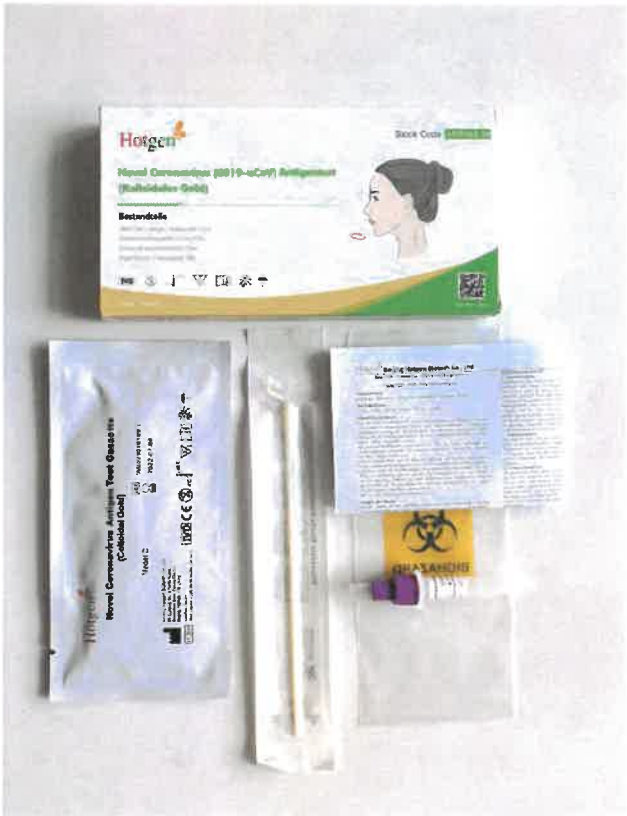
Hotgen

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

10	北京热景生物技术股份有限公司 Beijing Hotgen biotech Co., Ltd.	91110115777090586H	欧盟CE

Beijing Hotgen biotech Co., Ltd.

2020-11-23

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

Email: sales@hotgen.com.cn Website: www.hotgen.com.cn

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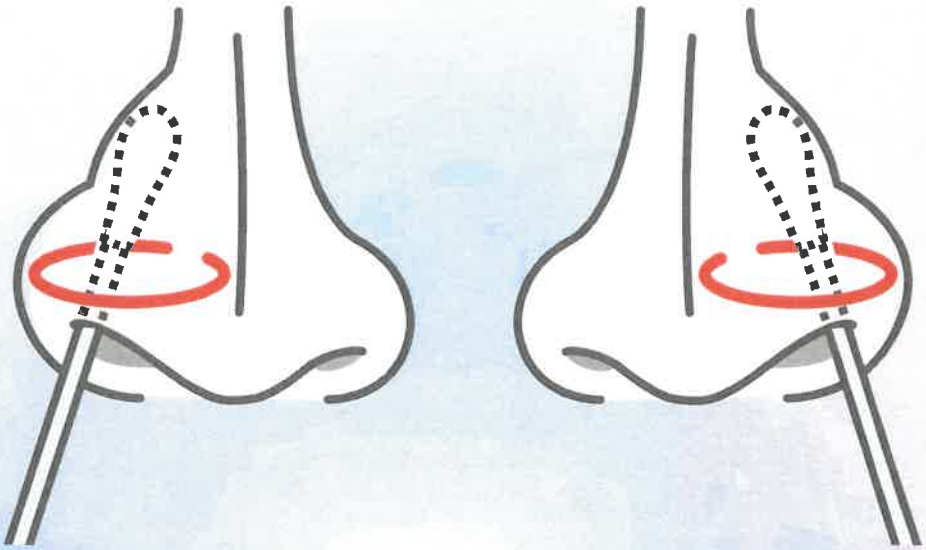

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

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

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Clinical Performance

(Disease Course 5-7 Days)

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

Novel Coronavirus 2019-nCoV Antigen Test(Colloidal Gold)

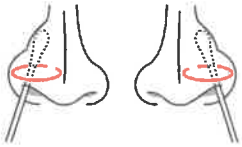
Specimen Requirements

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.

