PRODUCT INTRODUCTION

COVID-19 Antigen Detection Kit
(Sputum Sample)

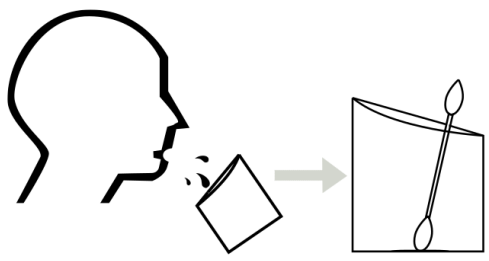
Product Feature

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

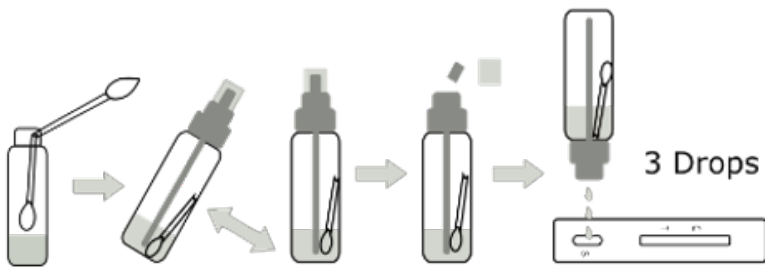
Components - 25PCS/Box

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

Test Procedure

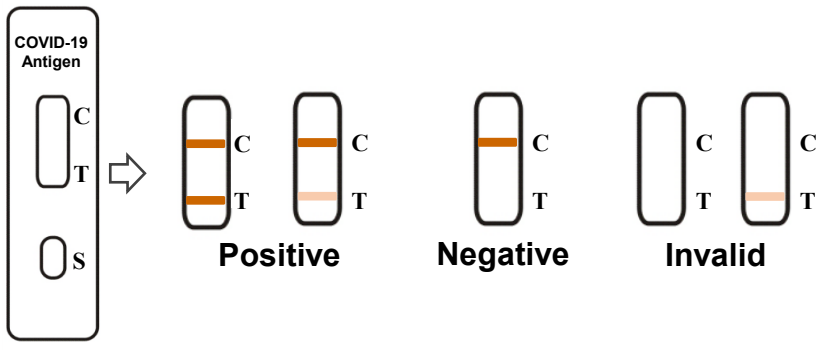


Sampling steps



Detection steps

Interpretation of Results



PRODUCT INTRODUCTION

COVID-19 Antigen Detection Kit
(Throat Swab Sample)

