Simple Operation Covid-19 Self Test Rapid Antigen Test

KINGSTAR INC is a professional leader China Simple Operation Covid-19 Self Test Rapid Antigen Test manufacturers with high quality and reasonable price. Simple operation covid-19 self test rapid antigen test is intended for in vitro qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swabs from individuals suspected of COVID-19.

High quality Simple Operation Covid-19 Self Test Rapid Antigen Test is offered by China manufacturers KINGSTAR INC.

Product Introduction

Simple operation covid-19 self test rapid antigen test is suitable for layperson use, children under age of 14 should be assisted by an adult. This can help people do testing at home by themselves. The test result from this test can help your healthcare provider make informed recommendations for your treatment / care and help limit the spread of COVID-19 to your family and others around you. Please always seek for assistance and supervision with the test when needed and follow your local guidelines for specimen collection by children.

Product Parameter (Specification)

Antigen test cassettes
Sample swabs
Antigen extraction tubes
Biohazard Waste Bag
Instruction for Use

Simple operation covid-19 self test rapid antigen test

convenient | accurate

For self-test

single serving

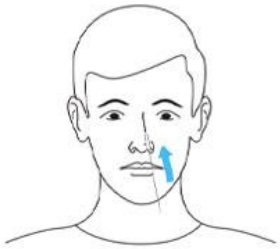
Product Feature and Application

Simple operation covid-19 self test rapid antigen test can be used by people themselves instead of medical staff. Its results come out quick which will save more time for us.

Tel: +86-574-62338878 **Phone:** +86-13858300666 **E-Mail:** info@nbkingstar.com

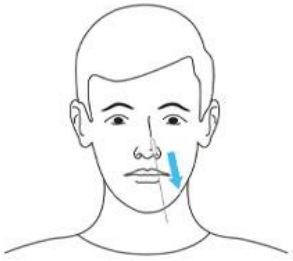
Test steps

Remove the swab from the package.

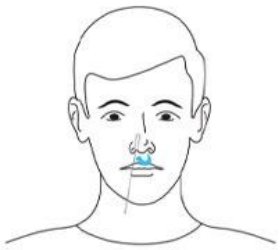


Insert the entire soft end of the swab into the nostril(about 1.5-2.0 cm).

Slowly rotate the swab, gently press against the inside of the nostril at least 5 times for a total of 15 seconds.

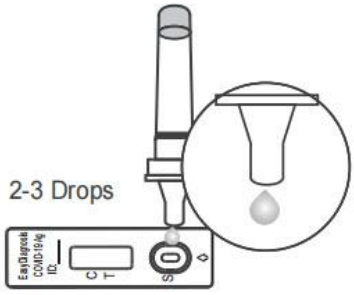


Gently remove the swab.



Using the same swab, repeat steps B-D in the other nostril with the same end of the swab.

Put the swab specimen into the extraction tube, rotate the swab in the liquid for about 10 seconds, and press the swab head against the tube wall to release the specimen in the swab.



Add 2-3 drops into the specimen well of the test cassette, and start the timer.

Wait for 15 minutes and read the result.

Product Details

Simple operation covid-19 self test rapid antigen test can read the result in 15 minutes. Strong positive results can be reported within 15 minutes; however, negative results must be reported after 15 minutes, and the results after 25 minutes are no longer valid

We have single serving,
5 servings and 20 servings.
(If you have specific requirement, ps let us know.)

Warning and precaution

1. Read the instructions carefully before using the kit, and strictly control the reaction time. If you do not follow the instructions, you may get inaccurate results.
2. The antigen test cassette, antigen extract R1, antigen extraction tube (with dropper head) and sample swab after use should be placed in the biohazard waste bag and disposed of with household waste.
3. Protect from moisture, do not open the aluminum foil bag before it is ready for testing. Do not use when the aluminum foil bag is damaged or the test cassette is damp.

4. Please use it within the validity period.
5. Wait all reagents and specimens back to room temperature (15 ~ 30℃) before use.
6. The product contains animal sourced antibodies and the antigen extract R1 contains casein. Do not touch the test strip in the middle of the test cassette and try to avoid touching the liquid of the antigen extract R1.
7. Do not replace the components in this kit with components in other kits.
8. Do not dilute the specimen for testing, otherwise you may get inaccurate results.
9. The kit shall be stored in strict accordance with the conditions specified in this Instruction for Use. Please do not store the kit under freezing conditions.
10. The test methods results must be interpreted in strict accordance with the Instruction for Use.

