SARS-CoV-2 Antigen (GICA) User Manual

【Product】

Name: SARS-CoV-2 Antigen (GICA)

【Intended Use】

Immunoassay for in vitro qualitative determination of SARS-CoV-2 antigens in human throat swab and nose swab sample.

The novel coronavirus SARS-CoV-2 is a positive-sense single-stranded RNA virus, belonging to betacoronaviruses. Its RNA sequence is approximately 30,000 bases in length. [1]The genome of SARS-CoV-2 encodes four structural proteins, known as the S (spike), E (envelope), M (membrane), and N (nucleocapsid) proteins; the N protein holds the RNA genome, and the S, E, and M proteins together create the viral envelope.

Spike protein, which is responsible for binding and membrane fusion of virus and host cell membrane receptor, mediates with human ACE2 to infect human respiratory epithelial cells.[2] Nucleocapsid protein is the most abundant protein in coronavirus. In the process of viral assembly, N protein binds to viral RNA and leads to the formation of spiral nucleocapsid. Nucleocapsid protein is a highly immunogenic phosphoprotein, which is related to viral genome replication and cell signaling.[3] Because of the conserved sequence and strong immunogenicity of N protein, N protein is often used as an immunoassay tool for coronaviruses.

SARS-CoV-2 antigens are recognized as a tool to confirm novel coronavirus pneumonia COVID-19.[4]

【Principle】

This test uses a sandwich immunodetection method. The antigens in the sample, bind to detector antibodies conjugate colloidal gold forming antigen-antibody complexes, and migrates onto nitrocellulose membrane to be captured by the other immobilized antibodies on detection line (T-Line). The red bind on T-Line indicating positive SARS-CoV-2 antigens. Under normal test conditions, the quality control area (C-Line) should be colored to indicate that the test is effective.

【Packing Specification and Components】

Components	model			
	10Tests / Kit	25Tests / Kit	50Tests / Kit	100Tests / Kit
Test Cartridge Nitrocellulose membrane (T line: SARS-CoV-2 antibody, C line: rabbit anti-chicken IgY antibody), Binding pad (Colloidal gold-labeled SARS-CoV-2 antibody and chicken IgY antibody), Sample pad (absorbent paper), All cartridges are individually sealed in an aluminum foil pouch containing a desiccant in a box.	10PCs	25PCs	50PCs	100PCs
Extraction Buffer Tris, EDTA-2Na, TritonX-100, SDS, NP40	10PCs	25PCs	50PCs	100PCs
Sterile Swab	10PCs	25PCs	50PCs	100PCs
Plastic Dropper	10PCs	25PCs	50PCs	100PCs
User Manual	1PCs	1PCs	1PCs	1PCs

Note：The components of different lot of reagent cannot change.

【Storage and Shelf Life】

Stored the reagent kits at 4~30°C, in sealed aluminium foil bag .

Shelf life: 18 months.

Open-bag shelf life: 1 hour. Especially under condition of high temp or high humidity, it should be used immediately after open the package.

Use the reagent kit before expiration date marked on the box.

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Location: Moldova

【Sample Requirements】

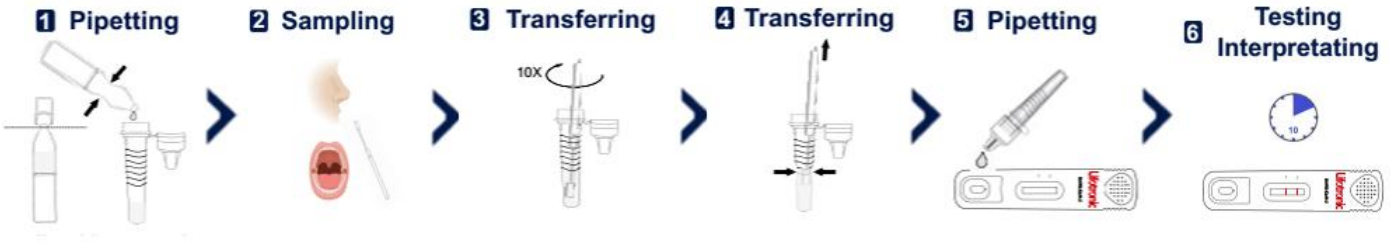
The test can be performed with throat swab and nose swab.