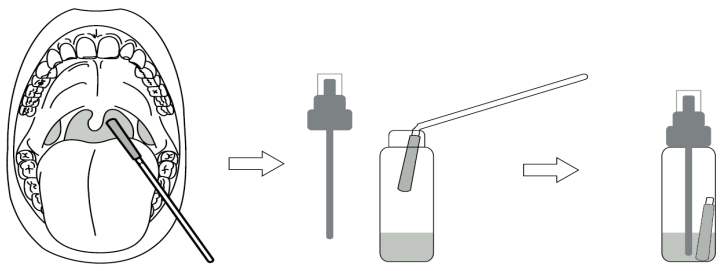
Product Feature

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

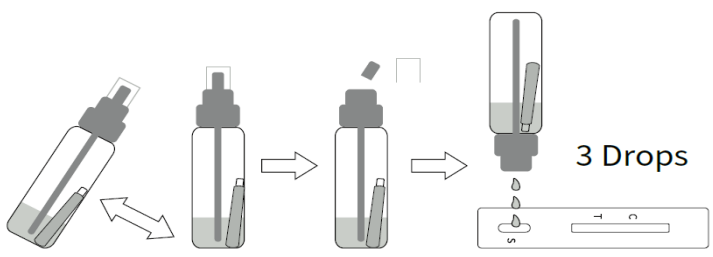
Components - 25PCS/Box

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

Test Procedure

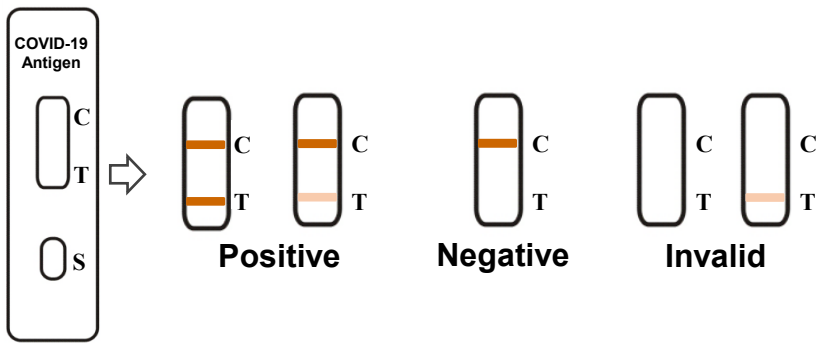


Sampling steps



Detection steps

Interpretation of Results



CE Certification – CIBG Registration Letter

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer R. Luo
Olympisch Stadion 24
1076 DE Amsterdam

Datum: 1 oktober 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Luo,

Op 30 september 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam New Gene (Hangzhou) Bioengineering Co., Ltd. met Europees gemachtigde SUNGO Europe B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

COVID-19 / Influenza A / Influenza B Detection Kit
(geen merknaam) (NL-CA002-2020-53701)
COVID-19 Antibody / Antigen Detection Kit
(geen merknaam) (NL-CA002-2020-53700)
COVID-19 Antigen Detection Kit
(geen merknaam) (NL-CA002-2020-53699)
COVID-19 Neutralizing Antibody Detection Kit
(geen merknaam) (NL-CA002-2020-53702)
Novel Coronavirus Ribonucleic Acid Detection Kit
(geen merknaam) (NL-CA002-2020-53698)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
M. Schmitz - Konte

medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20204772

Bijlagen
-

Uw aanvraag
30 september 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

CE Certification – CIBG Registration Letter

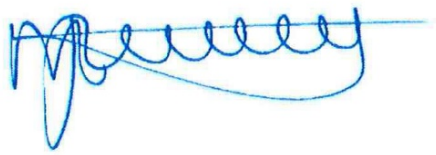
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, New Gene (Hangzhou) Bioengineering Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert SUNGO Europe B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

CE Certification – Declaration of Conformity

CE

DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

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: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: **COVID-19 Antigen Detection Kit**

Specification: 25Tests/Box 1Test/Box

Classification: Others (IVDD)

Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

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

Signature: Mingfu Li

Name/ Position: Mingfu Li / General Manager

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

Date: 29/09/2020

Place: Hangzhou, Zhejiang, China

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

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An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Information and Contact: BSI, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands. Tel: +31 (0) 20 3460 780
BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A Member of the BSI Group of Companies.

Analytical Sensitivity Study Report - Limit of Detection (LoD)

Product Name:
COVID-19 Antigen Detection Kit (Colloidal Gold)

Management of the study:
R&D Department of NEWGENE, Quality Management Department of NEWGENE

Place of Study:
Hangzhou, Zhejiang Province, China.

Sponsor:
New Gene (Hangzhou) Bioengineering Co., Ltd.

1. Objective

The purpose of this study is to estimate the LoD of this product.

2. Methodology

2.1 Description of the sample type

Positive Control - 2.7E7 pfu/mL (quantitated on Vero E6 cell line) heat inactivated SARS-CoV-2 stock (Lot#: 20200709).

Negative Control - 10% sputum solution, which is a pool of sputum samples from healthy donors diluted in Sample Extraction Solution (10% v/v ratio).

2.2 Number of samples tested (positive and negative)

150 tests from three sequential batches of the Novel Coronavirus Antigen Detection Kit (Colloidal Gold) (Lot#: 20200721-01, EXP: 07/20/2021; Lot#: 20200722-01, EXP: 07/21/2021; Lot#: 20200723-01, EXP: 07/22/2021).

120 tests are used for positive samples, and the other 30 tests are used for negative samples.

2.3 Sample characterization

The Positive Control is diluted in Negative Control to 250 pfu/mL, 500 pfu/mL, 750 pfu/mL, and 1000 pfu/mL.

