Hotgen Beijing Hotgen Biotech Co., Ltd. CE EN

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)
Instructions for Use

PRODUCT NAME

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

Model Number

Model A

SPECIFICATIONS

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

INTENDED USE

This kit is based on the Colloidal gold immunochromatographic technology, and uses double antibody sandwich method to detect N protein of SARS-CoV-2 antigen in human throat swabs or nasal swabs. 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.

A positive test result indicates that the samples contained novel coronavirus antigen. A negative test result does not rule out the possibility of infection.

This product is only used for clinical and emergency reserve during the pneumonia outbreak of novel coronavirus infection, and can not be used as a routine in vitro diagnostic reagent for clinical application . 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.

For professional use only.

PRINCIPLE OF THE ASSAY

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

1. Novel Coronavirus Antigen Test Cassette
2. Sterile extraction buffer
3. Disposable virus sampling swab

STORAGE AND SHELF LIFE

1. The kit should be stored at 4~ 30°C, the shelf life is set for 18 months.
2. After the foil bag is opened, it should be used within 30 minutes (temperature 10~30°C, humidity ≤70%), and it should be used immediately after opening at 30°C.
3. The sample extraction buffer should be used within 18 months after opening (temperature 10~30°C, humidity ≤70%).
4. Date of manufacture and expiration date see label.

SPECIMEN REQUIREMENTS

1. Sample collection:

Nasal swab: The sampling staff hold a swab and stick into the nostril and goes back slowly along the bottom of the lower nasal canal, when the top of the swab reaches the posterior wall of the nasopharyngeal cavity, rotate gently for a cycle (if reflex cough, stay for a moment), and then slowly remove the swab.

Throat swab: Let the patient's head tilt slightly, mouth open, and make „ah" sounds, exposing the pharyngeal tonsils on both sides. Hold the swab and wipe the pharyngeal tonsils on both sides of the patient with a little force back and forth at least 3 times. Then wipe up and down the Posterior pharyngeal wall at least 3 times.

2. Sample treatment

The swab after sampling is soaked below the liquid level of the sample extraction buffer, rotated and pressing 3 times, the swab soaking time is not less than 15s, the swab head is pressed, then taken out the swab and tighten the sampling tube. The liquid in the tube is the sample after treatment.

3. Sample preservation

The sample of treated should be tested within 1h. Specimens that can not be detected within 24 hours should be kept at -70℃ or below. Repeated freezing and thawing should be avoided during specimen transportation. Specimen collection should be sent to the laboratory as soon as possible. If it is necessary to transport the specimen for a long distance, it is recommended to preserve the specimen by refrigeration such as dry ice.

TEST PROCEDURE

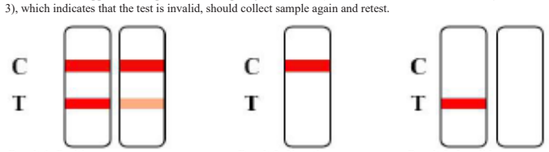
1. Place the test cassette, sample extraction buffer at room temperature for 15~30 minutes, and equilibrate to room temperature (10~30℃).
2. Open the aluminum foil pouch of the test cassette, place the test cassette on a flat surface.
3. Write sample ID on the plastic case of the test cassette.
4. Add 4~5 drops of the treated sample into the sample well of the test cassette. Incubate at 10~30℃ for 15 minutes.
5. Observe the results after Incubate at 10~30℃ for 15 minutes. Result got after 30 minutes is invalid.

This kit doesn't have quality control products. It is recommended that the users establish a quality control method suitable for its laboratory.

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), which indicates the test result of novel coronavirus antigen in the sample was 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 results of the novel coronavirus antigen in the sample were negative or the concentration was below the limit of detection of the kit. **Invalid: Invalid:** No line appears in the position of the quality control line (line C) in the observation window (as shown in result 3), which indicates that the test is invalid, should collect sample again and retest.



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

LIMITATIONS

1. This kit is a qualitative test and cannot quantify the concentration of the novel coronavirus antigen.
2. The test result of this kit is not the only confirmation indicator of clinical indications. If the test result is not in consistent with clinical evidence, it is recommended to conduct supplementary tests to verify the result.
3. Sample test results are related to the quality of sample collection, processing, transportation and storage. Any errors may cause inaccurate test results. If cross-contamination is not controlled during sample processing, false positive results may occur.

