Hotgen

CE

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) - Saliva

Instructions for Use

PRODUCT NAME

Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)

MODEL NUMBER

Model C

SPECIFICATIONS

40T/kit

INTENDED USE

This kit is used for in vitro qualitative determination of novel coronavirus antigen in human saliva samples from posterior oropharynx. 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 saliva. 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 coated 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 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 novel coronavirus antigen in human saliva.

COMPONENTS

1. Novel Coronavirus Antigen Test Cassette
2. Sample extraction buffer
3. Saliva collector
4. Biohazard specimen bag

Note: Components of different batches cannot be mixed use.

STORAGE AND SHELF LIFE

1. The kit has a shelf life of 18 months if all the components contained in the kit are sealed and it is stored at 4 ~ 30℃ and protected from moisture and heat.
2. After the foil bag is opened, it should be used within 30 minutes (temperature 10~30 ℃, humidity ≤70%), and it should be used immediately after opening at 30 ℃.
3. The sample extraction buffer should be used within 18 months after opening (temperature 10~30 ℃, humidity ≤70%).
4. Date of manufacture and expiration date see label.

SPECIMEN REQUIREMENTS

The test cassette and sample extraction buffer must be at room temperature for the test procedure. Therefore, the set must be in a room with a temperature of 10~30℃ for 15 ~ 30 minutes before testing, so that the set has already assumed room temperature during testing.

Saliva samples must be collected through clean and dry saliva collectors.

1. Sample collection and treatment

- Unscrew the cap of the sampling tube with the sample extraction buffer and place the saliva collector on it.
- Rinse the mouth with water. Deep cough three times, spit out saliva fro m the posterior oropharynx. Collect saliva (about 400μL) through the sa liva collector to make the lowest concave liquid level reach the scale mark position.
- Remove the saliva collector and screw the lid of the sample tube back on.
- Shake the sampling tube so that you thoroughly mix the saliva with the extraction buffer. After shaking, let it stand for at least 1 min (if abnormal samples are encountered, extend the standing time appropriately), mix again before adding the sample, and then add the treated sam ple to the sample well.

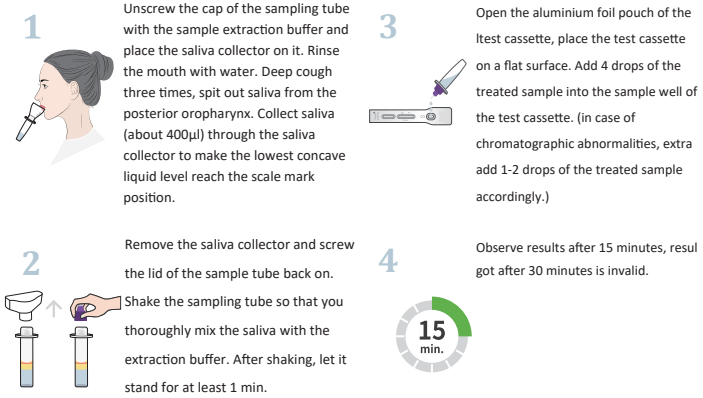
* If the saliva sample is visibly turbid, it needs to be centrifuged, filtered or left to settle before taking the supernatant liquid for testing.

2. Sample preservation

The saliva sample should be used as soon as possible after collection and should not be stored for long periods at room temperature. The saliva samples can be stored at 2 ~ 8 ℃ for 24 hours and must be brought to room temperature and mixed well before testing.

TEST PROCEDURE

1. Open the aluminum foil pouch of the test cassette, place the test cassette on a flat surface.
2. Write sample ID on the plastic case of the test cassette.
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.)
4. 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.



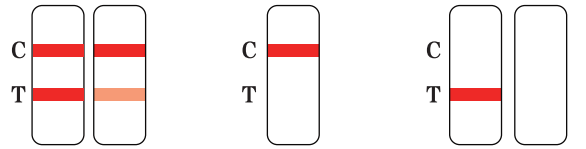
* Even with a negative test result, distance and hygiene rules must be observed!

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: 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 $1.0 \times 10^{6.2}$ $TCID_{50}$/mL of SARS-CoV-2 which was isolated from a COVID-19 confirmed patient in China.

6. Clinical Performance:

Clinical performance of Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) was determined by testing 125 positive and 457 negative specimens for SARS-CoV-2 antigen (Ag) to have a sensitivity of 96.00% (95% CI: 90.91-98.69%) and specificity of 99.78% (95% CI: 98.79-99.99%).

		PCR Test Results		
		Positive	Negative	Total
Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) Results	Positive	120	1	121
	Negative	5	456	461
	Total	125	457	582
		Sensitivity	Specificity	Overall Percentage Agreement
		96.00% [90.91%;98.69%]	99.78% [98.79%;99.99%]	98.97% [97.77%;99.62%]

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℃, humidity ≤70%), it should be used immediately after opening at 30℃, 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
	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

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IVD

APPROVAL DATE AND REVISION DATE OF THE INSTRUCTION

Approved on Jan., 2021;
Version number:V. 2021-01.03[Eng.]

Weitere Sprachen
auf www.MaiMed.de/
Further languages
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Maimed 5447