



Stock Code: 688068.SH

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) Summary Data



Beijing Hotgen Biotech Co., Ltd.

Explanation of The Export License

To whom it may concern

According to the No.12 Government Notice published by MOC, GAC and NMPA, CCCMHPIE announced the list of companies which were permitted to export novel coronavirus diagnostic products, Hotgen is in the list as aforesaid.



中国医药保健品进出口商会			
Hotgen			
10	北京热景生物科技股份有限公司 Beijing Hotgen biotech Co., Ltd.	91110115777090586H	欧盟CE

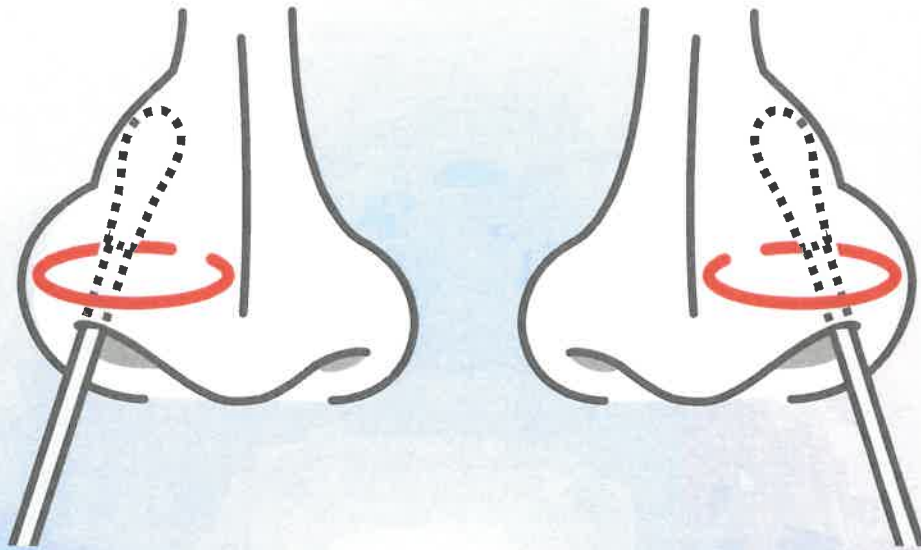
Beijing Hotgen biotech Co., Ltd.



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Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)



Product Features

- High Accuracy, Specificity and Sensitivity ●
- No need instrument, get results in 15 minutes ●
- Room temperature storage ●
- Sample : Human Anterior Nares Swab ●
- Detect the presence of viral proteins ●
- Identify acute or early infection ●

Clinical Performance

(Disease Course 5-7 Days)

Sensitivity: 96.30%; Specificity: 99.13%; Accuracy: 97.76%.

Novel Coronavirus 2019-nCoV Antigen Test(Colloidal Gold)

Specimen Requirements

1 Sample collection

Gently insert the entire soft tip of the swab into one nostril for 1.5cm until you feel a bit of resistance.

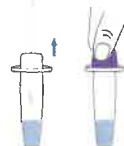
Using medium pressure, rub the swab slowly in a circular motion around the inside wall of your nostril 4 times for a total time of 15 seconds.

Repeat the same process with the same swab in the other nostril.

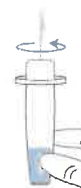


2 Sample treatment

The swab after sampling is soaked below the liquid level of the sample extraction buffer. Rotate and press 3 times. The swab soaking time is not less than 15s.



The swab head is pressed, then take out the swab and tighten the sampling tube.



3 Sample preservation

The treated sample should be tested within 1h.

Test Procedure



Place the test cassette, sample extraction buffer at room temperature for 15-30 minutes, and equilibrate to room temperature (10-30 °C).



Open the aluminum foil pouch of the test cassette, place the test cassette on a flat surface.

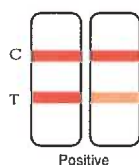


Add 4 drops of the treated sample into the sample well of the test cassette. (In case of chromatographic abnormalities, extra add 1-2 drops of the treated sample accordingly.) Incubate at 10-30 °C for 15 minutes.