PERFORMANCE CHARACTERISTICS

1. When testing with enterprise references, meet the following standards:

1.1 Negative references compliance rate: Use the enterprise negative references for testing, and the negative references should be detected at least 20/20 (-/-).

1.2 Positive references compliance rate: Use the enterprise positive references for testing, and the positive references should be detected at least 5/5 (+ / +).

1.3 Sensitivity references: When using enterprise sensitivity references for detection, at least 1/3 (+ / +) should be detected.

1.4 Repeatability: Use enterprise precision references for testing, and the test results of repeatable references should be consistent.

2. Limit of Detection (LoD)

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) was confirmed to detect $2.5\times10^{2.2}$ $TCID_{50}$/mL of SARS-CoV-2 which was collected from a COVID-19 confirmed patient in China.

3. Exogenous/Endogenous Interference Substances studies:

There was no interference for potential interfering substances listed below.

(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	Antibiotic	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)

4. Cross-Reactivity & Microbial interference:

There was no cross-reaction and interference with the potential cross-reacting 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 pneumoniae	Mutant 22	5×10^6 CFU/mL
49		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

5. Hook Effect:

There is no hook effect at $1.0\times10^{6.2}$ $TCID_{50}$/mL of SARS- CoV-2 which was isolated from a COVID-19 confirmed patient in China.

6. Clinical Performance:

(1) Nasal swab samples

Clinical performance of Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) was determined by testing 207 positive and 410 negative specimens for SARS-CoV-2 antigen (Ag) to have a sensitivity of 96.62% (95% CI: 93.16-98.63%) and specificity of 99.76% (95% CI: 98.65-99.99%).

		PCR Test Results		
		Positive	Negative	Total
Novel Coronavirus 2019-Co-VAntigen Test (Colloidal Gold) Results	Positive	200	1	201
	Negative	7	409	416
	Total	207	410	617
		Sensitivity	Specificity	Overall Peccenta-ge Agreement
		96,62% [93,16%; 98,63%]	99,76% [98,65%; 99,99%]	98,70% [97,46%; 99,44%]

(2) Throat swab samples

Clinical performance of Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) was determined by testing 207 positive and 410 negative specimens for SARS-CoV-2 antigen (Ag) to have a sensitivity of 97.10% (95% CI: 93.80-98.93%) and specificity of 99.76% (95% CI: 98.65-99.99%).

		PCR Test Results		
		Positive	Negative	Total
Novel Coronavirus 2019-CoV Antigen Test (Colloidal Gold) Results	Positive	201	1	202
	Negative	6	409	415
	Total	207	410	617
		Sensitivity	Specificity	Overall Percentage Agreement
		97,10% [93,80%; 98,93%]	99,76% [98,65%; 99,99%]	98,87% [97,68%; 99,54%]

PRECAUTIONS

1. This kit is for in vitro diagnostic use only. Please read this instruction carefully before experiment.
2. Please use the swab and sample extraction buffer provided by this kit, Do not replace the sample extract in this kit with components in other kits.
3. Operation should be strictly performed according to the instruction, and different batches should not be mixed use.
4. The user should test the specimen as soon as possible, and the clinical performance evaluation of frozen sample may be different from that of fresh sample.
5. Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods of little/no SARS-CoV-2 activity when disease prevalence is low. False negative test results are more likely when prevalence of disease caused by SARS-CoV-2 is high.
6. Sensitivity of the test after the first five days of the onset of symptoms has been demonstrated to decrease as compared to a RT-PCR SARS-CoV-2 assay.
7. 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 dryly stored.
8. Waste or excess samples produced during testing should be inactivated according to 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 re-presentative in the European Community		Manufacturer
IVD	For In Vitro Diagnostic Use		Keep away from sunlight		Keep dry

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IVD

APPROVAL DATE AND REVISION DATE OF THE INSTRUCTION

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Weitere Sprachen
auf www.MaiMed.de/
Further languages
at www.MaiMed.de