LIMING BIO
黎明生物
南京黎明生物制品有限公司
Nanjing Liming Bio-Products Co., Ltd.
统一社会信用代码 Tax No.：91320102728377745XD
地址：江苏省南京市玄武区花园路 12 号 邮编：210042
Add：No.12, Huayuan Road, Xuanwu District, Nanjing, Jiangsu, P.R. China，210042
Tel：+86-25-85476723/+86-25-85288506 Fax: +86-25-85476387
E-mail：sales@limingbio.com Web：www.limingbio.com

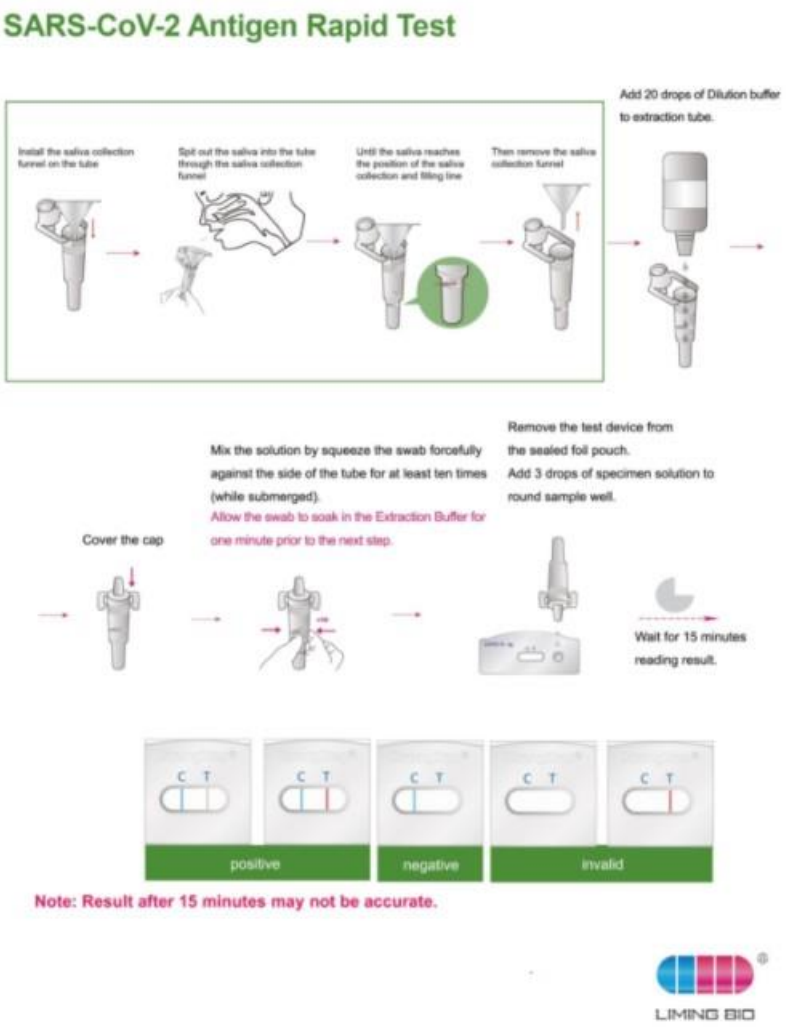
SARS-CoV-2 Antigen Rapid Test

Self-test: tampone naso/orofaringeo/salivare

Confezione da 5 test imbustati singolarmente

Il dispositivo Dual Biosafety System per il test dell'antigene SARS-CoV-2 viene utilizzato per il rilevamento qualitativo dell'antigene nucleocapsidico (N) del nuovo coronavirus (SARS-CoV-2) in campioni di tampone faringeo / nasofaringeo / salivare umano in vitro. Il kit deve essere utilizzato solo come indicatore supplementare o utilizzato insieme al rilevamento degli acidi nucleici nella diagnosi di casi sospetti di COVID-19. Non può essere utilizzato come unica base per la diagnosi e l'esclusione dei pazienti con polmonite infetta dal nuovo coronavirus e non è adatto per lo screening della popolazione generale. I kit sono molto adatti per l'uso per lo screening su larga scala in paesi e regioni in cui il nuovo focolaio di coronavirus si sta diffondendo rapidamente e per fornire diagnosi e conferma per l'infezione da COVID-19. Utilizzare un tampone nasale per ottenere campione fluido, i test antigenici possono produrre risultati in pochi minuti. Poiché questi test sono più veloci e meno costosi dei test molecolari, gli esperti considerano i test antigenici più pratici da usare per un gran numero di persone. Poiché i test antigenici sono ad alta specificità, un risultato positivo del test antigenico è considerato molto accurato.

ISTRUZIONI PER L'USO



1. Installare l'imbuto di raccolta della saliva sul tubo.
2. Sputare la saliva nel tubo attraverso la raccolta della saliva.
3. Fino a quando la saliva raggiunge la posizione della linea di raccolta e riempimento della saliva.
4. Quindi rimuovere l'imbuto di raccolta della saliva.
5. Aggiungere 20 gocce di tampone di diluizione alla provetta di estrazione.
6. Coprire il tappo.
7. Rimuovere il dispositivo di test dalla busta di alluminio sigillata. Aggiungere 3 gocce di soluzione campione al pozzetto rotondo del campione.
