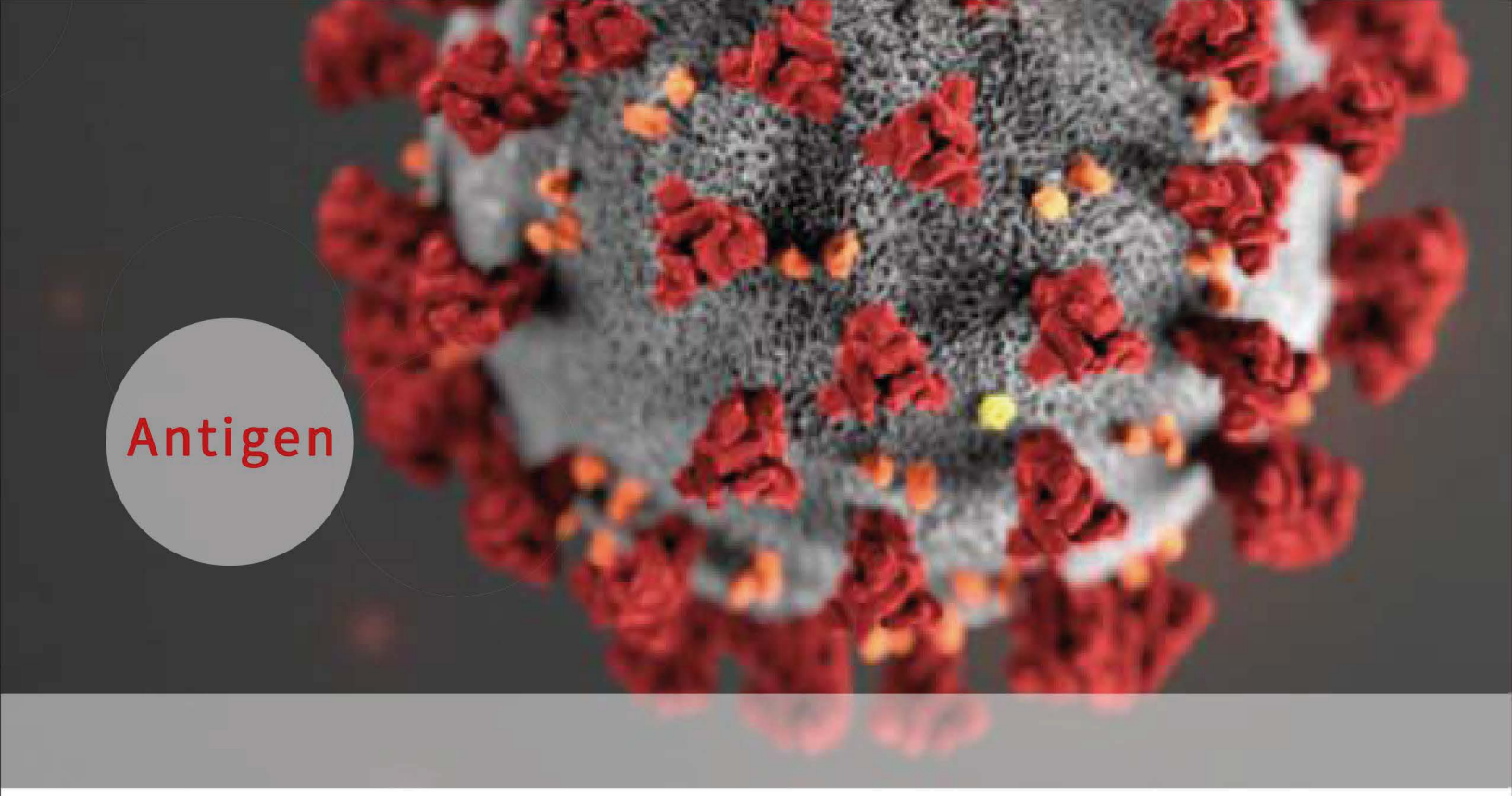


SARS-CoV-2 Antigen Lateral Flow Test Kit

Reliable

Rapid

Accurate

20 tests/kit

KISSH

Features

- No need for special instruments or equipment
- Storage at room temperature
- Result within 10-15 minutes
- Based on immunoassay, more practical than RT-PCR
- Know if infected with SARS-CoV-2 in real time

