PRODUCT INTRODUCTION 产品介绍

NEWGENE Bioengineering

COVID-19 Antibody / Antigen Detection Kit

FAST. SPECIFIC, ACCURATE, EASY, AFFORDABLE!

DUAL TEST!

15 MINUTE RESULTS!

ACCURACY APPROACHING PCR TEST w/ NO HI-TECH EQUIPMENT NEEDED, NO PAINFUL SWABS!

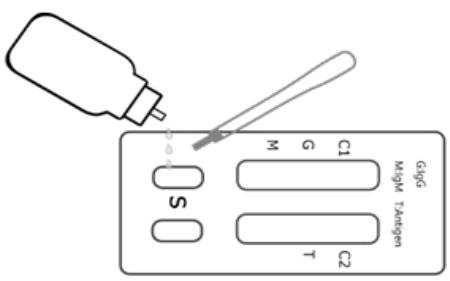
Product Feature

1. Antibody and Antigen Combo Detection.
2. Fast Detection: Result in 15 minutes.
3. High Accuracy.
4. Easy to Use.

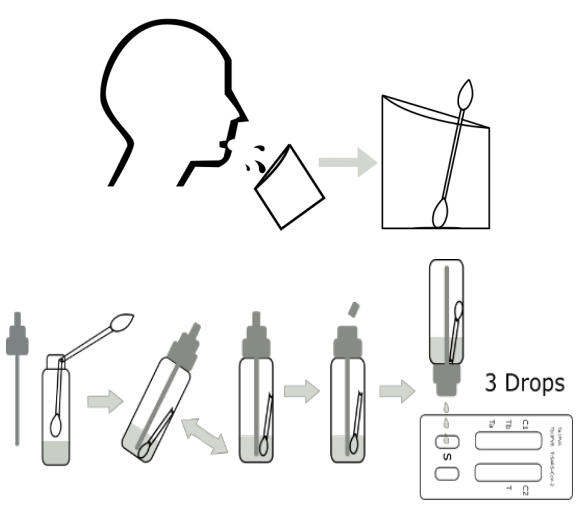
Components - 25PCS/Box

1. Test Card * 25
2. Sample Extraction Tube * 25
3. Cotton Swab * 25
4. Paper Cup * 25
5. Blood Collection Needle * 25
6. Dropper * 25
7. Antibody Detection Buffer * 1
8. Package Insert * 1

Test Procedur 聚

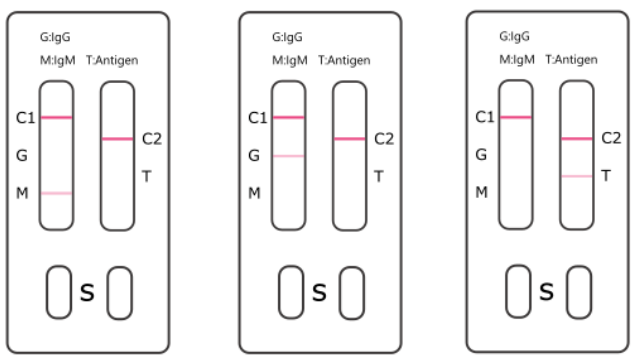


Antibody Detection



Antigen Detection

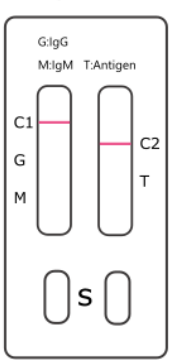
Interpretation of Result



IgM: Positive
IgM: 阳性

IgG: Positive
IgG: 阳性

Antigen: Positive
Antigen: 阳性



All: Negative
All: 阴性

If C line is not appeared, it is an invalid card.

New Gene (Hangzhou) Bioengineering Co., Ltd.
For Information:
Carolen Group for Covid-19 Help
sars2help.info

NEWGENE Bioengineering

CE

COVID-19 Antibody / Antigen Detection Kit

Package Insert

Cat: COVID-19-NG09
Specimens: For Antibody Detection: Whole Blood/Serum/Plasma
For Antigen Detection: Sputum

Version: 02 **Effective Date:** 2020-11

For professional and in vitro diagnostic use only.

