

SARS-CoV-2 Antigen Rapid Test

A Community of Shared Future for Mankind

Introduction of Company

Nanjing Liming Bio-Products Co., Ltd

It is a professional manufacturer of in vitro diagnostic reagents



2001 Time of establishment 10% Percentage of master degree or above 106 Existing employees 1500 Purification plant

Strongstep®

- » Rapid Diagnostic Test
- » 5 million Tests per Year

Limingbio diagnostics are ASSURED

2008

Transform to independent

research, development and production of IVD,

registration certificates, 1 class II Registration Certificate and 5 class I registration certificates

issued by the State Food

and drug administration

and obtain 6 class III

SIMPLE SAFE FAST ACCURATE

2001

The company was founded and became the distributor of

merier and alere

2019

Successful construction of molecular detection technology platform

2020

Successfully developed a novel coronavirus pneumonia test kit



Strongstep® SARS-CoV-2 Antigen Rapid Test Cassette



22.5×18×6.5CM



20 Tests/Kit CE

Specimens: nasal swab / nasopharyngeal swab

20 Individually packed test devices2 Extraction Buffer vials20 Extraction tubes1 Workstation1 Package insert

What is the Rapid Antigen Test?

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

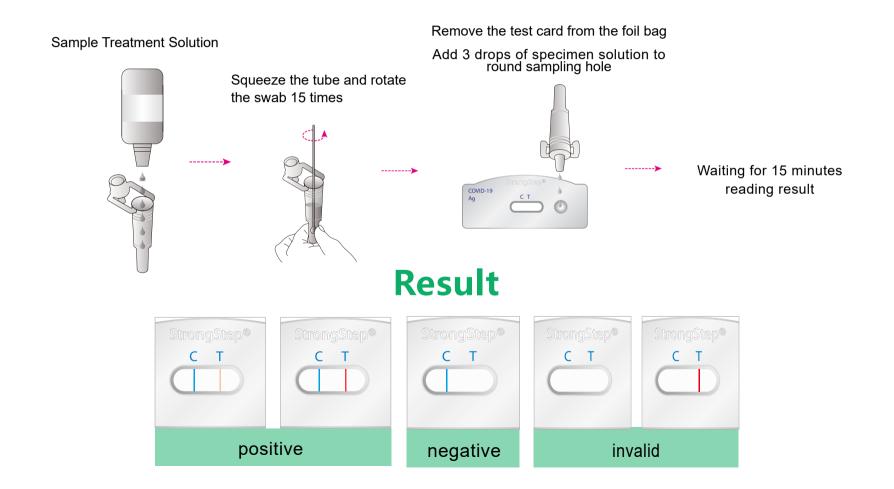
Sampling illustration





nasal swab nasopharyngeal swab

INSTRUCTION to USE



Strongstep® SARS-CoV-2 Antigen Rapid Test System Device





REF:500210 20 Tests/Kit

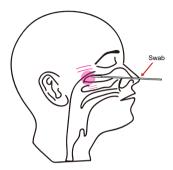
Specimens: nasal swab / nasopharyngeal swab

CE

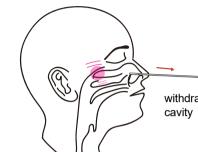
CONTENTS

- Individually Packed Test Devices : 20 Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions.
- Extraction Buffer vials in the device : 20
 0.1 M Phosphate buffered saline (PBS) and0.02% sodium azide.
- Package insert : 1
- Workstation : 1

