Instruction for SARS-CoV-2 Antigen Test Kit (Colloidal Gold)

IVD CE

1. Product Name

Generic name: SARS-CoV-2 Antigen Test Kit (Colloidal Gold)

Trade name: SARS-CoV-2 Antigen

2. Package

Specification 1: 1T/kit REF: 52104081

Specification 2: 5T/kit REF:52104081

Specification 3: 10T/kit REF:52112079

Specification 4: 25T/kit REF:52025096

Specification 5: 50T/kit REF: 52027077

3. Intended Use & Indication

Genrui SARS-CoV-2 Antigen Test Kit (Colloidal Gold) is an immunochromatographic assay for rapid, qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigen from the nasopharyngeal swab or opharyngeal swab specimen. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2.

The test provides preliminary test results. Negative results cannot exclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decision.

For in vitro diagnostic use only. For professional use only.

4. Test Principle

This product uses highly specific antibody-antigen reaction and colloidal gold immunochromatographic technology. The reagent contains anti- SARS-CoV-2 monoclonal antibodies pre-fixed on the test area (T) on the membrane and anti SARS-CoV-2 monoclonal antibody gold-labeled conjugate labeled on the gold label pad.

During the test, the processed sample to be tested is dropped into the reagent loading place. When the sample contains SARS-CoV-2 antigen, the SARS-CoV-2 antigen in the sample is first combined with the anti- SARS-CoV-2 antibody labeled with colloidal gold, and then the conjugate is chromatographed upward under the capillary effect, and it will be pre-immobilized on another membrane on the membrane. When the anti- SARS-CoV-2 monoclonal antibody binds, a purple-red band will appear in the test area (T). If there is no SARS-CoV-2 antigen in the sample, there will be no purple-red band in the test area (T). Regardless of whether the novel coronavirus antigen is present in the sample, a purple-red band will appear in the quality control area (C). The purple-red band in the quality control area (C) is the standard for judging whether there are enough samples and whether the chromatography process is normal, and it also serves as an internal control standard for reagents.

5. Precaution

(1) This kit is for in vitro diagnostic use only.

(2) All specimens should be treated as capable of transmitting diseases. Use appropriate precautions in the collection, handling, storage and disposal of patient samples and used kit contents.

(3) Wear appropriate personal protective equipment (e.g. protective gloves, medical mask, goggles and lab coat) when handing the contents of this kit.

(4) If the virus sampling solution is used for specimen processing, it can be directly detected without using extraction buffer.

(5) Proper specimen collection, storage and transport are critical to the performance of this test.

(6) Discard after first use. The sample extraction tube, the dropper and the test device cannot be used more than once.

(7) Avoid excessively high temperature in the experiment environment. Test cards and detection buffer stored at low temperature need to be returned to room temperature before opening to avoid moisture absorption.

(8) Do not touch the reaction area of test strip.

(9)Do not use test kit beyond the expiration date.

(10)Do not use the kit if the pouch is punctured or not well sealed.

(11)Testing should be applied by professionally trained staff working in certified laboratories or clinics at which the sample(s) is taken by qualified medical personnel.

(12) The test result should be interpreted by the physician along with clinical findings and other laboratory test results.

(13) Disposal of the diagnostic: All specimens and the used-kit has the infectious risk. The process of disposing the diagnostic must follow the local infectious disposal law or laboratory regulation.

6. Main Components& Additional required equipment

The test kit consists of test card, Sample diluent, Extraction tube and the instruction.

Component	Unpacked					Subpackaged				
Kit Size (# of Tests)	1	5	10	25	50	1	5	10	25	50
Test Card (#)	1	5	10	25	50	1	5	10	25	50
Sample diluent	1 × 6mL	1 × 6mL	1 × 6mL	2 × 6mL	4× 6mL	1× 0.4mL	5× 0.4mL	10× 0.4mL	25× 0.4mL	50× 0.4mL
Extraction tube	1	5	10	25	50	/	/	/	/	/

(1) The test card consists of the card housing and test strip. Test strip contains a sample pad, glass fiber (Colloidal gold labeled anti-SARS-CoV-2 monoclonal antibody), nitrocellulose (NC) membrane (test area (T) is coated with anti-SARS-CoV-2 monoclonal antibody, quality control area (C) is coated with goat anti-mouse antibody, absorbent paper and PVC plate.

(2) Sample diluent: the main component is phosphate buffer (PBS).