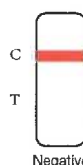


Observe the results after incubate at 10-30 °C for 15 minutes. The result after 30 minutes is invalid.

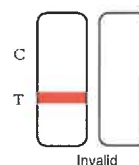
Interpretation of result



Positive



Negative



Invalid

Clinical Performance

This study enrolled a total of 223 human anterior nasal swab specimens, of which 108 were positives for RT-PCR Test, 115 negatives for RT-PCR Test; As for data collection of the corresponding RT-PCR Test results.

Assessment system	Reference system (clinical diagnostic results)		
Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	Positive (+)	Negative (-)	Total
Positive(+)	104	1	105
Negative(-)	4	114	118
Total	108	115	223

Sensitivity: 96.30%; Specificity: 99.13 %; Accuracy: 97.76%.

Product information

Product name	Test samples	Specifications	Storage conditions
Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	Human Anterior Nares Swab	1T/kit, 5T/kit, 20T/kit, 40T/kit	4-30 °C

Beijing Hotgen Biotech Co.,Ltd

Add.: 9 building, No.9 Tianfu Street, Daxing District, Beijing, 102600, P.R. China

Website: www.hotgen.com.cn

Declaration of Conformity

Manufacturer:

Name: Beijing Hotgen Biotech Co.,Ltd

Address: 9th building, No.9 Tianfu Street, Biomedical Base,Daxing District, Beijing,
102600, P.R.China

European Representative:

MedNet GmbH

Borkstrasse 10,48163 Muenster,Germany

Product Name:

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

Novel Coronavirus 2019-nCoV Antigen Test (Up-converting Phosphor Immunochromatographic Technology)

Classification : **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:

EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2012, EN 13975:2003,
EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002, EN ISO 17511:2003,
EN ISO 23640:2015, EN 13641:2002, EN 13975:2003, EN 62366:2008



Signature:

Lin Changqing

Name: Lin Changqing

Title: General manager

Place: Beijing, China.

Date of Issue: Aug 27, 2020

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG **General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG**

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority	
Code DE/CA22	
Bezeichnung / Name Bezirksregierung Münster, Dezernat 24	
Staat / State Deutschland	Land / Federal state Nordrhein-Westfalen
Ort / City Münster	Postleitzahl / Postal code 48143
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Telefon / Phone +49-251-4110	Telefax / Fax +49-251-4112525
E-Mail / E-mail mitteilungen-dimdi@brms.nrw.de	

Anzeige / Notification	
Registrierdatum bei der zuständigen Behörde Registration date at competent authority 25.01.2021	Registriernummer / Registration number DE/CA22/419-1848.1-IVD
Typ der Anzeige / Notification type ☐ Erstanzeige / Initial notification ☒ Änderungsanzeige / Notification of change ☐ Widerrufsanzeige / Notification of withdrawal	
Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn DE/CA22/419-1848-IVD	
Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG ☐ Hersteller / Manufacturer ☒ Bevollmächtigter / Authorised Representative ☐ Einführer / Importer ☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG ☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV ☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG	

Anzeigender / Reporting organisation (person)	
Code	DE/0000012115
Bezeichnung / Name	MedNet GmbH
Staat / State	Deutschland
Land / Federal state	Nordrhein-Westfalen
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ear-admin@medneteuropa.com	

Hersteller / Manufacturer	
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Staat / State	CN
Ort / City	Beijing
Postleitzahl / Postal code	102600
Straße, Haus-Nr. / Street, house no.	
9th Building, No. 9 Tianfu Street, Biomedical Base, Daxing District	
Telefon / Phone	0086-10-50973600
Telefax / Fax	
E-Mail / E-mail	

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG	
Bezeichnung / Name	Nicole Böhnisch
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info@medneteuropa.com	