PRODUCT NAME
COVID-19 Antibody / Antigen Detection Kit

PACKING
1 piece/bag, 25 pieces/box.

INTENDED USE
This product is suitable for the qualitative detection of COVID-19. 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 test kit contains two test strips:
In one of them, a burgundy colored conjugate pad containing Novel coronavirus recombinant envelope antigens conjugated with Colloid gold (Novel coronavirus conjugates), 2) a nitrocellulose membrane strip containing two test lines (IgG and IgM lines) and a control line (C1 line).
The IgM line is pre-coated with the mouse antihuman IgM antibody, IgG line is coated with Mouse anti-Human IgG antibody. When an adequate volume of test specimen is dispensed into the sample well of the test device, the specimen migrates by capillary action across the device. IgM anti-Novel coronavirus, if present in the specimen, will bind to the Novel coronavirus conjugates.
The immunocomplex is then captured by the reagent pre-coated on the IgM band, forming a burgundy colored IgM line, indicating a Novel coronavirus IgM positive test result. IgG anti-Novel coronavirus if present in the specimen will bind to the Novel coronavirus conjugates. The immunocomplex is then captured by the reagent coated on the IgG line, forming a burgundy colored IgG line, indicating a Novel coronavirus IgG positive test result. Absence of any T lines (IgG and IgM) suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.
In the other strip, 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 (C2) indicating that proper volume of sample has been added and membrane wicking has occurred.

COMPOSITION
1. Test Card

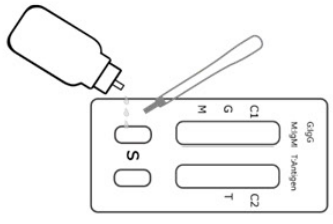
For Antibody Detection:
2. Blood Collection Needle
3. Dropper
4. Buffer

For Antigen Detection:
5. Sample Extraction Tube
6. Cotton Swab
7. Paper Cup

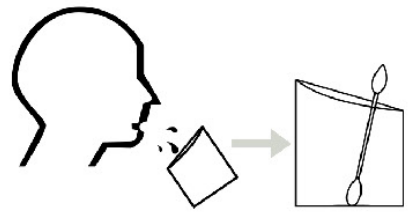
STORAGE AND STABILITY
1. Store as packaged in the hermetic bag at the temperature (2-30℃ or 38-86℉) and avoid direct sunshine. The kit is stable within the expiration date printed on the labeling.
2. Once open the hermetic bag, the test should be used within one hour. Prolonged exposure to hot and humid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

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

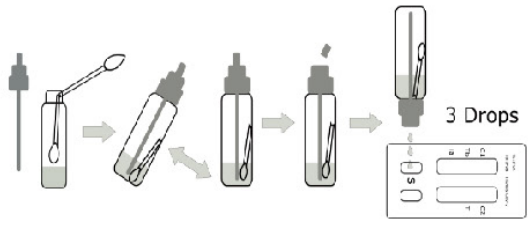
For Antibody Detection:
1. Remove the test device from the sealed pouch.
2. Hold the dropper vertically and transfer 1 drop of specimen to the specimen well(S) of the test device, then add 2 drops of buffer (approximately 70pl) and start the timer. See the illustration below.
3. Wait for colored lines to appear. Interpret the test results in 15 minutes. Do not read results after 20 minutes.



For Antigen Detection:



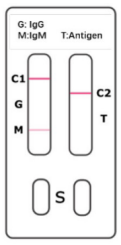
Sampling Steps



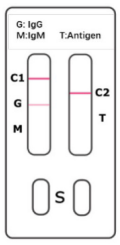
Detection Steps

1. Use the cotton swab to pick up 10-50 mg 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 until it mixed 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 into the sample hole vertically.
3. Read the result in 15 minutes. The result is considered inaccurate and invalid after 30 minutes.