8. Attendere 15 minuti per leggere il risultato.

INTERPRETAZIONE DEI RISULTATI

StrongStep®

www.limingbio.com

SARS-CoV-2 Antigen Rapid Test Self-Testing

REF: 500200

Per il rilevamento dell'antigene della proteina nucleocapsidica del virus SARS-CoV-2 nel tampone nasale / orofaringeo umano o nella saliva raccolti da individui sospettati di COVID-19 dal loro medico entro i primi cinque giorni dalla comparsa dei sintomi. Il test viene utilizzato come ausilio nella diagnosi di COVID-19.

Per l'uso da parte di laboratori clinici o operatori sanitari o per auto-test

Tenere lontano dalla portata dei bambini

IN CONFORMITÀ DELLA LA DIRETTIVA 98/79/EC, IVD AUTODIAGNOSTICI

EN ISO 13485:2016

Nanjing Liming Bio-Products CO.,Ltd.

No.12 Huayuan Road,Nanjing,Jiangsu,210042 P.R.China

EC REP **WeKang Ltd.** (www.CE-marking.eu)

Enterprise Hub,NW Business Complex,1 Beraghmore Rd, Derry,BT48 8SE, N. Ireland

Registrato sul sito del Ministero della Salute RDM 2064319

CE

EC Declaration of Conformity

according to the Directive 98/79/EC
(applicable to **self-testing** *IVD* Devices only)

Manufacturer: Nanjing Liming Bio-Products Co., Ltd.
Address: No. 12, Huayuan Road, Nanjing, Jiangshu, 210042. P.R. China
*Products:*Strongstep®SARS-CoV-2 Antigen Rapid Test(Cat.No.500200)
Model: 1Test/box、2Tests/box、3Tests/box、4Tests/box、5Tests/box、7Tests/box、10Tests/box、15Tests/box、20Tests/box、25 Tests/box

Category: **Self-testing**
Conformity assessment route: **Annex III(6), of Directive (**98/79/EC on IVDD**)**
Applicable Standards:

EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN 13612:2002
EN ISO 23640:2015	EN 13641:2002	EN ISO 14971:2019
EN ISO 15223-1:2016	EN ISO 13485:2016	EN 13975:2003
EN 62366:2015		

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Wellkang Ltd t/a Wellkang Tech Consulting located at Enterprise Hub,NW Business Comples,1 Beraghmore,Rd.Derry,BT48 8SE,N. Ireland,UK to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on 06 /(Day) 05 /(Month) of 2021. Place: Nanjing

Represented by: Zhang Shuwen

Signature (on behalf of the manufacturer) Zhang Shuwen

Full Name of authorized signatory: Zhang Shuwen
Position held in the company: President

Company Seal/Stamp:

Nanjing Liming Bio-products Co.,Ltd.

