LIMING BIO®

Strongstep®

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

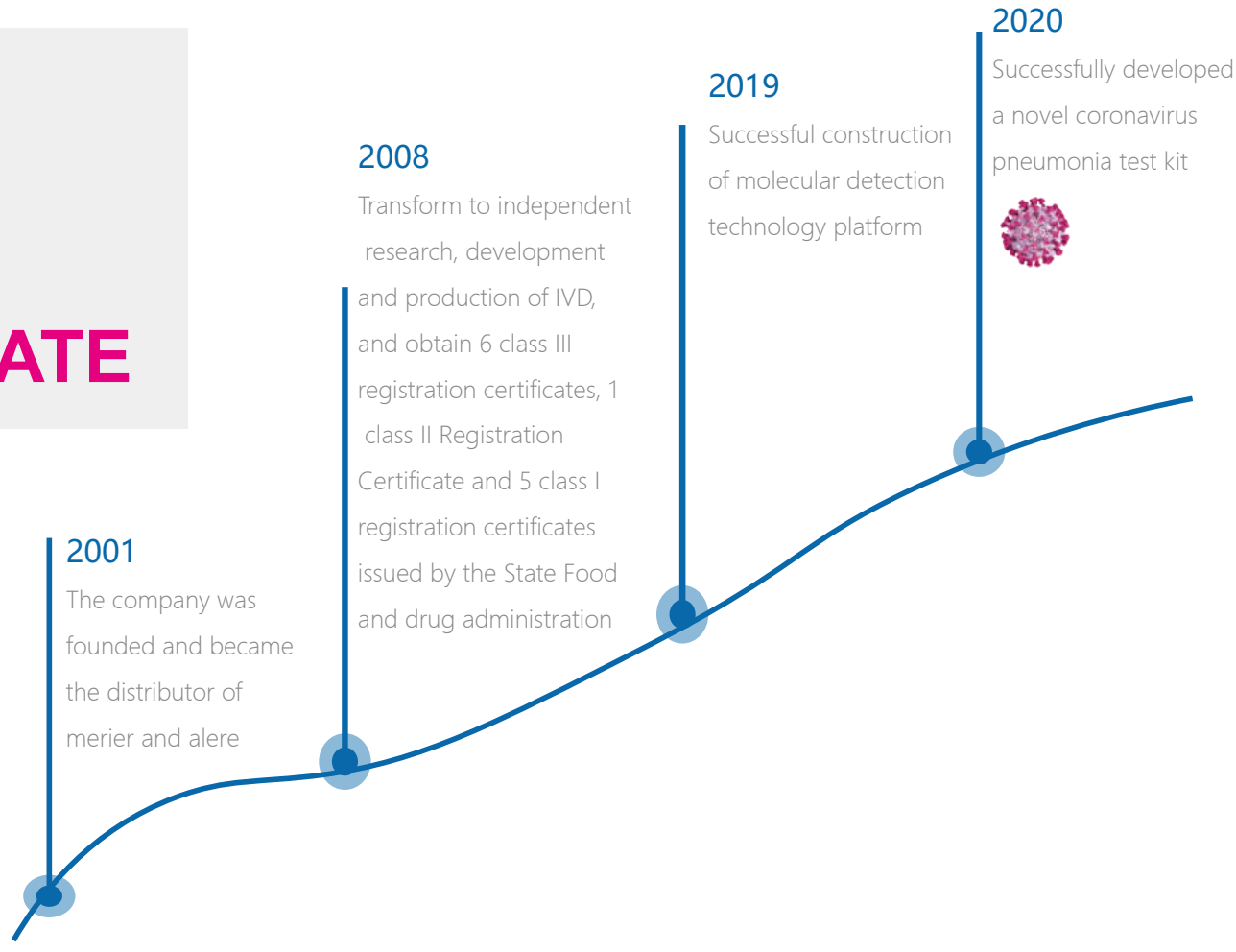
1500
Purification plant

Strongstep®

» Rapid Diagnostic Test
» 5 million Tests per Year

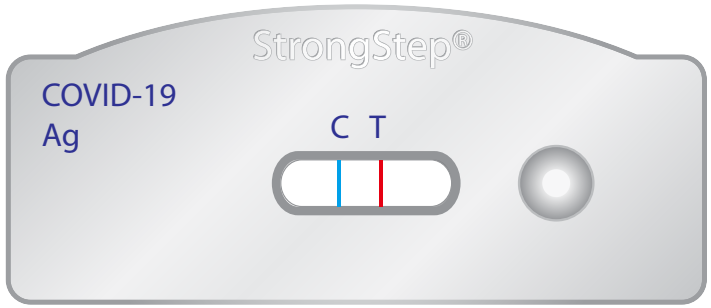
Limingbio diagnostics are ASSURED

SIMPLE
SAFE
FAST
ACCURATE



Strongstep® SARS-CoV-2 Antigen Rapid Test Cassette

22.5×18×6.5CM



REF:500200

20 Tests/Kit

CE

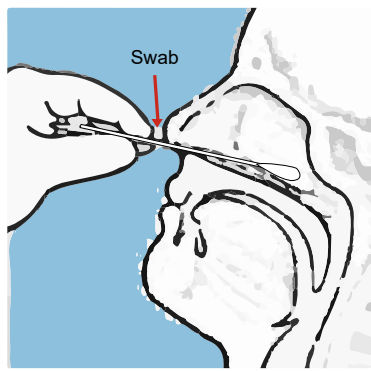
Specimens: nasal swab / nasopharyngeal swab

20 Individually packed test devices
2 Extraction Buffer vials
20 Extraction tubes
1 Workstation
1 Package insert

What is the Rapid Antigen Test ?

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

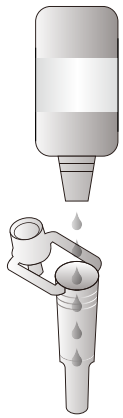