Vertreter / Deputy (optional)				
	Bezeichnung / Name Kristin Zurlinden			
	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; padding: 5px;"> Telefon / Phone +49 251 32266 0 </td> <td style="width: 5%; padding: 5px;"></td> <td style="width: 45%; padding: 5px;"> Telefax / Fax +49 251 32266 22 </td> </tr> </table>	Telefon / Phone +49 251 32266 0		Telefax / Fax +49 251 32266 22
Telefon / Phone +49 251 32266 0		Telefax / Fax +49 251 32266 22		
	E-Mail / E-mail info@medneteuropa.com			
	☐ Erstanzeige / Initial notification ☒ Änderungsanzeige / Notification of change			

In-vitro-Diagnostikum / In vitro diagnostic medical device	
Klassifizierung / Classification	☐ Produkt der Liste A, Anhang II / Device of List A, Annex II ☐ Produkt der Liste B, Anhang II / Device of List B, Annex II ☐ Produkt zur Eigenanwendung / Device for self-testing ☒ Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)
App (Software auf mobilen Endgeräten)	☐ ja / yes ☒ nein / no
Anzeige nach § 25 Abs. 3 Nummer 3 MPG Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG	☒ "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"
Handelsname des Produktes / Trade name of the device	Hotgen Biotech, CORA CHECK-19
Produktbezeichnung / Name of device	Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)
Angabe der benutzten Nomenklatur / Nomenclature used	☒ EDMS-Klassifikation / EDMS Classification ☐ GMDN
Nomenklaturcode / Nomenclature code	15-04-80-90-00
Nomenklaturbezeichnung / Nomenclature term	OTHER VIRAL ANTIGEN/ANTIBODY DETECTION
Kurzbeschreibung / Short description In Deutsch / In German	Modelle A+B: Dieser Kit wird für die qualitative In-vitro-Bestimmung von neuem Coronavirus-Antigen in menschlichen Nasen- oder Rachenabstrichen verwendet. Er dient zur schnellen Untersuchung von Verdachtsfällen auf neuartige Coronaviren und kann auch als Bestätigungsmethode für den Nukleinsäurenachweis in entladenen Fällen verwendet werden. Modelle C+D (Neuartiges Coronavirus 2019-nCoV-Antigentest (kolloidales Gold) - Speichel): Dieser Kit dient zur qualitativen in vitro-Bestimmung des neuen Coronavirus-Antigens im menschlichen Speichel. Er dient zur Schnelluntersuchung bei Verdacht auf neuartige Coronaviren und kann auch als Bestätigungsmethode für den Nukleinsäurenachweis in entladenen Fällen verwendet werden.
In Englisch / In English	Models A+B: This kit is used for in-vitro qualitative determination of novel coronavirus antigen in human nasal swabs or throat swabs. It is used as rapid investigation for suspected cases of novel coronaviruscan also be used as a reconfirmation method for nucleic acid detection in discharged cases. Models C+D (Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) - Saliva): This kit is used for in vitro qualitative determination of novel coronavirus antigen in human saliva. It is used as rapid investigation for suspected cases of novel coronavirus, can also be used as a reconfirmation method for nucleic acid detection in discharged cases.

Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung / Additional information for Annex II and self-testing in vitro diagnostic medical devices	
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	☐ In Übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A) In conformity with Common Technical Specifications (for Annex II List A devices)
	Ergebnisse der Leistungsbewertung Outcome of performance evaluation

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
 I affirm that the information given above is correct to the best of my knowledge.

