LEPU MEDICAL

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SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)

[Packing Specifications]

1 test/kit, 5 tests/kit, 10 tests/kit, 25 tests/kit, 50 tests/kit

No.	Catalogue number	Spec.
1	CG2701	1 test / kit
2	CG2705	5 tests / kit
3	CG2710	10 tests / kit
4	CG2725	25 tests / kit
5	CG2750	50 tests / kit

[Product Name]

Generic Name: SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)

[Intended Use]

This product is used to qualitatively detect the novel coronavirus (SARS-CoV-2) antigen in clinical specimens (nasal swabs and nasopharyngeal swabs).

[Introduction]

Coronavirus, as the broad family of viruses, is a single strand plus RNA virus with an envelope. The virus is known to cause major diseases such as cold, Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The core protein of SARS-CoV-2 is N protein (Nucleocapsid), which is a protein component inside the virus. It is relatively conservative among β-coronaviruses and is commonly used as a diagnostic tool for coronavirus. As the key receptor for SARS-CoV-2 to enter cells, ACE2 is significant for the study of viral infection mechanisms.

[Principle]

The current test kit is based on specific antibody-antigen reaction and immunoassay technique. The test card contains a gold-labeled novel coronavirus N protein monoclonal antibody pre-coated on the binding pad and a paired novel coronavirus N protein monoclonal antibody fixed in the test line (T) and corresponding antibodies in the quality control line (C).
During the test, the N protein in the specimen binds to the gold-labeled novel coronavirus N protein antibody pre-coated on the binding pad, and the conjugate moves upward under the capillary effect, and then is trapped by N protein monoclonal antibody conjugate fixed in the Test Line (T). The higher the N protein content in the specimen, the more conjugates are trapped, and the darker the color of the Test Line (T). If there is no novel coronavirus in the specimen or the virus content is below the detection limit, no color appears in the Test Line (T). A purple-red band will appear in the Control Line (C) regardless of whether there is a virus in the specimen. The purple-red band that appears in the Control Line (C) is the criteria for determining whether there is enough specimen and whether the chromatography process is normal.

[Main Components]

The product includes cards, instruction manual, swabs and sample treatment solution. Each reagent kit contains 1 novel coronavirus (SARS-CoV-2) antigen test card and 1 bag of desiccant.

Disposable sterile swab information:
Nasal Swab or Nasopharyngeal Swab could be provided based on customer's requirement.

	Spec.	Application
Disposable sterile swab information	4.7 mm	Nasal swab
	3.0 mm	Nasopharyngeal swab

CE 0123 MDD 93/42/EEC
Manufacturer 1: Zhejiang Gongdong Medical Technology Co., Ltd.
Beicheng Industrial Area 318020 Huangyan China

CE 0197 MDD 93/42/EEC
Manufacturer 2: Jiangsu Changfeng Medical Industry Co., Ltd.
Touqiao Town,Guangling District Yangzhou 225109 Jiangsu China

CE 0197 MDD 93/42/EEC
Manufacturer 3: Shenzhen KangDaAn Biological Technology Co., Ltd.
Liuxiandong industrial zone,Xili street Nanshan district,Shenzhen
518055 Guangdong China

CE 0413 MDD 93/42/EEC
Manufacturer 4: Medico Technology Co., Ltd.
Zhangbei Industrial Park, Longcheng Street, Longgang district, Shenzhen, 518100 Guangdong, China

CE 0197 MDD 93/42/EEC
Manufacturer 5: Goodwood Medical Care Ltd.
1-2 Floor, 3-919, Yongzheng Street, Jinzhou District, Dalian
116100 Liaoning, China

Spec.	Test card	Instruction manual	Sample treatment solution		Swabs
			Option A	Option B	
1 test / kit	1 test	1	300 μL ×1	300 μL ×1	1 piece
5 tests / kit	5 tests	1	1 mL ×1	300 μL ×5	5 pieces
10 tests / kit	10 tests	1	2 mL ×1	300 μL ×10	10 pieces
25 tests / kit	25 tests	1	3 mL ×2	300 μL ×25	25 pieces
50 tests / kit	50 tests	1	5 mL ×2	300 μL ×50	50 pieces

The test card consists of gold-labeled pad (sprayed with colloidal gold-labeled SARS-CoV-2 N protein monoclonal antibody), specimen pad, nitrocellulose membrane (T coated with SARS-CoV-2 N protein monoclonal antibody; C line coated with goat-anti-mouse antibody), absorbent paper, and hydrophobic hard card.

[Storage Conditions and Validity Period]

Stored in a dry and dark place with a room temperature of 4-30℃, valid for 18 months.
The validity period of the test card (1 test) is 1 hour after opening its inner package.
See package label for date of manufacture and expiration.

