

# 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

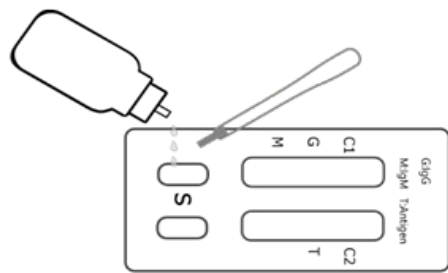
1. Antibody and Antigen Combo Detection.
2. Fast Detection: Result in 15 minutes.
3. High Accuracy.
4. Easy to Use.

### Components

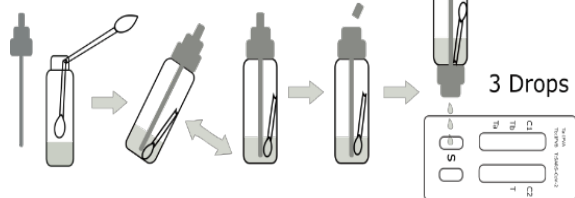
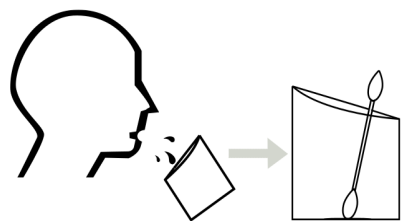
- 25PCS/Box

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 Procedure



Antibody Detection



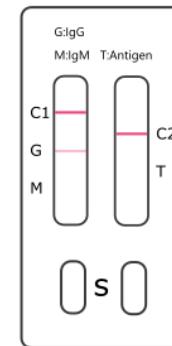
Antigen Detection

**For highest accuracy of antigen testing, it is important to ensure that thick sputum is tested...from a cough or throat clearing, not just watery saliva.**

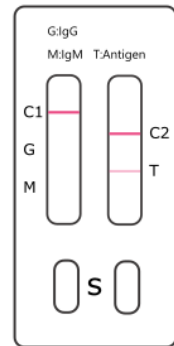
### Interpretation of Result



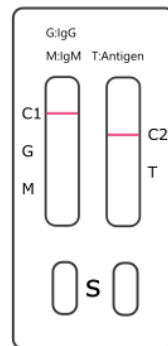
IgM: Positive  
IgM: 阳性



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.

# 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  $\beta$  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 anti-human 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

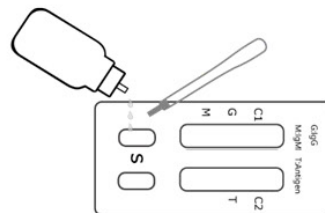
1. Store as packaged in the hermetic bag at the temperature (2-30°C or 38-86°F) and avoid direct sunshine. The kit is stable within the expiration date printed on the labeling.
2. Once open the hermetic bag, the test should be used within one hour. Prolonged exposure to hot and humid environment will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

### TEST PROCEDURE

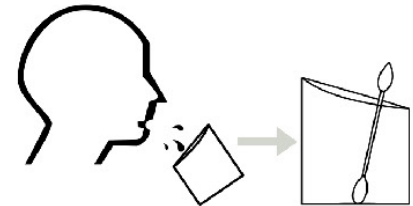
Allow the test device and specimens to equilibrate to temperature (15-30°C or 59-86°F) prior to testing.

#### For Antibody Detection:

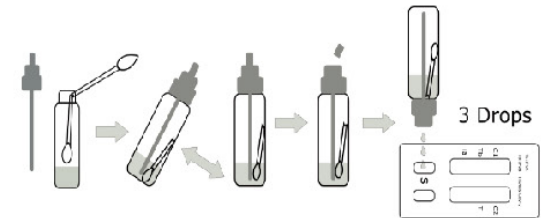
1. Remove the test device from the sealed pouch.
2. Hold the dropper vertically and transfer 1 drop of specimen to the specimen well(S) of the test device, then add 2 drops of buffer (approximately 70 $\mu$ l) and start the timer. See the illustration below.
3. Wait for colored lines to appear. Interpret 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:

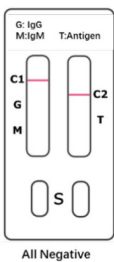
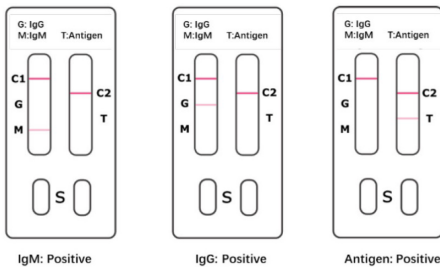
G area, IgG antibody positive;

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.