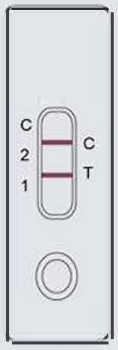
Overall Test Performance

- Sensitivity 99.57%
- Specificity 99.33%
- Total Conformity Rate 99.45%

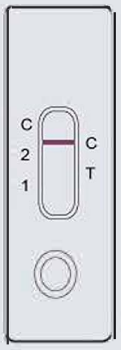
Procedure

Sample Collection >>> Sample Extraction >>> Sample Addition >>> Result within 15minutes

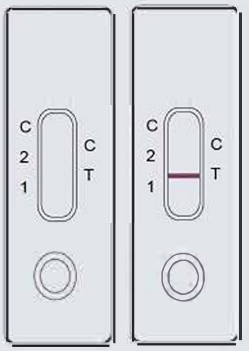
Result Interpretation



Positive



Negative



Invalid

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SARS-CoV-2 Antigen Test Kit (GICA) Manual

Product Name

SARS-CoV-2 Antigen Test Kit (GICA)

Packing Specification

1 test/kit, 20 tests/kit

Intended Use

The SARS-CoV-2 Antigen Test Kit is a gold immuno-chromatographic assay (GICA) that is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) and nasal (NS) swab, and saliva specimens directly from individuals who are suspected of COVID-19 by their healthcare provider.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The SARS-CoV-2 Antigen Test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings.

Test Principle

The SARS-CoV-2 Antigen Test uses the lateral flow immuno-chromatographic sandwich assay to detect nucleocapsid protein of SARS-CoV-2 in nasopharyngeal swab, nasal swab and saliva specimens.

The patient sample is placed in the Sample Tube, during which time the virus particles in the sample are disrupted, exposing internal viral nucleoproteins. After disruption, the sample is dispensed into the Test Cassette sample well. And the sample migrates through a test strip, if the SARS-CoV-2 virus antigen is present, a red color line will be showed on the T site. If SARS-CoV-2 viral antigen is absent, there is not a red line will be showed on the T site, however, a red line will be always showed on the C site indicating that the reaction system is properly happened.

Main Components

Item	Component	Vol/Qty.	
1	Test Cassette individually foil pouched with a desiccant	K701-01	K701-20
		1 test/kit	20 tests/kit
2	Sample Tube, with cap and antigen	1	20
3	Sampling swab	1	20
4	Instruction for use	1	1
Materials needed but not provided： Timer or watch, Nylon flocked, nasopharyngeal swab, Polyester wound swab, Viral Transport Media, Saliva sample collector, Clean sample cup, Disposable straw, Biosafety bag.			

Storage Conditions and Validity

1. The test kit is sensitive to humidity and as well as to heat.
2. Store kit components at 2-30°C, out of direct sunlight. Kit components are stable until the expiration date printed on the outer box.
3. Perform the test immediately after removing the test device from a foil pouch.
4. After the aluminum foil bag is unsealed, the test card should be used as soon as possible within **Two hours.**
5. Do not freeze.
6. Valid Period: The individual kits and/or box correctly stored kits are valid for 12 months.

Specimen Collection and preparation

1. Nasopharyngeal swab:

Take a swab to wipe the bilateral pharyngeal tonsils and posterior pharyngeal wall, put the swab into the sample tube that has been pre-filled with 0.5 ml of antigen extraction buffer, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigen in the swab.

2. Nasal swab:

To collect a nasal swab sample, let the patient's head relax, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, rotate the swab against the wall of the nostril into the patient's nostril to the nasal palate, and then slowly remove it while wiping. Using the same swab, wipe the other nostril in the same way. Place the swab into the sample tube that has been pre-filled with 0.5 ml antigen extraction buffer, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigen in the swab.

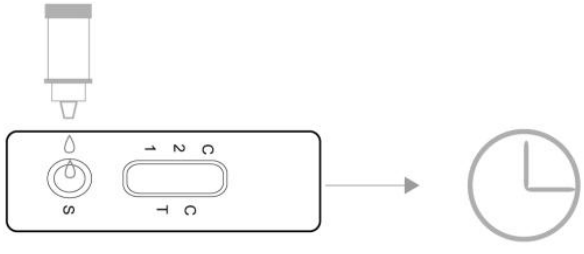
3. Saliva

Collect the saliva specimen 1-2 ml using a clean collecting cup, then take 1ml saliva sample into the sample tube.