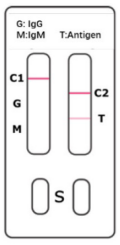
INTERPRETATION OF RESULTS
Positive(+): Test line appear in the control area (C) and test area (T, G, or M), corresponding to positive test items. If a test line appears in:
G area, IgG antibody positive;
M area, IgM antibody positive;
T area, SARS-CoV-2 antigen positive;
Negative(-): C1 and C2 line is appeared while no T line appeared in 15 minutes after the sample added.
Invalid: As long as the C1 or C2 line does not appear, it indicates that the test result is invalid, and should retest with another test card.



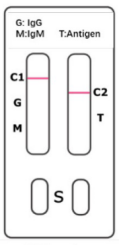
IgM: Positive



IgG: Positive



Antigen: Positive



All Negative

If C1 or C2 line does not appear, the test result is invalid.

NOTES
1. Please ensure that the appropriate amount of the sample is used for testing. Too much or too little sample size may lead to deviations in the results.
2. 10-15 minutes after the completion of the sample is the effective reading time, more than 30 minutes will not be regarded as a valid reading.
3. This test reagent is a one-time item, please use it within the validity period. The used test reagents and samples and other wastes should be disposed of in accordance with relevant national regulations.
4. If the test strip in the reagent is partially out of the detection window, do not use it, otherwise the test result will be invalid and another reagent must be used.