Sampling illustration



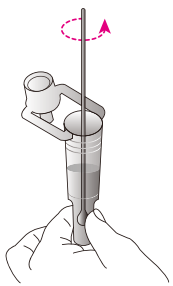
nasal swab
nasopharyngeal swab

INSTRUCTION to USE

Sample Treatment Solution

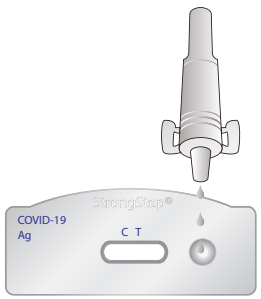


Squeeze the tube and rotate the swab 15 times



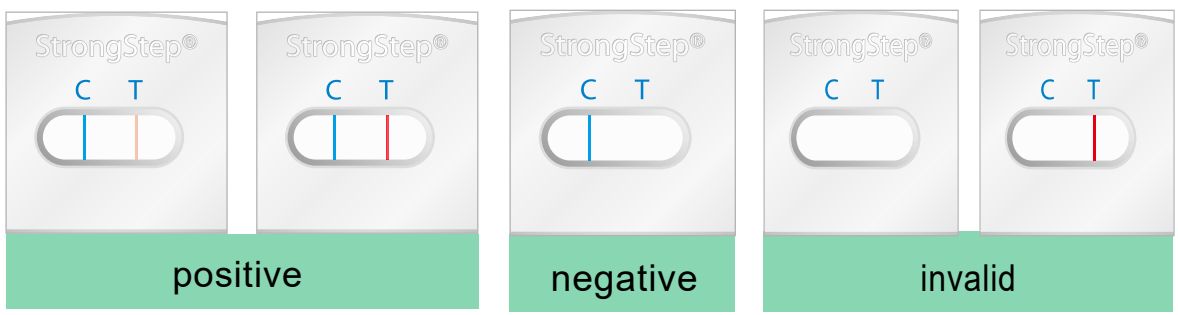
Remove the test card from the foil bag

Add 3 drops of specimen solution to round sampling hole



Waiting for 15 minutes reading result

Result



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

REF:500210

20 Tests/Kit

CE

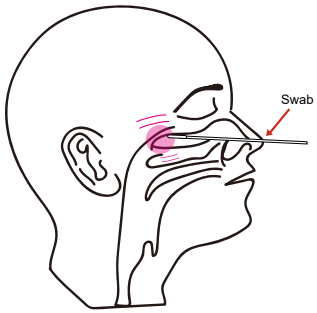
Specimens: nasal swab / nasopharyngeal swab

CONTENTS

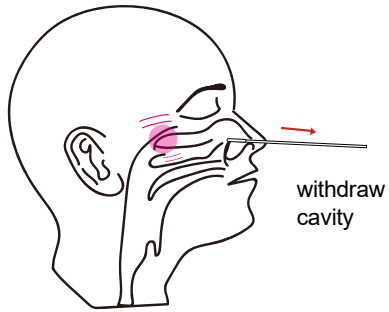
- Individually Packed Test Devices : 20
  Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions.

