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Product overview

COVID-19 Antigen Rapid Test

Assay typ	Lateral flow PoC test	Storage temp.	2 - 30°C
Test typ	Qualitativ	Shelf life	2 years
Test material	Nasopharynx Oropharynx	Sensitivity	92,1 %
Test duration	5-15 Minuten	Specificity	98,1 %
Pack size	20 tests / 1 test	Accuracy	96.7 %

Antigen test for direct pathogen detection of the coronavirus SARS-CoV-2

Description

Recently, antigen rapid tests have become a new and important pillar in the containment of the current COVID-19 pandemic. These tests can be performed on-site by trained personnel and detect the COVID-19 pathogen and its antigens quickly and directly. A swab is taken from the back of the nose or throat and applied to a test cassette. This test works according to the lateral flow principle and shows within 5 to 15 minutes whether COVID-19 antigens could be detected in the sample.



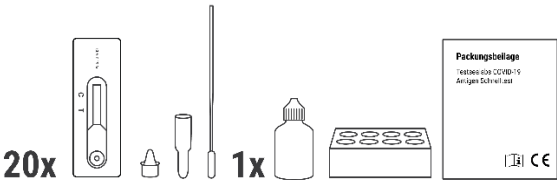
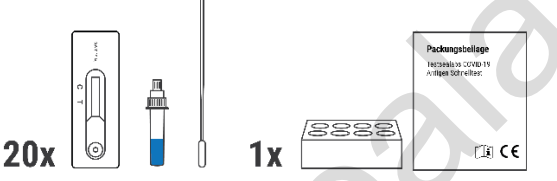
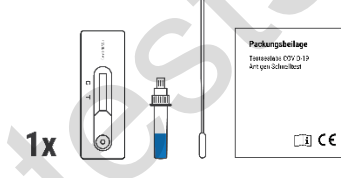
- CE certified test
- On-site implementation by medically trained personnel
- Result after 5 to 15 minutes
- Reliable exclusion of a Sars-CoV-2 infection with high accuracy
- Can be performed as nasopharyngeal swab and oropharyngeal swab.
- The test is developed as a Point of Care (POC) test. No equipment is required, all necessary materials are included

Performance data

The performance data of the test exceed the requirements for antigen rapid tests of worldwide recognized institutions such as the Robert Koch Institute (RKI) in Germany, the FDA in the US or the WHO. The performance data refer to the current PCR Gold Standard.

Sensitivity: 92.1% CI (87,7% - 93,3%),
Specificity: 98.1% CI (95,14% - 99,14%)
Accuracy: 96.7%

Models

Name	Description
Test-Kit: 20 tests 1 buffer Art. 0049841478241	1x package insert 1x tube rack 20 x test cassette 20x Sterile Swabs 20x sampling tubes with cap 1x test liquid 
Test-Kit: 20 tests 20 buffer Art. 0049841478258	1x package insert 1x tube rack 20 x test cassette 20x Sterile Swabs 20x sampling tubes with cap and pre-filled test liquid 
Test-Kit: 1 tests 1 buffer Art. 0049841478234	1x package insert 1 x test cassette 1x Sterile Swabs 1x sampling tubes with cap and pre-filled test liquid 

