PRODUCT INTRODUCTION

PRIVATE HARLEY STREET CLINIC LONDON

NEWGENE Bioengineering

Novel Coronavirus Antigen Detection Kit (Sputum Sample)

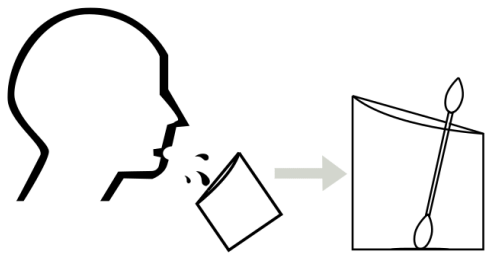
Product Feature

1. Novel Coronavirus Antigen Detection.
2. Using Sputum Sample.
3. Fast Detection: Result in 15 minutes.
4. High Accuracy.
5. Easy to Use.

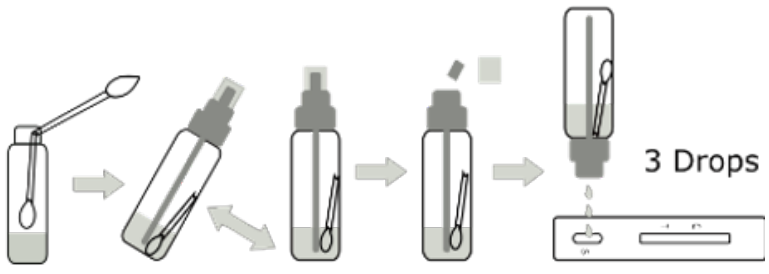
Components - 25PCS/Box

1. Detection Kit * 25
2. Sample Extraction Tube * 25
3. Cotton Swab * 25
4. Paper Cup * 25
5. Package Insert * 1

Test Procedure

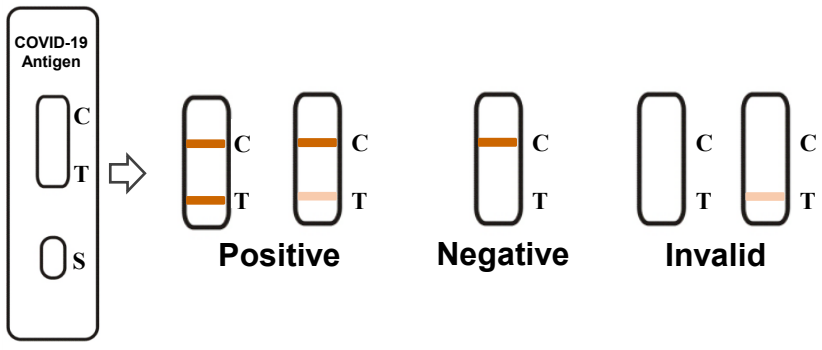


Sampling steps



Detection steps

Interpretation of Results



PRODUCT INTRODUCTION

PRIVATE HARLEY STREET CLINIC LONDON

NEWGENE Bioengineering

Novel Coronavirus Antigen Detection Kit (Throat swab Sample)

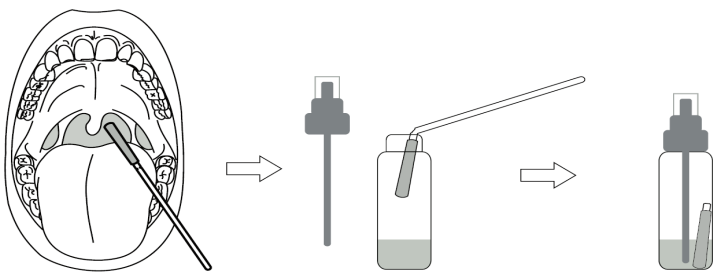
Product Feature

1. Novel Coronavirus Antigen Detection.
2. Sampling by Throat swab.
3. Fast Detection: Result in 15 minutes.
4. High Accuracy.
5. Easy to Use.