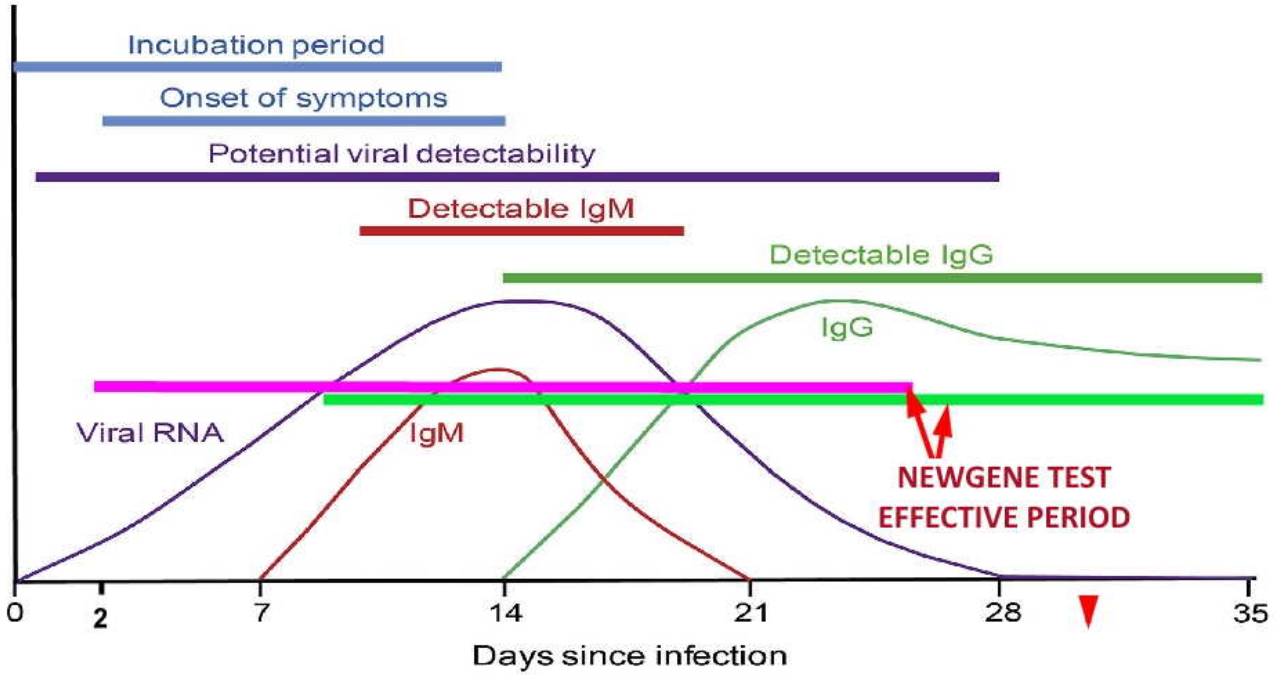
INDEX OF SYMBOLS

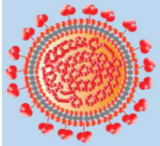
	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2℃ 30℃	Store between 2-30°C	LOT	Lot Number	REF	Catalogue number

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

CE

EC REP
SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands



Test	Basis of test	Measure	Value	Dependencies	Limitations/features
PCR 	• Nucleic acid amplification to detect presence of SARS-CoV-2 virus RNA	• Reflects current virus infection with SARS-CoV-2	• Diagnosis of infection • Determination of therapy • Informs exposure management to prevent transmission • Contact tracing • May be positive in presymptomatic or asymptomatic individuals	• Respiratory or other body sample (eg, nasopharyngeal swab, saliva, sputum) • PPE and safe sampling of patient • Sample swabs, sample media, test kits or reagents, and machines	• False negatives possible (dependent on assay or preanalytic factors, including sampling technique and site) • Turnaround times vary with test platform
ANTIGEN	Detection of viral nucleocapsid proteins (spike &/ or capsule)				Turnaround time of 15 minutes, Not as accurate as PCR, but saliva sampling is less distessing for patient & does not require med. technician No lab equipment needed
Serology 	• Detection of human antibodies (eg, IgM, IgG) against SARS-CoV-2 viral proteins	• Reflects current or past infection with SARS-CoV-2	• Epidemiology • Public health • Evaluate potential convalescent plasma donors When combined with an antigen test, can be valuable to cross-indicate an active infection	• Blood draw or finger-stick sample • Validation of tests to determine specificity and sensitivity	• Does not establish or exclude active infection, limiting use in acute management • Unknown whether positive antibody correlates with protective immunity (cannot be used to change employee PPE or exposure management) • Antibody response can be variable • Limited accuracy and variability between different serologic tests • Tests require validation to exclude cross-reactivity with other coronaviruses • Point-of-care not widely available

How the Newgene dual coronavirus test compares to RT-PCR testing, as well as to the Lucira test…and why the Newgene test is a major milestone in the race to ensure that a significant percentage of the population can access an accurate, affordable and fast test…with the potential to capture a major portion of the vital diagnostic tests market: ***(See this website if (See https://www.lucirahealth.com***

Strengths & Weaknesses of the RT-PCR test: *The sample to be gathered comes from deep in the nasal or throat, must be gathered by a nurse or trained technician and involves pain or extreme discomfort. (Some have described it as having one's brain extracted thru their nose!). The test involves a complicated multistep process and requires scarce & expensive reagents; scarce & expensive equipment; scarce & expensive reagents; trained laboratory technicians; and significant time.*

While the actual process can be completed in 3 hours or less, the combination of these various requirements causes the average test results to be obtained in no less than about 3 days, and often takes as long as 7-8 days. Plus, the test having to be performed by professional laboratories, has involved a cost of as much as several thousand dollars, which may or may not be paid by health insurance. Having said that, the test does have the advantage that it detects the actual viral RNA material and can detect a lower level of virus than "fast" tests. However, because it detects such a low level of virus, it is possible that a positive test result may be obtained when the viral load is below the minimum necessary to actually cause Covid-19 disease. The Newgene test threshold is likely above that necessary for infection.

