BETTER AG

Top quality at manufacturer prices

COVID-19 Rapid test for professional use

With an integrated buffer solution

3 in 1
Nasopharyngeal | Oropharyngeal | Nasal Swab

Listed for EU-wide recognition in the "EU common list"
of the European Commission - Directorate General for Health and Food Safety
Common list of COVID-19 rapid antigen tests
Click here to check the validity of the CE certificate

It only takes 10 seconds for the antigen to be released into the swab

Visible result in 10-15 Minutes

Sampling	3 en 1 : Nazofaringealni | Orofaringealni | Nasenabstrich
Sensitivity	92.1%
Specificity	98.1%
Result en	10-15 minutes
Packaging	25 pieces
BfArM list	AT 082/20

Packaging and content of the Testsealabs 3 in 1 rapid tests

TESTSEALABS®
Rapid Test Kit

Package Contents

Testsealabs Covid-19 Antigen (SARS-CoV-2) Test Cassette (Swab)

Rapid test for qualitative! detection of SARS-CoV-2 nucleocapsid antigen in nasopharyngeal, oropharyngeal, and nasal swabs. For professional in vitro diagnostic use only.

INTENDED USE

The COVID-19 Antigen Test Cassette is a chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigen in nasopharyngeal, oropharyngeal, and nasal swabs to aid in the diagnosis of SARS-CoV-2 virus infection.

PRINCIPLE

The COVID-19 Antigen Test Cassette is a qualitative membrane strip-based immunoassay for the detection of COVID-19 antigen in nasopharyngeal, oropharyngeal, and nasal swab specimen. In this test procedure, anti-SARS-CoV-2-N antibody is immobilized in the test line region of the device. After a nasopharyngeal swab specimen is placed in the specimen well, it reacts with anti-SARS-CoV-2-N antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized anti-SARS-CoV-2-N antibody.
If the specimen contains SARS-CoV-2 antigen, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain SARS-CoV-2 antigen, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains anti-SARS-CoV-2-N antibody as the capture reagent, another anti-SARS-CoV-2-N antibody as the detection reagent. A Goat anti-Mouse IgG is employed in the control line system.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after the expiry date.
- Make sure that the foil pouch containing the test cassette is not damaged before opening it for use.
- Wear gloves and personal protective equipment when taking and applying samples. Do not touch the reagent membrane and the sample window.
- Do not eat, drink, or smoke in the area where specimens and kits are handled.
- Handle all samples as if they contained infectious agents.
- Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Conduct the test at a room temperature of 15 - 30 °C. Humidity and temperature can adversely affect the results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (4-30°C). The test is stable to the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The COVID-19 Antigen Test Cassette is designed for use with nasopharyngeal, oropharyngeal, and nasal swabs. Have the swab performed by a medically trained person. For best results, a nasopharyngeal swab is recommended.

Instructions for the nasopharyngeal swab procedure

Insert the swab liberally through the nose into the nasopharynx and swab the nasopharynx in 2-3 circular motions.

Instructions for the nasal swab procedure

Insert the entire tip of the swab two to three centimeters into the left nostril. Rub the inside of the nostril in a circular motion for at least 15 seconds. Remove the swab and insert it into the right nostril. Swab the inside of the nostril in a circular motion for at least 15 seconds.

General information

Do not return the swab to its original paper wrapper. For best results, swabs should be tested immediately after collection. If it is not possible to test immediately, it is strongly recommended that the swab is placed in a clean, unused plastic tube labelled with patient information to maintain best performance and avoid possible contamination. The sample can be kept tightly sealed in this tube at room temperature (15-30°C) for a maximum of one hour. Make sure that the swab is firmly seated in the tube and that the cap is tightly closed. If a delay of more than one hour occurs, discard the sample. A new sample must be taken for the test.
If specimens are to be transported, they should be packaged according to local regulations for the transport of etiological agents.

MATERIALS

Materials provided

Test device	Extraction tubes with sample buffer	
Package insert	Sterile swab	Workstation

Materials required but not provided: Timer

DIRECTIONS FOR USE

Allow the test, sample, and buffer to reach room temperature 15-30°C (59-86°F) before running.