Ort City	Münster	Datum Date	2021-01-15
		Name	Nicole Böhnisch
			Unterschrift Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority	
Bearbeiter / Person responsible Frau Silvia Wenge	Telefon / Phone 0251-4115936

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

Instructions for Use

FREQUENTLY ASKED QUESTIONS

- When can I test myself?
You can always test yourself whether you have symptoms or not. Please note that the test results are a snapshot that is valid for this point in time. Tests should therefore be repeated according to the regulations of the responsible authorities.
- What should I pay attention to in order to obtain the most exact test result possible?
Always follow the instructions for use exactly. Perform the test immediately after collecting the sample. Dispense the drops from the test tube only into the designated well of the test cassette. Dispense four drops from the sample tube. Too many or too few drops can lead to an incorrect or invalid test result.
- The test strip is very discolored. What is the reason or what am I doing wrong?
The reason for a clearly visible discoloration of the test strip is that too large a quantity of drops has been dispensed from the sample tube into the test cassette well. The indicator strip can only hold a limited amount of liquid. If the control line does not appear or the test strip is very discolored, please repeat the test with a new test kit according to the instructions for use.
- What should I do if I took the test but didn't see a control line?
In this case, the test results to be considered invalid. Please repeat the test with a new test kit according to the instructions for use.
- I am unsure of the interpretation of the results. What should I do?
If you cannot clearly determine the result of the test, contact the nearest medical facility applying the regulations of your local authority.
- My results are positive. What should I do?
If a horizontal colored line is visible in the control area (C) as well as in the test area (T), your results are positive and you should immediately contact the medical facility in accordance with the requirements of your local authorities. Your test result may be checked and the next steps will be explained to you.
- My results are negative. What should I do?
If only a horizontal colored line is visible in the control area (C), this may mean that you are negative or that the viral load is too low to be recognized by the test. If you experience symptoms such as headaches, migraines, fever, loss of sense of smell and taste, contact the nearest medical facility applying the regulations of your local authority. In addition, you can repeat the test with a new test kit.
- Can this test cassette be reused or used by multiple people?
This test cassette is for one-time use and cannot be reused or used by multiple people.

MODEL NUMBER

Model A

SPECIFICATIONS

1T/kit, 5T/kit, 20T/kit, 25T/kit, 40T/kit, 50T/kit.

INTENDED USE

This kit is used for in vitro qualitative determination of SARS-CoV-2 antigens in human anterior nasal swab samples. It can be used for rapid investigation of suspected COVID-19 cases, and can also be used as a confirmation method for nucleic acid detection in discharged cases.

A positive test result indicates that the sample contains SARS-CoV-2 antigen. A negative test result does not rule out the possibility of infection. This kit is for home use by laymen in a non-laboratory setting (such as person's home or certain non-traditional sites such as offices, sporting events, airports, schools etc.). The test results of this kit are for clinical reference only. It is recommended to conduct a comprehensive analysis of the condition based on

the patient's clinical manifestations and other laboratory tests.

COMPONENTS

1. SARS-CoV-2 Antigen Test Cassette
2. Sample extraction buffer
3. Disposable virus sampling swab
4. Biohazard specimen bag

Note: Components of different batches cannot be mixed.

SPECIMEN REQUIREMENTS

1. Sample collection

- Gently insert the entire soft tip of the swab into one nostril for 1.5cm until you feel a bit of resistance.
- Using medium pressure, rub the swab slowly in a circular motion around the inside wall of your nostril 4 times for a total time of 15 seconds.
- Repeat the same process with the same swab in the other nostril.



2. Sample treatment

- The swab after sampling is soaked below the liquid level of the sample extraction buffer. Rotate and press 3 times. The swab soaking time is not less than 15 seconds.
- The swab head is pressed, then take out the swab and tighten the sampling tube.



3. Sample preservation: The treated sample should be tested within 1h.

TEST PROCEDURE



obtained after 30 minutes is invalid.

DISPOSAL THE SAMPLE AND CLEAN-UP



- Place the test cassette, sample extraction buffer and disposable virus sampling swab in the biohazard specimen bag and seal the bag.

- Throw away the remaining sample kit items.

- Re-apply hand sanitizer.

INTERPRETATION OF RESULT

Positive: Two color bands appear in the observation window, that is, a red or magenta line appears at the position of the quality control line (C line) and the detection line (T line) (as shown in result 1), indicating the test result of SARS-CoV-2 antigens in the sample is positive.