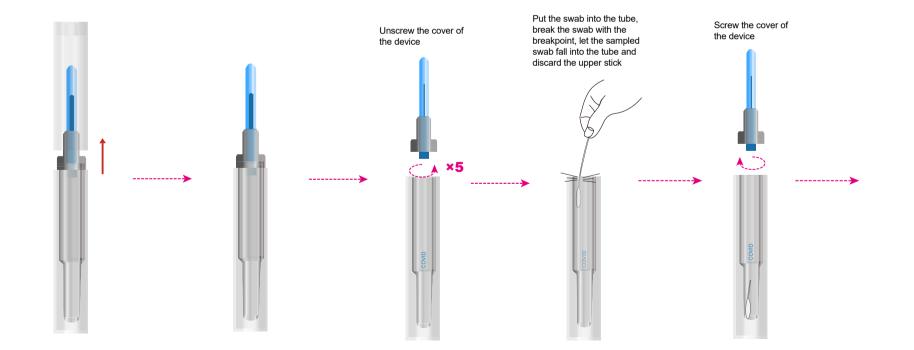
INSTRUCTION to USE

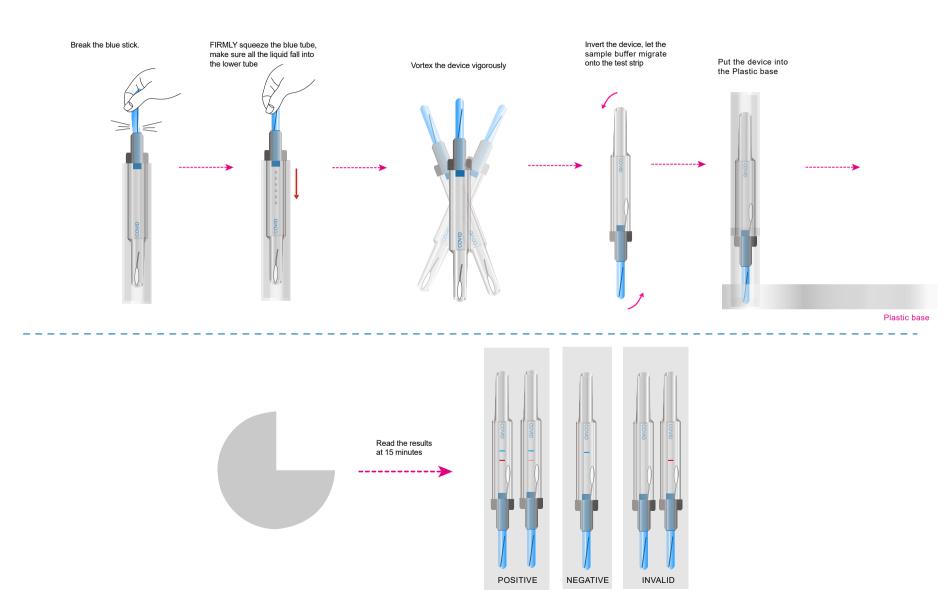


Inwert a sterite swab into the nostril of the patient.reaching the surface of the posterior nasopharynx. Swab over the surface of the posterior nasopharynx.



withdraw the sterile swab from the nasal cavity





Advantages of midstream:

- 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

INTERPRETATION OF RESULTS



Two colored bands appear within 15minutes. One colored band appears in the Control Zone (C) and another colored band appears in the Test Zone (T). The test result is positive and valid. No matter how faint the colored band appears in the Test Zone (T),the test result should be considered a s positive result.

NEGATI	/E RESULT	: One colored bands appears in the			
С		Control Zone (C) within 15 minutes. No			
Т		colored band appears in the Test Zone			
		(T). The test result is negative and valid.			
INVALID RESULT:		No colored band appears in the Control			
С	c	Zone (C) within 15 minutes. The test			
т		result is invalid. Repeat the test with a			
		new test device.			

Performance

Positive Percent Agreement:

(PPA)=73.02% (60.35%~83.43%)

Negative Percent Agreement:

(NPA)=98.08% (93.23%~99.77%)

	PCR (
	Antigen Test	Positive	Negative	Total
StrongStep [®] SARS CoV-2	FUSILVE 40	46	2	48
Antigen Test	Negative	17	102	119
	Total	63	104	167

LIMING issues the "List Of COVID-19 In Vitro Diagnostic Manufacturers and Exporters" and updates it regularly on the web site.

ISO 13485

	A	
C	TÜVRhein	land
Ce	rtificate	
	he Certification Body of einland LGA Products GmbH	
hereb	by certifies that the organization	
Nanjin	g Liming Bio-products Co., Ltd.	
No 2100	12 Huayuan Road 142 Nanjing, Jiangsu China	
has established and ap	plies a quality management system for medical devices for the following scope:	
In Vitro Immunoc	lopment, Manufacture and Distribution of hromatographic Diagnostic Reagents Kits fectious Diseases and Fertility	
Proof has bee	in furnished that the requirements specified in	
EN	I ISO 13485:2016	
are fulfilled. The quality	management system is subject to yearly surveillance.	
Effective Date:	2019-08-02	
Certificate Registration No.:	SX 60136624 0001	
An audit was performed. Report N	No.: 15047001 008	
This Certificate is valid until:	2022-02-01 Certification Body	
DAkkS Devisible Attrefforungsstelle 0-2M-14109-01-02	A	and a
Date 2019-08-02	Fuxiu Sheng	<u>n</u>
TÜV Rheinland LGA Produ	ucts GmbH - Tillystraße 2 - 90431 Nürnberg	



2. Medicines & Healthcare products Regulatory Agency

Please use RG3, the Registration form, to tell us about any of these changes. A ee of £70 is payable for each change or set of changes notified.