① Place the extraction tube in the Workstation.
② Peel off aluminum foil seal from the top of the extraction tube containing the extraction tube containing the extraction buffer.
③ Have the nasopharyngeal, oropharyngeal or nasal swab carried out by a medically trained person as described.
④ Place the swab in the extraction tube. Rotate the swab for about 10 seconds
⑤ Remove the swab by rotating against the extraction vial while squeezing the sides of vial to release the liquid from the swab.properly discard the swab.while pressing the head of the swab against the inside of the extraction tube to expel as much liquid as possible from the swab.
⑥ Close the vial with the provided cap and push firmly onto the vial.
⑦ Mix thoroughly by flicking the bottom of the tube.Place 3 drops of the sample vertically into the sample window of the test cassette.
Read the result after 10-15 minutes. Read the result within 20 minutes. Otherwise, a repetition of the test is recommended.

EVALUATION OF RESULTS

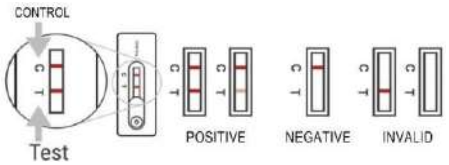
Positive Result: Two red lines appear. One red line appears in the control zone (C) and one red line in the test zone (T). The test is considered positive if even a faint line appears. The intensity of the test line can vary depending on the concentration ofthe substances present in the sample.

Negative Result: Only in the control zone (C) a red line appears, in the test zone (T) no line appears. The negative result indicates that there are no SARS-CoV-2 antigens in the sample, or the concentration of the antigens is below the detection limit.

Invalid Result: No red line appears in the control zone (C). The test is invalid even if there is a line in the test zone (T). Insufficient sample volume or incorrect handling are the most likely reasons for failure. Review the test procedure and repeat the test with a new test cassette.

QUALITY CONTROL

The test contains a colored line that appears in the control zone (C) as an internal



procedural control. It confirms sufficient sample volume and correct handling. Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and verify proper test performance.

LIMITATION

- This test detects both viable (live) and non-viable, SARS-CoV and COVID-19. Test performance depends on the amount of virus (antigen) in the sample and may or may not be correlated with viral culture results performed on the same sample.
- A negative test result may occur if the antigen concentration in a sample is below the detection limit of the test. The detection limit of the test was determined with recombinant SARS-CoV-2 nucleocapsid protein and is 100 pg/ml.
- The performance of the SARS-CoV-2 Antigen Test Cassette has been evaluated using only the procedures described in this package insert. Modifications to these procedures may alter the performance of the test.
- False negative results may occur if a sample is collected, transported, or handled improperly.
- False results may occur if samples are tested later than one hour after collection. Samples should be tested as soon as possible after collection.
- Positive test results do not exclude co-infection with other pathogens.
- Negative test results are not intended to be predictive of viral or bacterial infections other than SARS-CoV-2.
- Negative results from patients with symptom onset after more than seven days should be treated as presumptive and confirmation with another molecular assay should be performed.
- When differentiation of specific SARS-CoV-2 strains is required, additional testing is required in consultation with state or local health authorities.
- Children may tend to shed viruses longer than adults, which can lead to differences in susceptibility between adults and children and more difficult comparisons.

PERFORMANCE CHARACTERISTICS

Detection limit: The detection limit of the test was determined with infectious SARS-CoV-2 virus and is 50 x $TCID_{50}$.

Clinical Performance Characteristics of Nasopharyngeal Swab

To determine the sensitivity and specificity, the COVID-19 Antigen Test Cassette was compared with nasopharyngeal swabs using a commercial PCR test.

