BioGerm SARS-CoV-2 Antigen Self Test Instructions for use

[Product Name]
BioGerm SARS-CoV-2 Antigen Self Test
[Package Specification] 1 test/kit;5 tests/kit;20 tests/kit
[Intended Use]
BioGerm SARS-CoV-2 Antigen Self Test is an in vitro, visually read test for the qualitative determination of SARS-CoV-2 antigen in human anterior nasal swab. The novel coronaviruses belong to the β-coronavirus genus and is similar with the SARS in 2003 and MERS in 2012.The genome of Coronavirus encodes four structural proteins including Spike (S) protein, Envelope (E) proteins, Membrane (M) protein and Nucleocapsid (N). This product is intended for detection of nucleocapsid protein of SARS-CoV-2 from individuals to aid in the diagnosis of SARS-CoV-2 infection.
[Principle]
BioGerm SARS-CoV-2 Antigen Self Test adopts the solid phase colloidal gold immunochromatographic technology for the qualitative determination of SARS-CoV-2 antigen in human anterior nasal swab. The gold SARS-CoV-2 antibody conjugate are coated to the conjugate pad in advance. The test line (SARS-CoV-2 antibody), and the control line (antibodies against mouse IgG) are pre-coated on the surface of Nitrocellulose (NC) membrane. When the specimen is added to the sample pad, it migrates through the conjugate pad, the gold SARS-CoV-2 antibody conjugate - SARS-CoV-2 antigen - SARS-CoV-2 antibody complex is formed and test line T will be visible in the strip if there are enough SARS-CoV-2 antigen in the specimen (Positive); If the specific SARS-CoV-2 antigen are absent, or present at a very low level, no test line appears (Negative).
[Contents]

Components	Spec. & Qty			Content
	ZC-MY-001-01	ZC-MY-001-05	ZC-MY-001-20	
Test card	1 cassette	5 cassettes	20 cassettes	The gold SARS-CoV-2 antibody conjugate are coated to the conjugate pad in advance. The test line (SARS-CoV-2 antibody), and the control line (antibodies against mouse IgG) are pre-coated on the surface of Nitrocellulose (NC) membrane.
Extraction buffer	1 tube	5 tubes	20 tubes	Phosphate buffer
Disposable Swab	1	5	20	/
Disposable Bag	1	5	20	/

Note:
① *The components of different batches cannot be used interchangeably.*

② ***Swab Manufacturer 1****: certified by* ***CE 0197****(No.DD60151787 0001) :*

Shenzhen KangDaAn Biological Technology Co., Ltd.
East-1, 3rd floor, Building 2, Shunheda factory
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P.R. China

EC REP **Share Info Consultant Service LLC Repräsentanzbüro**
Heerdter Lohweg 83, 40549 Düsseldorf

③ ***Swab Manufacturer 2****: certified by* ***CE 0123****(No.02S 042464 0034 Rev.00):*

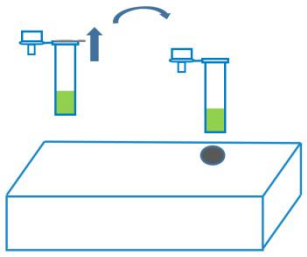
Zhejiang Gongdong Medical Technology Co., Ltd.
No.10, Beiyuan Ave., Huangyan,318020 Taizhou,
Zhejiang, PEOPLE'S REPUBLIC OF CHINA

EC REP **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestrasse 80, 20537 Hamburg, Germany

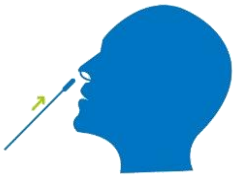
[Storage Conditions and Shelf life]
1. The test cassettes and the extraction buffer must be stored at 2℃~30℃ until expiration date. The shelf-life is 18 months.
2. After opening the test card, use it within 1 hour.
3. Do not use frozen or expired devices.
4. Production date and expiry date please refer to packing label.

[Specimen requirement]
1. Human anterior nasal swab is validated to be used with this assay.
2. The sample release solution provided in this kit should be used for processing as soon as possible after the sample is collected. If it cannot be processed in time, it can be stored for 1 hours at normal room temperature, or 4 hours at 2℃~8℃.

[Sample Preparation Procedure]



① Tear off the aluminum foil from the mouth of the extraction buffer tube without squeezing it. Put the tube into the dashed hole in the box.

