Accurate

Fast

Easy

Realy Tech®
COVID-19 Antigen
Rapid Test

Version
2020.10.27

www.realytech.com

Company Profile

Hangzhou Realy Tech Co., Ltd was founded in 2015. It is a China headquartered and globally operated in Vitro Diagnostic company, specializing in analytical medical devices, POCT kits for more than 5 years.

We are offering products lines of rapid tests, portable analyzer,PCR and operate strictly under EN ISO 13485:2016 and GMP guidelines.

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Product Description

Product Name: Novel Coronavirus（SARS-Cov-2）Antigen Rapid Test Cassette(swab)

Principle ： Rapid detection of sars-cov-2 nucleo protein antigen

Standard: In vitro diagnostic devices, Directive 98 / 79 / EC, EC

Clinical sensitivity =90.32%

Clinical specificity ＞99.9%

Accuracy=97.71%

CE

IVD

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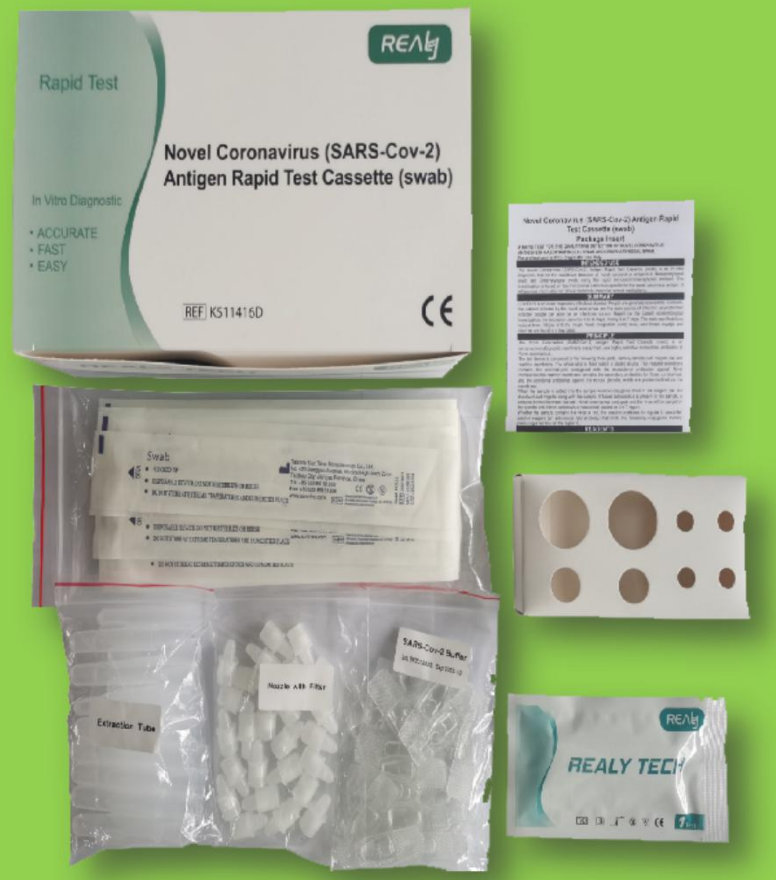
Components of the Test Kit

- 1 Package Insert
- 1 Tube Stand
- 25 Test Device
- 25 Sterilized Swab
- 25 Nozzle with Filter
- 25 Extraction Tube
- 25 Sample Extraction Buffer



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Components of the Test Kit

- 1 Package Insert
- 1 Tube Stand（test box）
- 5 Test Device
- 5 Sterilized Swab
- 5 Nozzle with Filter
- 5 Extraction Tube
- 5 Sample Extraction Buffer

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Packing Details

25 tests/kit

500 tests/carton

Carton size: 45*44*28cm Volume: 0.056CBM
Gross weight per carton: 7.5KG

Volume weight per carton via air cargo:9.5KG Volume

carton via express:11.5KG

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Packing Details

5 tests/kit

500 tests/carton

Carton size: 43*42*41cm

Volume: 0.0741CBM

Gross weight per carton: 9.2-9.7KG

Volume weight per carton via air cargo: 12.5KG

Volume weight per carton via express: 15KG

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Operation Notes

1.Professionals is needed when collecting and operating specimens.

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

3.Delivery the specimens according to local law and regulation.

4.Samples should be tested as soon as possible after collection. Based on data generated with influenza virus, throat swabs are stable for up to 24-hours at room temperature or 2 ° C to 8° C.

5.Special disposal of used waste according to local law and regulation.