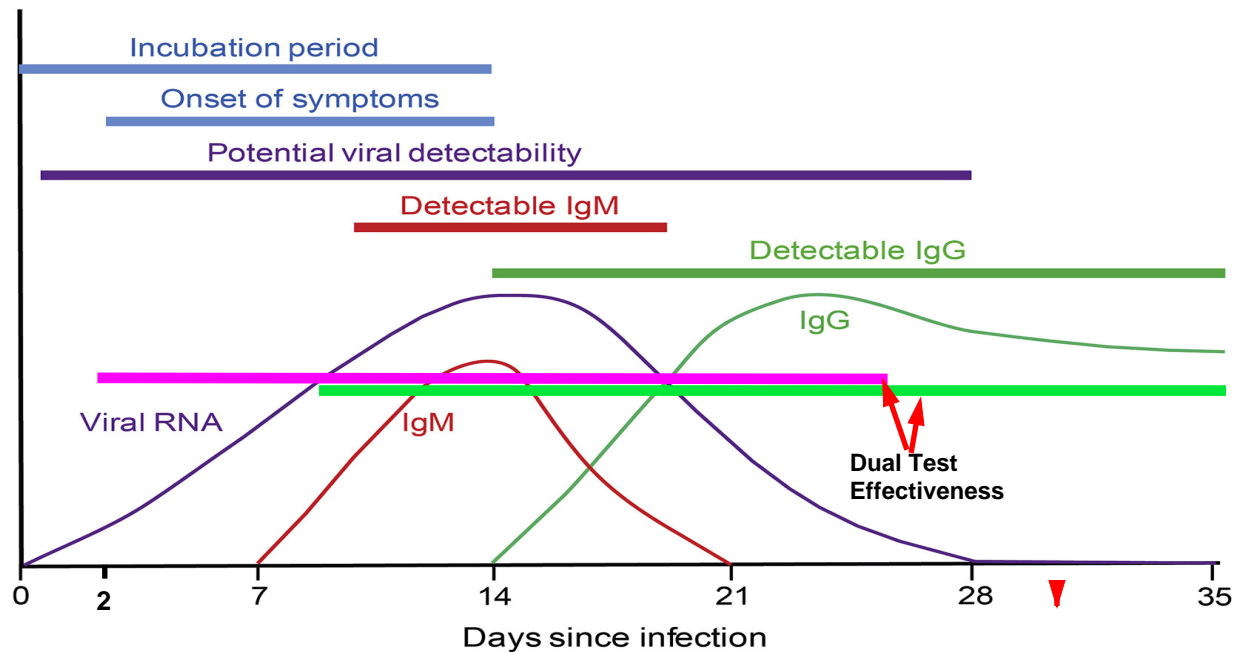
If C1 or C2 line does not appear, the test result is invalid.



### 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		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalogue number



Test	Basis of test	Measure	Value	Dependencies	Limitations/features
 <b>PCR</b>	<ul style="list-style-type: none"> <li>Nucleic acid amplification to detect presence of SARS-CoV-2 virus RNA</li> </ul>	<ul style="list-style-type: none"> <li>Reflects current virus infection with SARS-CoV-2</li> </ul>	<ul style="list-style-type: none"> <li>Diagnosis of infection</li> <li>Determination of therapy</li> <li>Informs exposure management to prevent transmission</li> <li>Contact tracing</li> <li>May be positive in presymptomatic or asymptomatic individuals</li> </ul>	<ul style="list-style-type: none"> <li>Respiratory or other body sample (eg, nasopharyngeal swab, saliva, sputum)</li> <li>PPE and safe sampling of patient</li> <li>Sample swabs, sample media, test kits or reagents, and machines</li> </ul>	<ul style="list-style-type: none"> <li>False negatives possible (dependent on assay or preanalytic factors, including sampling technique and site)</li> <li>Turnaround times vary with test platform</li> </ul>
<b>ANTIGEN</b>	Detection of viral nucleocapsid proteins (spike &/ or capsule)				<ul style="list-style-type: none"> <li>Turnaround time of 15 minutes, Not as accurate as PCR, but saliva sampling is less distressing for patient &amp; does not require med. technician</li> <li>No lab equipment needed</li> </ul>
 <b>Serology</b>	<ul style="list-style-type: none"> <li>Detection of human antibodies (eg, IgM, IgG) against SARS-CoV-2 viral proteins</li> </ul>	<ul style="list-style-type: none"> <li>Reflects current or past infection with SARS-CoV-2</li> </ul>	<ul style="list-style-type: none"> <li>Epidemiology</li> <li>Public health</li> <li>Evaluate potential convalescent plasma donors</li> </ul> <p>When combined with an antigen test, can be valuable to cross-indicate an active infection</p>	<ul style="list-style-type: none"> <li>Blood draw or finger-stick sample</li> <li>Validation of tests to determine specificity and sensitivity</li> </ul>	<ul style="list-style-type: none"> <li>Does not establish or exclude active infection, limiting use in acute management</li> <li>Unknown whether positive antibody correlates with protective immunity (cannot be used to change employee PPE or exposure management)</li> <li>Antibody response can be variable</li> <li>Limited accuracy and variability between different serologic tests</li> <li>Tests require validation to exclude cross-reactivity with other coronaviruses</li> <li>Point-of-care not widely available</li> </ul>