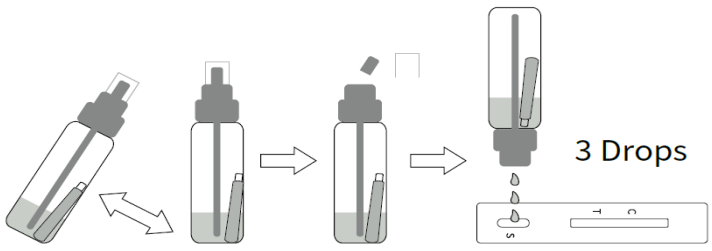
Components - 25PCS/Box

1. Detection Kit * 25
2. Sample Extraction Tube * 25
3. Throat swab* 25
4. Package Insert * 1

Test Procedure

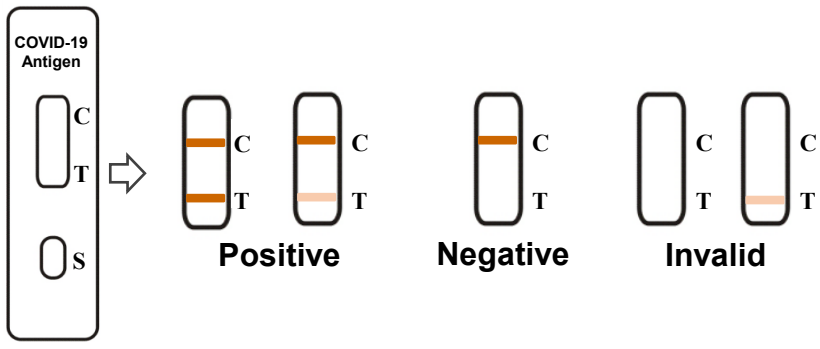


Sampling steps



Detection steps

Interpretation of Results



CE Certification – MHRA Registration Letter

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.

CE Certification – MHRA Registration Letter

Medicines & Healthcare products Regulatory Agency

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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Medicines & Healthcare products
Regulatory Agency

MHRA

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

Yours sincerely

Malcolm Ridgway
Data Integrity Support Officer

CE Certification – Declaration of Conformity

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 Antigen Detection Kit (Colloidal Gold)
	Type/model, identification of product allowing traceability (Where applicable)	COVID-19-NG02
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) Mingfu Li

Name of authorized signatory: Mingfu Li
Position held in the company: General Manager
Company Seal/Stamp:

ISO 13485 Certification

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

...making excellence a habit.™

NEWGENE Bioengineering

Novel Coronavirus Antigen Detection Kit (Colloidal Gold)

Package Insert

Cat: COVID-19-NG02 **Specimens:** Sputum
Version: 05 **Effective Date:** 2020-10

For professional and in vitro diagnostic use only.

PRODUCT NAME
Novel Coronavirus Antigen Detection Kit (Colloidal Gold)

PACKING
1 piece/bag, 25pieces/box.

INTENDED USE
This product is suitable for the qualitative detection of novel coronavirus in sputum sample. It provides an aid in the diagnosis of infection with novel coronavirus.

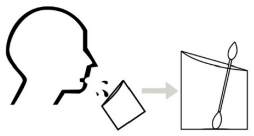
SUMMARY
The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE
The Novel Coronavirus Antigen Detection Kit (Colloidal Gold) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in throat swab. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen presents in the sample, a complex formed between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). Absence of the T line suggests a negative result. To serve as a procedural control a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

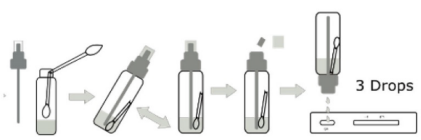
COMPOSITION
1. Disposable test card
2. Disposable sample extraction tube
3. Cotton swab
4. Disposable paper cup

STORAGE AND STABILITY
1. Store as packaged in the hermetic bag at the temperature (2-30℃ or 38-86℉) and avoid direct sunshine. The kit is stable within the expiration date printed on the labeling.
2. Once open the hermetic bag, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
3. The lot number and the expiration date are printed on the labeling.

TEST PROCEDURE
Allow the test device and specimens to restore to room temperature (15-30℃ or 59-86℉) prior to testing.



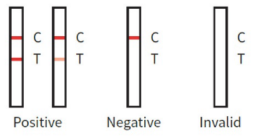
Sampling Steps



Detection Steps

1. Use the cotton swab to pick up 10-50mg sputum samples (equivalent to the size of a match head). Open the cap of sample extraction tube, break the swab tip into the tube. Close the disposable sample extraction tube and shake to mix the sample completely. Leave the swab in the extraction tube for one minute.
2. Take the test card from the packaging bag, place it on a table, cut off the protrusion of the collection tube, and add 3 drops of the sample solution into the sample loading hole vertically.
3. Read the result in 15 minutes. The result is considered inaccurate and invalid after 30 minutes.

