GB QUIK - COVID-19
ANTIGEN RAPID TEST KIT
(Colloid Gold Immuno-chromatography)

GENUINE BIOSYSTEM

KIT NAME	KIT SIZE	CAT. NO
GB QUIK –Corona Virus (Covid-19) ANTIGEN RAPID TEST Kit	25T	GBQCOV0025T

INTRODUCTION

This kit is used for the qualitative detection of the COVID-2019-NP antigen in human nasopharyngeal swab and oropharyngeal swab samples. It is mainly used for clinical reference but cannot be used as the basis of diagnosis of the COVID-2019.

PRICIPLE

This kit uses the principle of highly specific antibody-antigen reaction and colloidal gold labeling immune-chromatographic analysis technology. The reagent contains COVID-2019-NP antigen monoclonal antibody prefixed in the test area (T) on the membrane and the COVID-2019-NP Antigen monoclonal antibody coated on the label pad-colloidal gold mixture.

The sample is dripped into the sample well and reacts with the COVID-2019-NP antigen monoclonal antibody which is bound to the pre-coated colloidal gold particles when testing. Then the mixture is chromatographed upwards with capillary effects. If it is positive, the antibody labeled by colloidal gold particles will first bind to the COVID-2019-NP antigen virus in the sample during chromatography. Then the conjugates are bound by the COVID-2019-NP antigen monoclonal antibody fixed on the membrane, and a red line appears in the test area (T). If it is negative, there's no red line in the test area (T). Whether the sample contains COVID-2019 or not, a red line will appear in the quality control area (C). The red line appearing in the quality control area (C) is the standard for judging whether there are enough samples and whether the chromatographic process is normal, and it also serves as the internal control standard for the reagent.

KIT CONTENTS:

S. No	Component	QTY
1	Test Casette	25 nos
2	Prefilled Buffer Solution tube	25 nos
3	Sample Dropper	25 nos
4	Swab(Nasal & Oral)	25 nos

STORAGE AND STABILITY

The test kit should be stored at 4 ℃ ~ 30 ℃, and cannot be frozen.

The validity period is 12 months.

The test cassette shall be used within 1 hour after opening.

SPECIMEN

Polyester sponge swabs with PP (polypropylene) rods are recommended for aseptic swabs when collecting samples.

1. Nasal secretions collection:

Insert the swab into the nasal cavity where secretions are most when collect nasal secretions. Gently rotate and push the swab into the nasal cavity until the nasal turbinate is blocked (about 2.0-2.5cm from the nostril), then press the swab against the nasal wall for three times and remove the swab.

2. Throat secretions collection:

Insert the swab completely from the mouth into the throat, centering on the red part of the throat wall and maxillary tonsils, and rub the bilateral throat tonsils and throat wall moderately. Avoid touching the tongue and remove the swab.

3. The samples should be treated with the virus sampling solution or the sample extraction solution provided with this kit as soon as possible after collection. And complete the test in 5 minutes.

4. In order to ensure better results and sensitivity, we recommended to collect both Throat & Nasal secretion separately and dip into pre-filled buffer tubes and swirl for 1 minute to have complete mixing of swab tip into buffer solution.

TEST METHODS

Please read the instruction manual carefully before testing. Place the test kit and conduct the testing at room temperature.

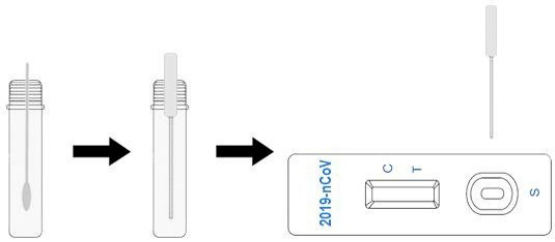


Figure I

1 Specimen extraction

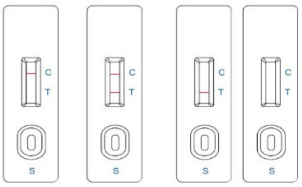
（See Figure I）

(1) Put the swab into the sampling tube and rotate it about 10 times to make the sample dissolve in the solution as much as possible.

2 Detection operations:

- Open the aluminum foil bag along the tear mouth and take the test cassette out, and put it in flat.
- Add 100ul (about 4 drops) of sample solution extract to the sample well of the test cassette.
- Observe the results showed within 10-20 minutes, and the results showed after 30 minutes have no clinical significance for aseptic swabs when collecting samples.