LIMING BIO

EC Declaration of Conformity

according to the Directive 98/79/EC

(applicable to Others/General IVD Devices only)

Manufacturer:

Company Name: Nanjing Liming Bio-Products Co., Ltd.

Address: No.12, Huayuan Road, Nanjing, Jiangsu, 210042. P.R. China

Tel:+86(25)85288506

E-mail:sales@limingbio.com

Whose single Authorized Representative:

Wellkang Ltd

Address:16 Castle St,Dover, Kent, CT16 1PW, England,UK

Tel:+44(20)3287 6300

E-mail:AuthRep@CE-marking.eu

We, the manufacturer, herewith declare that the products

Product/s: StrongStep®SARS CoV-2 Antigen Rapid Test

Cat. No.500200

Model: 20 Tests/Box

Category: Others/General

Applicable Standards: EN 375:2001

EN 980:2016

EN 13612:2002

EN 13640:2002

EN 13641:2002

EN 14254:2004

EN ISO 14971:2012

meet the provisions of Directive 98/79/EC which apply to them.

The medical device has been assigned to In Vitro Diagnostic Medical Devices Directive 98/79/EC.

It bears the mark CE

The product concerned has been designed and manufactured under a quality management system according to In Vitro Diagnostic Medical Devices Directive 98/79/EC.

ollowing the procedure relating to the EC Declaration of Conformity set out in Annex II (Section 6 is not applicable) of Directive 98/79/EC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsiblity of Nanjing Liming Bio-Products Co., Ltd.

Zhang Shuwen

Legally binding signature

Nanjing Liming Bio-products Co., Ltd 南京理明生物制品有限公司

Place,date:Nanjing Mar.10th 2020

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety

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Codice fiscale unificato del credito sociale: 9132010272837745XD
Indirizzo: No.12, Huayuan Road, Xuanwu District, Nanjing City, Jiangsu Province Codice postale: 210042
Aggiungere: No.12, Huayuan Road, Xuanwu District, Nanjing, Jiangsu, PR China, 210042 Tel: +
86-25-85476723 / + 86-25-85288506 Fax: + 86-25-85476387
E-mail: sales@limingbio.com Web: www.limingbio.com

Dichiarazione

Prodotto	RIF	produttore	rappresentante autorizzato	Antigene mirato
StrongStep ® SARS-CoV-2 Test rapido dell'antigene	500200	Nanjing Liming Bio-Products Co., Ltd.	Wellkang Ltd Regno Unito	nucleocapside proteina

Aggiornato il 27 aprile 2021, l'analisi dell'allineamento della sequenza ha mostrato che il sito di mutazione della variante SARS-CoV-2 con molte mutazioni osservate nel Regno Unito e in Sud Africa, la mutazione (N501Y) (trovata nel lignaggio del Regno Unito), la mutazione (E484K) (trovate in Brasile), due mutazioni (K417N e E484K) (trovate in Sud Africa (NGS-SA)) e due mutazioni (E484Q e L452R) (trovate in India) sono tutte mutazioni della proteina spike, non nella regione del proteina nucleocapside.

Il test rapido StrongStep® SARS-CoV-2 Antigen consente il rilevamento qualitativo dell'antigene della proteina nucleocapsidica da SARS-CoV-2 in tamponi nasali e orofaringei umani o nella saliva di pazienti sospettati di infezione da COVID-19. L'antigene mirato è la proteina nucleocapsidica antigene da SARS-CoV-2.

I ceppi mutanti (N501Y, K417N, E484K, E484Q e L452R) nel Regno Unito, Brasile, Sud Africa e India non influiscono attualmente sulle prestazioni poiché non vi è alcun cambiamento nell'antigene della proteina nucleocapside.