7. Accessories Required But Not Provided

(1) Nasopharyngeal swab or oropharyngeal swab

(2) Viral Transport Media (VTM)

(3) Tongue depressor

(4) Extraction tube holder

(5) Timer

(6) Personal protective equipment, such a protective gloves, medical mask, goggles and lab coat.

(7) Appropriate biohazard waste container and disinfectants.

8. Special storage &Transport conditions

(1) The test kit can be stored at 2-30℃, aluminum foil bag in a sealed state is valid for 18 months , once opened, it is valid for 1 hour when the humidity is less than 65%. Make sure to use the product immediately after opening the packing bags when humidity is higher than 65%. The opening period of sample solution is 1 month. And the production date is shown in the outer packing box.

(2) Transport at 2-30℃.

9. Sample Requirements

(1) Both human oropharyngeal swab and nasopharyngeal swab can be used for testing.

(2) The sample should be used as soon as possible after collection. If it cannot be used immediately, it must be stored at 2-8°C within 3 days. For long-term storage, it must be stored frozen below -70°C.

(3) The samples must be returned to room temperature (18-28°C) before testing. The frozen samples must be completely thawed, rewarmed, and mixed before use.

10. Specimen Collection And Preparation

The test can be performed with oropharyngeal swab and nasopharyngeal swab specimen.

(1) According to standard nasopharyngeal swab or oropharyngeal swab specimen collection procedure.

(2)nasopharyngeal swab specimen collection: Tilt patient's head back 70 degrees. Insert swab into nostril (Swab should reach depth equal to distance from nostrils to outer opening of the ear). Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it.

(3) Oropharyngeal swab specimen collection: Insert swab into the posterior pharynx and tonsillar areas. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.

(4) It is recommended that the specimen is tested at the time of specimen collection. If the specimens are not tested immediately, they should be stored in a dry, disinfected tube and tightly sealed (Place tip of swab into a tube and snap/cut off the

applicator stick). They may be stored at 2~8℃ for up to 8 hours, or they may be stored at -70℃ for a long time.

NOTE: If the viral transport medium (VTM) is needed for transporting samples, the dilution ratio for samples should be controlled at minimum level, since large diluent volume could result in false negative. If possible, the diluent volume should not exceed 1 mL (however, the tip of the swab must be immersed in the liquid). Taking influenza virus as a reference, the nasopharyngeal swab or oropharyngeal swab in the VTM can stay stable for up to 72 hours at 2 ~ 8°C.

11. Test Method

Carefully read the reagent instruction before using the test kit and strictly operate according to the instruction to ensure reliable results. Bring all reagents to room temperature (18-28℃) before use.

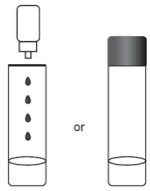
(1) Prepare

(a) Remove the test sample and required reagents from storage conditions and equilibrate to room temperature.

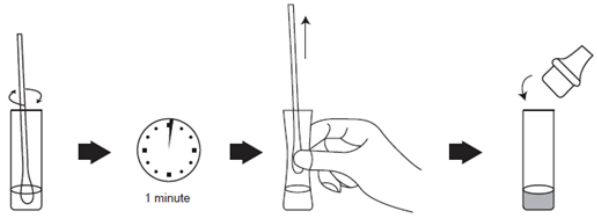
(b) Remove the test card from the packaging bag and lay it flat on a dry surface.

(2). Sample processing

① In the unpacked type, insert the extraction tube vertically into the extraction tube holder, open the sample diluent bottle cap, and drop 0.4mL (about 9~10 drops) vertically into the extraction tube; the pre-packed type can be used directly by opening the cap;



②Oropharyngeal swab and nasopharyngeal swab sample: insert the sampled into the above diluent, rotate the swab against the tube wall 5-6 times and squeeze the extraction tube wall by hand to make the swab on full release of the sample into the Sample diluent, let it stand for 1 min, squeeze the tube wall, take out the swab, and cover the dripper for later use;

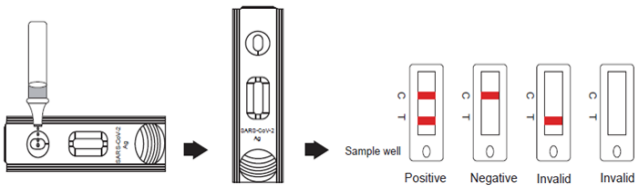


(3) Sampling:

① Add 0.1mL (about3~ 4 drops) of the evenly mixed solution in the extraction tube vertically to the sample hole of the test card; the result is interpreted within 15-20min, and the result is invalid after 20min.

