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Covid saliva & lollipop antigen test (Realy Tech)

FAST

EASY

ACCURATE

ADVENT life
Health in Your Hands

REALY TECH

THE COMPANY

Our ambition is to make healthcare widely accessible by empowering self-care globally.

Driven by our spirit of innovation, **Advent Life** specialises in self-tests for a wide range of medical conditions, while also offering other products that allow everyone to take health into their own hands. We enable people to take the first step themselves and at their own convenience.

Advent Life focuses on bringing the best from the world while prioritising safety and easy-to-use products. We design premium brands that are delivered to pharmacies, hospitals, laboratories, public organisations and government institutions.

For more information, visit **www.adventlife.net.**

WHAT IS COVID?

Covid-19 is an acute respiratory infectious disease caused by SARS-CoV-2. The most common symptoms are coughing and fever, but sore throat, headache and muscle aches, as well as general weakness and shortness of breath, may also occur.

Nausea, conjunctivitis, swollen lymph nodes and drowsiness, change or loss of taste and smell are some of the less common symptoms of the disease.

In some people, the infection may be asymptomatic, but it can also affect the respiratory system and other systems in the human body. In severe cases, symptoms may include shortness of breath and chest pains, and the disease may require specialist medical care or hospitalisation.

PURPOSE

For in vitro qualitative detection of SARS-CoV-2 nucleoprotein antigen in saliva samples directly from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days after onset of symptoms.

CLINICAL EVALUATION RESULTS

Sensitivity: 93.94%
Specificity: 99.00%
Accuracy: 98.79%

FAST AND RELIABLE RESULTS

Time: 10 minutes.
Store between +2°C and +30°C. Do not freeze!
1 test per box.

EU REGISTRATIONS AND CERTIFICATIONS

Standard: Directive 98/79/EC; EN ISO 13485: 2016.
EC Declaration of Conformity
Registration in Germany (www.antigentest.bfarm.de)
ISO 13485:2016 by TÜV SÜD

The test device should be used within 1 hour after taking out from the aluminum foil bag. Keep away from sunlight, moisture, and heat.

Easy to read.

CONTENT

PROVIDED MATERIALS:

1 sealed aluminium pouch containing:

1 test cassette
1 dropper (pipette)
1 saliva collection cup / 1 saliva collection lollipop
1 extraction buffer vial
1 plastic tube with nozzle cap
1 instruction for use

Only open the protective pouch when you are ready to use the test. The desiccant bag should not be used.

1 test/kit
100 tests/carton
Carton size: 0.056 m3
Gross weight per carton: 2 kg
Volumetric weight per carton via air cargo: 9.5 kg

INSTRUCTIONS

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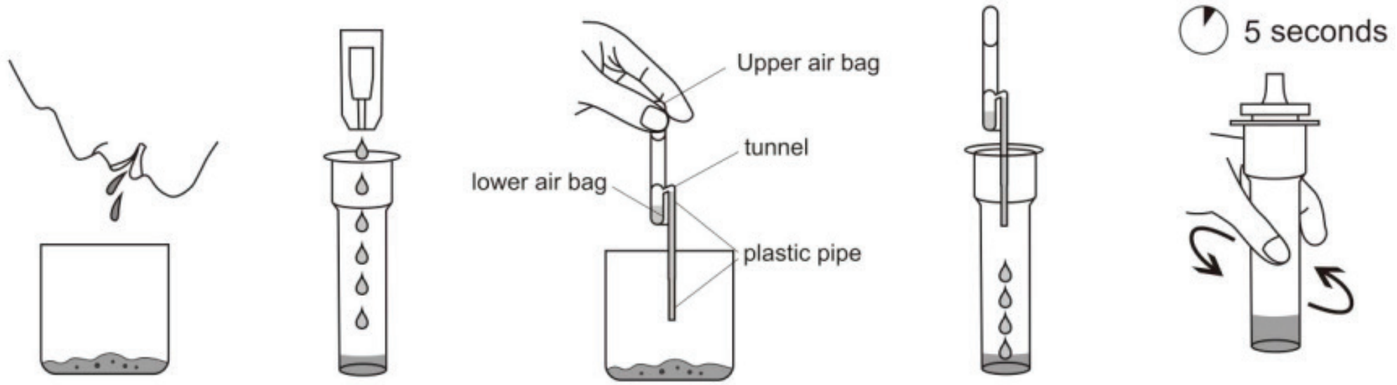
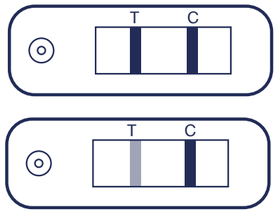
Allow the test device, sample, extraction buffer to equilibrate to room temperature (15-30°C) prior to testing. Do not place anything in the mouth including food, drink, gum, tobacco, water and mouthwash products for at least 10 minutes prior to collection of oral fluid sample.

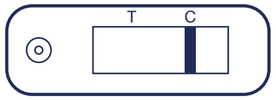
1. Spit enough saliva into the saliva collection cup or put the lollipop under your tongue until it soaks entirely.
2. Take out an extraction tube and a vial with extraction buffer. Remove the cap from the vial and add all the buffer into the tube.
3. Using the dropper, draw enough saliva from the cup, transfer it in the extraction tube.
4. Close the tube with a nozzle cap, gently shake it for about 5 seconds.
5. Remove the test device from the sealed foil pouch.
6. Put 3 drops of the sample into the sample well.
7. Read the results at 10-20 minutes. Don't interpret the result after 20 minutes.



