AUGURIX DIAGNOSTICS SA.

Simtomax CoronaCheck Antigen

SARS-CoV-2 Ag Rapid Test

Catalogue No: CCAg-020

User Manual / 20 tests

1. INTENDED USE

The Simtomax® CoronaCheck Antigen Rapid Test is a lateral flow assay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal (NP) swabs from individuals suspected of COVID-19. The kit is intended for professional use only.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in nasopharyngeal (NP) swabs 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 from patients with symptom onset beyond seven days, should be treated as

presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection 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.

2. INTRODUCTION

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore pharynx, myalgia and diarrhea are found in a few cases.

3. PRINCIPLE

This product uses capture colloidal gold immunochromatography to qualitatively detect SARS-CoV-2 nucleocapsid protein antigen in human nasopharyngeal (NP) swab samples. Colloidal gold labeled antibody and chicken IgY antibody are used. Coated the SARS-CoV-2 antibody-colloidal gold complex and the chicken IgY antibody-colloidal gold complex on the conjugate pad. The test line is coated with SARS-CoV-2 antibody, and the control line (C) is coated with goat anti-chicken IgY antibody. If the SARS-CoV-2 nucleocapsid protein antigen is present in the sample, the SARS-CoV-2 antigen and the colloidal gold-labeled antibody form a complex. Under the action of chromatography, the complex moves forward along the strip, and when reaching the test line, it reacts with the pre-coated SARS-CoV-2 antibody to form an immune complex and show a red line. Colloidal gold-labeled chicken IgY antibody combined with goat anti-chicken IgY antibody on the control line (C) showed a red line. The control line (C) should have lines when testing samples. The red line displayed on the control line (C) is the standard for judging whether the chromatography process is normal, and also serves as the internal control standard for reagents.

4. COMPONENTS

Components	Components	Quantity
Test Cassette	Test line (T): coated with SARS-CoV-2 antibodies; Control line (C): coated with goat anti-chicken IgY antibodies; Conjugate pad: coated with SARS-CoV-2 antibody colloidal gold complex and chicken IgY antibody-colloidal gold complex.	1 test cassette/bag, 20 bags/kit
Desiccant	/	1 piece/bag, 20 bags/kit
Extraction buffer	/	20 vails
Extraction tube	/	20 pieces
Nasal swab	/	20 pieces

5. STORAGE and EXPIRATION DATE

- Test should be stored at 2-30°C. DO NOT freeze the test;
- Test cassette is recommended to be used within 0.5 hour after opening the pouch.
- Refer to the labels to check the production date and expiry date of the kit.

6. MATERIALS NEEDED but NOT SUPPLIED

- Timer

7. SPECIMEN COLLECTION and PREPARATION

7.1 Simtomax® CoronaCheck Antigen Rapid Test is a rapid lateral flow immunoassay for the qualitative detection and diagnosis of SARS-CoV-2 directly from nasopharyngeal (NP) swabs, without viral transport media;

7.2 Collect nasopharyngeal (NP) swab according to the clinical collection guidelines of laboratory test samples. Avoid contamination during sample collection, transfer and storage;

7.3 To collect the nasopharyngeal (NP) swab sample, carefully insert the swab into the nostril and pharynx exhibiting the most visible drainage, or the nostril and pharynx that are most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinate and pharynx posterior wall. Rotate the swab 5 times or more against the nasal and pharyngeal wall then slowly remove from the nostril and pharynx.

7.4 Specimen storage

For best performance, direct nasopharyngeal (NP) swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasopharyngeal (NP) swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15-30°C) for up to (1) hour prior to testing. Ensure the nasopharyngeal (NP) fits securely within the tube and the cap is tightly closed. If greater than 1 hour delay occurs, dispose of sample. A new sample must be collected for testing.

8. Specimen extraction

8.1 Insert the extraction tube into the test tube rack;

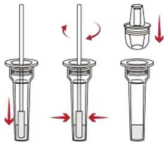
8.2 Twist off the head of the buffer, dispense all the buffer into the extraction tube;

8.3 Insert the swab into the extraction tube containing extraction buffer;

8.4 Rotate the swab at least 6 times while pressing the head against the bottom and sides of the extraction tube;

8.5 Place the swab in the extraction tube for 1 minute;

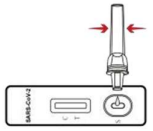
8.6 The extracted solution will be used as a test sample.