Sensitivity	**97.6% 95% CI:(94.9%-100%)**
Specificity	**98.4% 95%CI: (96.9%-99.9%)**

Determination of the specificity

Number of samples	PCR negative	COVID-19 Antigen Test Cassette
250	250	246/250 = 98.4%
Total	250	246/250 = 98.4% 95%CI: (96.9%-99.9%)

Determination of the sensitivity

Days post Symptom onset	Number of samples	PCR positive	COVID-19 Antigen Test Cassette
1	3	3	3/3=100%
2	9	9	9/9=100%
3	14	14	14/14=100%
4	17	17	17/17=100%
5	22	22	21/22=95.4%
6	26	26	25/26=96.1%
7	34	34	33/34= 97.0%
Total	125	125	122/125=97.6% 95% CI: (94.9%-100%)

Clinical Performance Characteristics of Nasal swab

To determine the sensitivity and specificity, the COVID-19 antigen rapid test kit with nasal swabs was compared with a commercial PCR test. All swabs were taken by the patients themselves and the results were evaluated by the patients together with the nursing staff.

Sensitivity	**93.6% 95% CI: (92.5%-94.7%)**
Specificity	**98.8% 95% CI: (98.5%-99.1%)**

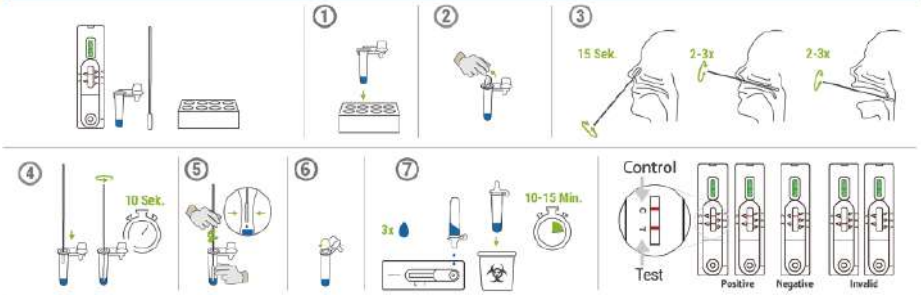
Determination of the specificity

Number of samples	PCR negative	COVID-19 Antigen Test Cassette
250	250	247/250 = 98.8%
Total	250	247/250 =98.8% 95% CI: (98.5%-99.1%)

Determination of the sensitivity

Days post Symptom onset	Number of samples	PCR positive	COVID-19 Antigen Test Cassette
1	3	3	3/3=100%
2	9	9	9/9=100%
3	14	14	14/14=100%
4	17	17	17/17=100%
5	22	21	21/22=95.4%
6	26	26	24/26=92.3%
7	34	34	29 /34= 87.8%
Total	125	125	117/125=93.6% 95% CI: (92.5%-94.7%)

Kurzanleitung



Cross-reactivity: The COVID-19 antigen rapid test cassette has been tested for specificity and cross-reactivity with other pathogens that may cause similar symptoms. The results showed no cross-reactivity.

Pathogen	Concentration
Pseudomonas aeruginosa	$1x10^8$ org/mL
Streptococcus sp group F	$1x10^8$ org/mL
Streptococcus salivary	$1x10^8$ org/mL
Streptococcus pyrenes	$1x10^8$ org/mL
Streptococcus pneumoniae	$1x10^8$ org/mL
Staphylococcus epidermidis	$1x10^8$ org/mL
Staphylococcus aur. subs aureus	$1x10^8$ org/mL
Neisseria sub llama	$1x10^8$ org/mL
Neisseria lactam lca	$1x10^8$ org/mL
Moraxella catarrhalis	$1x10^8$ org/mL
Escherichia coli	$1x10^8$ org/mL
Corynebacterium	$1x10^8$ org/mL
Candida albicans	$1x10^8$ org/mL
Arcanobacterium	$1x10^8$ org/mL
Human Coronavirus OC43	$2.45x\ 10^6 LD_{50}$/ml
Human Coronavirus NL63	$1.17x10^5$ U/ml
Influenza A H1N1	$3.16\ x\ 10^5 TCID_{50}$/ml
Influenza A H3N2	$1\ x10^6 TCID_{50}$/ml
Influenza B	$3.16x10^6 TCID_{50}$/ml
Human Rhinovirus 2	$2.81\ x10^4 TCID_{50}$/ml
Human Rhinovirus 14	$1.58x\ 10^6 TCID_{50}$/ml
Human Rhinovirus 16	$8.89x10^4 TCID_{50}$/ml
Masem	$1.58x10^4 TCID_{50}$/ml
Mumps	$1.58x\ 10^4 TCID_{50}$/ml
Parainfluenza Virus 2	$1.58x\ 10^7 TCID_{50}$/ml
Parainfluenza Virus 3	$1.58\ x\ 10^8\ TCID_{50}$/ml
Respiratory Syncytial-VirusM	$8.89x10^4\ TCID_{50}$/ml