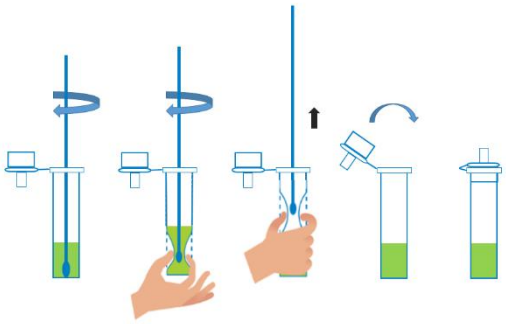


② Insert a disposable nasal swab into one nostril carefully. Gently push the swab up to 2.5 cm(1 inch) deep into the nostril.

③ Rotate the swab 5 times against the mucosa inside the nostril to ensure sufficient specimen collection.

④ Using the same swab, repeat this process in the other nostril to ensure that an adequate sample is collected from both nasal cavities.

⑤ Withdraw the swab from the nasal cavity. The sample is now ready for preparation. Put the swab front end into extraction tube

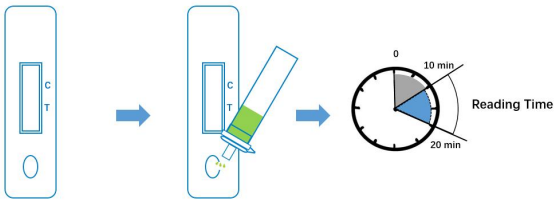


⑥ Insert the swab into the tube and swirl it for 30 seconds. Then rotate the swab at least 5 times while squeezing the sides of the tube.

⑦ Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

⑧Screw the dropper cap firmly onto the extraction buffer tube containing the sample. Mix thoroughly by swirling or flicking the bottom of the tube.

[Test Procedure]
PLEASE USE IN STRICT ACCORDANCE WITH THE INSTRUCTIONS FOR USE.
Equilibrate all specimens and the devices to room temperature before testing (at least 30 minutes).



1.Tear the aluminum foil bag, take out the test card, lay it flat and record the corresponding sample information.

2.Add 3 drops of the processed sample to the sample hole of the test card.

3.Wait for the colored line(s) to appear. The result should be read at 10~20 minutes.

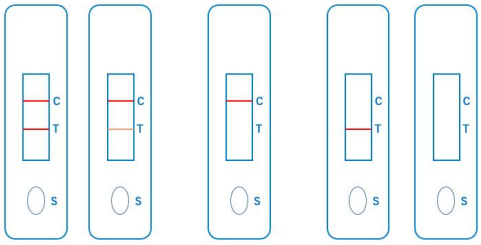
Finally, remove all the waste into the Disposable Bag, tighten the tie and put into the rubbish bin.

[Interpretation of Results]

Positive: Visible reddish-purple bands appear both at the Control Line and the Test Line of the cassette. Any Test Line, even very faint, is positive. It indicates a positive result for the novel coronavirus antigen in the specimen.

Negative: A visible reddish-purple band appears only at the Control Line of the cassette. It indicates that the concentration of the novel coronavirus antigen is zero or below the detection limit of the test.

Invalid Result: A test is invalid if the Control Line is not present at all, whether the Test Line is present or not. Repeat test with a new test card.



Positive Negative Invalid Result

Suggestions:

1. In the event of a positive test result:
- There is currently a suspicion of SARS-COV-2 infection
- Immediately contact a doctor/family doctor or the local health authority
- Comply with local self-insulation guidelines
- The test result should be confirmed by a professional laboratory.
2. In case of a negative test result:
- Continue to comply with all applicable rules regarding contact with others and protective measures.
- An infection may be present even if the test is negative.
- In case of suspicion, repeat the test after 1 - 2 days, as the coronavirus cannot be detected accurately in all phases of an infection.
3. In case of an invalid test result:
- Possibly caused by faulty test.
- Repeat the test
- If test results remain invalid, contact a doctor or SARS-COV-2 test center.

[Disposal of the product]

1.All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

2.The used cassette should be discarded according to federal, state, and local regulations.

[Quality Control]

The test card is equipped with quality control line, which will be purple red when the test is completed. If the quality control line has no color after the test, the test result cannot be used.

[Limitations]

1. This product is intended for detection of SARS-CoV-2 Antigen from individuals to aid in the diagnosis of SARS-COV-2 infection. The assay can be used for clinical reference and should not be the only basis for the diagnosis and treatment. The clinical management of patients should be considered in combination with patients' symptoms and medical history, other laboratory tests, treatment response, epidemiology and other information.
2. Due to the operation and the sample collection, the result may be suspected, at this time repeated testing should be done to ensure consistent results.
3. A false negative test result may be caused by low concentration of SARS-CoV-2 antigens in the sample so the possibility of infection with SARS-CoV-2 cannot be excluded. Therefore, the results obtained with the BioGerm SARS-CoV-2 Antigen Self Test should be used in conjunction with clinical findings to make an accurate diagnosis.
4. Inadequate specimen collection or improper sample handling/transport may yield a false negative result.
5. The negative results of patients with symptoms more than 7 days should be treated with caution and confirmed by a professional laboratory. Used for clinical management when necessary.