OTHER QUANTITIES	Boxes		/carton, list	Cartons		Cartons of 1000 Pieces**			
	Per 1 Box	Per 4 Boxes		1-9 Cartons	10+ Cartons	100+ Cartons	500+ Cartons	1,000+ Cartons	2,000+ Cartons
Tests/Pieces, Minimum/tier:	25	100	1,000	1K- 10K	+10K- 100K	PER CARTON			
						+100K- 500K	+500K- 1MM	+1MM- 2MM	+2MM- 3MM
* COVID-19 Antibody	323	1,290	12,900	10,900	8,900	7,900	6,900	5,900	4,900
* COVID-19 Antigen	323	1,290	12,900	10,900	8,900	7,900	6,900	5,900	4,900
* DUAL COVID-19	423	1,690	16,900	14,900	12,900	11,900	10,900	9,900	8,900
DUAL COVID-19, Influenza A/B	423	1,690	16,900	14,900	12,900	11,900	10,900	9,900	8,900
Lab in a Bag, Triple Self-Test	548	2,190	21,900	19,900	17,900	16,900	15,900	14,900	14,900
COVID-19, Professional	323	1,290	12,900	10,900	8,900	7,900	6,900	5,900	4,900
DUAL COVID-19, Influenza A/B Pro	423	1,690	16,900	14,900	12,900	11,900	10,900	9,900	8,900
VTM Sample Kit, Professional Use	32	129	1,290	1,090	890	790	690	590	490
Saliva Sample Kit, Home or Pro Use	32	129	1,290	1,090	890	790	690	590	490
Swab**	10	39	390	290	240	216	196	176	156
Swab & 3ml Vial (no reagent)	19	75	750	650	590	531	501	471	441
3ml Vial (no reagent)*	12	49	490	390	340	306	276	246	216
<b>50 Tests/Box: 2,000/carton</b>									
PCR Reagent Kit (fluorescent probe)	395	1,580	7,902	11,800	7,800	6,800	6,300	5,800	5,800

\* OEM Possible for these tests \*

OEM POSSIBLE, LOTS OF 1,000 CARTONS OF 1,000 TESTS

**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 24<sup>th</sup>, 2020- September 25<sup>th</sup>, 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 12<sup>th</sup>, 2020

## Summary

The Novel Coronavirus Antigen Detection Kit (Colloidal Gold) developed by New Gene (Hangzhou) Bioengineering Co., Ltd. can quickly and qualitatively detect the nucleocapsid 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  $\geq 90\%$ , clinical specificity  $\geq 90\%$ , and total agreement rate  $\geq 90\%$ .

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 asymptotically. 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

nucleocapsid (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 reagent as 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

$$\text{Clinical sensitivity (\%)} = [a / (a + c)] \times 100\%$$

$$\text{Clinical specificity (\%)} = [d / (b + d)] \times 100\%$$

$$\text{Total agreement rate (\%)} = [(a + d) / (a + b + c + d)] \times 100\%$$

### 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 (%) =  $[ 109 / (109 + 3) ] \times 100\% = 97.3\%$

Clinical specificity (%) =  $[ 96 / (1 + 96) ] \times 100\% = 99.0\%$

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

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 (%) =  $[ 112 / (112 + 5) ] \times 100\% = 95.7\%$

Clinical specificity (%) =  $[ 100 / (1 + 100) ] \times 100\% = 99.0\%$

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

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 (%) =  $[ 98 / (98 + 5) ] \times 100\% = 95.1\%$

Clinical specificity (%) =  $[ 113 / (1 + 113) ] \times 100\% = 99.1\%$

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

#### 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 (%) =  $[ 319 / (319 + 13) ] \times 100\% = 96.1\%$

Clinical specificity (%) =  $[ 309 / (3 + 309) ] \times 100\% = 99.0\%$

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

#### 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

# CE Certification – CIBG Registration Letter

## CE 认证 – 荷兰CIBG 注册信

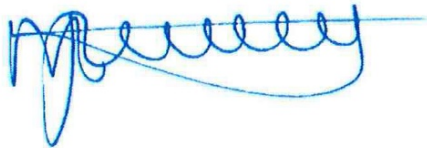
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, New Gene (Hangzhou) Bioengineering Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert SUNGO Europe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



### DECLARATION OF CONFORMITY

Relevant Directive (98/79/EC)

**Manufacturer:** [Redacted] ng Co., Ltd.  
**Address:** [Redacted] in 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)

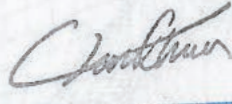
We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

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:**   
**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.*



  
Authorized Signature (S)

**Date:** 29/09/2020  
**Place:** Hangzhou, Zhejiang, China





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



Page: 1 of 1

...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

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

## 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.*

# CE Certification – CIBG Registration Letter

## 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 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.*