Interfering substances: The following compounds were tested with the COVID-19 rapid antigen test and no interferences was observed.

Substance	Concentration	Substance	Concentration
whole blood	20 pl/ml	Mupirocin	12 mg/ml
Muzin	50 pg/ml	Oxymetazoline	0.6 mg/ml
Budesonide Nasal spray	200 pl/ml	Phenylephrine	12 mg/ml
Dexamethasone	0.8 mg/ml	Rebetol	4.5 pg/ml
Flunisolide	6.8 ng/ml	Relenza	282 ng/ml

Symbol	Meaning	Symbol	Meaning
IVD	Medical in vitro diagnosis		Storage temperature limits (4-30°C)
	Manufacturer		Tests per set
LOT	Batch code		Do not reuse
	Follow the instructions for use	EC REP	Authorized Representative in the European Community
	Expiry date	REF	Catalogue number

HANGZHOU TESTSEA BIOTECHNOLOGY CO.,LTD.
3rd Floor, Building 6,
No.8-2 Keji Road,Yuhang District,
Hangzhou,China

EC REP **Lotus NL B.V.**
Koningin Julianaplein 10,
1e Verd, 2595AA, The Hague,
Netherlands.

NO：20210312 Version 10 Effective date ： 2021-3-12

Importer:

Better AG
General-Guisan-Str. 8
6300 Zug
Switzerland
IR: + 353 1 513 75 11
CH: + 41 (0) 71 58 80 248
E-Mail: info@OdemShop.com
Web: www.OdemShop.com

TESTSEALABS®
Rapid Test Kit
Hangzhou Testsea Biotechnology Co.,Ltd
Building 6 No.8-2 Keji Road , Yuhang Street Hangzhou -311121,China

Company Statement On Virus Mutation

According to the latest research，there are many mutant strains of the Covid-19 virus, which are the British variants (VOC202012/01, B.1.1.7 or 20B/50Y.V1). There are 4 mutation points on the nucleocapsid protein, which are located at D3L, R203K, G203R and S235F. South Africa variants (501.V2, 20C/501Y.V2 or B.1.315) do not have any mutation points on the nucleocapsid protein .The new Indian variants have nucleocapsid protein mutation points located at P6T, P13L and S33I .And the B.1.1.529 has the protein mutation points located at P13L,R203K,G204R,E31,R32,S33

Figure 1: Potential impact of mutations - B.1.1.529(Omicron)

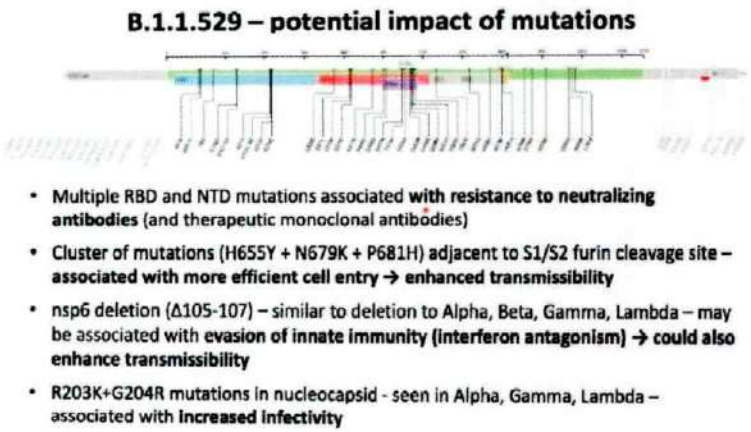


Figure 2: Position of mutations - B.1.1.529(Omicron)