2.4. Testing algorithm

Each concentration of Positive Control and the Negative Control is tested by each batch of the Novel Coronavirus Antigen Detection Kit (Colloidal Gold) for 10 times.

For each single test, three drops of Positive Control or Negative Control is used.

A color chart is used to semi-quantitate the color intensity of test results (L0~L10). The color chart is for R&D use only. It is not included in the product packaging for end users.

2.5. Acceptance criteria

The product LoD is determined at the lowest concentration with positive rate no less than 95%.

3. Result

Concentration (pfu/mL)	Lot#: 20200721-01		Lot#: 20200722-01		Lot#: 20200723-01	
	T Line	C Line	T Line	C Line	T Line	C Line
Negative Control	L0	L8	L0	L9	L0	L9
	L0	L8	L0	L8	L0	L8
	L0	L8	L0	L9	L0	L8
	L0	L8	L0	L8	L0	L8
	L0	L8	L0	L9	L0	L8
	L0	L8	L0	L8	L0	L9
	L0	L9	L0	L9	L0	L8
	L0	L8	L0	L9	L0	L8
	L0	L8	L0	L8	L0	L8
	L0	L8	L0	L8	L0	L9
250	L4	L8	L0	L8	L0	L8
	L0	L8	L0	L8	L0	L8
	L0	L8	L0	L8	L0	L8
	L0	L9	L0	L8	L0	L9
	L4	L8	L0	L8	L0	L8
	L0	L8	L0	L8	L5	L8
	L5	L8	L0	L8	L0	L8
	L0	L8	L4	L8	L0	L8
	L0	L8	L4	L9	L0	L8
	L4	L8	L5	L8	L0	L8
500	L5	L8	L0	L8	L5	L8
	L5	L8	L5	L8	L0	L8
	L5	L8	L5	L8	L6	L8
	L4	L8	L5	L8	L5	L8
	L0	L8	L0	L8	L0	L8
	L5	L8	L4	L8	L5	L8
	L4	L8	L0	L8	L5	L9
	L0	L8	L6	L8	L5	L8
	L5	L8	L5	L9	L6	L8
	L0	L8	L5	L8	L5	L8
750	L5	L8	L5	L8	L6	L8
	L5	L8	L5	L9	L6	L8
	L5	L8	L0	L8	L6	L8
	L5	L8	L6	L8	L5	L8
	L6	L8	L6	L8	L6	L8
	L0	L8	L5	L8	L6	L8
	L6	L8	L5	L8	L6	L9
	L5	L8	L5	L8	L5	L8
	L5	L8	L0	L8	L5	L8
	L6	L9	L6	L8	L5	L9
1000	L5	L8	L5	L8	L6	L8

	L6	L8	L6	L8	L5	L8
	L5	L8	L6	L8	L5	L8
	L5	L8	L6	L9	L6	L8
	L6	L8	L5	L8	L6	L8
	L5	L8	L5	L8	L6	L8
	L6	L9	L6	L8	L6	L8
	L5	L8	L5	L8	L5	L8
	L6	L8	L6	L8	L6	L8
	L6	L8	L6	L8	L6	L8

Positive rate at each concentration:

Negative Control	0/30
250 pfu/mL SARS-CoV-2	8/30
500 pfu/mL SARS-CoV-2	22/30
750 pfu/mL SARS-CoV-2	27/30
1000 pfu/mL SARS-CoV-2	30/30

SPSS probit regression analysis shows that the product LoD (Positive Rate≥95%) is 785.8 pfu/mL, 95% Confidence Intervals: 682.3 pfu/mL to 977.2 pfu/mL.

4. Conclusion

The LoD of this product is 785.8 pfu/mL, 95%CI: 682.3 pfu/mL to 977.2 pfu/mL

COVID-19 Antigen Detection Kit

Clinical Study Report

Name of in vitro diagnostic reagents used in the test: COVID-19 Antigen Detection Kit

Specifications: 25 Tests/Box

Start and end time of the test: August 24th, 2020- September 7th, 2020

Applicant: 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

Report Date: September 16th, 2020

Summary

The COVID-19 Antigen Detection Kit developed by New Gene (Hangzhou) Bioengineering Co., Ltd. can quickly and qualitatively detect the nucleocaspid protein of novel coronavirus (SARS-COV-2) in human sputum/swab samples. It can be used as a supplementary test for COVID-19 diagnosis.

