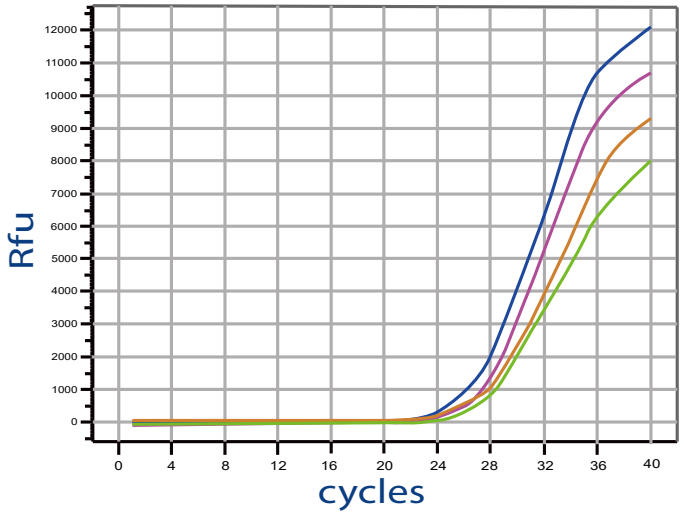
Results come out in 70mins, satisfactory performance done by clinical trials. room -temperature transportation and storage.



Components

Kit Components	Description	Amount & Package
SARS-CoV-2 RT-qPCR reagent	Lyophilized ready-to-use PCR beads in 8-Strip Tubes	12×vacuum seal bags
	New 8-Strip Caps	
Positive control	Lyophilized Armored RNA containing target gene.	1×1.5 ml tube
Instructions for Use		1

Intended to be used to achieve qualitative detection of SARS-CoV-2 viral RNA extracted from Nasal and Nasopharyngeal swab from patients.



- This kit provides multiplex detections of SARS-CoV-2's ORF1ab gene、E gene and N genein a single tube. Reduce false negative caused by mutation, At least one of the three positives can be used to determine the presence of virus infection.
- An internal Control (IC) amplifying human RNase P gene was used to evaluate extraction of RNA and detect PCR inhibition in PCR.
- The kit is supplied as lyophilized PCR BEADS, which contains nucleic acid amplification enzyme, reaction buffer, specific primers and probes. The kit can be directly put into qPCR instrument after adding sample and water.
- The kit cover and detect the genotyping of the UK, Brazilian, South Africa variants(N501Y ,K417N,E484K,B117,VOC202012/01 and 501.V2 variants).

1 Quadruple detections of three independent genes of SARS-CoV-2 in a singletube

Detection of conserved region of SARS-CoV-2's ORF1ab gene, E gene and N gene, respectively, avoiding non-specific interference of SARS2003 and Bat SARS-like virus strains.

An internal Control (IC) amplifying human RNase P gene was used to identify possible PCR inhibition, to measure extraction purity and to confirm the integrity of the PCR run.

2 Ready to use

The kit is supplied as ready-to-use lyophilized PCR beads, After adding water and purified template, it can be tested on the machine.

