Product Name

Genrui Generic Name: SARS-Cov-2 Antigen Test Kit (Colloidal Gold)

Trade Name: SARS-CoV-2 Antigen

Intended Use and Indications

The SARS-CoV-2 Antigen Test Kit (Colloidal Gold), Genrui Model, is an immunochromatographic assay for the rapid and qualitative detection of the antigen of Severe Acute Respiratory Syndrome-Coronavirus 2 (SARS-CoV-2) from a nasal, nasopharyngeal, oropharyngeal, or saliva sample. The test is indicated for any person suspected of being infected with Covid-19 and should be used as an aid in the diagnosis of coronavirus infectious disease (Covid-19), caused by SARS-CoV-2.

This test provides preliminary results. Negative results cannot exclude SARS-CoV-2 infection nor can they be used as the sole basis for basis for treatment or other patient management decisions. For in vitro diagnostic use only. For professional use only.

Principle of the test

This product uses a highly specific antibody-antigen reaction and a colloidal gold immunochromatographic colloidal gold immunochromatographic technology. The reagent contains a anti-SARS-CoV-2 monoclonal antibody pre-attached to the test area (T) of the membrane and an anti-SARS-CoV-2 monoclonal antibody conjugated to colloidal gold on the gold labeling pad.

During the test, the treated sample to be tested is deposited in the reagent loading zone of the reagent. When the sample contains SARS-CoV-2 antigen, this antigen is first combined with the colloidal gold-labeled anti-SARS-CoV-2 antibody and the conjugate is chromatographed upwards under capillary action, and it will be pre-immobilized on another membrane. When the monoclonal antibody anti-SARS-CoV-2 monoclonal antibody binds to the conjugate, a red-violet band appears in the test area (T). If the sample does not contain SARS-CoV-2 antigen, there will be no red-purple band in the test area (T). Whether or not the new coronavirus antigen is present in the sample, a purple-red band will appear in the quality control area (C). This band appearing in the quality control area (C) is the standard for judging the sufficiency of the sample and whether the chromatography process is normal, and it also serves as an internal control standard for internal control standard for the reagents.

Test Method

Read the reagent instructions carefully before using the test kit and operate strictly according to the instructions to ensure reliable results. Bring all reagents to room temperature (18-28°C) before use.

(1) Preparation

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

b) Remove the test card from the package and place it on a flat, dry surface.

(2) Nasal swab collection

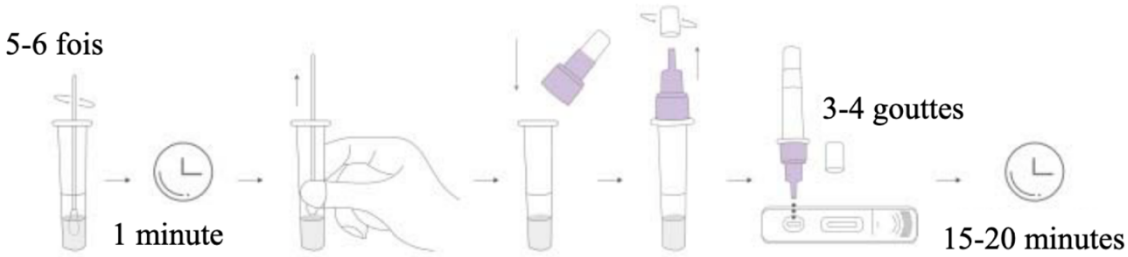
Insert the entire absorbent end of the swab (usually 2 cm) into the left nostril. Brush firmly against the inside of the nostril in a circular motion 5 or more times for at least 15 seconds. Remove the swab and insert it into the right nostril. Brush

firmly against the inside of the nostril in a circular motion 5 or more times for at least 15 seconds.

(3) Sample Processing

Put the sample in the above diluent, rotate the swab against the wall of the tube 5-6 times, so that the swab enters the sample diluent when the sample is completely released, let it stand for 1 minute, squeeze the wall of the tube and remove the swab, then cover the dripper and mix well. Add 0.1ml (about 3~4 drops) of the evenly mixed solution into the mixed solution in the extraction tube vertically to the sample hole of the test card

Read and interpret the test result at 15 minutes; the test result should not be read and interpreted after 20 minutes.

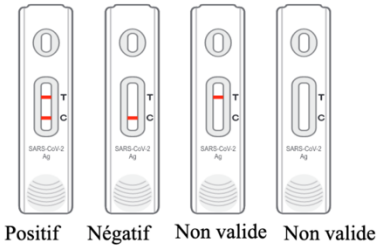


Results:

(1) Positive result: The presence of the control line (C) and the test line (T) indicates a positive result for SARS-CoV-2 antigen.

(2) Negative: The presence of only the control line (C), and the absence of the test line (T), indicates a negative result.

(3) Invalid result: If the control line (C) is not visible after the test is performed, the result is considered invalid.



Limitations

(1) This test kit is intended for in vitro diagnostic use only and the results cannot be used as a basis for diagnosis. A complete judgment must be made in combination with clinical symptoms, epidemiological conditions and other clinical data.

(2) The accuracy of the test depends on the sample collection process. An inappropriate collection, poor storage conditions or repeated freezing and thawing of the sample may affect the test result.

(3) Positive test results do not exclude co-infection with other pathogens. A negative result from this reagent may be caused by:

a) Improper collection, improper transfer, improper handling

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

c) Variations in viral genes may result in changes in antibody determinants.

(4) This product can only qualitatively detect SARS-CoV-2 antigen in the specimen and cannot determine the concentration of antigen in the sample (The detection limit of this kit is 1.8x10 2 TCID 50/mL).
(5) For professional medical use only.