Thank you for registering the following generic groups of devices 1. Part 5: IVDs which are not Annex II and not self-test devices 2. 3. For reagnets, reagent products, calibration and control materials: 4. group by common technological characteristics and/or analytes 5. 6. New products: 7. None 8. 9. For performance evaluation: 10. None 11. 12. Neither: HSV Antigen 13. 14. Gonococcal Antigen Detection 15. Candida albicans 16. Other Parasitology 17. Other Bacteriology Rapid Tests 18. Rotavirus 19. Adenovirus Other Multiple Viruses 20. 21. H. Pylori Antibody Assays 22. H. Pylori Antigen Detection 23. Strep B - Rapid Test 24. Human Papilloma Virus 25. Strep A - Rapid Test 26. Haemoglobin (Hb) 27. Procalcitonin 28. Salmonella Antigen Detection 29. Salmonella Antibody Assays 30. Legionella Antibody Assays 31. Other Mycology Immunoassays 32. Other Specific Proteins Rapid Tests 33 Other Individual and Specified Hormones/Proteins RT & POC 34. 35. Coronavirus Coronavirus - NA Reagents 30. 37. 38. For other IVDs, group by appropriate indications 39.

40 New products

(MHRA) CE certificate

FIND	Search Q EB CONTACT	FIND	Search Q
Eccaure diagnosis matters	WHO WE ARE WHAT WE DO RESOURCES NEWSROOM PARTNERS & DONORS PerfectQ COVID-19 Coronavirus Real Time PCR Kit (RUO) IN Medsys, ProTect Covid-19 RT-qPCR kit (RUO) Contact KtH Medical Co. Ltd, RADI COVID-19 Detection Kit and RADI COVID-19 Triple Detection Kit (RUO) Contact KdH Medical Co. Ltd, PowerChekTM 2019-nCoV Real-time PCR Kit (Korea MFDS-EUA; CE-IVD) Contact Liferiver, Liferiver Novel Coronavirus (2019-nCoV) Real-time PCR Kit (Korea MFDS-EUA; CE-IVD) Contact Liferiver, Liferiver Novel Coronavirus (2019-nCoV) Real-time PCR Kit (Korea MFDS-EUA; CE-IVD) Contact Liferiver, Liferiver Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCRT kit (China FDA-EUA; CE-IVD) Liming Bio-Products Co., Ltd, StrongStep@Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit (CE-IVD) Contact Luminex, Corp., NxTAG CoV Extended Panel (RUO) Contact Mabsky Bio-Tech Co., Ltd Real-Time PCR Method Contact COVID-19 virus (2019-nCoV) Dual-Detection Kit (RUO) Influenza A virus, Influenza B virus & COVID-19 virus (2019-nCoV) Triple-Detection Kit (RUO) Influenza A virus, Influenza B virus & COVID-19 virus (2019-nCoV) Triple-Detection Kit (RUO) Medical Innovation Ventures Sch Bhd. GenoAmp@ Real-Time RT-PCR SARS-CoV-2 (RUO) Contact Nanjing Varyme Medical Technology Co., LTD., 2019-Novel Coronavirus (2019-nCoV) Triplex RT-qPCR Detection Kit (CE-IVD) Contact NanoBio Lab. A*STAR Research Entities, Isothermal Exponential Amplification for COVID-19 Detection (RUO) Contact National Institute for Control of Vaccines and Biologicals, Accupid nCoV 2019 Detection Kit (RUO) Contact National Institute for Control of Vaccines and Biologicals, Accupid nCoV 2019 Detection Kit (RUO) Contact National Institute for Control of Vaccines and Biologicals, Accupid nCoV 2019 Detection Kit (RUO) Contact National Institute for Control of Vaccines and Biologicals, Accupid nCoV 2019 Detection Kit (RUO) Contact National Institute for Control of Vaccines and Biologicals, Accupid nCoV 2019 Detection Kit (RUO) Contact National Institute for Control of Vacci	Because diagnosis nutters	 WHO WE ARE WHAT WE DO RESOURCES NEWSROOM PARTNERS & D Anti-SARS-CoV-2 ELISA (IgG) (manual; automated; RUO) Guangzhou Danui Biotechnology Co.Ltd Contact 2019 Novel Coronavirus (2019-nCoV) IgM Antibody Detection Kit (ELISA Method) (RUO) 2019 Novel Coronavirus (2019-nCoV) IgG Antibody Detection Kit (ELISA Method) (RUO) Novel Coronavirus 2019-nCoV IgG Antibody Detection Kit (Colloidal Gold Method) (RUO) Novel Coronavirus 2019-nCoV IgG Antibody Detection Kit (Colloidal Gold Method) (RUO) Novel Coronavirus 2019-nCoV IgG Antibody Detection Kit (Colloidal Gold Method) (RUO) Novel Coronavirus 2019-nCoV IgG Antibody Detection Kit (Colloidal Gold Method) (RUO) Novel Coronavirus 2019-nCoV IgG Antibody Detection Kit (Colloidal Gold Method) (RUO) Novel Coronavirus 2019-nCoV IgG Antibody Detection Kit (Colloidal Gold Method) (RUO) Novel Coronavirus 2019-nCoV IgG Antibody Detection Kit (Colloidal Gold Method) (RUC) Utiming Bio-Products Co., Ltd., COVID-19 Antigen Rapid Test Device (CE-IVD) Contact Sbenzhen Yhlo Biotech Co. Ltd Contact iFlash-SARS-CoV-2 IgG (CE-IVD) iflash-SARS-CoV-2 IgG (CE-IVD) SARS-CoV-2 IgG (CE-IVD) Sugentech_Inc, (manual, RUO) Contact SGTi-flex COVID-19 IgM SGTi-flex COVID-19 IgM