① For throat swab: The head is tilted slightly and the mouth is opened wide to reveal the pharyngeal tonsils on either side. Swab the base of the tongue, gently swab back and forth the pharyngeal tonsils on both sides of the subject at least 3 times, then swab up and down the posterior pharyngeal wall at least 3 times.

② For nose swab: Insert the swab into the nostril parallel to the palate. The swab depth should be equal to the distance from the nostril to the outer opening of the ear. Leave the swab in place for a few seconds to absorb the secretion. Slowly remove the swab as you rotate it.

【Test Procedure】

Please read the instruction for use carefully before performing the test.



① Unseal the reagent tube. Squeeze reagent tube to transfer the extraction buffer into plastic dropper.

② Collect specimen with a sterile swab.

③ Place swab into the extraction buffer and roll the swab ant least 10 times and squeeze the swab to extract the sample into the buffer.

④ Firmly squeeze the dropper to release all specimen into buffer while pulling out the swab.

⑤ Cap the dropper and squeeze it into pipette 5 drops of solution onto the sample hole.

⑥ Wait for 10~15 minutes at room temperature (10~30℃) and read the results. Do not read results after 20 minutes.

【Quality Control】

A procedural control is included in the test. A colored line appearing in the control region (C-Line) is considered an in ternal procedural control. It confirms sufficient specimen volume, adequate menbrance wicking and correct procedural technique.

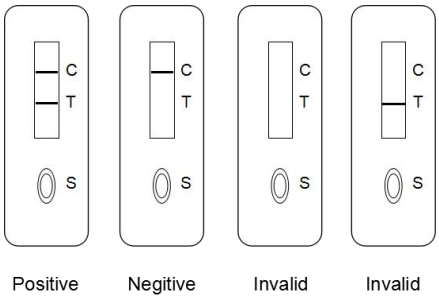
【Explanation of Test Results】

The results obtained from the detection of SARS-CoV-2 antigens can be explained as follows:

1. Positive Result: Colored bands appear at both test line (T-Line) and control line (C-Line). It indicates a positive result for the SARS-CoV-2 antigens in the specimen.

2. Negitive Result: Colored band appear at control line (C-Line) only. It indicates that the concentration of the SARS-CoV-2 antigens is zero or below the detection limit of the test.

3. Invalid Result: No visible colored band appear at control line after performing the test may have deteriorated. It is recommended that the specimen be re-tested.



【Limitation of Test Method】

1. The test results of this product are for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be combined with their symptoms, signs, medical history, other laboratory tests (especially pathogenic tests), treatment response, and epidemiology. And other information. A negative test result does not exclude the possibility of viral infection. The results of this test are an aided diagnosis, and appropriate clinical management is required in conjunction with clinical manifestations, medical history

and other diagnostic results.

2. Improper sampling, transportation, handling, and low levels of virus in samples can lead to false negatives.

【Performance Indicators】

1. Positive reference product compliance rate: The company's positive reference product compliance rate should be: 10/10.

2. Negative reference product compliance rate: The enterprise negative reference product compliance rate should be: 10/10.

3. Lowest Limit of Detection compliance rate: Limit of Detection reference L1,L2 should be positive, L3 can be positive or negative, L4and L5 should be negative.

4. Repeatability: Test 2 Enterprise Repeatability References (J1~J2), and each repeat for 20 times respectively, J1 should be negative, J2 should be positive.

5. Difference between batches: Take three batches of kits and repeat the test for Enterprise Repeatability References 10 times, J1 should be negative, J2 should be positive.