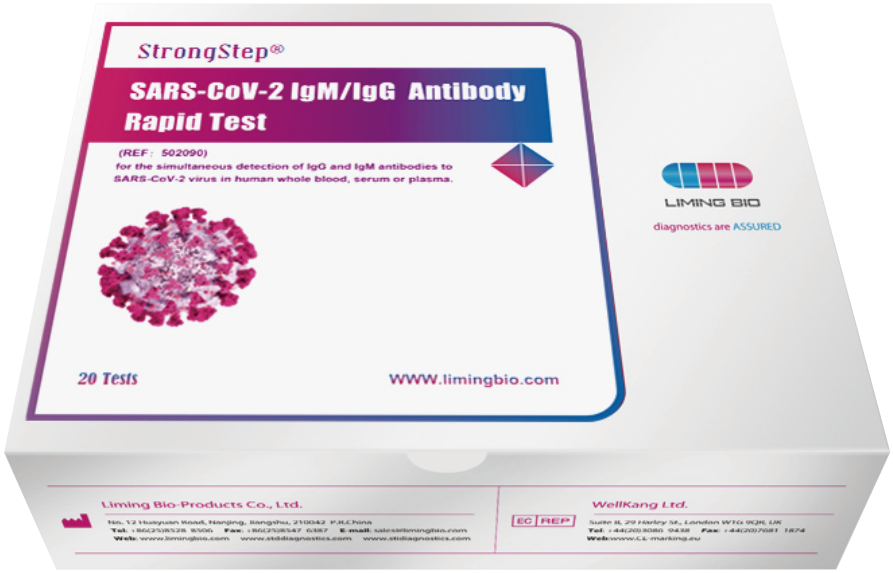
3 Very strong thermal stability

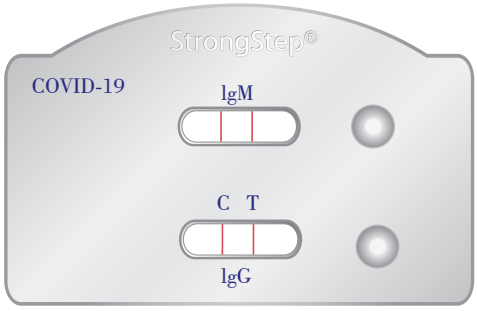
The reagents are freeze-dried and sealed in vacuum bags. The kit can be stable at room temperature. After accelerating at 56 ° C for 9 weeks, he reagent form and performance remained unchanged.

4 Ambient temperature storage and transportation

No need for cold chain, no need to store at low temperature before opening to fully free up cold storage space.

StrongStep®
SARS-CoV-2 IgM/IgG Antibody Rapid Test





22.5×18×6.5CM

REF:502090

20 Tests/Kit

Indivdually Packed Test Devices:20
Dilution Buffer: 1*5mL
Package insert: 1
Workstation:1

Specimens: Whole Blood / Serum / Plasma

Fast: use fingertip tip blood to give results in 15 minutes

Simple: no auxiliary equipment is needed in the operation. Normal temperature storage and transportation

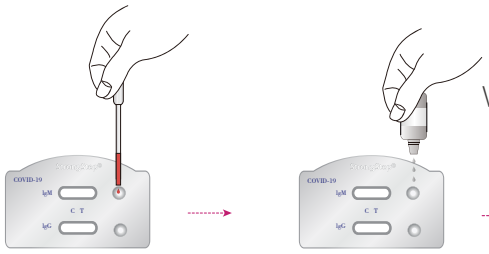
Intended use

The Strogstep® SARS-CoV-2 IgM/IgG Antibody Rapid Test is a rapid immuno-chromatographic assay intended for qualitative detection of IgM and IgG antibodies to SARS-CoV-2 in human venous whole blood, fingerstick whole blood, serum or plasma.

Antibody detection method is a convenient, fast and low-cost detection technology, which is suitable for screening and complementary to PCR detection method. The combination of the two methods can improve the detection rate of patients or asymptomatic virus carriers.

INSTRUCTION to USE

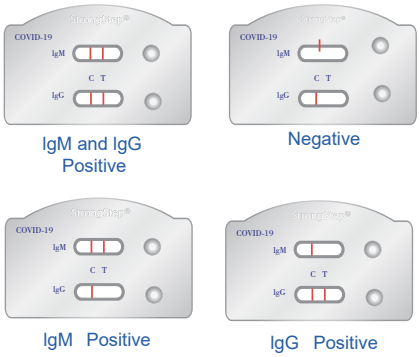
Apply 10μL of serum, plasma or whole blood to the sample well.



Add 2-3 drops of buffer to sample well

Waiting for 15 minutes reading result

Result



Note: Control band fails to appear should be regarded as invalid results.

Performance

Test	Sensitivity	Specificity
IgM	71.9%	100%
IgG	93.3%	98.7%
Total	93.5%	98.7%

Use of these tests

1)The first-visit suspected patients(no molecular results or molecular negative), if antibody positive, should be managed as confirmed case; if antibody negative, it suggests to do PCR again, and test antibody after one week.

2)The asymptomatic close contacts or investigation crowd, if antibody positive, no matter how the PCR result is, should be managed as carriers; if antibody negative, it suggests to do PCR firstly and follow up with antibody detection, it can be excluded from COVID infection if results negative again.

3) For asymptomatic quarantined-14-days people, if antibody positive, it suggests to do PCR again and be kept under observation.

All test results need to be combined with the patient's clinical symptoms and signs, and the interpretation of the test results must follow the local diagnostic guidelines in each country.