- Extraction Buffer vials in the device : 20
  0.1 M Phosphate buffered saline (PBS) and0.02% sodium azide.
- Package insert : 1
- Workstation : 1

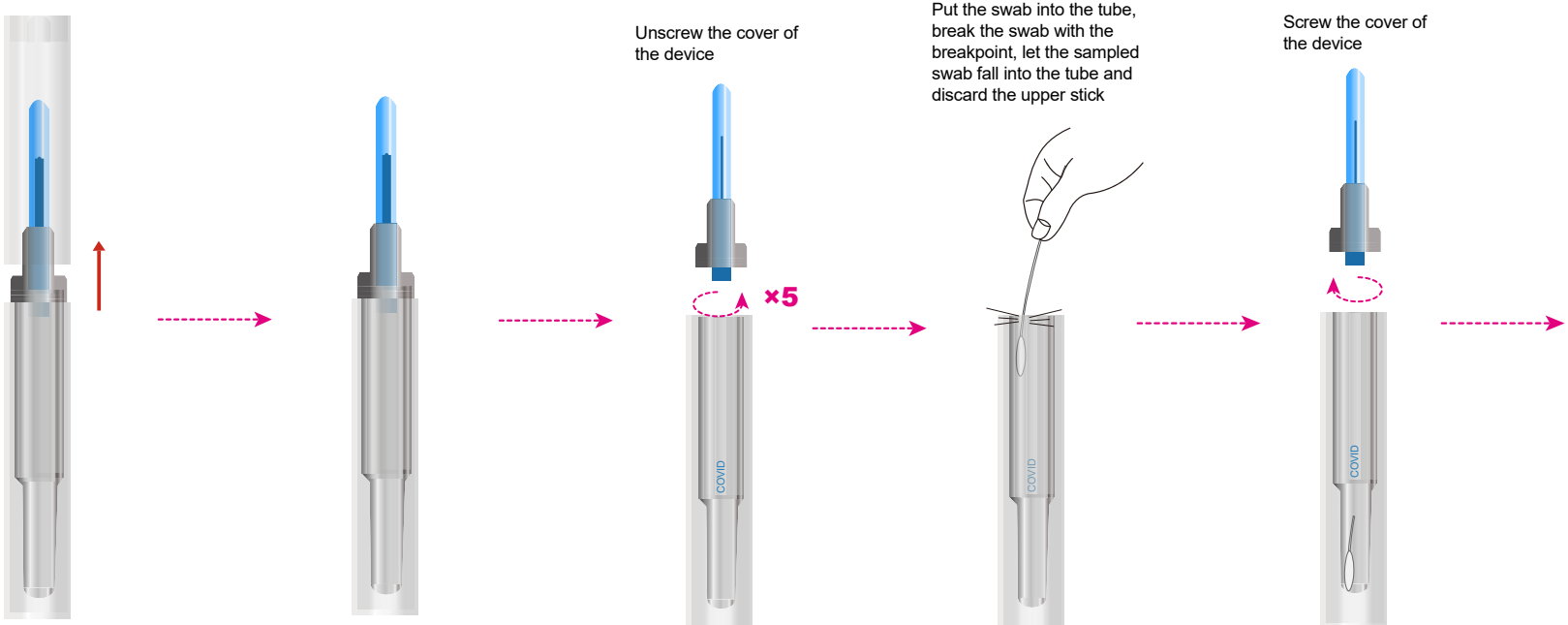
INSTRUCTION to USE



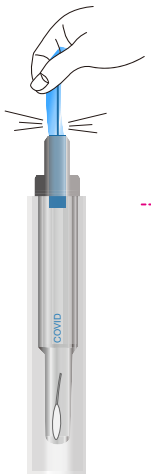
Inwert a sterite swab into the nostril of the patient.reaching the surface of the posterior nasopharynx.
Swab over the surface of the posterior nasopharynx.