According to the clinical trial plan, the COVID-19 Antigen Detection Kit or "test reagent", is to test sputum and swab samples from COVID-19 suspects. Test results are compared with another commercial SARS-COV-2 nucleic acid detection kit with NMPA approval, which is defined as the "gold standard". The sensitivity, specificity, and total agreement rate are used to evaluate the reliability of the test reagent in clinical applications.

Method: A collection of clinical samples are examined by the test reagent and the gold standard in parallel, to calculate the clinical sensitivity, clinical specificity, and total agreement rate of the test reagent.

Standard of criteria for a qualified test reagent: Clinical sensitivity ≥90%, clinical specificity ≥90%, and total agreement rate ≥90%.

Results: Compared to the gold standard, the clinical sensitivity of test reagent is 96.5%, the clinical specificity is 99.0%, and the total agreement rate is 97.7%. For different sample types, the sensitivity, specificity, and total agreement rate are 97.3%, 99.0%, and 98.1% in sputum samples, 95.7%, 99.0%, and 97.2% in swab samples, respectively.

Conclusion: Compared to the gold standard reagent, the test reagent has reliable performance in diagnosing COVID-19 cases.

Acronyms

Test reagent: The COVID-19 Antigen Detection Kit developed by New Gene (Hangzhou) Bioengineering Co., Ltd.

SARS-COV-2: Novel Corona Virus 2019

Main contents

Introduction

The novel coronavirus SARS-COV-2 is the causative pathogen for the global pandemic of COVID-19. It is contagious in humans, either symptomatically or asymptomatically. Based on current epidemic knowledge, the asymptomatic infection may last for 1 day to 14 days, mainly 3 days to 7 days. Symptoms of COVID-19 include fever, fatigue, and cough. Some patients also complains about nasal obstruction, runny nose, score throat, muscle aches, and diarrhea.

In response to the emergent market needs, New Gene (Hangzhou) Bioengineering Co., Ltd. has developed the COVID-19 Antigen Detection Kit. Since studies report that nucleocaspid (N protein) is the most abundant viral protein during infection, N protein is chosen as the detection target of this product to achieve its best sensitivity in clinical applications.

Production of the COVID-19 Antigen Detection Kit is implemented in Class 100,000 cleanrooms, by proficient operators. Multiple quality control processes are included in the manufacture procedures to examine the quality of raw materials, semi-finished products, and finished products. The construction of cleanrooms, personnel training, and manufacture practices are implemented under relevant laws and regulations.

To evaluate the clinical performance of the COVID-19 Antigen Detection Kit, the current clinical trial is jointly carried out by the applicant and multiple clinical sites. The applicant is responsible for providing reagents and training relevant personnel with the operating procedures and technical principles to minimize operational bias. The clinical sites are responsible for the collection and storage of clinical trial samples, the implementation of clinical trials, the compilation of clinical trial records, and sharing test results with the applicant.

Trial objective

The objective of current trial is to evaluate the performance of test reagent in clinical applications, using a NMPA approved commercial SARS-COV-2 nucleic acid detection reagentas the “gold standard” reagent.

Trial design

Clinical samples for the current trial are collected by the clinical sites. Each sample is tested by both the test reagent and gold standard reagent. The clinical sensitivity, clinical specificity, and total agreement rate of test reagent are calculated based on the test results.

Results and analysis

Determining the sample size.

Considering the uncertainty of obtaining positive samples, the number of samples for this clinical trial shall be no less than 194, of which the number of positive samples shall not be less than 62 for each sample type.

Sample collection, storage, and transportation.

Clinical samples are collected from COVID-19 suspects, and kept frozen at -15°C~-25°C until used.