Regerence: Diagnosis and treatment plan for the novel coronavirus disease (COVID-19)
http://www.nhc.gov.cn/yzygj/s7652m/202003/a31191442e29474b98bfed5579d5af95.shtml

REF:502130

40 Tests/Kit

22.5×18×6.5CM

Test Cassette with test strip : 40 pcs
Sample buffer (bottle) : 1 bottle
20μL Pipette : 40 pipette
Instructions for Use leaflet : 1 pcs
Packing materials : 1 pcs

Fast : use fingertip tip blood to give results in 15 minutes.
Simple : no auxiliary equipment is needed in the operation. Normal temperature storage and transportation.

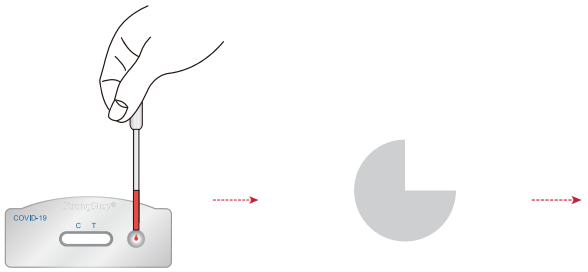
Intended use

The Strogstep® SARS-CoV-2 Neutralization Antibody Rapid Test is a rapid immuno-chromatographic assay intended for qualitative detection of neutralizing antibodies to SARS-CoV-2 in clinical samples (serum/plasma/whole blood).

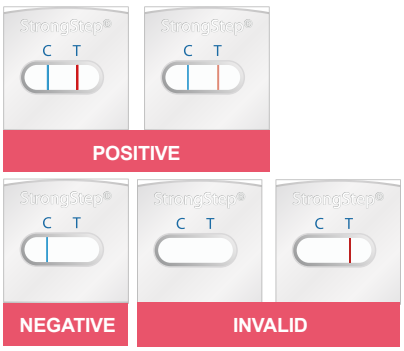
Method of operation of kit illustrated

Add about 80μL specimen into the sample well of the test

Waiting for 15 minutes reading result



Result



Performance

	GenScript sVNT Kit		
		Positive	Negative	Total
Strogstep® SARS-CoV-2 Neutralization Antibody Rapid Test	Positive	108	2	110
	Negative	4	119	123
	Total	112	121	233

Positive Percent Agreement: (PPA)= 96.43% (91.11% ~ 99.02%)*
Negative Percent Agreement: (NPA)= 98.35% (94.16% ~ 99.80%)*
Kappa: 0.9076 (0.9076 ~ 0.9891)
*95% Confidence Interval

REF :500210S
225×180×65mm
25 Tests / Box
Specimens :Saliva

CONTENTS

I Individually packed test devices: 25 •
Package insert : 1 •

System Device for SARS-CoV-2 Antigen Rapid Test

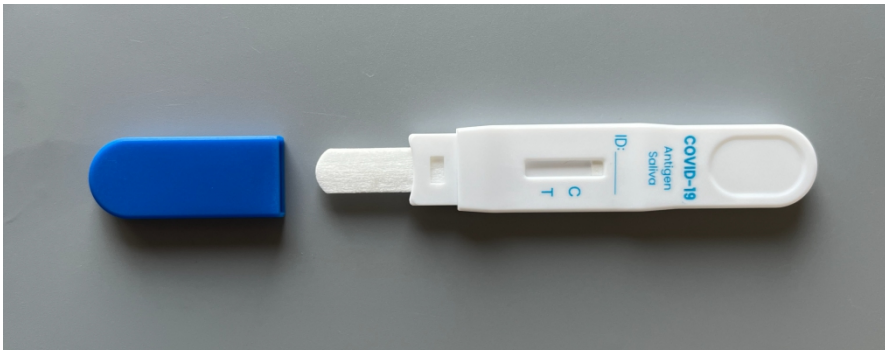
For use by clinical laboratories or healthcare workers or self-test

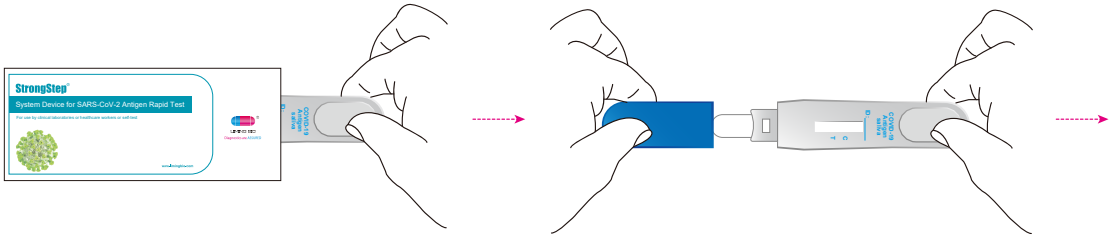
For the detection of SARS-CoV-2 virus Nucleocapsid Protein antigen in human Saliva collected from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms.