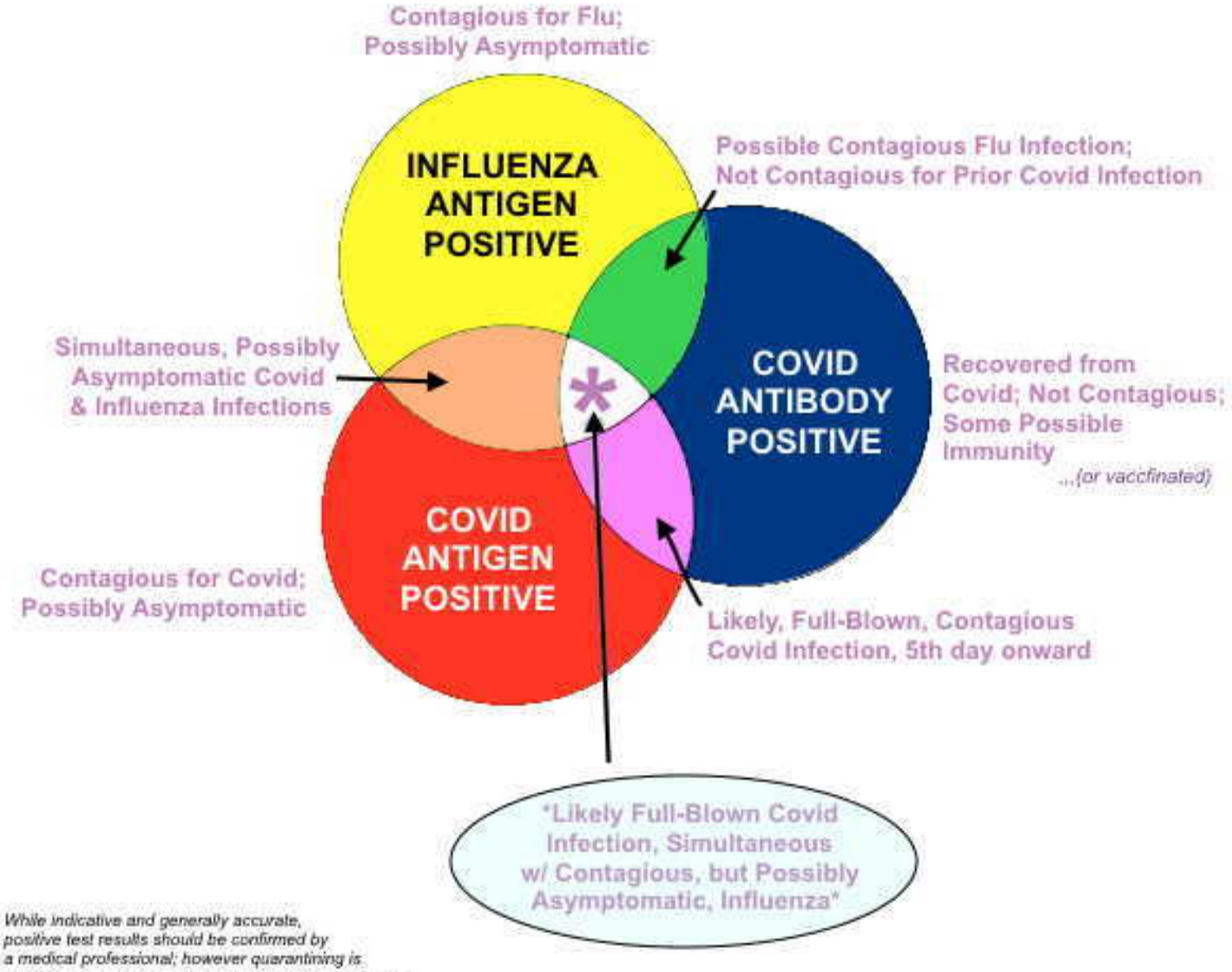
The Newgene & Lucira tests vs RT-PCR & first-gen fast or "self" tests: *Compared to the RT-PCR test, the new fast tests are cheaper, do not require expensive labs, equipment, trained techs, or reagents; The fast tests give results in 30 minutes (Lucira) or 15 minutes (Newgene). Vs the first-gen fast tests, the new fast tests detect antigens (or antigens & antibodies as with the* ***Newgene*** *test), whereas the first fast tests only detected antibodies; the new fast tests have an accuracy, sensitivity and specificity that approaches that of RT-PCR tests; the results are almost immediate, in situ, whereas some initial "self-tests" or self-sampling saliva tests still required submission of the sample to a lab for analysis. Perhaps most importantly; the percent of false positives & false positives is low, also approaching that of RT-PCR tests, whereas with the first fast tests having an accuracy as low as 50%, a coin toss would have been as accurate!*