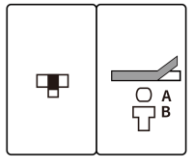
[Specimen Requirements]

This test kit is suitable for testing human nasal swab specimens or nasopharyngeal swab specimen:
Specimen collection: During the collection process, relevant personnel should be well protected to avoid direct contact with the specimen. In case of accidental contact, timely disinfection should be carried out and necessary measures should be taken.
Nasal swab specimen collection: During sampling, the nasal swab head should be entirely inserted into the nasal cavity and gently rotated 5 times. When it was removed, specimen should be taken in the same way in the other nasal cavity to ensure the collection of enough specimens.
Nasopharyngeal swab specimen collection: During sampling, tilt the patient's head back slightly about 45-70 degrees. The nasopharyngeal swab head should be inserted from the nostril, reach depth equal to distance from nostrils to outer opening of the ear, gently rotated 5 times. and leave the swab in place for 3 seconds to absorb secretions. After sampling, slowly remove swab while rotating it.
Specimen preservation: After the specimen are collected, please complete the test within 1 hour.
Specimen should be tested after returning to room temperature.

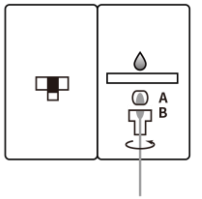
[Test Method]

You must read the instruction manual completely before performing any test, and use the reagents and specimens after returning to room temperature.
1. Refer to the standard nasal swab or nasopharyngeal swab specimen collection procedure to collect specimen.
2. Remove the covering layer of double-sided adhesive to prevent liquid splashing before adding liquid to test kit.
3. Insert the swab head into the well A from the bottom of the well B, add 6 drops of the sample treatment solution, and rotate it clockwise and counterclockwise twice in the sample treatment solution.
4. In the process of testing, the test card should be placed on a horizontal table, and it should not be moved.
5. Turn the left area upside down so that both sides fit together completely, start timing, and wait for the appearance of purple-red band. Test results should be read within 15-20 minutes.

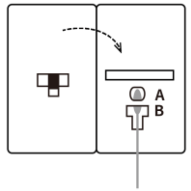
Remove the covering layer of double-sided adhesive to prevent liquid splashing



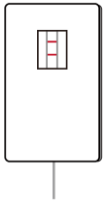
Insert the swab head into the well A from the bottom of the well B, add 6 drops of the sample treatment solution, and rotate it clockwise and counterclockwise twice in the sample treatment solution



Turn the left area upside down so that both sides fit together completely, and start timing.

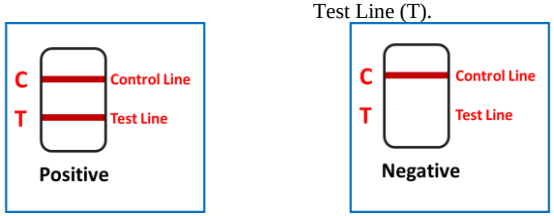


Wait for the appearance of purple-red band. Test results should be read within 15-20 minutes

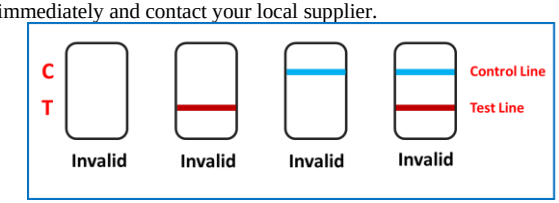


[Explanation of Test Results]

- Positive (+): A purple-red band appears in the Control Line (C) and Test Line (T).
- Negative (-): Only the Control Line (C) shows a purple-red band. No purple-red band appears in the Test Line (T).



- Invalid: If “no purple-red band appears in Control Line (C)” and “a blue band appears in the Control Line (C)”, it indicates that the operation process is incorrect or the test paper has been damaged. In this case, please read the instruction manual carefully again and retest with a new test paper. If the problem persists, please stop using this batch of products immediately and contact your local supplier.



[Limitations of the testing method]

1. The test results of this product should be combined with other clinical information and comprehensively judged by physicians, and should not be used as the only criterion.
2. This product is only used to determine the novel coronavirus (SARS-CoV-2) antigen in the specimen.

[Product Performance Index]

1. Description

1.1 Appearance

The test card should be clean and complete, free of burrs, damage and contamination; the material should be firmly attached; the label should be legible and undamaged. The specimen buffer should be clear and transparent, free of impurities and floccules.

1.2 Liquid migration speed

The liquid migration speed should not be less than 10 mm/min.

1.3 Film strip width

The width of the film strip of the test card is ≥ 2.5mm.

1.4 Sample treatment solution volume

The volume of the sample treatment solution is not less than the labeled value.