Continueremo a prestare attenzione alle ultime modifiche del virus. Una volta che le mutazioni possono influenzare la capacità di rilevamento del prodotto. Cambieremo immediatamente il design del prodotto, studieremo e verificheremo le prestazioni di rilevamento degli ultimi ceppi mutanti e invieremo la ricerca rapporto di verifica.

Nanjing Liming Bio-Products Co., Ltd. 27

aprile 2021

LIMING BIO®
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南京黎明生物制品有限公司
Nanjing Liming Bio-Products Co., Ltd.

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E-mail：sales@limingbio.com Web：www.limingbio.com

Statement

product	REF	manufacturer	authorized rep	Targeted antigen
StrongStep®SARS-CoV-2 Antigen Rapid Test	500200	Nanjing Liming Bio-Products Co., Ltd.	Wellkang Ltd UK	nucleocapsid protein

Updated 27 April 2021,Sequence alignment analysis showed that the mutation site of the SARS-CoV-2 variant with much mutations observed in the United Kingdom and South Africa, the mutation (N501Y) (found in the UK lineage),the mutation (E484K) (found in Brazil), two mutations (K417N and E484K) (found in South Africa (NGS-SA)) and two mutations(E484Q and L452R)(found in India) are all spike protein mutations, not in the region of the nucleocapsid protein.

The StrongStep® SARS-CoV-2 Antigen Rapid Test allows qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human Nasal and Oropharyngeal swabs or saliva from patients who are suspected of COVID-19 infection. The targeted antigen is nucleocapsid protein antigen from SARS-CoV-2.

The mutants (N501Y, K417N, E484K, E484Q and L452R) strain in the United Kingdom, Brazil , South Africa and India do not affect the performance at present. Because there is no change in the nucleocapsid protein antigen.

We will continue to pay attention to the latest changes of virus. Once the mutations may affect the detection ability of the product. we will immediately change the design of product, study and verify the detection performance of the latest mutant strains, and submit the research verification report.

Nanjing Liming Bio-Products Co., Ltd.

April 27, 2021

Medicines & Healthcare products Regulatory Agency

MHRA

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Our Ref:IVD000560

Dr Edward Wang
Wellkang Ltd
16 Castle Street
Dover
Kent
CT16 1PW

20 March 2020

Dear Dr Wang

IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATIONS 2002: REGULATION 44
Registration of manufacturers of *In-Vitro Diagnostic* Medical Devices and devices for Performance Evaluation

Thank you for informing the Competent Authority of the change to the original notification dated (date the registration was registered); ***Manufacturers*** **Name:- Liming Bio-Products Co Ltd** located at **Manufacturers Address:- No.12 Huayuan Road Nanjing, Jiangsu, China 210042** for whom you are acting as the authorised representative and for supplying the medical device information.

The change(s) to your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "in vitro diagnostic medical device", and that you have classified it/them correctly taking into account the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation or approval by the UK Competent Authority.

Your registration is based upon your declaration on the RG3 form and means that you should now be operating under the In Vitro Diagnostic Medical Devices Directive and the 2002 Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products or labelling them as such.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us as required by the Regulations. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the Regulations.

The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

Please inform us of any changes to:

- the company information
- additional generic groups of devices or, for Annex II or Self-Test devices, additional devices
- discontinuation of a generic group of devices or, for Annex II or Self-Test devices, discontinuation of devices

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:***
41. ***None***
42.
43. ***For performance evaluation:***
44. ***None***
45.
46. ***Neither:***
47. ***None***
48.
49.
50. ***Part 6: IVDs which are Annex II or self-test devices***
51.
52. ***For reagnets, reagent products, calibration and control materials:***

53. group by common technological characteristics and/or analytes
54.
55. New products:
56. None
57.
58. For performance evaluation:
59. None
60.
61. Neither:
62. None
63.
64.
65. For other IVDs, group by appropriate indications
66.
67. New products:
68. None
69.
70. For performance evaluation:
71. None
72.
73. Neither:
74. None
75.

If you have any queries regarding your registration, please do not hesitate to contact us.

Yours sincerely

Malcolm Ridgway
Data Integrity Support Officer