Hotgen

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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 result is 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 three 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 result is 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 result is 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 result is 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 result is 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.

TRADE NAME

SARS-CoV-2 Antigen Test (Colloidal Gold)

MODEL NUMBER

Model E

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 reconfirmation 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

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, add an extra of 1~2 drops of the treated sample accordingly). Incubate at 10~30℃ 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 kit items.

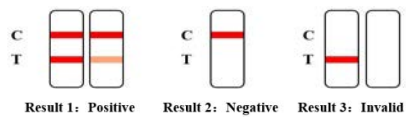
- Re-apply hand sanitizer.

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 the 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 recollect and retested.



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

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 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 shelf life is set for 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 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 × $10^{2.2}$ $TCID_{50}$/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	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)

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 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

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 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 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 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 extract in 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 of the 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 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℃, 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 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

Approved on February, 2021;

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