The Newgene vs the Lucira test:

1. **BOTH** the **Newgene** & Lucira tests are relatively cheap and easy to produce and detect the presence of the live virus relatively early in infections. Because the virus is detectable before antibodies ore present, and before symptoms of illness develop, a positive antigen test can disclose those who are contagious before they are aware of it. This is crucial in controlling the pandemic, because it is believed that the wide spread of the coronavirus is due to those "asymptomatic" persons freely traveling & mingling with others because they Feel well and don't realize when they are infecting other people…and when they actually should be quarantining themselves! Also, whereas the prior suggested protocol was for a person displaying a positive fast test result to have a follow-up RT-PCR test. But, with the high accuracy, specificity and close correlation of the new fast tests, with the "gold standard" RT-PCR test, such a follow-up test becomes redundant and unnecessary.
2. The Lucira test is a self-test, but requires prescription from a doctor. That means a potential Covid victim must pay the cost to visit doctor to get prescription, plus cost of the test. Plus, requiring a prescription for the test defeats the intent to encourage more fast tests, on demand. The goal of the **Newgene** company is to obtain a approval which provides for the sale of the test w/o a prescription.
3. The Lucira test requires a little reader device. Even if a cheap test, compared to PCR tests, it's cost (+/- $50) is still significantly above the cost at which the **Newgene** tests can be profitably sold (less than $10-$15 each, or $20 including USPS postage).
4. The Lucira test uses a shallow nasal swab sample, that the home users obtain themselves., While easier and less painful to obtain than the deep swab that must be obtained by a health professions, for the RT-PCR test, the saliva sample used by the **Newgene** antigen test is even easier to obtain.
5. The Lucira test, as does the **Newgene** test, detects the presence of live virus, but **Newgene** test has the advantage of two tests that can confirm an infection.
6. The **Newgene** test more than triples the length of time that the test is valuable because each individual Newgene test overcomes some of the weaknesses of the other test: The conoravirus antigens are detectable before the antibodies; and the antibodies are detectable. Hence, there is value to a positive response from one test, before antibodies are detectable, as well as a positive response from the other test, after the living virus (and antigens) are gone from the body.

It should be obvious that the Newgene dual test is a major milestone in coronavirus testing, and the only choice that makes sense for those who want a convenient, fast and affordable test!

LIKELY IMPLICATIONS OF SINGLE OR MULTIPLE POSITIVE TEST RESULTS FROM THE "LAB IN A BAG" SELF-TEST KIT:



While indicative and generally accurate, positive test results should be confirmed by a medical professional; however quarantining is suggested until such professional consultation is made.

"LAB IN A BAG" TRIPLE FAST ANTIBODY (BLOOD) & ANTIGEN (SPUTUM) TEST FOR NOVEL CORONAVIRUS (SARS2COV-19) & INFLUENZA A/B

PRICING EFFECTIVE FEBRUARY 18, 2021

"Door to Door" price, including "ground" shipping, excluding any customs duty, if any:

10K (MOQ) to 100K $17.90/Test
+100K to 500K Tests $16.90/Test
+500K to 1MM Tests $15.90/Test
+1MM TO 3MM Tests $14.90/Test