[Performance Characteristics]

1. Diagnostic specificity and sensitivity

BioGerm	PCR		total
	Positive	Negative	
Positive	103	1	104
Negative	3	315	318
Total	106	316	422

The tests gave the following results:

- Diagnostic sensitivity (positive coincidence rate) =103/106 ×100% =97.17% (95% CI: 92.01-99.03%)
- Diagnostic specificity (negative coincidence rate) =315/316 ×100% =99.68% (95% CI: 98.23-99.94%)
- Total coincidence rate =418/422 ×100% =99.05% (95% CI: 97.59-99.63%)

2. Limit of detection（LoD）

LoD studies determined the lowest detectable concentration of SARS-CoV-2 at which ≥95% of all replicates test positive. The results show that the LoD is $2\times10^2 TCID_{50}$/mL.

3. Analytical specificity

Endogenous interference: There is no endogenous interference found when tested at the concentration of presented in the table below.

Potential Cross Interference	Test Concentration	Interference
Tobramycin	10mg/ml	No
Histamine Hydrochloride	10mg/ml	No
Phenylephrine	10mg/ml	No
Oxymetazoline	0.1mg/ml	No
Meropenem	5mg/ml	No
Beclomethasone	0.1mg/ml	No
Dexamethasone	0.5mg/ml	No
Flunisolide	10mg/ml	No
Triamcinolone acetonide	10mg/ml	No
Budesonide	0.5mg/ml	No
Mometasone	10mg/ml	No
Fluticasone	0.5mg/ml	No
Sodium chloride	10mg/ml	No
Ceftriaxone	10mg/ml	No
alpha interferon	5mg/ml	No
Zanamivir	0.1mg/ml	No
Ribavirin	50mg/ml	No
Oseltamivir Phosphate	50mg/ml	No
Peramivir	5mg/ml	No
Lopinavir	5mg/ml	No
Ritonavir	10mg/ml	No
Abidor	10mg/ml	No
Levofloxacin	5mg/ml	No
Azithromycin	10mg/ml	No
Mucin	0.5mg/mL	No
Blood sample	dilute 10 times	No
EDTA anticoagulated plasma	dilute 10 times	No

Cross-reactivity evaluation: There is no cross-reactivity found when tested with various potentially interfering viruses or cross-reactive samples at the concentration of presented in the table below.

Cross-reactant/interferant analyte	Strain	Titer ($TCID_{50}$)
Human coronavirus	229E	2.20×10^8
Human coronavirus	NL63	$4,68 \times 10^4$
Human coronavirus	OC43	3.80×10^5
MERS-CoV	Florida/USA-2_Saudi Arabia_2014	$1,17 \times 10^5$
Adenovirus Type 1	Species C	3.80×10^5
Adenovirus Type 2	Species C	1.05×10^5
Adenovirus Type 11	Species B	1.02×10^7
Enterovirus Type 68	2014 Isolate	2.10×10^5
Human Metapneumovirus (hMPV) 16 Type A1	IA10-2003	3.80×10^5
Parainfluenza Virus Type 1	PREDICT_SNAH0005	2.52×10^5

