ExactSign™

COVD-19 Antigen Rapid Test Cassette

Nasal Swab - For Self-Testing

Summary Date

Hangzhou Biotest Biotech Co., Ltd

目录

(Contents)

Company Profile

Hangzhou Biotest Biotech Co., Ltd was established in 2008 and is headquartered in Hangzhou China. It is mainly engaged in the R&D, production and sales of in vitro diagnostic (IVD) reagents. It's one of the leading companies in the IVD industry in China.

The company's main product is POCT rapid diagnostic reagent products, which is one of the manufacturers with a relatively complete product line of POCT diagnostic reagents in the world. Products are mainly divided into 5 categories, drug abuse testing, infectious disease testing, fertility health testing, tumor marker testing, cardiology marker testing. Products are widely used in medical institutions at all levels at home and abroad, judicial testing systems, third-party testing institutions, CDC, private clinics, etc. The POCT diagnostic reagent products produced by the company are developed based on colloidal gold/latex/fluorescent particle preparation and labeling technology, immunochromatography technology, monoclonal antibody technology, etc., which have strong specificity, high sensitivity and simplicity compared with traditional diagnostic methods. The advantages of fast, low cost, no need for special equipment and suitable for screening use, are of great significance to the development of laboratory medicine.

Since its establishment, the company has focused on research in the field of biotechnology and R&D of bio-high-tech products. As of June 2021, the company has 161 patented technologies, including 133 domestic patents (6 invention patents) and 28 overseas patents (2 Invention patents). Obtained 34 NMPA certificates, 5 EU CE certificates covering 16 products, 138 CE self-declaration categories, and 3 US FDA 510(k) certificates covering 21 test products. Products are sold to more than 100 countries and regions around the world.

In February 2020, the rapid test kit for the SARS-CoV-2 successfully developed by Biotest has been certified by a total of 20 countries (regions) including the United States, Germany, France, etc. It is one of the earliest domestic company to obtain the European Union CE certification and the U.S. FDA for emergency use, and Biotest SARS-CoV-2 antibody IgG/IgM rapid test is the only product of the same principal that has been evaluated by the US National Cancer Institute (NIC), and both positive predictive value and negative predictive value are 100%. After that, Biotest successfully developed a series of SARS-CoV-2 antigen rapid tests, and the performance has been generally recognized by institutions and customers. Two of the SARS-CoV-2 antigen products have passed the test of Oxford University in the United Kingdom. This series of products are suitable for the tests of a variety of samples, including nasopharyngeal swab, nasal swab, saliva, etc. The SARS-CoV-2 antigen tests have been registered in many countries including the EU, the Philippines, Brazil, and Colombia, and are sold in more than 35 countries and regions helping prevent and control the global epidemic.

Hangzhou Biotest Biotech Co., Ltd (Stock Code: 688767) made its initial Public Offering successfully on the SSE Science and Technology Board on the morning of September 8, 2021. The successful listing on the board marks a brand new stage in the development of Biotest, which will further enhance the technology level and added value of products with the power of capital market and provide new growth points for the future company development.