杭州泰熙生物技术有限公司
HANGZHOU TESTSEA BIOTECHNOLOGY CO., LTD
Brian Zhou

Nucleocapsid phosphoprotein [Severe acute respiratory syndrome coronavirus 2]

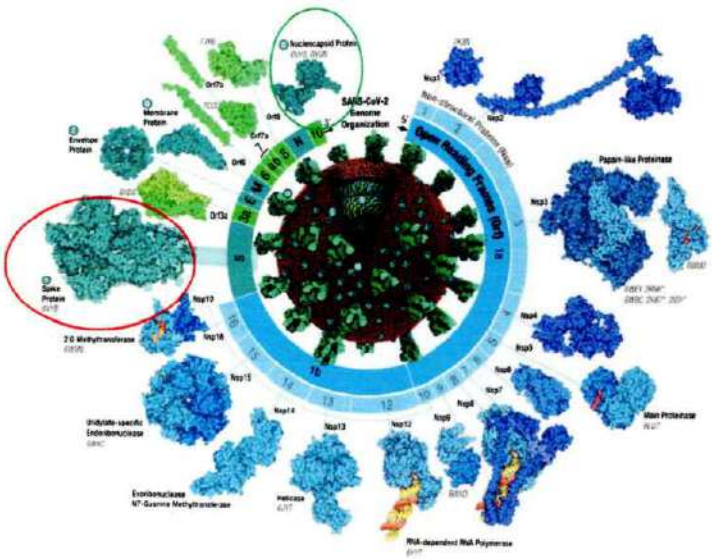
ORIGIN

1 msdngpqnqr napritfggp sdstgsnqng arsgarskqr rpqglpnnta swftaltqhg
61 kedlkfprgq gvpintnssp ddqigyyrra trrirggdgk mkdlsprwyf yylgtgpeag
121 lpygankdgi iwvategaln tpkdhigtrn pannaaivlq lpqgttlpkg fyaegsrggs
181 qassrsssrs rnssrnstpg ssrgtsparm agnggdaala lllldrlnql eskmsgkgqq
241 qqgqtvtkks aaeaskkprq krtatkaynv tqafgrrgpe qtqgnfgdqe lirqgtdykh
301 wpqiaqfaps asaffgmsri gmevtpsgtw ltytgaikld dkdpnfkdqv illnkhiday
361 ktfpptepkk dkkkkadetq alpqrqkkqq tvtllpaadl ddfskqlqqs mssadstqa

● *Label Red: The mutations of nucleocapsid phosphoprotein - B.1.1.529*(Omicron)

● *Label Yellow: Recognition epitopes which the corresponding antigen are located in N47-A173 (NTD region)*

Figure 3: Virus Structure



We, Hangzhou testsea here solemnly declare that Covid-19 tests which we produce use nucleocapsid phosphoprotein monoclonal antibodies for detection,recognition epitopes which the corresponding antigen are located in N47-A173 (NTD region), as a result, our tests are qualified for these virus variants.

杭州泰熙生物技术有限公司
Hangzhou Testsea Biotechnology Co.,Ltd
HANGZHOU TESTSEA BIOTECHNOLOGY CO., LTD
Brian Zhou

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)

Signed for and on behalf of the manufacture

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

(Signature and Position)

Hangzhou Testsea Biotechnology Co.,Ltd
Building 6 No.8-2 Keji Road , Yuhang Street Hangzhou -311121,China

TO WHOM IT MAY CONCERN,

It is hereby certified and declared that company:
"Better AG" located in General-Guisan-Str. 8,

6300 Zug, Switzerland

Is authorized to import, sell, distribute the "Testsea" branded goods in Europe, Asia and Africa.

We hereby confirm the authenticity of the test kits sold by this distributor.