Negative: A red or magenta line appears at the position of the quality control line (C line) in the observation window, and no line appears at the position of the test line (T line) (as shown in the result 2), indicating the test result of SARS-CoV-2 antigens in the sample is negative or the concentration is below the limit of detection of the kit.

Invalid: No line appears in the position of the quality control line (line C) in the observation window (as shown in result 3), indicating that the test is invalid, and the sample should be recollected and retested.



PRINCIPLE OF THE ASSAY

This kit is based on the colloidal gold immunochromatographic technology, and uses the double antibody sandwich method to detect N protein of SARS-CoV-2 antigen in human anterior nasal swab samples. The detection line (T line) of the SARS-CoV-2 antigen test cassette was coated with SARS-CoV-2 antibody, and the quality control line (C line) was coated with sheep anti-mouse antibody. During the test, the sample is dropped into the test cassette and the liquid is chromatographed upward under the capillary effect. The SARS-CoV-2 antigen in the sample first binds to the colloidal gold-labelled SARS-CoV-2 antibody to form a solid phase SARS-CoV-2 antibody-SARS-CoV-2 antigen-labelled SARS-CoV-2 antibody-colloidal gold complex at the T line position, and form a solid phase sheep anti-mouse-labelled SARS-CoV-2 antibody-colloidal gold complex was formed at the C line position. After the test is completed, observe the colloidal

gold immunochromatographic technology, and uses the double antibody sandwich method to detect N protein of SARS-CoV-2 antigen in human anterior nasal swab samples. The detection line (T line) of the SARS-CoV-2 antigen test cassette was coated with SARS-CoV-2 antibody, and the quality control line (C line) was coated with sheep anti-mouse antibody. During the test, the sample is dropped into the test cassette and the liquid is chromatographed upward under the capillary effect. The SARS-CoV-2 antigen in the sample first binds to the colloidal gold-labelled SARS-CoV-2 antibody to form a solid phase SARS-CoV-2 antibody-SARS-CoV-2 antigen-labelled SARS-CoV-2 antibody-colloidal gold complex at the T line position, and form a solid phase sheep anti-mouse-labelled SARS-CoV-2 antibody-colloidal gold complex was formed at the C line position. After the test is completed, observe the colloidal

gold color reaction of T line and C line to determine results of SARS-CoV-2 antigen in human anterior nasal swab samples.

STORAGE AND SHELF LIFE

1. The kit should be stored at 4~ 30°C, the shelflife is setfor 18 months.
2. After the foil bag is opened, it should be used within 30 minutes (temperature 10~30°C, humidity ≤70%).
3. The sample extraction buffer should be used within 18 months after opening (temperature 10~30°C, humidity ≤70%).

See label for manufacture date and expiration date.

LIMITATIONS

1. The test result of this kit is not the only confirmation indicator of clinical indications. The infection should be confirmed by a specialist along with other laboratory results, clinical symptoms, epidemiology, and additional clinical data.
2. In the early stages of infection, low levels of antigen expression can result in negative results.
3. The sample test results are related to the quality of sample collection, processing, transportation and storage. Any errors may lead to inaccurate results. If cross-contamination is not controlled during sample processing, false positive results may occur.

PERFORMANCE CHARACTERISTICS

1. Limit of Detection (LoD)
Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) has been confirmed can detect SARS-CoV-2 at $2.5 \times 10^{-2.2}$ TCID₅₀/mL, which was collected from a confirmed COVID-19 patient in China.
2. Study on Exogenous/Endogenous Interference Substances:
The potential interfering substances listed below do not interfere.