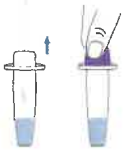
Using medium pressure, rub the swab slowly in a circular motion around the inside wall of your nostril 4 times for a total time of 15 seconds.

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

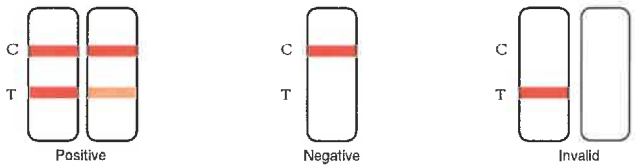
1 Place the test cassette, sample extraction buffer at room temperature for 15~30 minutes, and equilibrate to room temperature (10~30℃).

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

3 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℃ for 15 minutes.

4 Observe the results after Incubate at 10~30℃ for 15 minutes. The result after 30 minutes is invalid.

Interpretation of result



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 Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	Reference system (clinical diagnostic results)		
	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℃

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

CE

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**
	Straße, Haus-Nr. / Street, house no. **Domplatz 36**		
	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**
	Ort / City **Muenster**		Postleitzahl / Postal code **48163**
	Straße, Haus-Nr. / Street, house no. **Borkstrasse 10**		
	Telefon / Phone **+49-251-32266-0**		Telefax / Fax **+49-251-32266-22**
	E-Mail / E-mail **ear-admin@medneteurope.com**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Beijing Hotgen Biotech Co., Ltd.**		
	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**		
	Staat / State **Deutschland**		Land / Federal state **Nordrhein-Westfalen**
	Ort / City **MÜNSTER**		Postleitzahl / Postal code **48163**
	Straße, Haus-Nr. / Street, house no. **Borkstrasse 10**		
	Telefon / Phone **+49-251-32266-0**		Telefax / Fax **+49-251-32266-22**
	E-Mail / E-mail **info@medneteurope.com**		

Vertreter / Deputy (optional)			
	Bezeichnung / Name **Kristin Zurlinden**		
	Telefon / Phone **+49 251 32266 0**		Telefax / Fax **+49 251 32266 22**
	E-Mail / E-mail **info@medneteurope.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 / Addtional 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**

Hotgen

CE

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 thatthe test resultis a snapshotthatis valid for this pointin time. Tests should therefore be repeated according to the regulations ofthe responsible authorities.

- What should I pay attention to in order to obtain the most exacttest result possible?

Always follow the instructions for use exactly. Perform the testimmediately after collecting the sample. Dispense the drops from the testtube only into the designated well ofthe 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. Whatis the reason or what am I doing wrong?

The reason for a clearly visible discoloration ofthe test strip is thattoo 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 ofliquid. Ifthe control line does not appear or the test strip is very discolored, please repeatthe 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 resultis to be considered invalid. Please repeatthe test with a new test kit according to the instructions for use.

- I am unsure ofthe interpretation ofthe results. What should I do?

If you cannot clearly determine the result ofthe test, contactthe nearest medical facility applying the regulations of your local authority.

- My resultis 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 resultis positive and you should immediately contactthe 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 resultis 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 thatthe 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, contactthe nearest medical facility applying the regulations of your local authority. In addition, you can repeatthe 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 kitis 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 reconfirmation method for nucleic acid detection in discharged cases.

A positive test resultindicates thatthe sample contains SARS-CoV-2 antigen. A negative test result does not rule outthe possibility ofinfection.

This kitis 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 ofthis kit are for clinical reference only. Itis recommended to conduct a comprehensive analysis ofthe 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 insertthe entire soft tip ofthe 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.
- Repeatthe same process with the same swab in the other nostril.