② The virus sampling solution is used for specimen processing, it can be directly detected without using sample diluent.

12. Explanation for Test Results



(1) Positive Result: If both the quality control line (C) and the detection line (T)appears, the result is positive for the SARS-CoV-2 antigen.

(2) Negative Result: If only the quality control line (C) appears and the detection lines (T) not visible, the result is negative.

(3) Invalid result: No quality control line (C) appears, indicating that the test is invalid, and the sample needs to be tested again.

13. Limitations

(1) This test kit is for in vitro diagnostic use only. And the results cannot be used as a basis for diagnosis. Comprehensive judgment should be made in combination with clinical symptoms, epidemiological conditions and further clinical data.

(2) The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage, or repeated freezing and thawing of the sample will affect the test result.

(3) Positive test results do not rule out co-infections with other pathogens. A negative result of this reagent can be caused by:

a) Improper sample collection, improper sample transfer or handing, the virus titer in the sample is too low;

b) The level of SARS-CoV-2 antigen is below the detection limit of the test.

c) Variations in viral genes may cause changes in antibodies determinants.

d) Some special virus preservation solutions may not be applicable

(4).This product can only qualitatively detect the SARS-CoV-2 antigen in the sample, and cannot determine the concentration of the antigen in the sample.

(5) Diagnosis and treatment can not only rely on this test result, taking into account the clinical history and other laboratory test results.

(6) For medical professional use only.

14. Performance characteristic

Clinical performance: 272 clinical case samples which include 67 confirmed as COVID-19 positive and 205 confirmed as COVID-19 negative by PCR assay, were obtained for testing, and then compared the test results between Genrui SARS-CoV-2 Antigen Test Kit (Colloidal Gold) and the PCR results. The results are shown below.

		PCR		Subtotal
		Pos	Neg	
SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	Pos	59	2	61
	Neg	8	203	211
Subtotal		67	205	272

Positive Percent Agreement: 88.06% (95%CI: 77.82%~94.70%)

Negative Percent Agreement: 99.02%(95%CI: 96.52%~99.88%)

Overall Percent Agreement: 96.32%(95%CI: 93.34%~98.22%)

15. Internal quality control

Each test card has a built-in control. A red colored line at the control line can be considered an internal positive procedural control. The control line will appear if the procedure has been correctly performed. If the control line does not appear, the test is invalid and new test must be performed. If the problem persists, the use of this batch of products should be stopped immediately, please contact your local vendor for technical support.

16. Interfering substance

(1) Mucin, blood, pus can't interfere with the test results.

(2) Oxymetazoline, Dexamethasone,Sulfur ,Zanamivir, Mupirocin,Tobramycin,can't interfere with the test results.

(3) This product does not cross react with Human coronavirus 229E (heat inactivated), Human coronavirus OC43, Human coronavirus NL63, Adenovirus, Human Metapneumovirus, Parainfluenza virus 1~4 ,Influenza A ,Influenza B, Enterovirus, Respiratory syncytial virus, Rhinovirus, Haemophilus influenza, Streptococcus pneumonia, Streptococcus pyogenes, Candida albicans, Bordetella pertussis, Mycoplasma pneumonia, Chlamydia pneumonia, Legionella pneumophila, Pooled human nasal wash

17. Precautions

(1) Once opened, use the test cards as soon as possible,. Do not re-use the test cards.

(2) Do not use expired products. Reagents should not be used if the product packaging bag is damaged or the sample diluent is leaking.

(3) Components in test kit of different batches cannot be used interchangeably.

(4) For substances containing sources of infection or suspected of containing sources of infection, there should be proper bio-safety assurance procedures. Pay attention to the following matters:

a) Wearing protective clothing, protection glasses, and wear gloves when handling sample, operational process and disinfecting test cards and consumables after using.

b) Disinfect spilled sample or reagent with disinfectant.

c) Disinfect or handle potential contamination sources of all samples or reagents in accordance with local regulations.

d) Disposal of the device after use is according to local regulations.

18. Explanation of graphic symbol

	Consult Instructions for use		Temperature Limitation
LOT	Lot No.		Expiry Date
IVD	In Vitro Diagnostic Reagent	CE	CONFORMITE EUROPEENNE
	Production Date		Biohazard
	Manufacturer		Volume
Σ	Contains sufficient for < n>tests		Keep away from sunlight
	Do not re-use		Keep dry
EC REP	Authorized representative in the European community	REF	Catalogue number

19. Help Information

If you need help please contact after-sales

20. Manufacturer

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IVD CE EC REP

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