Access to WHO emergency approval channel



Rekomendasi Merk RDT Antibodi COVID-19 yang dapat digunakan di Indonesia, diklasifikasikan sebagai berikut:

 Rekomendasi: Berdasarkan edaran WHO (WHO does not endorse any of these products) yang dipublikasikan pada 27 April 2020 terkait alat diagnostik untuk Diagnosis COVID-19 dan Sertifikasi oleh CE (Sertifikasi yang dikeluarkan Uni Eropa). PAO (Sertifikasi yang dikeluarkan Amerika Serikat), atau sertifikasi yang steara.

•Alternatif Rekomendasi: Berdasarkan edaran WHO yang dipublikasikan pada 27 April 2020 terkait alat diagnostik untuk Diagnosis COVID-19 atau Sertifikasi yang disebut di atas

Daftar Rekomendasi RDT Antibodi COVID-19

Diperbaharui tanggal 28 April 2020



iugus Tugas Percepatan Penanganan COVID-19

Alternatif Rekomendasi RDT Antibodi untuk COVID-19

- 31. Covid-19 IgG/IgM Antibody Rapid Test Kit Wuhan UNscience Biotechnology Co., Ltd
- 32. COVID-19 IgG/IgM BIO QUIBASA QUIMICA BASICA LTDA
- 33. COVID-19 IgG/IgM Combo Rapid Test Device Liming Bio-Products Co., Ltd
 - 34. COVID-19 IgG/IgM Detection Kit (Colloidal Gold) Hunan Lituo Biotechnology Co., Ltd
 - 35. COVID-19 IgG/IgM Duo (automated) NanoEnTek
 - 36. COVID-19 IgG/IgM ECO Test Eco Diagnostica Ltd
 - 27 COMID. 10 IAC MANNIE . ADWAGEN DIOTECH ITDA

Access to Indonesian official website procurement list

A large number of orders have been received from the United States, South Korea, Japan, Italy, Hungary, Austria, Saudi Arabia, Iran, France, Spain, Georgia, Chile, Brazil, the Philippines, Mexico, Bulgaria and other countries.

We Shall Overcome Together

A Community of Shared Future for Mankind



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THANKS