2. Sample treatment

- The swab after sampling is soaked below the liquid level ofthe 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 outthe swab and tighten the sampling tube.

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

TEST PROCEDURE

1. Place the test cassette, sample extraction buffer at room temperature for 15~30 minutes, and equilibrate to room temperature (10~30℃).

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

3. Add 4 drops ofthe treated sample into the sample well of the test cassette. (In case of chromatographic abnormalities, add an extra of 1~2 drops of the treated sample accordingly). Incubate at 10~30°C for 15 minutes.
4. Observe the results after Incubating at 10~30℃ for 15 minutes. The result 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 kititems.

- Re-apply hand sanitizer.

INTERPRETATION OF RESULT

Positive: Two color bands appear in the observation window, thatis, a red or magenta line appears atthe position ofthe 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 atthe position ofthe quality control line (C line) in the observation window, and no line appears atthe position ofthe test line (T line) (as shown in the result 2), indicating the test result ofthe SARS-CoV-2 antigens in the sample is negative or the concentration is below the limit of detection ofthe kit.

Invalid: No line appears in the position ofthe quality control line (line C) in the observation window (as shown in result 3), indicating thatthe testis invalid, and the sample should be recollect and retested.

Result 1: Positive **Result 2: Negative** **Result 3: Invalid**

PRINCIPLE OF THE ASSAY

This kitis 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) ofthe 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 atthe T line position, and form a solid phase sheep anti-mouse-labelled SARS-CoV-2 antibody-colloidal gold complex was formed atthe C line position. After the testis 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℃, humidity ≤70%).
3. The sample extraction buffer should be used within 18 months after opening (temperature 10~30℃, humidity ≤70%).

See label for manufacture date and expiration date.

LIMITATIONS

1. The test result ofthis kitis notthe 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 ofinfection, low levels of antigen expression can resultin 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 × $10^{2.2}$ $TCID_{50}$/mL, which was collected from a confirmed COVID-19 patientin China.

2. Study on Exogenous/Endogenous Interference Substances:

The potential interfering substances listed below do notinterfere.

(1) Exogenous factor

No.	Exogenous factor	Interfering substances	Test conc.
1	Nasal sprays or drops	Phenylephrine	128μg/mL
2		Oxymetazoline	128μg/mL
3		Saline Nasal Spray 10%	10%(v/v)
4	Nasal corticosteroids	Dexamethasone	2μg/mL
5		Flunisolide	0.2μg/mL
6		Triamcinolone acetonide	0.2μg/mL
7		Mometasone	0.5μg/mL
8	Throat lozenges	Strepsils (flurbiprofen 8.75mg)	5% (w/v, 50mg/mL)
9		Throat candy	5% (w/v, 50mg/mL)
10	Oral anaesthetic	Anbesol (Benzocaine 20%)	5% (v/v)
11	Anti-viral drugs	α-Interferon-2b	0.01μg/mL
12		Zanamivir (Influenza)	2μg/mL
13		Ribavirin (HCV)	0.2μg/mL
14		Oseltamivir (Influenza)	2μg/mL
15		Peramivir(Influenza)	60μg/mL
16		Lopinavir(HIV)	80μg/mL
17		Ritonavir(HIV)	20μg/mL
18		Arbidol((Influenza)	40μg/mL
19	Antiblotic	Levofloxacin Tablets	40μg/mL
20		Azithromycin	200μg/mL
21		Ceftriaxone	800μg/mL
22		Meropenem	100μg/mL
23	Antibacterial, systemic	Tobramycin	128μg/mL
24	Other	Mucin: bovine submaxillary gland, type	100 μg/mL
25		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
2	Serum protein	Whole Blood (human), EDTA anticoagulated	10% (w/w)