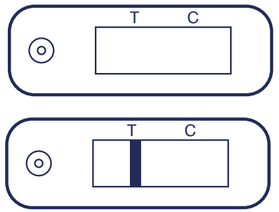
RESULTS



POSITIVE: Two red lines appear. One red line appears in the control region(C), and one red line in the test region (T). The shade of colour may vary, but it should be considered positive whenever there is even a faint line.



NEGATIVE: Only one red line appears in the control region (C), and no line in the test region (T). The negative result indicates that there are no Novel coronavirus particles in the sample or the number of viral particles is below the detectable range.



INVALID: No red line appears in the control region (C). The test is invalid even if there is a line in the test region (T).

NOTE:
The intensity and the colour of the lines do not have any importance for the interpretation of the test results.

IMPORTANT INFORMATION

This product is only suitable for a qualitative test and auxiliary diagnosis.

The test results are only for clinical reference and should not be the only basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with their symptoms, physical signs, medical history, other laboratory tests, therapeutic reaction, and epidemiological information. Users should test samples as quickly as possible after sample collection.

Positive test results do not rule out co-infections with other pathogens.

Results from the test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.

A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of SARS-CoV-2 infection.

The amount of antigen in a sample may decrease as the duration of illness increases. Samples collected after day 5 of the illness are more likely to be negative compared to an RTPCR assay.

Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.

The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from nasal swab samples only.

IMPORTANT INFORMATION

Do not use after the expiration date.

Perform the test at room temperature 15° to 30°C.

Collecting and working with samples requires professionals.

Make sure the foil pouch containing the test device is not damaged before opening for use.

Personal protective equipment (PPE) such as a lab coat, medical mask, medical goggles and gloves is highly recommended to protect user from getting infected.

All samples and used accessories should be treated as infectious and discarded according to local regulations.

Avoid using bloody samples.

Samples should be tested as soon as possible after collection. Based on data generated with the influenza virus, throat swabs are stable for up to 24 hours at room temperature.

Dispose of used waste according to local law and regulations.

CERTIFICATES

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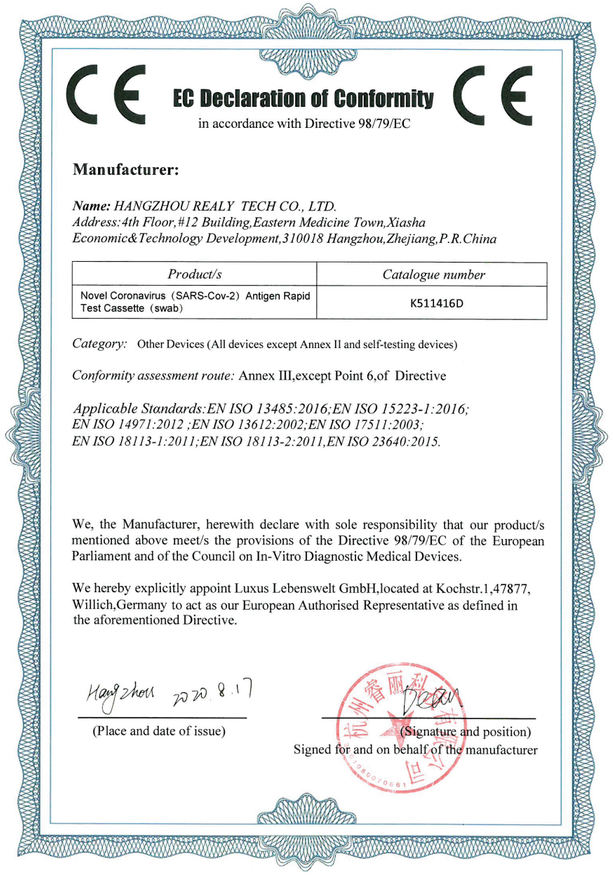

CE **EC Declaration of Conformity** CE

in accordance with Directive 98/79/EC

Manufacturer:

Name: *HANGZHOU REALY TECH CO., LTD.*
Address:4th Floor,#12 Building,Eastern Medicine Town,Xiasha Economic&Technology Development,310018 Hangzhou,Zhejiang,P.R.China

Product/s	*Catalogue number*
Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)	K511416D

Category: Other Devices (All devices except Annex II and self-testing devices)

Conformity assessment route: Annex III,except Point 6,of Directive

Applicable Standards:EN ISO 13485:2016;EN ISO 15223-1:2016; EN ISO 14971:2012 ;EN ISO 13612:2002;EN ISO 17511:2003; EN ISO 18113-1:2011;EN ISO 18113-2:2011,EN ISO 23640:2015.

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Luxus Lebenswelt GmbH,located at Kochstr.1,47877, Willich,Germany to act as our European Authorised Representative as defined in the aforementioned Directive.

Hangzhou 2020.8.17

(Place and date of issue)

(Signature and position)
Signed for and on behalf of the manufacturer

ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT 認證證書

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 094846 0002 Rev. 01

Holder of Certificate: **Hangzhou Realy Tech Co., Ltd.**
4th Floor, #12 Building
Eastern Medicine Town
Xiasha Economic&Technology Development
310018 Hangzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Hangzhou Realy Tech Co., Ltd.
4th Floor, #12 Building, Eastern Medicine Town, Xiasha Economic&Technology Development, 310018 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of POCT Analyzers and Related Diagnostic Kits**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH19105604

Valid from: 2020-03-05
Valid until: 2023-01-23

Date, 2020-03-05

Christoph Dicks
Head of Certification/Notified Body

A4 / 07.17

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TÜV®