9. TEST PROCEDURE

9.1 Carefully refer to the instruction for use prior to performing the test;

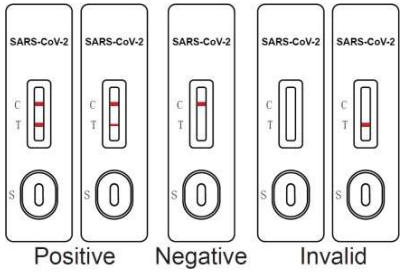
9.2 Take out the kits 30 mins before test, ensure that tests and samples are at room temperature;



9.3 Place test cassettes on flat and clean bench; add 2 drops unknown extracted samples into sample pad;

9.4 Read and record the results after 10-15 minutes (No longer than 20 minutes). Abnormal results may occur after 20 minutes.

10. INTERPRETATION of RESULTS



Positive (+):	Presence of two red lines, test line (T) and control line (C), indicates SARS-CoV-2 nucleocapsid protein antigens present in samples.

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Negative (-):	Appearance of single control line (C), no red test line (T), indicates the absence of SARS-CoV-2 nucleocapsid protein antigens present in samples.
Invalid:	No red control line (C) appears. Invalid results may be due to incorrect operation or loss of efficacy in tests. Repeat test firstly, if problem remains, stop using products in same lot number and contact with local distributor for support.

11.Product Performance

11.1 Cross Reactivity

No false positive SARS-CoV-2 test results were observed on 1-15 specimens from the following disease states or specific conditions, respectively

Virus/Bacteria	Result
HAV positive serum	Negative
HBV positive serum	Negative
HCV positive serum	Negative
HEV positive serum	Negative
HIV positive serum	Negative
TB positive serum	Negative
H. pylori positive serum	Negative
Dengue positive serum	Negative
Influenza A H1N1 Isolate	Negative
Influenza A H3N2 Isolate	Negative
Influenza A H5N1 Isolate	Negative
Influenza B Isolate	Negative
RSV Isolate	Negative
Adenovirus III Isolate	Negative
Adenovirus VII Isolate	Negative

11.2 Clinical performance

The Simtomax® Coronacheck Antigen Rapid Test has been evaluated with specimens obtained from patients. A commercialized molecular assay was used as the reference method. The results show that the Simtomax® Coronacheck Antigen Rapid Test has a high overall relative accuracy. From the clinical evaluation results, the clinical sensitivity of this product is 95.45%, the clinical specificity is 98.29%, and the total accuracy rate is 97.27%.

Simtomax® Coronacheck Antigen Rapid test	PCR result		Total
	Positive	Negative	
Positive	63	2	65
Negative	3	115	118
Total	66	117	183

12.LIMITATIONS of METHODOLOGY

- The contents of this kit are to be used for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal (NP) swabs.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- False negative results may occur if a specimen is improperly collected, transported, or handled.
- False results may occur if specimens are tested past 1 hour of collection. Specimens should be test as quickly as possible after specimen collection.
- False negative results may occur if inadequate extraction buffer is used.
- False negative results may occur if swabs are stored in their paper sheath after specimen collection.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- Negative results, from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.

13. PRECAUTIONS

- The product is only for in vitro diagnosis. The test result shall not be used as the only index for evaluating the patient's condition, and the patient's clinical manifestation and other laboratory tests must be combined to conduct a comprehensive analysis of the condition.
- Inspection of product packing and sealing as well as expiration date is necessary prior to performing the test.
- Test should be performed as quickly as possible. Long-time exposure of test to air and moisture will cause invalid results.
- Overload of specimens may result in unexpected results, such as false positives.
- Accuracy of test can be affected by environment temperature (<10°C or >40°C) and relative humidity (>80%).

14. MANUFACTURER

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Symbol	Description
	Use-by date
	Lot Number
	Manufacture Date
	Manufacturer
	Keep Away from Sunlight
	Temperature Limitation
	In Vitro Diagnostic Medical Device
	Do not Re-use
REF:	CCA-020
	CE Mark

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