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		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	Human Metapneumovirus (hMPV)	hMPV 3 Type B1 / Peru2-2002	2 × 10^5 $TCID_{50}$/mL
15		hMPV 16 Type A1 / IA10-2003	2 × 10^5 $TCID_{50}$/mL
16	Parainfluenza virus	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		Type 4A	2 × 10^5 $TCID_{50}$/mL
20	Influenza A	H1N1	2 × 10^5 $TCID_{50}$/mL
21		H3N2	2 × 10^5 $TCID_{50}$/mL
22		H5N1	2 × 10^5 $TCID_{50}$/mL
23		H7N9	2 × 10^5 $TCID_{50}$/mL
24	Influenza B	Yamagata	2 × 10^5 $TCID_{50}$/mL
25		Victoria	2 × 10^5 $TCID_{50}$/mL
26	Enterovirus	Type 68	2 × 10^5 $TCID_{50}$/mL
27		09/2014 isolate 4	2 × 10^5 $TCID_{50}$/mL
28	Respiratory syncytial virus	Type A	2 × 10^5 $TCID_{50}$/mL
29		Type B	2 × 10^5 $TCID_{50}$/mL
30	Rhinovirus	A16	2 × 10^5 $TCID_{50}$/mL
31		Type B42	2 × 10^5 $TCID_{50}$/mL
32	Chlamydia pneumoniae	TWAR strain TW-183	5 × 10^6 CFU/mL
33	Haemophilus influenzae	NCTC 4560	5 × 10^6 CFU/mL
34	Legionella pneumophila	Bloomington-2	5 × 10^6 CFU/mL
35		Los Angeles-1	5 × 10^6 CFU/mL
36		82A3105	5 × 10^6 CFU/mL
37	Mycobacterium tuberculosis	K	5 × 10^6 CFU/mL
38		Erdman	5 × 10^6 CFU/mL
39		HN878	5 × 10^6 CFU/mL
40		CDC1551	5 × 10^6 CFU/mL
41		H37Rv	5 × 10^6 CFU/mL
42	Streptococcus pneumonia	4752-98 [Maryland (D1)6B-17]	5 × 10^6 CFU/mL
43		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	Streptococcus pyrogens	Typing strain T1 [NCIB 11841, SF 130]	5 × 10^6 CFU/mL
47	Bordetela pertussis	NCCP 13671	5 × 10^6 CFU/mL
48	Mycoplasma	Mutant 22	5 × 10^6 CFU/mL
49	pneumoniae	FH 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 [IFO 13956]	5 × 10^6 CFU/mL

4. Hook Effect:

There is no hook effect at 1.0 × $10^{6.2}$ $TCID_{50}$/mL of SARS-CoV-2 isolated from a SARS-CoV-2 confirmed patientin 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 99.13% (95% CI: 95.25-99.98%).

		PCR Test Results		
		Positive	Negative	Total
Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) Results	Positive	104	1	105
	Negative	4	114	118
	Total	108	115	223
		Sensitivity	Specificity	Overall Percentage Agreement
		96.30% [90.79%;98.98%]	99.13% [95.25%;99,98%]	97.76% [94.85%;99.27%]

PRECAUTIONS

1. This kitis 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 extractin this 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 ofthe disease is low and SARS-CoV-2 has little/no activity, a positive test results is more likely to represent a false positive result; when the prevalence ofthe disease is high, false negative test results are more likely.
5. Compared with a RT-PCR SARS-CoV-2 assay, this testis less sensitive when used to detect patient samples within the firstfive days ofthe onset of symptoms.
6. The test cassette must be used within 30 minutes after opening (temperature 10~30℃, humidity ≤70%), it should be used immediately after opening at 30℃, and the unused test cassette must be sealed and dryly stored.
7. Waste or excess samples produced during testing should be inactivated according to regulations on infectious agents.

EXPLANATION FOR IDENTIFICATION

	Use by date	LOT	Batch		Consult Instruction for use
Σ	Content Sufficient For <n> Tests		Temperature limitation	REF	Catalog Number
	Manufacturing date		Caution		Do not reuse

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

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