



LIMING BIO

Strongstep®

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

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

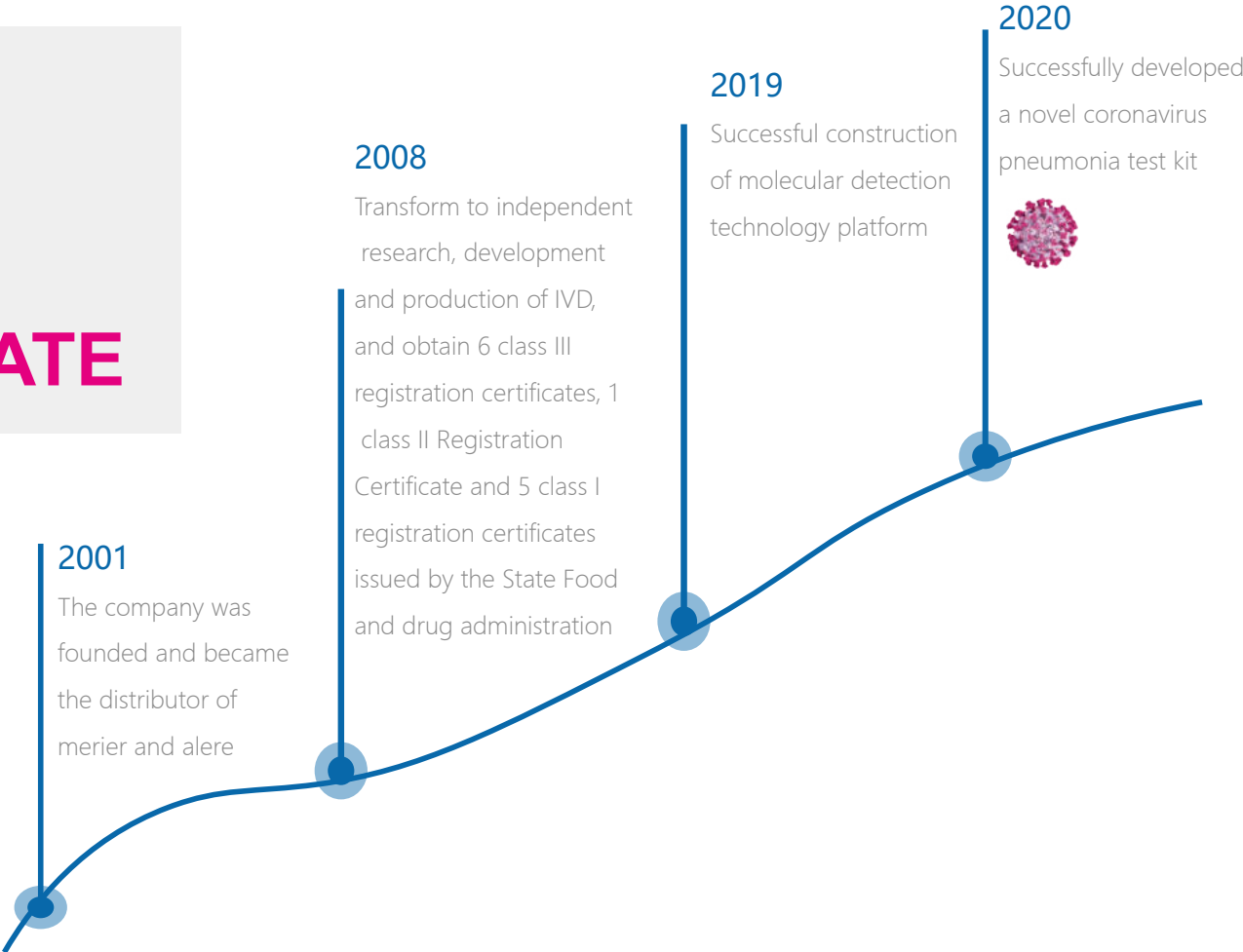
Purification plant

Strongstep®

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

Limingbio diagnostics are ASSURED

**SIMPLE
SAFE
FAST
ACCURATE**





16cm×11cm×5.5cm

REF:500190

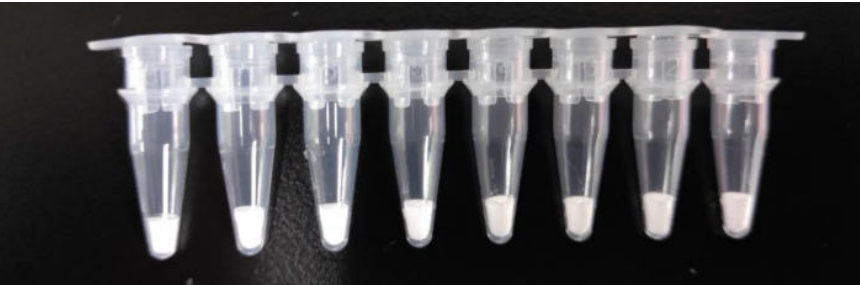
96 Tests/Kit



Specimens:

nasopharyngeal (NP) swab
oropharyngeal (OP) swab
sputum
BALF

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



Kit Components

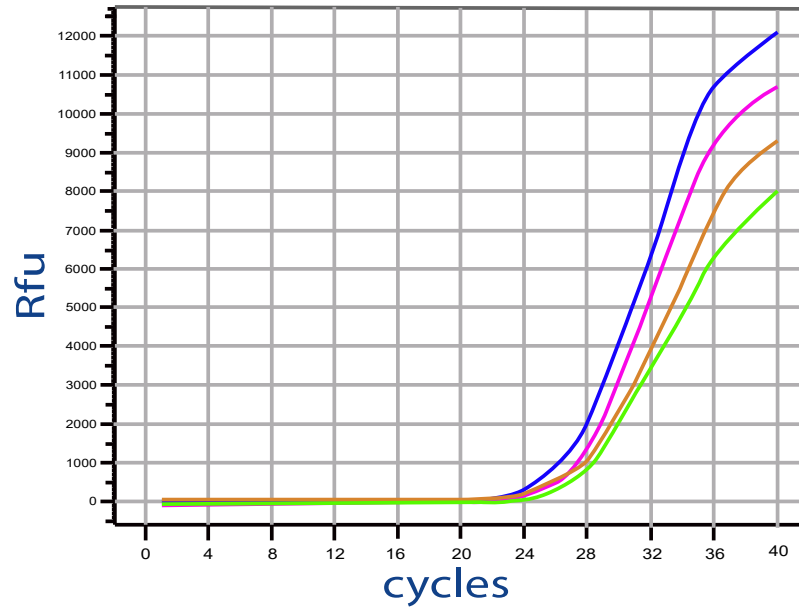
- Lyophilized qPCR reagents
- Positive control
- PCR CAP

Package

- 12x8-Strip Tubes (lyophilized)
- 1.5 mL Tube (lyophilized)
- 12x8-Strip Caps

Kit Components

Kit Components	Description	Amount & Package
SARS-CoV-2 rt-qPCR reagent	Lyophilized ready-to-use PCR beads in 8-Strip Tubes	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, S gene and N gene in 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.

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, S 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, the 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.

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



ISO 13485



Medicines & Healthcare products
Regulatory Agency



Please use RG3, the Registration form, to tell us about any of these changes. A fee 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 reagents, 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

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
37. *COVID-19 IgG/IgM 15* - ADVAGEN BIOTECH LTDA

Access to Indonesian official
website procurement list



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



ACKNOWLEDGEMENT RECEIPT

The Food and Drug Administration (FDA) hereby acknowledges the receipt of your document with the following details and duly recorded in the FDA Inventory System (FIS):

Document Tracking No.: 
20200529083508
Communication Type: Certificate of Exemption
From: FIRST ASSOCIATED MEDICAL DISTRIBUTION CO.,
INC.
Routed To: Center for Device Regulation, Radiation Health
Document Title: Application for Special Certification
Strong StepsR Novel Coronavirus (SARS-Cov-2) Multiplex
Real-Time PCR Kit

Contact Information:

joy_dominguez@famed.com.ph

Received By: DCPong-Pong

Date and Time Received: 29 May 2020 08:43:20 AM

The determination of the completeness of the documentary requirements submitted, if any, is subject to the evaluation of the technical person in charge.

You may follow-up the status of your document through the DocTrack Status at the FDA website, <http://www.fda.gov.ph/doctrack-status-know-the-status-of-your-application>, using the document tracking number and the contact information stated above.

The receipt is systems generated and does not require signature.

PCR Philippines
FDA acceptance
confirmation letter

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