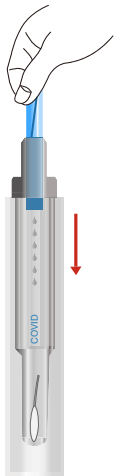
withdraw the sterile swab from the nasal cavity



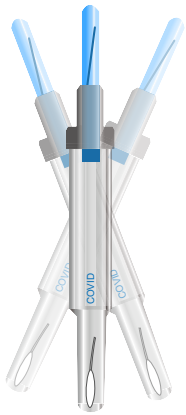
Break the blue stick.



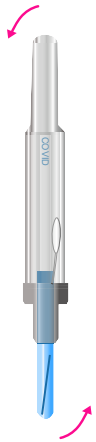
FIRMLY squeeze the blue tube, make sure all the liquid fall into the lower tube



Vortex the device vigorously



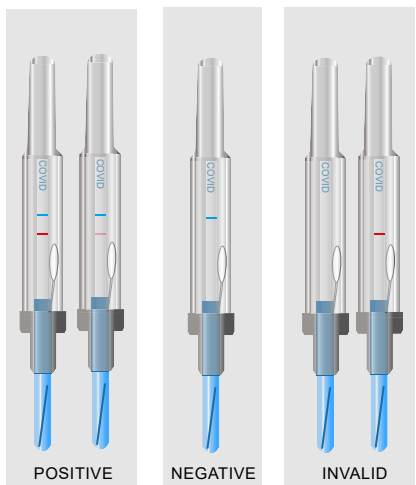
Invert the device, let the sample buffer migrate onto the test strip



Put the device into the Plastic base

Plastic base

Read the results at 15 minutes



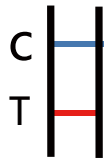
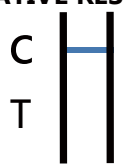
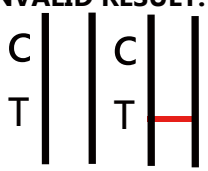
INTERPRETATION OF RESULTS

Advantages of midstream:

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

POSITIVE RESULT: 	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.
NEGATIVE RESULT: 	One colored bands appears in the Control Zone (C) within 15 minutes. No colored band appears in the Test Zone (T). The test result is negative and valid.
INVALID RESULT: 	No colored band appears in the Control Zone (C) within 15 minutes. The test result is invalid. Repeat the test with a new test device.

Performance

Positive Percent Agreement:

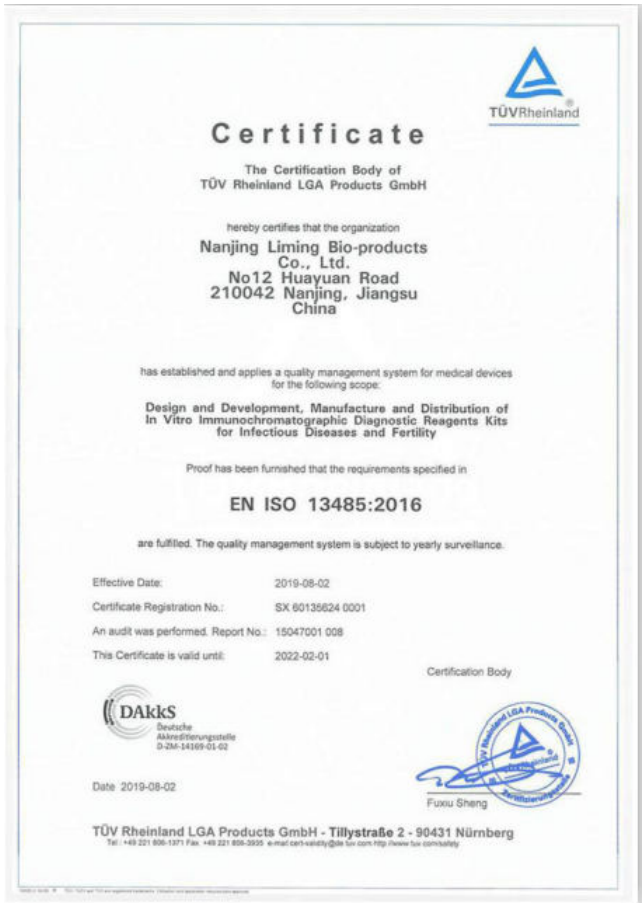
(PPA)=73.02% (60.35%～83.43%)

