English

CE 1434 IVD

One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)

User Manual for self-test

INTENDED USE

One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) is intended for the qualitative detection of SARS-CoV-2 antigens in human nasal swab samples. This test is used for individuals suspected of COVID-19 within the first seven days of the onset of symptoms, such as headache, fever, cough, sore throat, loss of the sense of smell or taste, shortness of breath, muscle pain. Meanwhile the test can also be applied for individuals without symptoms.

Results are for the identification of SARS-CoV-2 antigen. Positive results indicate the presence of SARS-CoV-2 antigens, but individual history and other diagnostic information is necessary for determine infection status. Negative results do not rule out SARS-CoV-2 infection. Negative results for individuals with symptoms similar to COVID-19 infection for more than seven days should be treated as negative possibly. If necessary, it should be confirmed by molecular assay. One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) is intended to be used to help the diagnosis of SARS-CoV-2 infection. This test is used for self-testing.

CONTENTS

SARS-CoV-2 antigen test card N test	Extraction tube with sample extraction solution and tip N pc	Kit bag N pc
User manual 1 pc/kit	Sterile swab N pc	Timer (Not included)

PREPARING THE TEST

1. Check integrity of the out package,components and the expiration date.
2. Operation Video — Read the user manual before starting the test. Check operation video for more help.
3. Open the pouch. Check the result window and sample well (S).

TEST PROCEDURE

1. Remove the lid from the top of the extra-ction tube with sample extraction solutionand keep the tube vertical.
2. Open the swab packag. Gently insert the tip of the swab into one nostril. Do not insert the swab more than 1.5 cm into your nose.
3. Rotate ≥ 4 times — Rotate the swab around the inside wall of your nostril at least 4 times. Repeat the same process with the same swab in the other nostril.
4. Rotate 10 times — Insert the swab after sampling to the extraction tube and rotate the swab 10 times in the solution.
5. Squeeze the swab tip along the inner wall of the extraction tube 3 times. Discard the swab in the kit bag.
6. Sample: 2-3 drops — Put the lid of extraction tube on tightly. Gently squeeze the extraction tube and add 2-3 drops of solution into the sample well (S).
7. 10-15 min — Read the result visually in 10-15 min, don't read results after 20 min.
8. Put all of the used test kit contents in the kit bag provided and put this in household waste. If necessary, discarded all used tests according to local regulations. Wash your hands thoroughly after disposal.

TEST RESULTS

Positive

Positive (+):
Both the control line (C) and test line (T) appear indicates the presence of SARS-CoV-2 antigen. Any faint line in the test line (T) should be considered positive.
Note: Positive results indicate the very likely infected COVID-19. Contact your doctor or the local health department immediately. Follow the local guidelines for self-isolation and confirmed by a molecular testing method.

Negative

Negative (-):
Only the control line (C) and no test line (T) appear indicates no SARS-CoV-2 antigen was detected.
Note: Negative results indicate the unlikely infected COVID-19. Continue to follow all applicable rules and protective measures when contacting with others. There may be an infection even if the test is negative. If it is suspected, repeat the test after 1 - 2 days or confirmed by a molecular testing method.

Invalid

Invalid :
Control area (C) fails to appear, the test result is invalid. Not enough sample volume or incorrect operation are the likely reasons for an invalid result. Read the instructions again and test with a new test . If the same situation reappears, please stop using this batch of products and contact your doctor or a COVID-19 test center.

SPECIMEN COLLECTION

Note: Please follow your local guideline for specimen collection.

STORAGE AND STABILITY

Store the test kit at 4-30℃ with a valid period of 24 months.
Use the test card within 1 hour once the foil pouch is opened.

PRINCIPLE

The test uses anti-SARS-CoV-2 nucleocapsid protein (N protein) monoclonal antibody I conjugated with colloidal gold coated on the sample pad, and another anti-SARS-CoV-2 N protein monoclonal antibody Ⅱ coated on test line. After the samples have been applied to the test strip, the colloidal gold-labelled anti-SARS-CoV-2 N protein monoclonal antibody I bind with SARS-CoV-2 antigens in sample and form marked antigen-anti-body complexes. These complexes move to the test card detection zone by capillary action. Then marked antigen-anti-body complexes will be captured on test line by anti-SARS-CoV-2 N protein monoclonal antibody Ⅱ. The color intensity of each test line increases in proportion to the amount of SARS-CoV-2 antigen in sample.