The “gold standard” reagent

Nucleic acid testing is currently the "gold standard" for COVID-19 diagnosis. A NMPA approved nucleic acid test reagent, namely the Novel Coronavirus (SARS-COV-2) Real Time Multiplex RT-PCR Kit produced by Shanghai ZJ Bio-Tech Co., Ltd. is chosen as the “gold standard” reagent. It targets the ORF1ab gene, N gene, and E gene of the SARS-COV-2, and is used as an auxiliary diagnosis and emergency reserve reagent for COVID-19.

Information of test reagent and the "gold standard" reagent.

Test reagent	COVID-19 Antigen Detection Kit		
Specification	25 Tests/Box	Lot No.	20200721-01 20200722-01
Period of Validity	1 year	Storage	2°C~30°C
Manufacturer	New Gene (Hangzhou) Bioengineering Co., Ltd.		

Gold Standard reagent	Novel Coronavirus (SARS-COV-2) Real Time Multiplex RT-PCR Kit		
Approval Number	NMPA NO:20203400057		
Specification	50 Tests/Box		
Period of Validity	Six month	Storage:	Store at -20±5°C, keep away from light
Manufacturer	Shanghai ZJ Bio-Tech Co., Ltd.		

Quality control methods

The clinical trial is strictly implemented in accordance with the corresponding instruction manual.

Statistical analysis method of clinical trial data

		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	a	b	a + b
	Negative	c	d	c + d
Total		a + c	b + d	a + b + c + d

Clinical sensitivity (%) = [a / (a + c)] ×100%

Clinical specificity (%) = [d / (b + d)] ×100%

Total agreement rate (%) = [(a + d) / (a + b + c + d)] ×100%

Clinical trial results and analysis

Sample characterization

A collection of 427 sputum samples, including 209 sputum samples and 218 swab samples have been tested. These samples are taken from 427 suspected patients, of which 197 (46.1%) are female, and 230 (53.9%) are male. Their ages range from 17 to 88 years old, and are 47 years old on average. Cough (79.4%) and fever (69.1%) are the most common complained symptoms. Their sampling time is between Day 1 to Day 4 post onset, mainly on Day 2 (36.1%).

Result analysis

Product performance in different sample types

In 209 sputum samples, the test reagent finds out 110 positive results, of which 109 samples are reported positive by both reagents. One sample is reported positive only in test reagent, and another 3 samples are reported positive only in gold standard reagent. The other 96 samples are reported negative by both reagents. Testing results are presented in table below.

Sputum		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	109	1	110
	Negative	3	96	99
Total		112	97	209

Clinical sensitivity (%) = [109 / (109 + 3)] ×100% = 97.3%

Clinical specificity (%) = [96 / (1 + 96)] ×100% = 99.0%

Total agreement rate (%) = [(109 + 96) / (109 + 1 + 3 + 96)] ×100% = 98.1%

In 218 throat swab samples, the test reagent finds out 113 positive results, of which 112 samples are also reported positive by the gold standard reagent. One sample is reported positive only in test reagent, and another 5 samples are reported positive only in gold standard reagent. The other 100 samples are reported negative by both reagents. Testing results are presented in table below.

Throat Swab		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	112	1	113
	Negative	5	100	105
Total		117	101	218

Clinical sensitivity (%) = [112 / (112 + 5)] ×100% = 95.7%

Clinical specificity (%) = [100 / (1 + 100)] ×100% = 99.0%

Total agreement rate (%) = [(112 + 100) / (112 + 1 + 5 + 100)] ×100% = 97.2%

Product performance in all sample types

The test reagent finds out 223 positive results, of which 221 samples are reported positive by both reagents. Two samples are reported positive only in test reagent, and another 8 samples are reported positive only in gold standard reagent. The other 196 samples are reported negative by both reagents. Testing results are presented in table below.