Negative Percent Agreement:

(NPA)=98.08% (93.23%～99.77%)

	PCR Comparator		
StrongStep® SARS CoV-2 Antigen Test	Antigen Test	Positive	Negative	Total
	Positive	46	2	48
	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.



TÜVRheinland

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Nanjing Liming Bio-products
Co., Ltd.
No12 Huayuan Road
210042 Nanjing, Jiangsu
China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of In Vitro Immunochromatographic Diagnostic Reagents Kits for Infectious Diseases and Fertility

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-08-02
Certificate Registration No.:	SX 60135624 0001
An audit was performed. Report No.:	15047001 008
This Certificate is valid until:	2022-02-01

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Date 2019-08-02

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

ISO 13485

Medicines & Healthcare products Regulatory Agency

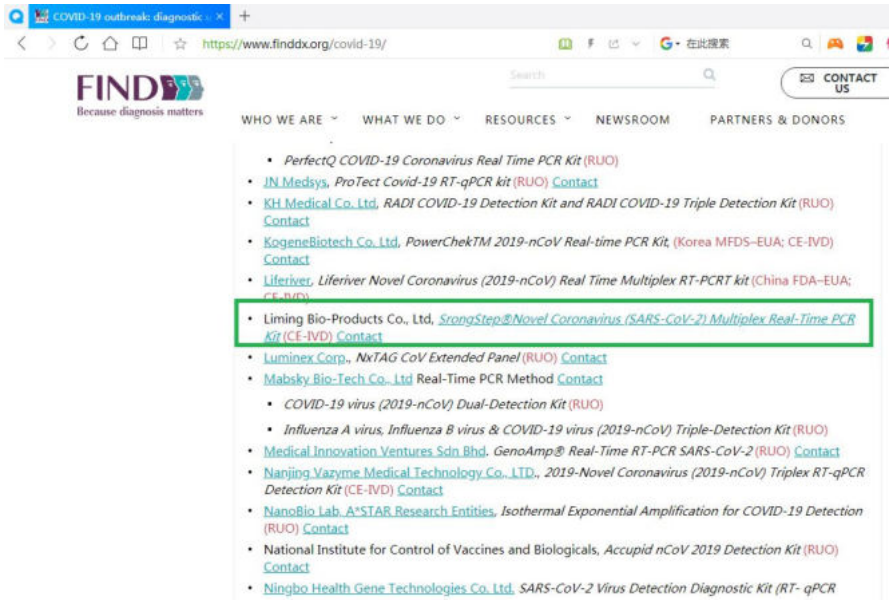
MHRA

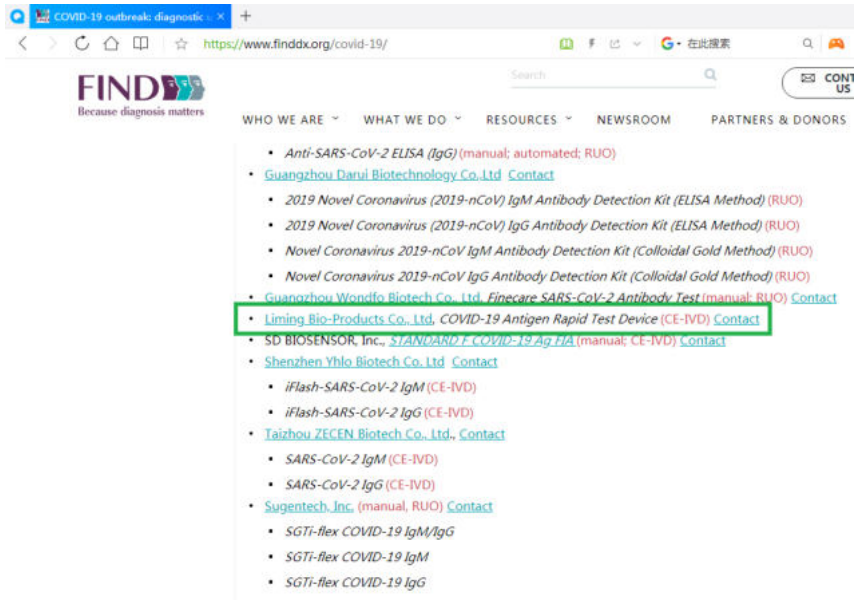
Please use RG3, the Registration form, to tell us about any of these changes. A ee of £70 is payable for each change or set of changes notified.