(1) Exogenous factor

No.	Exogenous factor	Interfering substances	Test conc.
1	Nasal sprays or drops	Phenylephrine	128 µg/mL
2		Oxymetazoline	128 µg/mL
3		Saline Nasal Spray 10%	10% (v/v)
4	Nasal corticosteroids	Decongestant	2 µg/mL
5		Flunisolide	0.2 µg/mL
6		Triamcinolone acetonide	0.2 µg/mL
7		Mometasone	0.5 µg/mL
8	Throat lozenges	Strepsils	5% (w/v, 50mg/mL)
9		Throat candy	5% (w/v, 50mg/mL)
10	Oral anaesthetic	Anbesol	5% (v/v)
11		Benzocaine 20%	5% (v/v)
12	Anti-viral drugs	α-Interferon-2b	0.01 µg/mL
13		Zanamivir (Influenza)	2 µg/mL
14		Ribavirin (HCV)	0.2 µg/mL
15		Osetamivir (Influenza)	2 µg/mL
16		Peramivir (Influenza)	60 µg/mL
17		Loxianvir (HIV)	80 µg/mL
18		Ritonavir (HIV)	20 µg/mL
19		Atidol (Influenza)	40 µg/mL
20		Levofloxacin Tablets	40 µg/mL
21		Azithromycin	200 µg/mL
22		Ceftriaxone	800 µg/mL
23	Antibacterial, systemic	Meropenem	100 µg/mL
24		Tobramycin	128 µg/mL
25	Other	Mucin: bovine submaxillary gland, type B	100 µg/mL
		Biotin	100 µg/mL

(2) Endogenous factor

No.	Endogenous factor	Interfering substances	Test conc.
1	Autoimmune disease	Human anti-mouse antibody, HAMA	800 ng/mL

3. Cross-Reactivity & Microbial Interference:

There is no cross-reaction and no interference with the potentially cross-reactive microorganisms listed below.

No.	Crossing reacting substance	Strain	Concentration of cross reacting substance
1	Human Coronavirus	HKU1	2×10^5 TCID ₅₀ /mL
2		229E	2×10^5 TCID ₅₀ /mL
3		OC43	2×10^5 TCID ₅₀ /mL
4		NL63	2×10^5 TCID ₅₀ /mL
5		SARS	2×10^5 TCID ₅₀ /mL
6		MERS	2×10^5 TCID ₅₀ /mL
7	Adenovirus	Type 1	2×10^5 TCID ₅₀ /mL
8		Type 2	2×10^5 TCID ₅₀ /mL
9		Type 3	2×10^5 TCID ₅₀ /mL
10		Type 4	2×10^5 TCID ₅₀ /mL
11	Human Metapneumovirus (hMPV)	Type 5	2×10^5 TCID ₅₀ /mL
12		Type 7	2×10^5 TCID ₅₀ /mL
13		Type 55	2×10^5 TCID ₅₀ /mL
14		hMPV 3 Type 81 / Peruv-2002	2×10^5 TCID ₅₀ /mL
15	Parainfluenza virus	hMPV 16 Type A1 / IALD-2003	2×10^5 TCID ₅₀ /mL
16		Type 1	2×10^5 TCID ₅₀ /mL
17		Type 2	2×10^5 TCID ₅₀ /mL
18		Type 3	2×10^5 TCID ₅₀ /mL
19	Influenza A	Type 4A	2×10^5 TCID ₅₀ /mL
20		H1N1	2×10^5 TCID ₅₀ /mL
21		H3N2	2×10^5 TCID ₅₀ /mL
22		H5N1	2×10^5 TCID ₅₀ /mL
23	Influenza B	H7N9	2×10^5 TCID ₅₀ /mL
24		Yamagata	2×10^5 TCID ₅₀ /mL
25		Victoria	2×10^5 TCID ₅₀ /mL
26		Type 68	2×10^5 TCID ₅₀ /mL
27	Enterovirus	09/2014 isolate 4	2×10^5 TCID ₅₀ /mL
28		Type A	2×10^5 TCID ₅₀ /mL
29		Type B	2×10^5 TCID ₅₀ /mL
30		A16	2×10^5 TCID ₅₀ /mL
31	Chlamydia pneumoniae	Type B42	2×10^5 TCID ₅₀ /mL
32		TVAR strain TW-183	5×10^6 CFU/mL
33		NCTC 4560	5×10^6 CFU/mL
34		Bloomington-2	5×10^6 CFU/mL
35	Legionella pneumophila	Los Angeles-1	5×10^6 CFU/mL
36		82A3105	5×10^6 CFU/mL
37		K	5×10^6 CFU/mL
38		Erdman	5×10^6 CFU/mL
39	Mycobacterium tuberculosis	HN878	5×10^6 CFU/mL
40		CDC1551	5×10^6 CFU/mL
41		H37Rv	5×10^6 CFU/mL
42		4752-98 (DJ)58-17	5×10^6 CFU/mL
43	Streptococcus pneumoniae	178 [Poland 23F-16]	5×10^6 CFU/mL
44		262 [CIP 104340]	5×10^6 CFU/mL
45		Slovakia 14-10 [29055]	5×10^6 CFU/mL
46		Typing strain T1 [NCIB 11841, SF 130]	5×10^6 CFU/mL
47	Bordetella pertussis	NCP 13671	5×10^6 CFU/mL
48		Mutant 22	5×10^6 CFU/mL