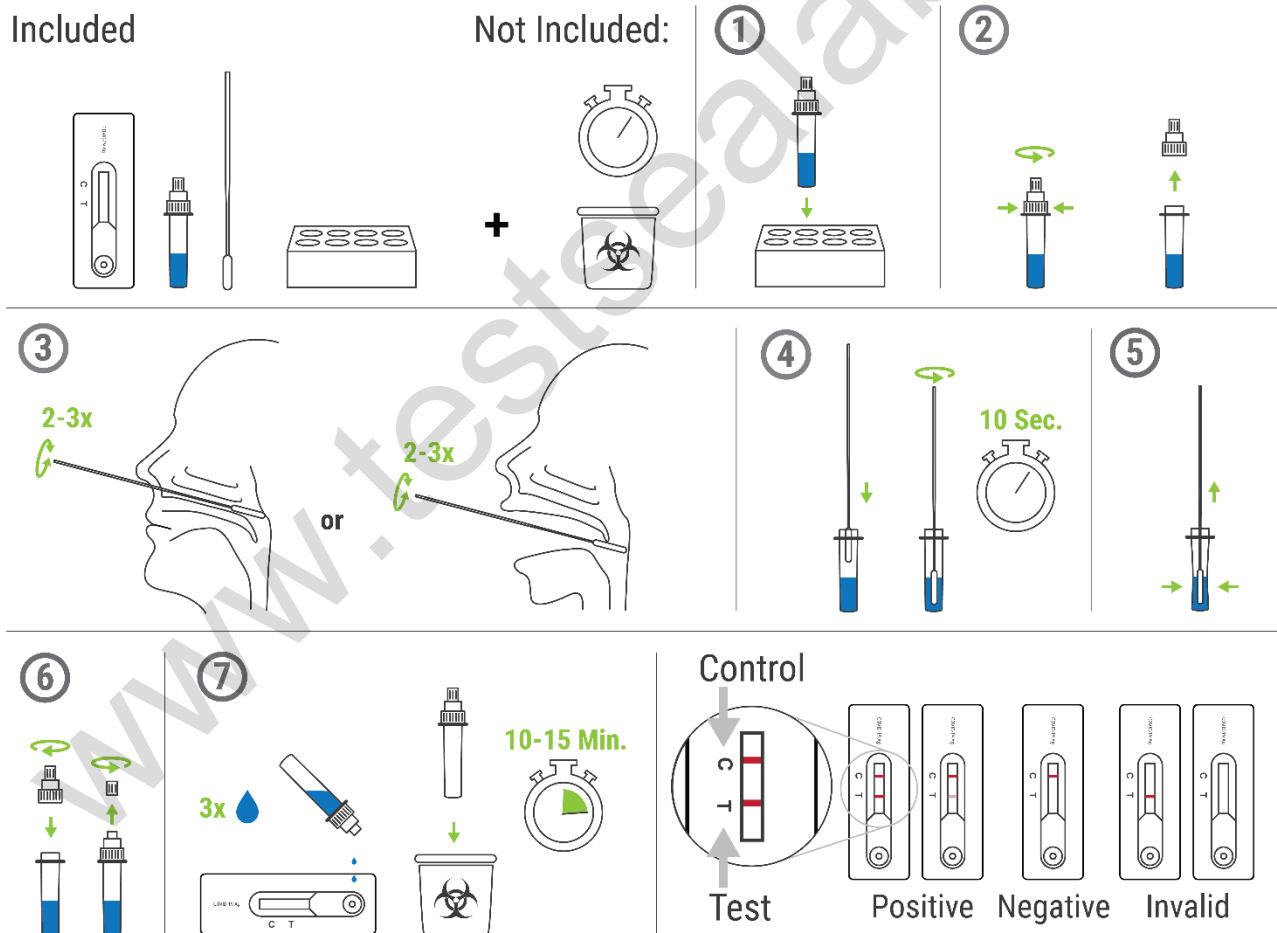
Order

- Orders should be sent to info@testsealabs.de
- Product available
- Shipment within 5 days after order and payment from manufacturer or warehouse in Germany

Further product data regarding approval, validation and the safety data sheet are available on request.

Quick Guide: prefilled buffer

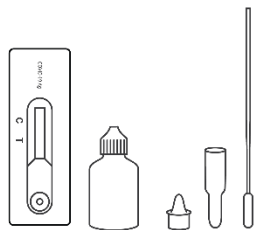
- ① Take the tube rack and place the extraction tube.
- ② Open the extraction tube by unscrewing the whole cap. The extraction tube is prefilled with the right amount of buffer.
- ③ Unpack the included sterile swab. Let a medical professional take a nasopharyngeal or oropharyngeal swab.
- ④ Place the swab in the prepared extraction buffer for 10 seconds. Stir it slightly to release captured antigen.
- ⑤ Take the swab out of the extraction buffer, while carefully squeezing the extraction tube.
- ⑥ Place the cap back on the extraction tube. Unscrew the the small cap of the filter nozzle.
- ⑦ Dispense three drops of the specimen solution into the specimen window of the test cassette. Wait approx. 10 minutes until the control strip appears. The test is only valid if the control strip appears. The test is positive if a second strip appears in the test region.



