NEWGENE
Bioengineering

JEDNORÁZOVÝ RYCHLOTEST na detekci COVID-19

Souprava k detekci hrotového glykoproteinu nového koronaviru (ligand-receptorová kompetitivní chromatografie)

New Gene (Hangzhou) Bioengineering Co., Ltd.
Room 1606, Floor 16, Building 5, 688 Bin'an Road, Chaghe Street,
Binjiang District, Hanzhou City, Zhejiang Province, P. R. China

CE EC REP

Wellkang Ltd (www.CE-marking.eu)
16 Castle St, Dover, CT16 1PW, UK

NEWGENE Bioengineering

PŘEDSTAVENÍ PRODUKTU

Obsah testovací sady Newgene

VÝHODY ANTIGENNÍCH TESTŮ

- Použití vzorku sputa (hlen)
- Rychlá detekce - výsledek do 15-ti minut
- Vysoká přesnost - klinická účinnost 95.8%
- Snádné a nebolestivé použití

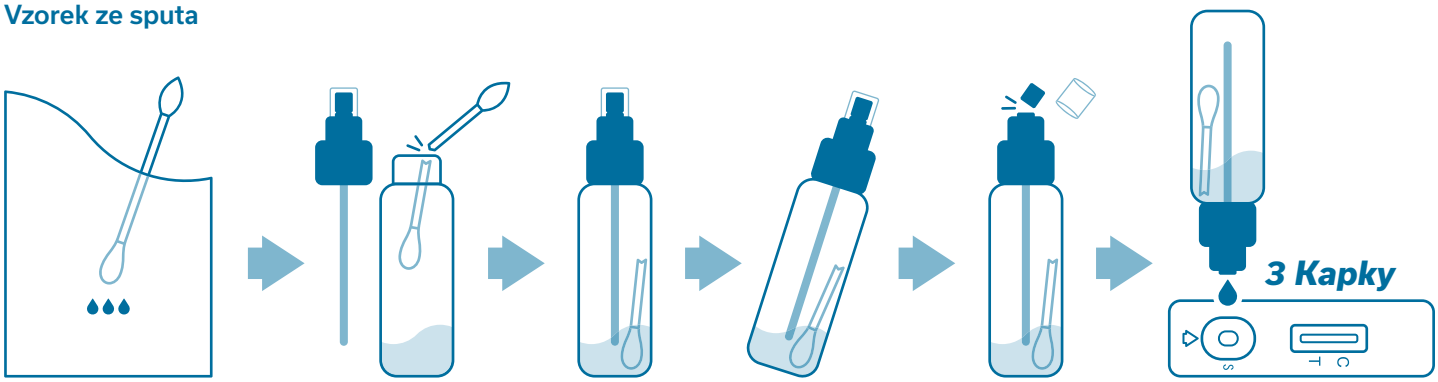
ZOBRAZENÍ VÝSLEDKŮ

Výsledek se zobrazí do 15-ti minut

Pozitivní | Negativní | Neplatný

POSTUP PŘI TESTOVÁNÍ

Vzorek ze sputa



Pomocí vatové tyčinky naberte 10 až 50 mg vzorků sputa (odpovídá velikosti zápalkové hlavičky).

Otevřete krytku extrakční zkumavky na vzorek a ulomte špičku stěrové tyčinky do zkumavky. Zavřete jednorázovou extrakční zkumavku na vzorek a protřepáváním nechte zcela promíchat.

Vytáhněte z balicího sáčku testovací kazetu, uložte ji na stůl, odlomte vyčnívající část odběrové zkumavky a vertikálně přidejte 3 kapky vzorku do otvoru na vzorek.

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RETAILOVÉ BALENÍ

EAN	8456713601546
Počet kusů v balení	1x testovací sada
Doba dodání	Do 14-ti dní

NEWGENE Bioengineering

CE - REGISTRACE MHRA

Medicines & Healthcare products Regulatory Agency

MHRA

Our Ref: IVD001178

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

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

18 May 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 details of ***Manufacturers*** **Name:- New Gene (Hangzhou) Bioengineering Co., Ltd.** located at **Manufacturers Address:- Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street, Binjiang District, Hangzhou City, Zhejiang, China 310000** for whom you are acting as the authorised representative and for supplying the medical device information.