2	Serum protein	Whole Blood (human), EDTA anticoagulated	10% (w/w)
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49	pneumoniae	PH strain of Eaton Agent (NCTC 10119)	5×10^6 CFU/mL
50		M129-B7	5×10^6 CFU/mL
51	Pneumocystis jirovecii (PJP)	N/A	N/A
52	Pooled human nasal wash	N/A	N/A
53	Candida albicans	3147	5×10^6 CFU/mL
54	Pseudomonas aeruginosa	R. Hugh 813	5×10^6 CFU/mL
55	Staphylococcus epidermidis	FDA strain PCI 1200	5×10^6 CFU/mL
56	Streptococcus salivarius	S21B [FO 13956]	5×10^6 CFU/mL

4. Hook Effect:

There is no hook effect at $1.0 \times 10^{3.2}$ TCID₅₀/mL of SARS-CoV-2 isolated from a SARS-CoV-2 confirmed patient in China.

5. Clinical Performance:

Clinical performance of Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) has been determined by testing 108 positive and 115 negative specimens for SARS-CoV-2 antigen (Ag). The sensitivity is 96.30% (95% CI: 90.79-98.98%), and the specificity is 95.13% (95% CI: 95.25-99.98%).

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) Results	PCR Test Results			
	Positive	Negative	Total	Overall Percentage Agreement
	104	1	105	
	4	114	118	
	108	115	223	
Sensitivity	96.30% [90.79%;98.98%]	Specificity	99.13% [95.25%;99.98%]	97.76% [94.85%;99.27%]

PRECAUTIONS

1. This kit is for in vitro diagnostic use only. Please read this instruction carefully before the test.
2. Please use the swab and sample extraction buffer provided in this kit, and do not replace the sample extraction kit with components in other kits.
3. Operations should strictly follow the instructions.
4. Positive and negative predictive values are highly dependent on the prevalence. When the prevalence of the disease is low and SARS-CoV-2 has little/no activity, a positive test result is more likely to represent a false positive result; when the prevalence of the disease is high, false negative test results are more likely.
5. Compared with a RT-PCR SARS-CoV-2 assay, this test is less sensitive when used to detect patient samples within the first five days of the onset of symptoms.
6. The test cassette must be used within 30 minutes after opening (temperature 10~30°C, humidity ≤70%), it should be used immediately after opening at 30°C, and the unused test cassette must be sealed and dry stored.
7. Waste or excess samples produced during testing should be inactivated according to regulations on infectious agents.

EXPLANATION FOR IDENTIFICATION

Use by date	Content Sufficient For <=> Tests	Manufacturing date	Batch	Consult instruction for use	Catalog Number	Do not reuse
			Temperature limitation			
			Caution			

	CE Marking – IVDD 98/79/EC		Authorized representative in the European Community		Manufacturer
	For In Vitro Diagnostic Use		Keep away from sunlight		Keep dry
	For self-testing		/	/	/

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APPROVAL DATE AND REVISION DATE OF THE INSTRUCTION

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