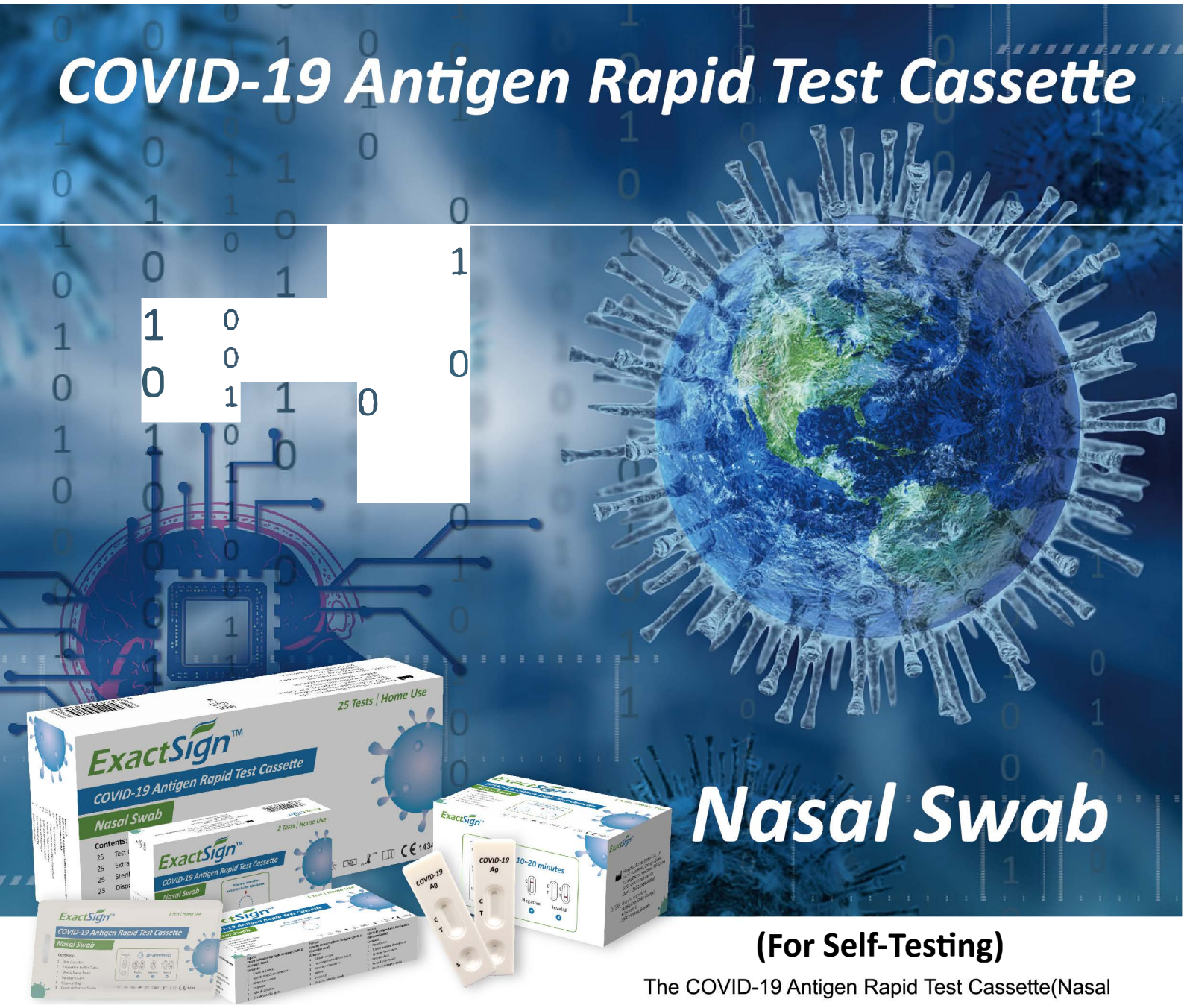
As one of the leading manufacturers of POCT in vitro diagnostic reagents in China, Biotest has an excellent R&D team and a high-quality management team with a positive and innovative

concept and spirit, and advocates a technology-based green health new life concept. We can continue to provide customers with technologically advanced, high-quality and low-cost products and services, and are committed to providing innovative, timely, and high-quality diagnostic products and solutions for global users, to meet unending medical needs, and to provide global users with Cost-effective rapid in vitro diagnostic products and services.

ExactSign™

Home use CE 1434

COVID-19 Antigen Rapid Test Cassette



Nasal Swab

(For Self-Testing)

The COVID-19 Antigen Rapid Test Cassette(Nasal Swab) is a rapid chromatographic immunoassay for the qualitative detection of COVID-19 antigen in Nasal Swab in symptomatic individuals. The identification is based on the monoclonal antibodies specific for the Nucleocapsid (N) protein of SARS-CoV-2. It is intended to aid in the rapid differential diagnosis of current COVID-19 infections.