杭州泰[illegible]技术有限公司

HANGZHOU TESTEA BIOTECHNOLOGY CO.,LTD

HZJZ

HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO

Rockefellerova 7 HR-10000
Zagreb T: +385 1 4863 222
F: +385 1 4863 366
www.hzjz.hr

VALIDATION STUDY REPORT

OBJECTIVE:

To establish the performance (sensitivity and specificity) of TESTSEALABS Rapid test Kit COVID-19 Antigen Test Cassette, HANGZHOU TESTSEA BIOTECHNOLOGY CO., LTD, China (LOT No.: TL2B17A; MDD: 02/2024).

Samples included:

100 RT-PCR SARS-CoV-2 positive samples from persons within the first 7 days from the onset of COVID-19 symptoms during the period from 19 to 24 November 2022.

50 RT-PCR SARS-CoV-2 negative symptomatic or asymptomatic persons

Samples were taken at the drive-in test station of the Croatian Institute of Public Health from symptomatic and asymptomatic persons. The samples were collected by healthcare professionals. Nasopharyngeal swabs were taken and placed into the viral transport medium (2 ml). The swabs were transported to the laboratory and tested with the COVID-19 Antigen Rapid Test and with confirmatory RT-PCR test (Allplex™ 2019-nCoV Assay, Seegene Inc, Republic of Korea, Lot:RV9121L95, Exp.:1/2023). RT-PCR and COVID-19 Antigen Rapid Test were performed from the same nasopharyngeal swab.

Diagnostic acceptance criteria:

- Assay should have sensitivity over 80%, or over 90% for subjects with a Ct < 25
- Assays should have a specificity over 98%.

Ethical approval

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by theEthics Committee of the Croatian Institute of Public Health (Protocol No. 030-02/22-05/4, Approved on October 28, 2022).

Results:

	POSITIVE RT-PCR (all, Ct<30; Ct<25)	NEGATIVE RT-PCR	TOTAL
POSITIVE RAT	**80/80/71**	**0**	**80/80/71**
NEGATIVE RAT	**20/20/0**	**50**	**70/70/50**
TOTAL	**100/100/71**	**50**	**150/150/121**

All samples	**Statistic Value**	**95% CI**
Sensitivity	80.00%	70.82% to 87.33%
Specificity	100.00%	92.89% to 100.00%
Positive Predictive Value	100.00%	
Negative Predictive Value	71.43%	62.82% to 78.72%
Accuracy	86.67%	80.16% to 91.66%

Samples (Ct<25)	**Statistic Value**	**95% CI**
Sensitivity	100.00%	94.94% to 100.00%
Specificity	100.00%	92.89% to 100.00%
Positive Predictive Value	100.00%	
Negative Predictive Value	100.00%	
Accuracy	100.00%	97.00% to 100.00%

The CT values for the tested samples were <=36. Statistical analysis was done using online tool (https://www.medcalc.org/calc/diagnostic_test.php).

The assay has overall sensitivity 80% (80.0%) and over 90% for subjects with a Ct < 25 (100%) and specificity 100.00% which is in line with the requirements MDCG Guidance on performance evaluation of SARS-CoV-2 *in vitro* diagnostic medical devices.

Zagreb, January 05, 2023

Irena Tabain, PhD, MD
Head of Virology Department
Croatian Institute of Public Health

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

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

TÜV SÜD Product Service

Certificate

No. Q5 104467 0001 Rev. 00

Holder of Certificate: **Hangzhou Testsea Biotechnology Co., Ltd.**
3rd Floor, Building 6 north, No. 8-2 Keji Avenue
Yuhang District
311121 Hangzhou, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Hangzhou Testsea Biotechnology Co., Ltd.
3rd Floor, Building 6 north, No. 8-2 Keji Avenue, Yuhang District,
311121 Hangzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of In-Vitro Diagnostic Kits for Fertility, Drug of abuse and Infectious Diseases**

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.: SH19155901

Valid from: 2020-02-21
Valid until: 2023-02-20

Date, 2020-02-21

Christoph Dicks
Head of Certification/Notified Body

TÜV®

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