6. Analytical specificity

① Cross-reactivity

Evaluation was performed using positive samples of different pathogen antigen, SARS-CoV-2 detection is non-reactive with the following positive pathogen antigen samples:

Virus					
1	Corona virus - FCV(3A2)	8	Coxaievirus A2	15	HCMV-AD-169
2	Corona virus - FIP(2A4)	9	Coxaievirus A4	16	HSV-1 - F(3A20)
3	Influenza A virus H3N2 Hongkong	10	Coxakie virus B1 - conn5	17	HSV-2 - MS(4A6)
4	Influenza B virus B/Lee/40	11	Coxakie virus B3 – nancy (5A1)	18	Meales virus
5	Respiratory Syncytial virus A	12	Echovirus 6	19	Mumps virus
6	Adenovirus type1	13	Echovirus 9	20	Polio virus - sabin(3A4)
7	Adenovirus type7	14	Enterovirus 71	21	Rhinovirus - RV21
Bacteria					
1	*Chlamydia pneumoniae*	5	*Streptococcus pyrogenes*	9	*Mycoplasma pneumoniae*
2	*Haemophilus influenzae*	6	*Pseudomonas aeruginosa*	10	*Mycobacterium tuberculosis*
3	*Legionella pneumophila*	7	*Staphylococcus epidermis*	11	*Bordetella pertussis*
4	*Streptococcus pneumoniae*	8	*Staphylococcus salivarius*	12	*Candida albicans*

② Interference

There was no significant interference effect on from these substances.

No.	Interference materials	Conc.	No.	Interference materials	Conc.
1	Nasal sprays drop	20%	7	Analgesic (Acetaminophen)	10 mg/mL
2	Nasal corticosteroids	20%	8	Analgesic (Ibuprofen)	10 mg/mL
3	Homeopathic allergy relief medicine	20%	9	Povidone-iodine	1%
4	Mouth wash (Listerin)	5 mg/mL	10	Acetylsalicylic acid (Aspirin)	20 mg/mL
5	Antiviral drugs (Tamiflu; Oseltamivir)	5 mg/mL	11	Antibacterial (cefadroxil)	5 mg/mL
6	Whole blood	1%	12	Mucin (Porcine stomach)	0.5%

7. Clinical performance evaluation

SARS-CoV-2 Antigen (GICA) has demonstrated the following clinical performance results.

		Reference criteria		
		Positive	Negative	Total
SARS-CoV-2 Antigen (GICA)	Positive	228	9	237
	Negative	21	476	497
	Total	249	485	734

Clinical Sensitivity (positive coincidence rate) : 91.57%

Clinical Specificity (negative coincidence rate) : 98.14%

【Precautions】

1. Only for In-Vitro Diagnostic(professional use only) .
2. Please strictly follow the instructions in use manual. Test strip should be used within 1 hour once removed package, tested strip should be read timely after 15 minutes incubation finished, or the result will be invalid.
3. The resource material of test strip has been inactivated , and HBsAg, anti-HCV, anti-HIV(1&2), anti-TP has been tested negative which was approved by CFDA ; But there is no test method to be absolute safe. Since all the samples that are taken from human blood, the samples and test strips should be treated as potentially infectious source and disposed according to local regulation.

【Literature References】

1. Lu R, Zhao X, Li J et al. Genomic characterisation and epidemiology of 2019 novel coronavirus: implications for virus origins and receptor binding. The Lancet 2020; 395: 565-574.
2. Wrapp D, Wang N, Corbett KS et al. Cryo-EM structure of the 2019-nCoV spike in the prefusion conformation. Science 2020; eabb2507.
3. Laude H, Masters PS. The Coronavirus Nucleocapsid Protein. In Siddell SG (ed) The Coronaviridae. Boston, MA: Springer US 1995; 141-163.
4. Diagnosis and Treatment Schemes for Novel Coronavirus Pneumonia COVID-19 (7th Trial Edition). General Office of NHC, General Office of NATCM of P. R. China, 2020.
http://www.gov.cn/zhengce/zhengceku/2020-03/04/content_5486705.htm

【Symbol explanation】

Symbol	Title of symbol
	manufacturer
	Authorized representative in the European Community
	Date of manufacture
	Use-by date
	Batch code
	Temperature limit
	Consult instructions for use
	In vitro diagnostic medical device
	Contains sufficient for <n> tests
	Catalogue number
	CE marking of conformity

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【Version and Modification Date】

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