Parainfluenza Virus Type 2-1	1/2015 Isolate #4	1.51 x 10^5
Parainfluenza Virus Type 2-2	1/2015 Isolate #3	2.52 x 10^5
Parainfluenza Virus Type 3	4/2015 Isolate #2	3.39 x 10^6
Parainfluenza Virus Type 4B	HPIV4b/Seattle/USA/SC 9597/2019	3.80 x 10^5
Respiratory Syncytial Virus Type A	Isolate: 2006	2.10 x 10^5
Respiratory Syncytial Virus Type B	12/2014 Isolate #1	1.55 x 10^4
Rhinovirus Type 1A	HRV-1A_P25	1.70 x 10^5
Influenza A Virus H3N2	HK/8/68	1.51 x 10^5
Influenza A Virus H1N1	Brisbane/59/07	1.51 x 10^5
Influenza A Virus H1N1pdm	Canada/6294/09	4.57 x 10^5
Influenza B Virus	Washington/02/19	2.52 x 10^5
Influenza B Virus	Texas/6/11	2.52 x 10^5
Influenza B Virus	Alabama/2/17	3.16 x 10^5
Staphylococcus epidermidis	PCI 1200	4.90 x 10^9
Staphylococcus epidermidis	Fussel	5.10 x 10^9
Staphylococcus epidermidis	1955 Castellani	6.30 x 10^9
Bordetella pertussis	Walker	2.71 x 10^9
Bordetella pertussis	Sato and Arai	2.02 x 10^9
Legionalle pneumophila	Philadelphia-1	4.50 x 10^9
Legionalle pneumophila	Los Angeles-1	1.17 x 10^9
Streptococcus pyogenes	SF130, T1	1.37 x 10^8
Streptococcus pyogenes	S. Koshimura, Sv	9.30 x 10^7
Streptococcus pyogenes	NCCP 11610	1.08 x 10^8
Haemophilus influenzae	TD-4	7.77 x 10^7
Haemophilus influenzae	Maryland	1.41 x 10^8
Haemophilus influenzae	Pittman 576	1.23 x 10^8
Mycobacterium tuberculosis	BCGT, tice	4.69 x 10^8
Streptococcus pneumoniae	SV1	4.05 x 10^8
Streptococcus pneumoniae	Jorgensen262	3.80 x 10^7
Streptococcus pneumoniae	Gyeonggi	2.70 x 10^8
Mycoplasma pneumoniae	Eaton Agent, FH	>10^6 cells/ml
Mycoplasma pneumoniae	M129-B7	>10^6 cells/ml
Candida albicans	NIH 3147	6.53 x 10^8
Candida albicans	132	2.39 x 10^8
Candida albicans	806M	2.55 x 10^8
Pseudomonas aeruginosa	Boston 41501	1.90 x 10^9
Pseudomonas aeruginosa	Schutze	5.70 x 10^9
Pseudomonas aeruginosa	PAO1	5.17 x 10^9
Streptococcus salivarius	275	7.89 x 10^8
Streptococcus salivarius	21367	7.37 x 10^8

4. Precision experiments were carried out by different people, in different places and at different times, and the results met the performance requirements of the product.
5. **Hook Effect**
   The highest concentration of inactivated SARS-CoV-2 stock available（3×$10^7$$TCID_{50}$/mL）was tested. There was no Hook effect detected.
6. **Genetic variants**
   In the 109 positive samples studied in clinical investigation, below genetic variants were detected:
   - 4 out of 4 samples of Alpha variant (B.1.1.7)
   - 3 out of 3 samples of Beta variants (lineage B.1.351)
   - 12 out 13 samples of Delta variant (B.1.617.2)
   - 23 out 23 samples of Omicron variant (B1.1.529)

[Warnings and Precautions]

1. This product is only used for in vitro diagnosis, and any form of in vivo use is prohibited.
2. This product is used for individuals 18 years and elder, teenagers under age should operate with the assistance of adults.
3. Incorrect reporting and false results may occur if not used in strict accordance with the instructions for use.
4. Patient samples and test cards should be handled as though they could transmit disease. Observe established precautions against microbial hazards.
5. All the test is single-use.
6. Desiccant in the aluminum foil bag is not allowed to be taken orally.
7. If the aluminum foil bag is damaged, it shall not be used.
8. Different batches of test cards and sample extraction solution should not be mixed.
9. If infection with SARS-CoV-2 is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities， specimens should be collected with appropriate infection control precautions for SARS-CoV-2 and sent to state or local health departments for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.
10. The sample extraction solution packaged in this kit contains saline, detergents and preservatives that will inactivate cells and virus particles. Samples eluted in this solution are not suitable for culture.
11. Sample extraction solution contains Tween-20 and ProClin 300. Warning; may cause an allergic skin reaction, causes serious eye irritation. Please rinse with plenty of water if the solution contacts skin or eyes.
12. Follow your national, regional, and local ordinances accordingly for waste disposal regulations.

[References]

[1] Kaden R. Early phylogenetic diversification of SARS-CoV-2: determination of variants and the effect on epidemiology, immunology, and diagnostics[J]. Journal of Clinical Medicine, 2020, 9(6) : 1615.
[2] Soebandrio Amin, Kusumaningrum Tina, Yudhaputri Frilasita A., Oktavianthi Sukma, Malik Safarina G., Myint Khin Saw Aye. Characteristics of children with confirmed SARS-CoV-2 infection in Indonesia[J]. Journal of Clinical Virology Plus, 2021, 1(3):

[Date of Issue] Version 05, 25 Sep 2022

[Explanation of the symbols used]

	**Caution**
	**Temperature limit at 2°C~30°C.**
LOT	**Batch code**
	**Date of manufacture**
IVD	**In vitro Diagnostic use Medical device**
	**Consult instructions for use**
	**Do not use if package is damaged**
	**Use by**
	**Contains sufficient for <n> tests.**
	**Do not reuse**
	**Manufacturer**
EC REP	**Authorised representative in the European Union**
CE 1434	**CE marking**
	**Keep dry**
REF	**Catalogue number**
	**Keep away from sunlight**

EC REP

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