Sputum/Throat Swab		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	221	2	223
	Negative	8	196	204
Total		229	198	427

Clinical sensitivity (%) = [221 / (221 + 8)] ×100% = 96.5%

Clinical specificity (%) = [196 / (2 + 196)] ×100% = 99.0%

Total agreement rate (%) = [(221 + 196) / (221 + 2 + 8 + 196)] ×100% = 97.7%

Discussion and conclusion

In this clinic trial, performance of the test reagent "COVID-19 Antigen Detection Kit" is evaluated on a collection of 427 clinical samples. Compared to a commercial Real Time Multiplex RT-PCR, the test reagent have shown sensitivity, specificity, and agreement rate of 96.5%, 99.0%, and 97.7%. For different sample types, the sensitivity, specificity, and total agreement rate are 97.3%, 99.0%, and 98.1% in sputum samples, 95.7%, 99.0%, and 97.2% in swab samples, respectively. These results suggest a promising future of test reagent in clinical applications.

Although the antigen test directly detect viral proteins without amplification process, which makes it less sensitive than conventional nucleic acid tests, the antigen tests have two inherent advantages for clinical applications. The first advantage is short turn around time. Antigen tests usually take 20 to 30 minutes, making it possible for point-of-care testing (POCT). However, nucleic acid tests take 2 to 3 hours. In some countries, it may even take days to report a nucleic acid test result to suspects. Such a delay will absolutely hinder the control and prevention of disease transmission. The second advantage of antigen tests is easy-to-use. Antigen tests don't require large investment in laboratory construction, or complicated procedures like RNA extraction, and reagent preparation. The operators will be able to run a antigen test independently, with a one-hour simple training. Therefore, antigen tests are most suitable for large applications in resource limited areas.

In summary, the current clinical trial has proven the reliable performance of COVID-19 Antigen Detection Kit. This product is promising to assist the diagnosis of COVID-19 cases in large scales.

Interference Study Report

Product Name:

COVID-19 Antigen Detection Kit (Colloidal Gold)

Management of the study:

R&D Department of NEWGENE, Quality Management Department of NEWGENE

Place of Study:

Hangzhou, Zhejiang Province, China.

Sponsor:

New Gene (Hangzhou) Bioengineering Co., Ltd.

1. Objective

The purpose of this study is to evaluate the impact of potential interfering materials to the accuracy of test result.

2. Methodology

2.1 Description of the sample type

Positive Control - 2.7E7 pfu/mL (quantitated on Vero E6 cell line) heat inactivated SARS-COV-2 stock (Lot#: 20200709).

Negative Control - 10% sputum solution, which is a pool of sputum samples from healthy donors diluted in 1×PBS solution (10% v/v ratio)

Potential interfering materials in sputum samples:

1) Endogenous substances (mucin, hemoglobin, and bilirubin)
2) Antibiotics (levofloxacin, azithromycin, ceftriaxone, and meropenem)
3) Antiviral drugs (α-interferon, zanamivir, ribavirin, oseltamivir, paramivir, lopinavir, ritonavir, and abidol)
4) Systemic antibacterial drugs (tobramycin)
5) Allergic symptom relief medicine (histamine hydrochloride)
6) Nasal spray or nasal drops (phenylephrine, and oxymetazoline)
7) Nasal skin steroids (beclomethasone, dexamethasone, flunisolide, triamcinolone acetonide, budesonide, mometasone, and fluticasone)

2.2 Number of samples tested (positive and negative)

504 tests from three sequential batches of the Novel Coronavirus Antigen Detection Kit (Colloidal Gold) (Lot#: 20200721-01, EXP: 07/20/2021; Lot#: 20200722-01, EXP: 07/21/2021; Lot#: 20200723-01, EXP: 07/22/2021).

252 tests are used for positive samples, and the other 252 tests are used for negative samples.

2.3 Sample characterization

The Positive Control is diluted in Negative Control to 1500 pfu/mL.

Interference materials are spiked into each Positive Control or Negative Control to final concentration of 20μg/mL.

2.4. Testing algorithm

Each Positive Control and Negative Control is tested by each batch of the Novel Coronavirus Spike Glycoprotein Detection Kit (Ligand-receptor Competitive Chromatography) for 3 times.

For each single test, three drops of Positive Control or Negative Control is used.

A color chart is used to semi-quantitate the color intensity of test results (L0~L10). The color chart is for R&D use only. It is not included in the product packaging for end users.