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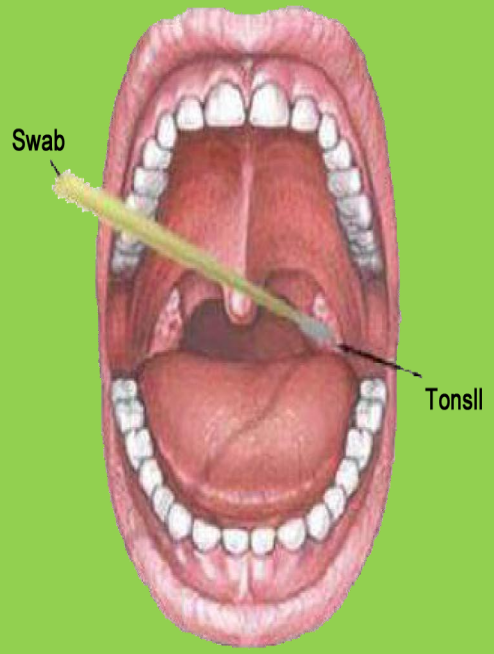
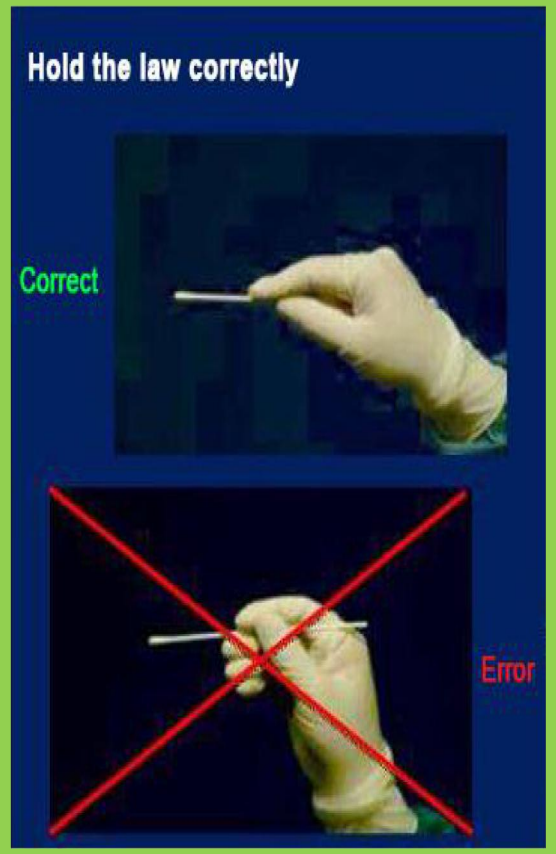
Throat Swab Specimen Collection

Let the patient's head tilt slightly, mouth open, and make 'ah' sounds, exposing the pharyngeal tonsils on both sides. Hold the swab and wipe the pharyngeal tonsils on both sides of the patient with moderate force back and forth for at least 3 times.



Swallow swab is to wipe the tonsils or the posterior pharyngeal wall



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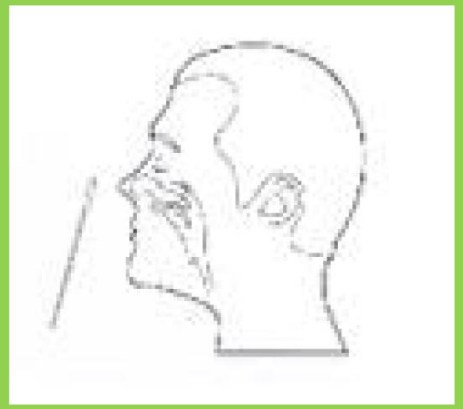
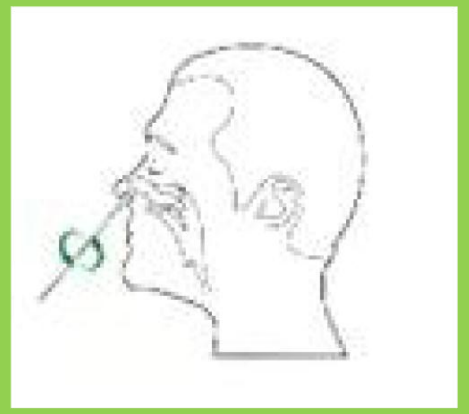
Nasal Swab Specimen Collection

1.Insert the swab into one nostril of the patient. The swab tip should be inserted up to 2.5cm(1 inch) from the edge of the nostril.
2.Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.
3.Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities. Withdraw the swab from the nasal cavity.





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Interpretation of test 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 color 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 coroinavirus 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 on test region(T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Medical Device Manufacture License

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医疗器械生产许可证

许可证编号：浙食药监械生产许 20170022 号

企业名称：杭州睿丽科技有限公司

生产地址：杭州经济技术开发区 3 号大街 28 号 3 号楼 2 楼

法定代表人：丁鹏飞

生产范围：第二类 6840 临床检验分析仪器

企业负责人：丁鹏飞

住　　所：杭州经济技术开发区白杨街道 21 号大街 600 号 4 幢 506 室

发证部门：浙江省食品药品监督管理局

有效期限：至 2022 年 5 月 8 日

发证日期：2017 年 5 月 9 日

国家食品药品监督管理总局制

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Quality System-ISO 13485:2016

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

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

Page 1 of 1
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Product Certification-CE

CE **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 20200817

(Place and date of issue)

General manager:

(Signature and position)

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Expecting our new product

Realy Tech®

SARS-Cov-2 & Influenza A&B Combo Rapid Test Cassette(Swab)

Expecting

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