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 considering 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.

Please note this letter does not represent any form of accreditation, certifcation or approval by the UK Competent Authority.

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 of the following changes;

- 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

You should submit your change of registration via DORS with the required statutory fee, which should be accompanied with the information when it is supplied, (the fee is payable for each record notified, and you may place multiple changes on one record).

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.

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MHRA

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. *Coronavirus*
14. *Multiple Drugs of Abuse/Toxicology Rapid Tests*
15.
16.
17. *For other IVDs, group by appropriate indications*
18.
19. *New products:*
20. *None*
21.
22. *For performance evaluation:*
23. *None*
24.
25. *Neither:*
26. *None*
27.
28.
29. *Part 6: IVDs which are Annex II or self-test devices*
30.
31. *For reagnets, reagent products, calibration and control materials:*
32. *group by common technological characteristics and/or analytes*
33.
34. *New products:*
35. *None*
36.
37. *For performance evaluation:*
38. *None*
39.
40. *Neither:*
41. *None*
42.
43.
44. *For other IVDs, group by appropriate indications*
45.
46. *New products:*
47. *None*
48.
49. *For performance evaluation:*
50. *None*
51.
52. *Neither:*
53. *None*
54.

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

Yours sincerely

Malcolm Ridgway
Data Integrity Support Officer

NEWGENE Bioengineering

CE - PROHLÁŠENÍ O SHODĚ

CE

EC Declaration of Conformity

CE

according to the Directive 98/79/EC

(applicable to IVD Devices of NOT **Annex II and NOT self-test***)*

Manufacturer:	**New Gene (Hangzhou) Bioengineering Co., Ltd.**
Address:	Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street, Binjiang District, Hangzhou City, Zhejiang Province, P. R. China
EC Representative:	Wellkang Ltd 16 Castle Street, Dover, CT16 1PW, England, UK

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	Product Name	Novel Coronavirus Spike Glycoprotein Detection Kit (Ligand-Receptor Competitive Chromatography)
	Type/model, identification of product allowing traceability (Where applicable)	COVID-19-NG04
of Category	: **Common/Others IVD** (Devices of NOT **Annex II** and **NOT self-test**)	

is/are in conformity with the relevant provisions and requirements of Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Applied harmonised standards, national standards or other normative documents	EN 23640-2015	EN 13640:2002
	EN 980:2016	EN 13641:2002
	EN ISO 14971:2019	EN ISO 18113-1 2011
	EN 13612:2002	EN ISO 18113-4 2011
Conformity assessment procedure	**Module A (EC Declaration of Conformity) (Annex III, except point 6)**	
Notified Body (name & number)	**NOT applicable**	

Signed on: 7 May 2020. Place: Hangzhou City, Zhejiang Province, P. R. China

Signature (on behalf of the manufacturer)

Name of authorized signatory: Mingfu Li

Position held in the company: General Manager

Company Seal/Stamp:

NEWGENE Bioengineering

ISO 13485

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

New Gene (Hangzhou) Bioengineering Co., Ltd.
Room 1606,16th Floor, No.5 Building
688 Bin'an Road
Binjiang District
Hangzhou
Zhejiang
310052
China

诺迦（杭州）生物工程有限公司
中国
浙江省
杭州市
滨江区
长河街道滨安路688号
5幢16层1606室
邮编：310052

Holds Certificate No: **MD 729179**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design and Development, Manufacture and Distribution of In-vitro Diagnostic Rapid Test Kit of Drug Abuse, Manufacture and Distribution of In-vitro Diagnostic Rapid Test Kit of Infectious Diseases.
药物滥用体外诊断快速检测试剂盒的设计，开发，制造和销售，传染病体外诊断快速检测试剂盒的制造和销售。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-07-27
Latest Revision Date: 2020-07-27

Effective Date: 2020-07-27
Expiry Date: 2023-07-26

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...making excellence a habit.™