2.5. Acceptance criteria

Negative Control samples spiked with/without interfering materials should report negative test results, with no obvious diminished color intensity at Control Lines.

Positive Control samples spiked with/without interfering materials should report positive test results, with no obvious diminished color intensity at Test Lines.

3. Result

Interference test results on sputum samples:

Samples	Lot#: 200301		Lot#: 200302		Lot#: 200303	
	T Line	C Line	T Line	C Line	T Line	C Line
Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L9/L8
Positive Control	L6/L6/L6	L8/L9/L8	L6/L6/L6	L8/L8/L8	L6/L6/L5	L9/L9/L9
Mucin + Negative Control	L0/L0/L0	L9/L8/L8	L0/L0/L0	L8/L9/L9	L0/L0/L0	L8/L8/L8
Mucin + Positive Control	L6/L6/L6	L8/L8/L8	L6/L6/L6	L9/L9/L8	L6/L6/L6	L9/L8/L8
Hemoglobin + Negative Control	L0/L0/L0	L8/L9/L8	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L9/L8
Hemoglobin + Positive Control	L6/L6/L6	L8/L8/L9	L6/L6/L6	L8/L8/L8	L6/L5/L6	L8/L8/L8
Bilirubin + Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L8/L8
Bilirubin + Positive Control	L6/L6/L6	L9/L8/L9	L6/L6/L6	L9/L9/L8	L5/L6/L6	L9/L9/L8
Levofloxacin + Negative Control	L0/L0/L0	L8/L8/L9	L0/L0/L0	L8/L9/L9	L0/L0/L0	L8/L8/L9
Levofloxacin + Positive Control	L6/L6/L6	L9/L8/L9	L5/L6/L6	L8/L8/L8	L6/L6/L5	L8/L9/L8
Azithromycin + Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L8/L9	L0/L0/L0	L8/L8/L9
Azithromycin + Positive Control	L6/L6/L6	L9/L8/L8	L6/L6/L6	L9/L8/L8	L6/L6/L6	L8/L8/L8
Ceftriaxone + Negative Control	L0/L0/L0	L8/L9/L8	L0/L0/L0	L8/L8/L8	L0/L0/L0	L9/L9/L9
Ceftriaxone + Positive Control	L6/L6/L6	L8/L8/L8	L5/L6/L6	L8/L8/L8	L5/L6/L6	L8/L8/L9
Meropenem + Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L8/L8	L0/L0/L0	L9/L9/L9
Meropenem + Positive Control	L6/L6/L6	L8/L8/L9	L6/L6/L6	L8/L9/L8	L6/L6/L6	L8/L8/L8
α-interferon + Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L8/L8	L0/L0/L0	L9/L8/L8
α-interferon + Positive Control	L6/L6/L6	L8/L8/L8	L6/L6/L6	L8/L8/L8	L6/L6/L6	L8/L9/L8
Zanamivir + Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L9/L8
Zanamivir + Positive Control	L6/L6/L6	L8/L8/L8	L6/L6/L6	L9/L8/L8	L6/L6/L6	L8/L8/L8
Ribavirin + Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L9/L8/L8	L0/L0/L0	L9/L8/L9
Ribavirin + Positive Control	L6/L5/L6	L8/L8/L9	L6/L6/L6	L8/L9/L8	L6/L6/L6	L8/L8/L8
Oseltamivir + Negative Control	L0/L0/L0	L8/L9/L8	L0/L0/L0	L8/L9/L9	L0/L0/L0	L8/L8/L9
Oseltamivir + Positive Control	L6/L6/L6	L9/L8/L8	L6/L6/L6	L8/L8/L8	L6/L5/L6	L8/L9/L8
Paramivir + Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L9/L8	L0/L0/L0	L8/L9/L9