SINGLE TEST,WITH PRIORITY POSTAGE: $24.90

Production Capability: 1-3MM tests / day

COMPARISON OF FEATURES/BENEFITS OF NEWGENE DUAL VS OTHER CORONAVIRUS TESTS	NEWGENE DUAL TEST	Lucira Antigen	RT-PCR Antigen	Old, Fast Antibody	Old, Fast Antigen
Fast	■	■		■	■
Accurate/Specific Covid-19/Coronavirus Detection	■	■	■		
Affordable	■	■		■	
Potential for Very Widespread Distribution	■			■	
Antigen & Antibody Detection	■				
No Trained Techs, Expensive Lab or Long Analysis	■	■		■	**
Does Not Use Supplemental Detection Equipment	■			■	
Early, Useful Test for Asymptomatic Persons	■	■	■		
Useful After Live Virus Disappears	■			**	**
Prescription or Other Authorization Not Required	*Proposed*			■	
Easy, Painless Saliva Sample Used	■			■	
Simple Procedure, Compatible w/ Self-Testing	■	■		■	■

Most prior fast tests were relatively innaccurate/insensitive &/or still required equipment &/or techs

Novel Coronavirus Antigen Detection Kit (Colloidal Gold)

Clinical Study Report

Name of in vitro diagnostic reagents used in the test: Novel Coronavirus Antigen Detection Kit (Colloidal Gold)

Specifications: 25 Tests/Box

Start and end time of the test: August 24th, 2020- September 25th, 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: October 12th, 2020

Summary

The Novel Coronavirus Antigen Detection Kit (Colloidal Gold) 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 Novel Coronavirus Antigen Detection Kit (Colloidal Gold) 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 96.1%, the clinical specificity is 99.0%, and the total agreement rate is 97.5%. 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 throat swab samples, 95.1%, 99.1%, and 97.2% in nasal 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 Novel Coronavirus Antigen Detection Kit (Colloidal Gold) 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 Novel Coronavirus Antigen Detection Kit (Colloidal Gold). 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 Novel Coronavirus Antigen Detection Kit (Colloidal Gold) 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 Novel Coronavirus Antigen Detection Kit (Colloidal Gold), 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	Novel Coronavirus Antigen Detection Kit (Colloidal Gold)		
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 644 sputum samples, including 209 sputum samples, 218 throat swab samples, and 217 nasal swab samples have been tested. These samples are taken from 644 suspected patients, of which 274 (42.5%) are female, and 370 (57.5%) are male. Their ages range from 17 to 88 years old, and are 47 years old on average. Cough (73.6%) and fever (63.4%) are the most

common complained symptoms. Their sampling time is between Day 1 to Day 6 post onset, mainly on Day 2 (32.0%).

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%

In 217 nasal swab samples, the test reagent finds out 99 positive results, of which 98 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 113 samples are reported negative by both reagents. Testing results are presented in table below.

Nasal Swab		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	98	1	99
	Negative	5	113	118
Total		103	114	217

Clinical sensitivity (%) = [98 / (98 + 5)] ×100% = 95.1%

Clinical specificity (%) = [113 / (1 + 113)] ×100% = 99.1%

Total agreement rate (%) = [(98 + 113) / (98 + 1 + 5 + 113)] ×100% = 97.2%

Product performance in all sample types

The test reagent finds out 322 positive results, of which 319 samples are reported positive by both reagents. Three samples are reported positive only in test reagent, and another 13 samples are reported positive only in gold standard reagent. The other 309 samples are reported negative by both reagents. Testing results are presented in table below.