PRECAUTIONS

1. Always keep out of the reach of children. Small parts of the kit can be a choking hazard.
2. Sample extraction solution is a phosphate buffer contained low concentration of sodium chloride, Tween, hexadecyl trimethyl ammonium bromide and sodium azide. If extraction solution splashes your body or into eyes, please wash with water.
3. This product can only be used for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
4. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
5. Do not touch swab tip when handling the swab sample.
6. Do not use kit past its expiration date.
7. Do not mix components from different kit lots.
8. All kit components are single use items. Do not use with multiple specimens. Do not reuse the used test card.
9. Use of gloves is recommended when conducting testing.
10. Wear safety mask or other face covering when collecting anterior nares swab specimen from a child or another individual.
11. Dispose of kit components and patient samples in household trash.

LIMITATIONS

1. False-negative result may occur if the level of antigen in sample is below the detection limit of the test or the sample was collected incorrectly.
2. Clinical diagnosis and treatment cannot be made without consulting with the physician.
3. A negative result, from an individual have symptoms similar to COVID-19 beyond seven days should be treated as negative possibly. If necessary, confirmed with the molecular assay.
4. The product One Step Test For SARS-CoV-2 Antigen (Colloidal Gold) showed no drop off in sensitivity when compared the wild type with variants listed in the WHO's website, http://ww-w.who.int/en/activities/tracking-SARS-CoV-2-variants/. We will keep evaluating the impact of new variants.

PERFORMANCE CHARACTERISTICS

1. Limit of Detection (LoD)

The LoD for nasal swab was established using heat-inactivated SARS-CoV-2 isolate strain. The strain was spiked with negative human nasal swab into a series of concentrations. The final LoD was determined to be the lowest concentration resulting in positive detection of twenty (20) out of twenty (20) replicates. The confirmed LoD for nasal swab was 200 $TCID_{50}$/mL (8000 copies/mL).

2. Clinical Agreement Study

The clinical performance of One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) was evaluated by comparing the test result with an RT-PCR assay (Vitassay qPCR SARS-CoV-2, Vitassay Healthcare S.L.U, IU_046 Ed06 Ene22). A total 569 nasal swab samples from 569 individuals were tested by themselves, and 569 nasopharyngeal swabs from the same individuals were tested by clinical professionals (including 146 asymptomatic individuals, 45 positive and 101 negative). Overall study results were shown in the table below.

Total		Vitassay's RT-PCR kit		
		Positive	Negative	Subtotal
Getein's kit	Positive	166	3	169
	Negative	4	396	400
	Subtotal	170	399	569

Diagnostic sensitivity = 166/ (166+4) × 100%=97.65% [95% CI: 94.11%~99.08%]
Diagnostic specificity = 396/ (396+3) × 100%=99.25% [95% CI: 97.81%~99.74%]
Total percent agreement = (166+396)/569 × 100%=98.77% [95% CI: 97.48%~99.40%]
The clinical positive percent agreement (PPA) of positive symptomatic and asymptomatic samples is as follows:

Symptomatic samples Days since onset of symptoms	RT-PCR Positive (+)	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) Positive (+)	PPA	95 % Confidence Interval
1	7	7	100.00%	64.57%~100.00%
2	14	14	100.00%	78.47%~100.00%
3	34	34	100.00%	89.85%~100.00%
4	33	33	100.00%	89.57%~100.00%
5	12	11	91.67%	64.61%~98.51%
6	14	13	92.86%	68.53%~98.73%
7	11	11	100.00%	74.12%~100.00%
Total	125	123	98.40%	94.35%~99.56%

Asymptomatic samples	RT-PCR Positive (+)	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) Positive (+)	PPA	95 % Confidence Interval
Total	45	43	95.56%	85.17%-98.77%

The clinical positive percent agreement (PPA) across the dynamic range of the viral load is as follows:

Ct value (FAM)	RT-PCR Positive (+)	Proportion of the total positive samples	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) Positive (+)	PPA	95 % Confidence Interval
≤25	42	24.70%	42	100.00%	91.62%~100.00%
25<Ct≤30	83	48.82%	83	100.00%	95.58%~100.00%
30<Ct≤35	22	12.94%	21	95.45%	78.20%~100.00%
>35	23	13.53%	20	86.96%	67.87%~100.00%

Ct value (ROX)	RT-PCR Positive (+)	Proportion of the total positive samples	One Step Test for SARS-CoV-2 Antigen (Colloidal Gold) Positive (+)	PPA	95 % Confidence Interval
≤25	58	34.12%	58	100.00%	93.79%~100.00%
25<Ct≤30	70	41.18%	70	100.00%	94.80%~100.00%
30<Ct≤35	23	13.53%	21	91.30%	73.20%~97.58%
>35	19	11.18%	17	89.47%	68.61%~97.06%

3. Analytical Specificity

3.1 Cross-Reactivity & Microbial Interference

Each organism and virus was tested in triplicate in the absence and presence of SARS-CoV-2 respectively. According to the test results, there was no cross-reactivity with the following viruses or organisms.