INTERPRETATION OF TEST RESULTS



Negative **Positive** **Invalid**

Positive （+）: Two red lines appear. One is in the test area (T) and the other is in the quality control area (C).

Negative （-）: Only a red line appears in the quality control area (C), and no line appears in the test area (T).

Invalid: No red line displays in the quality control area (C). This indicates that the incorrect operation or the test cassette has deteriorated or damaged.

LIMITATIONS OF TEST METHODS

a. This kit is only for the detection of respiratory secretions from nasopharyngeal swabs and oropharyngeal swabs.

b. The accuracy of the test depends on the sample collection process. Improper sample collection, improper storage of samples, unfresh samples, or repeated freeze-thaw cycles of samples will affect the test results.

c. The presence of individual drugs in the sample collected, such as high concentrations of over-the-counter drugs and prescription drugs (nasal sprays), can interfere with the results. If the results are suspicious, please retest.

d. The test cassette only provides qualitative detection of the SARS-COV-2 in the sample. If you need to detect the specific content of an indicator, please use the relevant professional instruments.

e. The test result of this kit is 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 considered in combination with their symptoms / signs, medical history, other laboratory tests, and treatment responses.

f. Due to the limitation of the method of antigen detection reagents, its analytical sensitivity is generally lower than that of nucleic acid reagents. Therefore, the experimenters should pay more attention to the negative results and need to make a comprehensive judgment in combination with other test results. It is recommended to review the suspicious negative results by using nucleic acid detection or virus culture identification methods.

g. Analysis of the possibility of false negative results：

①Unreasonable sample collection, transportation and processing, and too low concentration of tested substances in samples may lead to false negative results.

②Genetic variations of virus can cause changes in antigenic determinants, which can lead to false negative results. This is more likely to occur by using monoclonal antibody reagents.

③The optimal sample type and sampling time (peak virus titer) after infection have not been verified, so collecting samples fractionally, in multiple parts on the same patient may avoid false negative results.

PRODUCT PERFORMANCE INDEX

1、Physical performance

1.1.1 Appearance

- The test kit and its components should be complete
- The packaging bag should be sealed well, with no breakage and with clear label
- The material is firmly attached, and the strip width is suitable for the cassette.

1.1.2 Film strip width: ≥ 3.0mm.

1.1.3. Liquid migration velocity: The liquid moving speed should not be less than 10 mm/min.

1.2 Accuracy and repeatability

Repeat the test 10 times with negative quality control solution (0 ng/mL) and 10 ng/mL, 20 ng/mL, and 40 ng/mL COVID-2019-NP recombinant antigen control solutions. Positive quality control solution must not show negative results, and negative quality control solution cannot have positive results.

1.3 Inter-batch difference

Testing 10ng/mL, 40ng/mL samples 10 times for each by using three batches test kits. 10 ng/mL samples should be shown weakly positive results, and no positive or strongly positive results should appear. 40 ng/mL samples should be shown strongly positive results, and no positive or weakly positive results should appear. Negative results should be negative.

1.4 HOOK effect： Test the 100 ng/mL COVID-2019-NP recombinant antigen sample, the result should be strongly positive.

Specificity: Test the 100 ng/mL canine coronavirus, feline coronavirus, and porcine coronavirus positive samples, the result should be negative.

MATTERS NEEDING ATTENTION

1. This kit is single-use for in vitro diagnosis. Do not use if expired.
2. It indicates an error if no line appears in the quality control area (C) and test area (T). Please retest.
3. The high temperature of the experimental environment should be avoided. The test kit which was stored at low temperature needs to be restored to room temperature before opening to prevent moisture absorption.
4. It is recommended to use fresh samples, do not use repeatedly freeze-thaw samples.
5. Please use the swab and sample extraction solution provided in this kit when sampling. Do not mix test cassettes and sample extraction solutions from different batches.
6. If the virus sampling solution is used to treat the specimen, then it can be directly detected without using sample extraction solution.
7. The laboratory requires bio-safety level II or operation in a bio-safety cabinet.
8. Pay attention to safety measures during operation, such as wearing protective clothes and gloves. Used swabs, test cassettes, extraction tubes, etc. should be decontaminated before disposal. High-pressure steam disinfection is recommended.
9. There is desiccant inside the aluminum foil bag. Do not eat.

IVD CE

Genuine Biosystem Private Limited
Plot 97 & 98, Kattabomman street,
Parvathy nagar Extn,
Old Perungalatur, Chennai-600063.TN.India
Ph:044-48681845
Email:info@gb-group.co.in
Web: www.genuinebiosystem.com