Sputum/Throat Swab/Nasal Swab		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	319	3	322
	Negative	13	309	322
Total		332	312	644

Clinical sensitivity (%) = [319 / (319 + 13)] ×100% = 96.1%

Clinical specificity (%) = [309 / (3 + 309)] ×100% = 99.0%

Total agreement rate (%) = [(319 + 309) / (319 + 3 + 13 + 309)] ×100% = 97.5%

Discussion and conclusion

In this clinic trial, performance of the test reagent “Novel Coronavirus Antigen Detection Kit (Colloidal Gold)” is evaluated on a collection of 644 clinical samples. Compared to a commercial Real Time Multiplex RT-PCR, the test reagent have shown sensitivity, specificity, and agreement rate of 96.1%, 99.0%, and 97.5%. 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

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CE 认证 – 荷兰CIBG 注册信

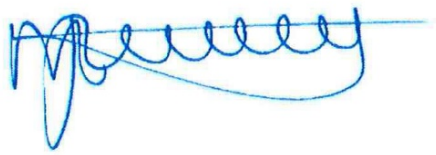
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, New Gene (Hangzhou) Bioengineering Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert SUNGO Europe 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认证 – 符合性声明

CE

DECLARATION OF CONFORMITY

R[redacted]rective (98/79/EC)

Manufactur[redacted]ng Co., Ltd.

Address: [redacted]n Road, Changhe Street, Binjiang [redacted]e, P. R. China

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: **COVID-19 Antibody / 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

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

Name/ Position: Mingfu Li / General Manager

Sungo global service

Authorized Signature (S)

Date: 29/09/2020

Place: Hangzhou, Zhejiang, China

ISO 13485 Certification
ISO 13485 体系认证

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: New Gene (Hangzhou) Bioengineering Co., Ltd.

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 Certific

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.™

CFS (India as an example)
自由销售证明（以印度为例）

Ministry of Health, Welfare and Sport
CIBG
P.O. Box 16114
2500 BC The Hague
THE NETHERLANDS

STATEMENT

The undersigned herewith declares that according to the Decree on In-Vitro Diagnostics, which is based on the European Directive 98/79/EC concerning in-vitro diagnostic medical devices,

SUNGO Europe B.V.
Olympisch Stadion 24
1076 DE Amsterdam
THE NETHERLANDS

acts as authorised representative of the manufacturer.

The manufacturer:

New Gene (Hangzhou) Bioengineering Co., Ltd.

is authorised to manufacture and/or supply the medical device/devices mentioned below:

COVID-19 / Influenza A / Influenza B Detection Kit
COVID-19 Antibody / Antigen Detection Kit
COVID-19 Antigen Detection Kit
COVID-19 Neutralizing Antibody Detection Kit
Novel Coronavirus Ribonucleic Acid Detection Kit

This device/these devices may be placed on the Dutch market and on the markets of the other Member States of the European Union, and be exported to non-EU Member States. This free sale certificate may only be used for export outside the European Union.

The present statement is drawn up at the request of the interested party in order to be submitted to the Health Authorities of **INDIA**.

This statement is valid until May 26, 2022.

The Hague, October 20, 2020

On behalf of the Minister for Medical Care and Sport
Farmatec | CIBG

Dr. M.J. van de Velde

Mr. M.J. van de Velde
Head of Department

Our reference: 20204982
Certificate number: 29432

CFS (India as an example)
自由销售证明（以印度为例）

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

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
T.I. van Langeveld - Baas

medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20204982

Bijlagen
1

Uw aanvraag
14 oktober 2020

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

Datum: 20 oktober 2020
Betreft: exportverklaring(en) medische hulpmiddelen/AIMD/IVD/MDR/IVDR

Geachte heer Luo,

Hierbij ontvangt u de door u aangevraagde exportverklaring(en) voor:

INDIA (29432)

Afgegeven exportverklaringen IVD Klasse other producten of gecombineerde exportverklaringen van IVD Klasse other producten met hogere risicoklasse producten vervallen per 26 mei 2022.
Valt uw IVD product onder een hogere risicoklasse (lijst A, B of zelftesten)? Dan mag uw product tot en met uiterlijk 25 mei 2025 op de markt blijven als IVD product

Met vriendelijke groet,
Farmatec

T.I. van Langeveld - Baas

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CE 认证 – 荷兰CIBG 注册信

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.