Note: 1. Specimens shall be used as soon as possible after collection. If it is frozen, it needs to be completely thawed, reheated, mixed well and used, do not freeze and thaw repeatedly.2. If it needs to be transferred, it should be transported within 48 hours under the condition of 2 ~ 8℃, and the sample box should have a clear packaging mark; if the collected samples can not be used immediately, they can be stored at 2 ~ 8 ℃ for not more than 48 hours, and should be stored at-70 ℃ or below.

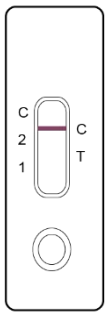
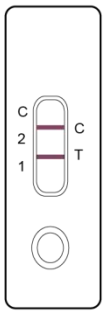
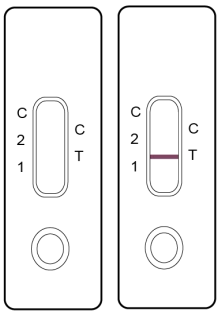
Test Procedure

Please read the instruction for use carefully before testing, and complete the test in strict accordance with the directions of the manual, otherwise reliable results cannot be guaranteed.
1. Open the aluminum foil bag, put the test cassette on a clean, horizontal bench.
2. Place the sample tube on the workbench. Insert the collected swab into the sample tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigen in the swab. Squeeze the swab over the head to remove the swab so as to remove as much liquid as possible from the swab. Dispose of swabs according to biohazard waste disposal method.
3. Install the dropper cap onto the sample tube, put two drops of the extraction solution into the sample well and start the timer.
4. Read the results within 15 minutes, and the results after 15 minutes are invalid.



1. Drop in the sample 2. Read result in 15 min

Interpretation of Test Results

Negative result	Positive result	Invalid result
		

1. Positive: A red line appears on the test line (T) and the control line (C).

NOTE: A positive result does not rule out co-infections with other pathogens.

2. Negative:

Only the control line (C) appears, and no red line appears on the test line (T).

NOTE: A negative result does not exclude infection.

3. Invalid:

There is no red line at the position of the control line (C). Regardless of whether the TEST line (T) is displayed, it is an invalid result and the sample should be tested again.

Performances

LoD: The LoD of the test kit is 1.0 ng/ml for detection the internal reference.
The negative coincidence rate (NCR):
The NCR of the test kit should not be less than 19/20 using an internal negative reference panel.
The positive coincidence rate (PCR):
The PCR of the test kit should be 10/10 using an internal positive reference panel.
Repeatability:
The repeatability of the test kit should be tested using same batch number, and all of the test results should be positive, and the T lines have even intensities.

Limitations

1. This test is for in vitro diagnostic use only.
2. This test is a qualitative test and cannot determine the specific content of antigen in the sample.
3. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
4. Test results must be evaluated in conjunction with other clinical data available to the physician.
5. This test cannot distinguish between asymptomatic carriers and infected persons of the SARS-CoV-2.
6. A false negative result may be obtained if the concentration of the viral antigen in the nasopharyngeal and nasal swab is below the sensitivity.
7. Negative results should be treated as presumptive and confirmed with an approved molecular assay.

Precautions

1. For in vitro diagnostic use only.
2. Please read this manual carefully prior to using this test kit. And follow the testing procedures strictly described in the manual, otherwise it will lead to incorrect results.
3. Do not use expired reagents.
4. Do not re-use the test kit.
5. All throat swab samples, used reagents, test cards, and other materials used during testing are considered to be infectious, and personal protection should be done during the experiment.
6. Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples. Wear suitable protective clothing and eye/face protection when handling the contents of this kit.
7. Sample handling and waste disposal must comply with relevant regulations. Wash hands thoroughly after handling.
8. Avoid using visually bloody or overly viscous samples for testing.
8. Do not use components from different batch lots.
9. The sample tube contains a salt solution. If the solution contacts the skin or eye, flush with copious amounts of water.
10. Sample collection and handling procedures require specific training and guidance.

Labeling Symbols

Symbol	Interpretation
	In Vitro diagnosis
	Storage temperature
	Do not re-use
	Do not use if package is damaged
	Manufacturer

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