Performance

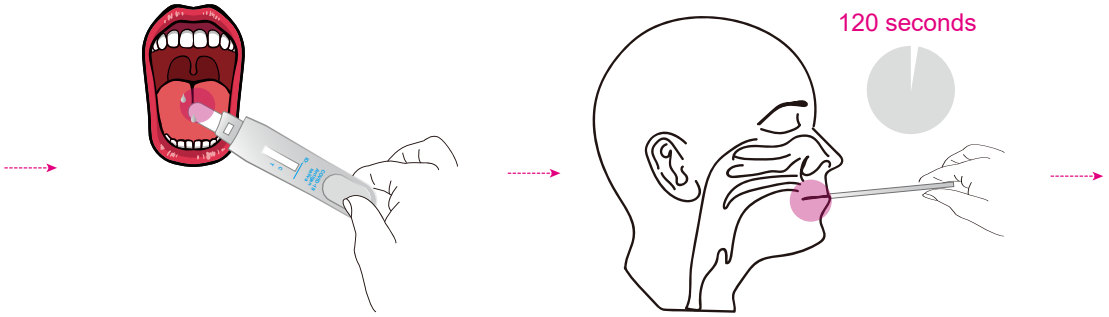
	PCR Comparator		
		Positive	Negative	Total
StrongStep® System Device for SARS-CoV-2 Antigen Rapid Test	Positive	101	3	104
	Negative	4	402	406
	Total	105	405	501

Positive Percent Agreement:
(PPA)= 96.19% (90.53%～98.95%)*
Negative Percent Agreement:
(NPA)= 99.26% (97.85%～99.85%)*
Kappa: 0.9579 (0.9269～0.9889, highly consistent)*
*95% Confidence Interval

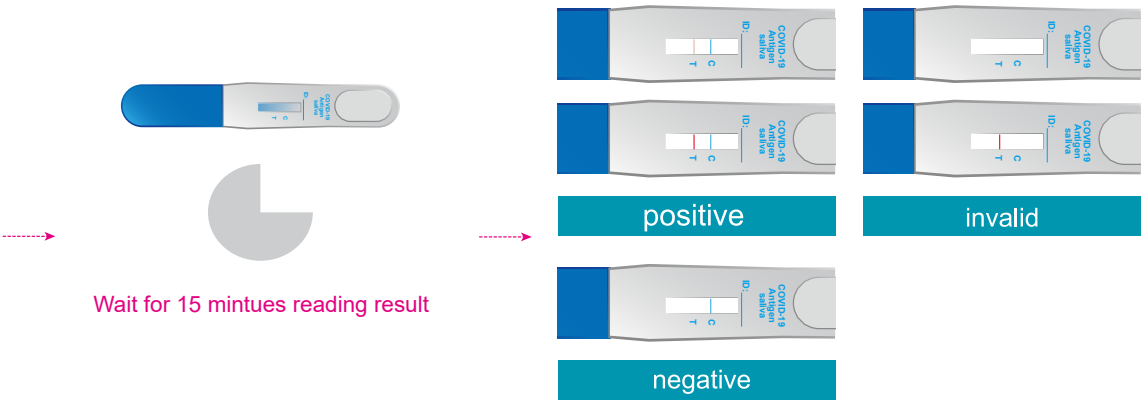




Step 1:
Open the bag, take out the test cassette, open the cover of the end of thetest cassette.



Step 2: Hold the test cassette, put the saliva adsorption stick into the mourth and contact with tongue, start the timer. After at least 120 seconds, cover the end of saliva adsorption stick, and place the detection card horizontally on the workbench.



Step 3: Re-time and read the detection result 15 minutes later.
The test result should not be read and interpreted after 30 minutes.
Safely throw away the waste into biohaz-ard container.

- After sampling, it can be tested on site immediately and the result will be given in 15 minutes
- No auxiliary equipment is required during operation
- If get positive results, please Self-quarantinen and inform your family doctor promptly
- Poor quality of samples may result in false negative, therefore, novel coronavirus pneumonia is not
- completely excluded by negative results
- No drop off in sensitivity when compared with the wild type with respect to the following variant s - VOC1 Kent, UK, B.1.1.7 and VOC2 South Africa, B.1.351.

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