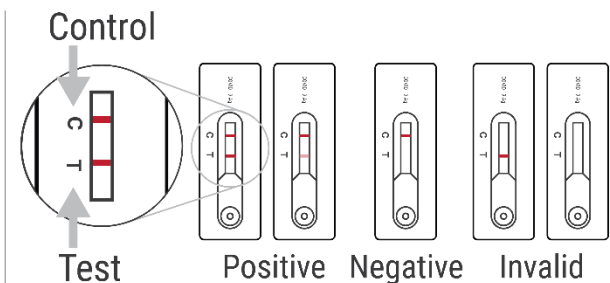
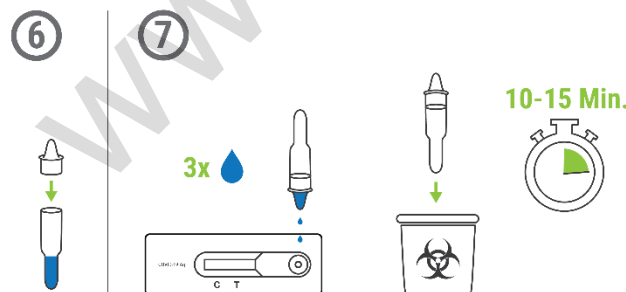
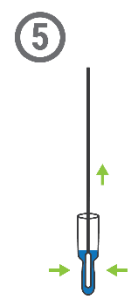
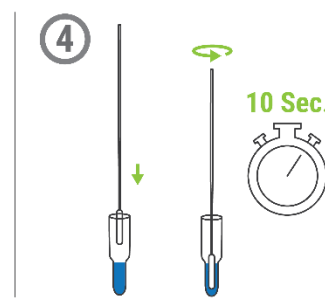
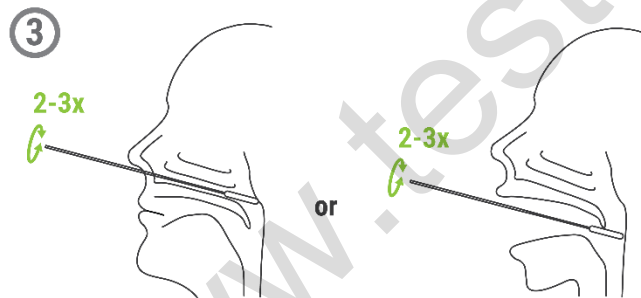
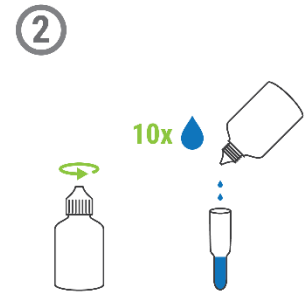
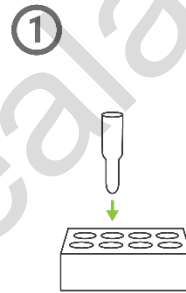
Quick Guide: buffer flask

- ① Take the tube rack and place the extraction tube.
- ② Open the extraction buffer and give 10 drops of the buffer into the extraction tube.
- ③ Unpack the included sterile swab. Let a medical professional take a nasopharyngeal or oropharyngeal swab.
- ④ Place the swab in the prepared extraction buffer for 10 seconds. Stir it slightly to release captured antigen.
- ⑤ Take the swab out of the extraction buffer, while carefully squeezing the extraction tube.
- ⑥ Place the filter cap on the extraction tube.
- ⑦ Dispense three drops of the specimen solution into the specimen window of the test cassette. Wait approx. 10 minutes until the control strip appears. The test is only valid if the control strip appears. The test is positive if a second strip appears in the test region.

Included:



Not Included:



CE Declaration of Conformity CE

According to the In-vitro Diagnostic Medical Device Directive 98/79/EC

Manufacturer: Hangzhou Testsea Biotechnology Co.,Ltd

Address: Building 6 No.8-2 Keji Road , Yuhang Street, Hangzhou -311121, China

Authorized Representative: Lotus NL B. V.

Address: T.a.v. de heer X. Wei Koningin Julianaplein 10 2595 AA's-Gravenhage

Product: COVID-19 Antigen Test

Model: TSCOVID-19AG

Classification: Other IVD

The manufacture, herewith, declares that the product as specified above meets the applicable provisions of the follow the Directive and standards and fulfil the obligations imposed by AnnexIII of Directive 98/79/EC. All supporting documentations is retained under the premise of authorized representative.

Directive:

In vitro Diagnostic Medical Device Directive: DIRECTIVE 98/79/EC OF THE EUROPEAN PARLLAMENT AND OF THE COUNCIL of October 1998 on invitro diagnostic medical device.

Standard:

All application harmonized standards(published in the Official Journal of the European Communities on 17th November 2017)

The above declaration of conformity is issued under the sole responsibility of the manufacture.

2020.09
(Place and Date of Issue)

杭州泰生生物技术有限公司
HANGZHOU TESTSEA BIOTECHNOLOGY CO., LTD

Signed for and on behalf of the manufacture

(Signature and Position)



LETTER OF AUTHORIZATION

TO WHOM IT MAY CONCERN

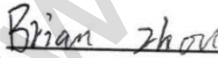
We, Hangzhou Testsea Biotechnology Co Ltd, based in Building 6 No 8-2 Keji Road, Yuhang Street, Hangzhou – 311121, China, herewith confirm that BRAWA GmbH, located at Steinrader Hauptstr. 57A, 23556 Lubeck, Germany, and GTRD GmbH, located at Von-Anckeln-Str. 15, 21029 Hamburg, Germany, are authorized to present, offer, marketing, tender and sell on behalf of our company

Authorized product name:

- SARS-COV2 (Covid-19) IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) Antibody Rapid Test
- SARS-COV2 (Covid-19) Antigen Rapid Test

Yours sincerely

Hangzhou, 01.05.2020



Brian Zhou

CEO

Hangzhou Testsea Biotechnology Co. Ltd