Paramivir + Positive Control	L6/L5/L6	L8/L8/L8	L6/L6/L6	L8/L8/L8	L6/L6/L6	L8/L8/L8
Lopinavir + Negative Control	L0/L0/L0	L8/L9/L8	L0/L0/L0	L9/L9/L8	L0/L0/L0	L8/L8/L9
Lopinavir + Positive Control	L6/L6/L6	L8/L8/L8	L6/L6/L6	L8/L9/L8	L6/L6/L6	L8/L9/L8
Ritonavir + Negative Control	L0/L0/L0	L9/L9/L8	L0/L0/L0	L8/L8/L9	L0/L0/L0	L8/L8/L8
Ritonavir + Positive Control	L6/L6/L6	L8/L9/L8	L5/L6/L6	L8/L8/L8	L6/L6/L6	L8/L9/L8
Abidol + Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L8/L8	L0/L0/L0	L9/L8/L8
Abidol + Positive Control	L6/L6/L6	L9/L8/L8	L6/L6/L6	L8/L9/L8	L5/L6/L6	L8/L8/L8
Tobramycin + Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L8/L8	L0/L0/L0	L9/L8/L9
Tobramycin + Positive Control	L6/L6/L6	L9/L8/L8	L6/L6/L6	L8/L8/L8	L6/L5/L6	L8/L8/L8
Histamine hydrochloride + Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L8/L9	L0/L0/L0	L8/L8/L8
Histamine hydrochloride + Positive Control	L5/L6/L6	L9/L8/L9	L5/L6/L6	L8/L8/L8	L6/L6/L6	L8/L8/L8
Phenylephrine + Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L9/L8
Phenylephrine + Positive Control	L6/L6/L6	L8/L9/L8	L6/L6/L5	L9/L8/L9	L6/L6/L6	L8/L8/L8
Oxymetazoline + Negative Control	L0/L0/L0	L8/L8/L9	L0/L0/L0	L8/L8/L9	L0/L0/L0	L9/L9/L8
Oxymetazoline + Positive Control	L6/L6/L5	L8/L8/L8	L5/L6/L6	L8/L8/L8	L5/L6/L6	L8/L8/L8
Beclomethasone + Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L8/L9
Beclomethasone + Positive Control	L6/L6/L6	L9/L9/L8	L6/L6/L6	L8/L8/L9	L6/L6/L6	L8/L9/L8
Dexamethasone + Negative Control	L0/L0/L0	L8/L9/L8	L0/L0/L0	L9/L8/L9	L0/L0/L0	L9/L8/L8
Dexamethasone + Positive Control	L6/L5/L6	L8/L8/L9	L6/L5/L6	L8/L8/L8	L6/L6/L6	L8/L8/L9
Flunisolide + Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L9/L8/L8	L0/L0/L0	L8/L8/L8
Flunisolide + Positive Control	L6/L6/L6	L9/L8/L8	L5/L6/L6	L8/L8/L9	L6/L5/L6	L8/L9/L8
Triamcinolone + Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L9/L8
Triamcinolone + Positive Control	L6/L5/L6	L8/L9/L8	L5/L6/L6	L8/L8/L8	L6/L6/L6	L8/L8/L8
Acetonide + Negative Control	L0/L0/L0	L8/L9/L8	L0/L0/L0	L9/L9/L8	L0/L0/L0	L8/L8/L8
Acetonide + Positive Control	L6/L6/L6	L9/L8/L8	L5/L6/L6	L8/L8/L9	L6/L6/L6	L8/L8/L9
Budesonide + Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L8/L9/L9	L0/L0/L0	L8/L8/L8
Budesonide + Positive Control	L6/L6/L6	L8/L8/L8	L6/L6/L6	L8/L8/L8	L6/L6/L6	L8/L8/L8
Mometasone + Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L9/L8/L9	L0/L0/L0	L8/L9/L8
Mometasone + Positive Control	L6/L6/L6	L8/L9/L9	L6/L6/L6	L8/L8/L8	L6/L6/L6	L8/L8/L9
Fluticasone + Negative Control	L0/L0/L0	L8/L8/L8	L0/L0/L0	L9/L8/L8	L0/L0/L0	L9/L8/L8
Fluticasone + Positive Control	L6/L6/L6	L9/L9/L8	L6/L6/L6	L8/L8/L8	L6/L6/L6	L8/L8/L8

The color intensity of Test lines and Control Lines remains stable with the presence of potential interfering materials in sputum samples.

6. Conclusion

This product has no obvious interference with materials tested above in sputum samples.