Viruses or organisms	Concentration
Human coronavirus 229E	1 x 10^5 PFU/mL
Human coronavirus OC43	1 x 10^5 PFU/mL
Human coronavirus NL63	9.87 x 10^3 PFU/mL
Human coronavirus HKU1	1.4 x 10^5 PFU/mL
MERS coronavirus	7930 PFU/mL
Adenovirus (e.g. C1 Ad. 71)	1 x 10^5 PFU/mL
Human Metapneumovirus (hMPV)	1 x 10^5 PFU/mL
Parainfluenza virus Type 1	1 x 10^5 PFU/mL
Parainfluenza virus Type 2	1 x 10^5 PFU/mL
Parainfluenza virus Type 3	1 x 10^5 PFU/mL
Parainfluenza virus Type 4a	1 x 10^5 PFU/mL
Influenza A	1 x 10^5 PFU/mL
Influenza B	2.92 x 10^4 PFU/mL
Enterovirus	1 x 10^5 PFU/mL
Respiratory syncytial virus	1 x 10^5 PFU/mL
Rhinovirus	4.17 x 10^5 PFU/mL
Epstein Barr Virus	1 x 10^5 PFU/mL
Haemophilus influenzae	1 x 10^6 CFU/mL
Streptococcus pneumoniae	1 x 10^6 CFU/mL
Streptococcus pyogenes	1 x 10^6 CFU/mL
Candida albicans	1 x 10^6 CFU/mL
Pooled human nasal wash	14% v/v
Bordetella pertussis	1 x 10^6 CFU/mL
Mycoplasma pneumoniae	1 x 10^6 CFU/mL
Chlamydia pneumoniae	1 x 10^6 CFU/mL
Legionella pneumophila	1 x 10^6 CFU/mL
Mycobacterium tuberculosis	1 x 10^6 CFU/mL
Pneumocystis jirovecii	1 x 10^6 CFU/mL
Pseudomonas Aeruginosa	1 x 10^6 CFU/mL
Staphylococcus Epidermidis	1 x 10^6 CFU/mL
Streptococcus Salivarius	1 x 10^6 CFU/mL

3.2 Interferences

The potentially interfering substances that may be found in the upper respiratory tract in symptomatic subjects (including over the counter medications). No false positive or false negative results were seen at the following concentrations.

Potentially Interfering Substances	Concentration
Blood (human)	5%
Mucin	5 mg/mL
Nasal GEL (NeilMed)	5% v/v
CVS Nasal Drops (phenylephrine)	15% v/v
Afrin (Oxymetazoline)	15% v/v
CVS Nasal Spray (Cromolyn)	15% v/v
Zicam Cold Remedy	5% v/v
Homeopathic (Alkalol)	10 % v/v
Sore Throat Phenol Spray	15% v/v
Tobramycin	3.3 mg/dL
Mupirocin	0.15 mg/dL
Fluticasone	5% v/v
Tamiflu (Oseltamivir phosphate)	500 mg/dL
Biotin	0.35 mg/dL
Methanol	0.15% w/v
Diphenhydramine	0.0774 mg/dL
Dextromethorphan	0.00156 mg/dL
Dexamethasone	1.2 mg/dL
Human Anti-mouse Antibody (HAMA)	600 ng/mL
Throat lozenges	1.5 mg/mL
Anbesol, Benzocaine 20%	5% v/v

4. Precision

For Intra-assay precision, 3 samples (negative, 2×LoD and 7×LoD) were tested 10 times with 3 batches test kit under the same conditions in one day. Totally 90 test results were recorded. The agreement percent of negative samples and positive samples were all 100%. For Inter-assay precision, 3 samples (negative, 2×LoD and 7×LoD) were test 2 times per day by three batches test kit, for totally 5 days by four researchers (A, B, C, D) at two laboratories. Totally 360 test results were recorded. The agreement percent of negative samples and positive samples were also 100%.

DESCRIPTION OF SYMBOLS USED

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limit	IVD	In vitro diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community
	Keep away from sunlight		Do not use if package is damaged
REF	Catalogue number		Keep dry
	For self-testing	CE 1434	CE mark
UK RP	UK Responsible Person		

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn overseas@getein.com.cn
Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054

UK RP CMC Medical Devices Ltd
Add: Office 32 19-21 Crawford Street, London, W1H 1PJ, United Kingdom
Tel: +442 074 594243 (UK)
E-mail: ukrp@cmcmedicaldevices.co

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Specification (N)	REF
1 T/kit	CG20615
2 T/kit	CG206152
3 T/kit	CG206153
5 T/kit	CG206155
6 T/kit	CG206156
7 T/kit	CG206157
8 T/kit	CG206158
9 T/kit	CG206159
10 T/kit	CG2061510
12 T/kit	CG2061512
15 T/kit	CG2061515
20 T/kit	CG2061520
25 T/kit	CG2061525