RESULTS OF INTERPRETATION
Positive(+): Both of T and C lines are appeared in 15minutes.
Negative(-): C line is appeared while no T line appeared in 15 minutes after the sample is loaded.
Invalid: As long as the C line does not appear, it indicates that the test result is invalid, and should retest the sample with another test card.



NOTES
1. The Novel Coronavirus Antigen Detection Kit (Colloidal Gold) is applicable to sputum samples. Blood, serum, plasma, urine and other samples may cause abnormal results.
2. Please make sure that a proper amount of sample is added for testing. Too much or too little sample amount may cause deviations in results.
3. For positive judgement, it can be confirmed as soon as both T and C line appeared. That may take 3-15 minutes after the sample is loading. For negative judgement, please wait for 15 minutes after sample loading. The result is invalid after 30 minutes after sample loading.
4. This product is disposable. DO NOT recycle.
5. Dispose of used products, samples, and other consumables as medical wastes under relevant regulations.
6. If the test line or control line is out of the test window, do not use the test card. The test result is invalid and retest the sample with another one.

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by	2	Do not reuse
2℃ 30℃	Store between 2-30°C	LOT	Lot Number	REF	Catalogue number

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

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

NEWGENE Bioengineering

Novel Coronavirus Antigen Detection Kit (Colloidal Gold)

Package Insert

Cat: COVID-19-NG02 **Specimens:** Throat Swab
Version: 03 **Effective Date:** 2020-10

For professional and in vitro diagnostic use only.

PRODUCT NAME
Novel Coronavirus Antigen Detection Kit (Colloidal Gold)

PACKING
1 piece/bag, 25pieces/box.

INTENDED USE
This product is suitable for the qualitative detection of novel coronavirus in throat swab sample. It provides an aid in the diagnosis of infection with novel coronavirus.

SUMMARY
The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

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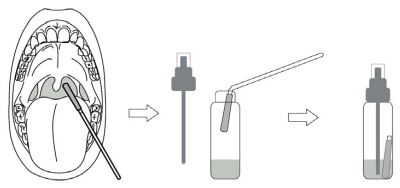
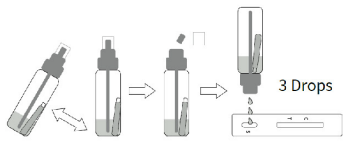
COMPOSITION
1. Disposable test card
2. Disposable sample extraction tube
3. Throat swab

STORAGE AND STABILITY
1. Store as packaged in the hermetic bag at the temperature (2-30℃ or 38-86℉) and avoid direct sunshine. The kit is stable within the expiration date printed on the labeling.
2. Once open the hermetic bag, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
3. The lot number and the expiration date are printed on the labeling.

SAMPLE COLLECTION
1. Use the throat swab provided in the kit to swab over the lateral and posterior walls of pharynx, as well as the intratonsillar cleft.
2. Open the cap of disposable sample extraction tube, break the swab tip into the tube.
3. Close the disposable sample extraction tube. Keep the sample for test.

TEST PROCEDURE


Allow the test device and specimens to equilibrate to temperature (15-30℃ or 59-86℉) prior to testing.
1. Shake the disposable sample extraction tube to dissolve sample on the swab.
2. Take the disposable test card from the packaging bag, place it on a table.
3. Break off the tip of disposable sample extraction tube. Close the disposable sample extraction tube and shake to mix the sample completely. Leave the swab in the extraction tube for one minute.
4. Squeeze the tube to expel 3 drops of the sample solution into the sample loading hole on disposable test card.
5. Read the test result in 15 minutes.



RESULTS OF INTERPRETATION
Positive(+): Both of T and C lines are appeared in 15 minutes.
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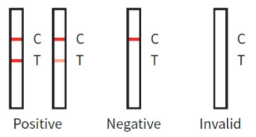

NOTES
1. The Novel Coronavirus Antigen Detection Kit (Colloidal Gold) is applicable to throat swab sample. Blood, serum, plasma, urine and other samples may cause abnormal results.
2. Please make sure that a proper amount of sample is added for testing. Too much or too little sample amount may cause deviations in results.
3. For positive judgement, it can be confirmed as soon as both T and C line appeared. That may take 3-15 minutes after the sample is loading. For negative judgement, please wait for 15 minutes after sample loading. The result is invalid after 30 minutes after sample loading.
4. This product is disposable. DO NOT recycle.
5. Dispose of used products, samples, and other consumables as medical wastes under relevant regulations.
6. If the test line or control line is out of the test window, do not use the test card. The test result is invalid and retest the sample with another one.

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