Thank you for registering the following generic groups of devices

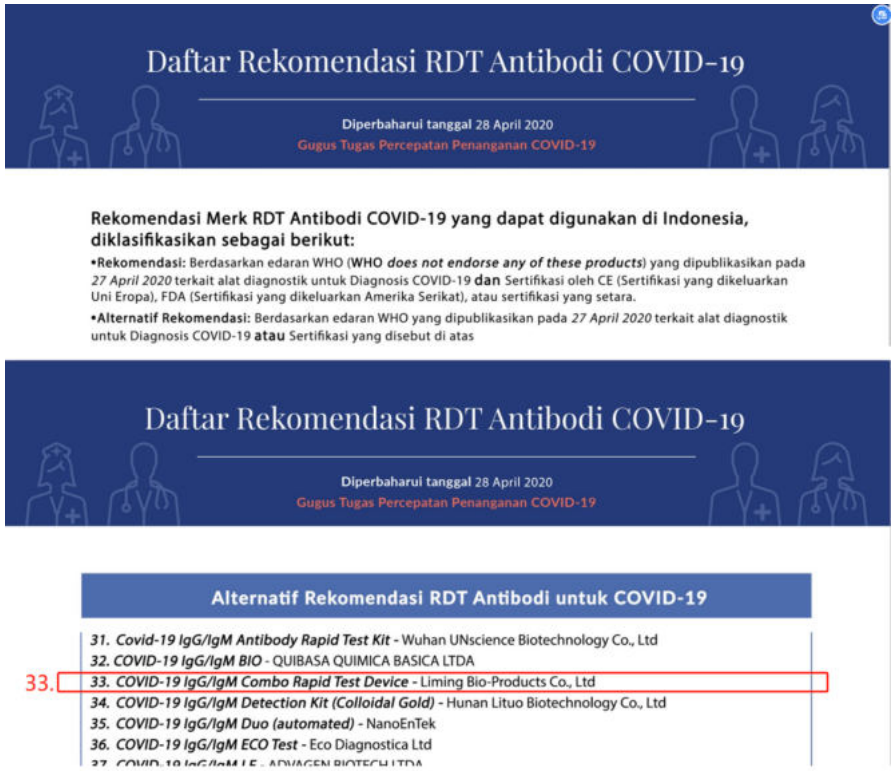
1. ***Part 5: IVDs which are not Annex II and not self-test devices***
2.
3. ***For reagnets, reagent products, calibration and control materials:***
4. ***group by common technological characteristics and/or analytes***
5.
6. ***New products:***
7. ***None***
8.
9. ***For performance evaluation:***
10. ***None***
11.
12. ***Neither:***
13. ***HSV Antigen***
14. ***Gonococcal Antigen Detection***
15. ***Candida albicans***
16. ***Other Parasitology***
17. ***Other Bacteriology Rapid Tests***
18. ***Rotavirus***
19. ***Adenovirus***
20. ***Other Multiple Viruses***
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. ***Coronavirus***
35. ***Coronavirus - NA Reagents***
36.
37.
38. ***For other IVDs, group by appropriate indications***
39.
40. ***New products:***

(MHRA) CE certificate





Access to WHO emergency approval channel



Daftar Rekomendasi RDT Antibodi COVID-19

Diperbaharui tanggal 28 April 2020

Gugus Tugas Percepatan Penanganan COVID-19

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), FDA (Sertifikasi yang dikeluarkan Amerika Serikat), atau sertifikasi yang setara.
- **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

Gugus 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

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

LIMING BIO®

THANKS