Storage and stability

1. Store at 2℃~30℃, and it is valid for 12 months. DO NOT FREEZE.
2. After the aluminum foil bag is unsealed, the test cassette should be used as soon as possible.

The following is the certificates of Simple operation covid-19 self test rapid antigen test.

CERTIFICATE

EC Certificate No. 1434-IVDD-485/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies that manufactured by:

2021 -11- 10

[redacted]

in vitro diagnostic medical devices
for self-testing

COVID-19(SARS-CoV-2) Antigen Test Kit

REF: W-AgH-01S, W-AgH-01, W-AgH-02S, W-AgH-02, W-AgH-05S, W-AgH-05, W-AgH-07, W-AgH-07S, W-AgH-08S, W-AgH-08, W-AgH-10S, W-AgH-10, W-AgH-15S, W-AgH-15, W-AgH-20S, W-AgH-20, W-AgH-25S, W-AgH-25

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC
Validity of the Certificate: from 10.11.2021 to 27.05.2024

The date of issue of the Certificate: 10.11.2021

The date of the first issue of the Certificate: 10.11.2021

CE 1434

Issued under the Contract No. MD-81/2021
Application No: 157b/2021
Certificate bears the qualified signature.
Warsaw, 10/11/2021
Module A1

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.11.10 16:17:43 +01'00'
Vice-President

POLISH CENTRE FOR TESTING AND CERTIFICATION 02-844 Warsaw, 469 Puławska Street, tel. +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2055510-1

Organization: [redacted]

Scope: Design and Development, Manufacture and Distribution of In-Vitro-Diagnostic Test Kits for the Diagnosis of Cancer, Amniorrhexis, Thrombotic Diseases and Hypercoagulation, Cardiac Markers, Kidney Function Testing, Immune Status, Pregnancy Testing, Prostate Function, Diabetes Testing, Neurodegenerative Diseases, Endocrine Disorders, Infection Diseases, Disease Status, Blood Gases and Genetic Testing as well as for the Monitoring of the Disease Status including Near Patient/Point of Care, Immune Quantitative Analyzer, Full[redacted]Chemiluminescence Analyzer, Chemiluminescence Immu[redacted]alyzer, Blood Gas Analyzer, Portable ECG, Fluorescence Immu[redacted]yzer, Real-time PCR System.

2021 -01- 28

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190129510 110

Effective date: 2021-01-27

Expiry date: 2024-01-26

Issue date: 2021-01-25

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: [redacted]

Authorized EU Representative: Osmunda Medical Technology Service GmbH
Treskowallee 108, 10318 Berlin, Germany

DIMDI No.: DE/0000047267

We,as manufacturer,declare under our sole responsibility that:

Product Name: COVID-19 (SARS-CoV-2) Antigen Test Kit
Analyte: Nucleocapsid protein antigen from SARS-CoV-2 in nasal swab from individual suspected of COVID-19

Type/Model:

Specification	REF
1 Test/kit	W-AgH-01, W-AgH-01S
5 Tests/Kit	W-AgH-05, W-AgH-05S
7 Tests/Kit	W-AgH-07, W-AgH-07S
8 Tests/Kit	W-AgH-08, W-AgH-08S
10 Tests/Kit	W-AgH-10, W-AgH-10S
15 Tests/Kit	W-AgH-15, W-AgH-15S
20 Tests/Kit	W-AgH-20, W-AgH-20S
25 Tests/Kit	W-AgH-25, W-AgH-25S

of class: self-test
according to direct. 98/79/EC

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it.

Conformity assessment procedure: Directive 98/79/EC Annex III（section 6）

list of applied standard: ISO 14971:2019, EN ISO 15223-1: 2016,
EN ISO 13485:2016, EN ISO 18113-1:2011,
EN ISO 18113-2:2011, EN13612:2002,
EN 13612:2002/AC:2002, EN ISO 23640:2015
EN 62366-1-2015, EN 13532-2002,
EN 18113-4-2013

Notified Body: Polish Centre for Testing and Certification
469 Puławska Street, 02-844 Warsaw, Poland

Identification number:1434

(EC)Certificate(s): No.1434-IVDD-444/2021

Start of CE-Marking: July 13,2021

Wuhan, July 28 ,2021
Place, date

Name and function: Yingwen [redacted] regulatory representative

CE 1434