2. Limit of Detection

2.1 Determination of the Limit of Detection

Through gradient dilution of SARS-CoV-2 recombinant N protein, the result showed that the positive rate was between 90% and 95% under $1/(2\times10^6)$ dilution condition, so the dilution ratio of lowest detection limit was finally determined to be $1/(2\times10^6)$, and the corresponding SARS-CoV-2 recombinant N protein concentration was about 1ng/ml through calculation. LOD virus concentration is 200TCID50/ml.

2.2 Verification of the Limit of Detection

Detect the sensitivity reference substance and the positive rate should not be less than 90%.

3. Accordance rate of negative reference substance

Test the enterprise negative reference substance and the negative rate should be 100%.

4. Accordance rate of positive reference substance

Test the enterprise positive reference substance and the positive rate should be 100%.

5. Repeatability

Test the enterprise repeatable reference substances, and the results should all be positive and uniform in color.

6. Analysis of specificity

6.1 Cross-reaction: This product does not cross-react with endemic human coronavirus OC43, endemic human coronavirus HKU1, endemic human coronavirus NL63, endemic human coronavirus 229E, influenza A virus, influenza B virus, respiratory syncytial virus, adenovirus, Epstein-Barr virus, measles virus, cytomegalovirus, rotavirus, norovirus, mumps virus, varicella-zoster virus, mycoplasma pneumoniae, metapneumovirus, staphylococcus aureus, staphylococcus epidermidis, pseudomonas aeruginosa, streptococcus pneumoniae and high concentration of N protein.

6.2 Interfering substances: When mucin concentration ≤5mg/mL and human whole blood ≤2%, there will be no interference with the test results of this product; the following drugs have no effect on the test results of this product under the verification concentration, including quinine, zanamivir, ribavirin, oseltamivir, peramivir, lopinavir, ritonavir, arbidol, acetaminophen, acetylsalicylic acid, ibuprofen, levofloxacin, azithromycin, ceftriaxone, meropenem, tobramycin, histamine hydrochloride, phenylephrine, oxymetazoline, sodium chloride (containing preservatives), beclomethasone, dexamethasone, flunisolide, triamcinolone acetonide, budesonide, mometasone, fluticasone, strepsils (flurbiprofen 8.75mg), and Lozenges (mint).

7. Clinical performance

A total of 508 clinical specimens based on nucleic acid assay (PCR) were collected, including 243 positive specimens and 265 negative specimens. After comparing this product with nucleic acid assay (PCR) through the collected clinical samples, the results are summarized as follows:

SARS-CoV-2-Antigen Rapid Test Kit	Nucleic acid assay (PCR)	
	Positive	Negative
Positive	231	1
Negative	12	264
Analysis of sensitivity	95.06% (95%CI: 91.57%~97.15%)	/
Analysis of specificity	/	99.62% (95%CI: 97.89%~99.93%)

Performance against the Comparator Method - by Cycle Threshold Counts.

SARS-CoV-2-Antigen Rapid Test Kit	Nucleic acid assay (PCR)	
	Positive (Ct≤32)	Positive (Ct≤25)
Positive	227	202
Negative	8	3
Sensitivity	96.60% (95%CI: 93.43%~98.27%)	98.54% (95%CI: 95.79%~99.50%)

[Precautions]

1. This test card is only suitable for professionals as an in vitro diagnostic aid. Do not use expired products.
2. Do not refrigerate or use after the expiration date (see packaging bag for expiration date).
3. The temperature and humidity of the experimental environment should be avoided to be too high, the reaction temperature should be 15-30°C and the humidity should be below 70%.
4. The packaging bag contains desiccant, do not take.
5. When testing, please wear protective clothing, gloves and goggles.
6. Please do not use the test card with damaged card bag packaging, unclear marking or beyond the expiration date.
7. Dispose of used specimens, test cards and other waste in accordance with relevant local laws and regulations.
8. A test card should be used within 1 hour after it is taken out from the aluminum foil bag.
9. Users shall take samples according to the instruction manual.
10. Remove the covering layer of double-sided adhesive to prevent liquid splashing before testing.
11. Do not drop the sample treatment solution into the wrong well
12. In the process of testing, the test card should be placed on a horizontal table, and it should not be moved.

[Explanation of Symbols]

	DO NOT USE IF PACKAGE IS DAMAGED		CONSULT INSTRUCTIONS FOR USE
	DO NOT REUSE		USE-BY DATE
4℃ 30℃	TEMPERATURE LIMIT		DATE OF MANUFACTURER
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE	LOT	BATCH CODE
	KEEP AWAY FROM SUNLIGHT		KEEP DRY
	MANUFACTURER	CE	CE MARK
EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	REF	CATALOGUE NUMBER

[Basic Information]

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[Date of Approval and Revision of the Manual]

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