Painless
Avoid the discomfort of nasopharyngeal swab sampling

Convenient
Easy to operate, Interpret result at 10 minutes

Accurate
Excellent performance compared to molecular methods

Hangzhou Biotest Biotech Co., Ltd.
17#, Futai Road, Zhongtai Town, Yuhang District, Hangzhou -311121 P.R. China

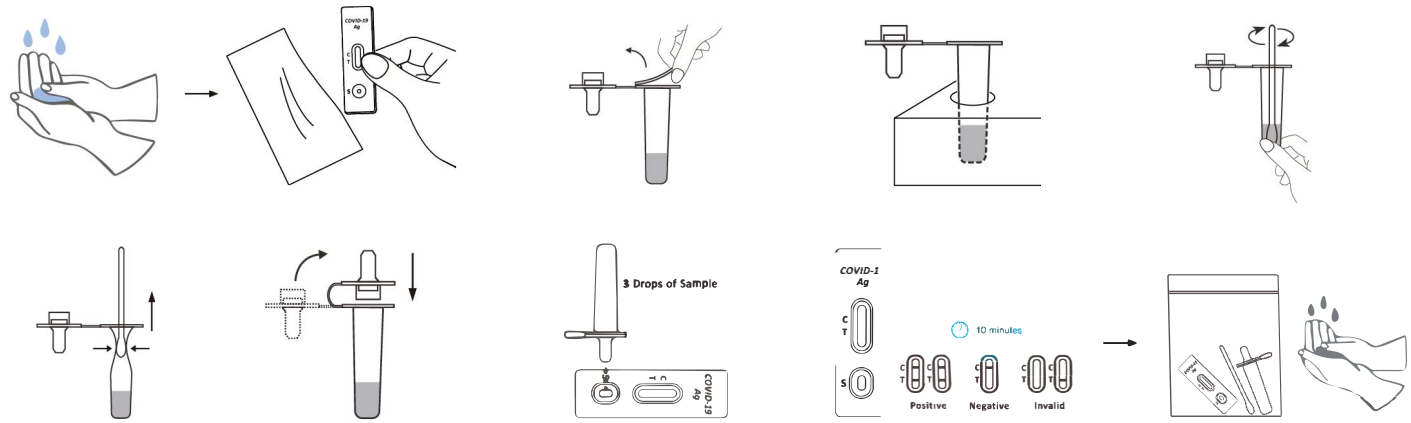
ExactSign™

COVID-19 Antigen Rapid Test Cassette

MATERIALS

- Test cassette
- Extraction Buffer Tube
- Sterile Nasal Swab
- Package Insert
- Quick Reference Guide
- Disposal bag
- Workstation (25T Only)

Convenient Procedure



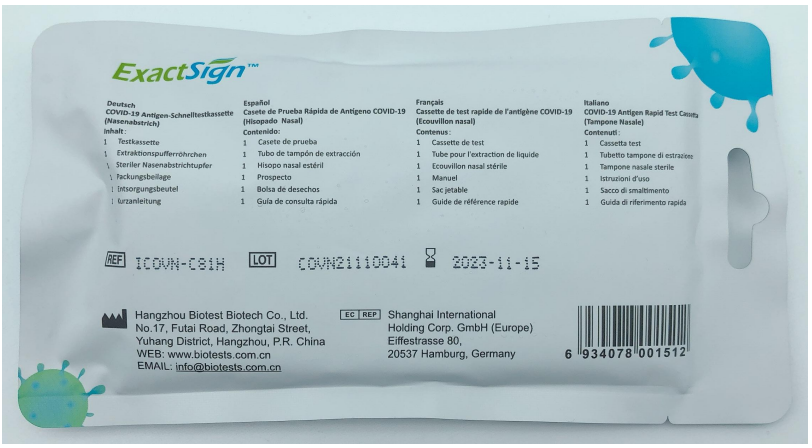
Ordering Information

	Cat.No.	Product	Specimen	Format	Pack
	ICOVN-C81H	COVID-19 Antigen Rapid Test Cassette (For Self-testing) CE1434	Nasal Swab	Cassette	1 T (soft packaging)
	ICOVN-C81H	COVID-19 Antigen Rapid Test Cassette (For Self-testing) CE1434	Nasal Swab	Cassette	1 T
	ICOVN-C81H	COVID-19 Antigen Rapid Test Cassette (For Self-testing) CE1434	Nasal Swab	Cassette	2 T
	ICOVN-C81H	COVID-19 Antigen Rapid Test Cassette (For Self-testing) CE1434	Nasal Swab	Cassette	5 T
	ICOVN-C81H	COVID-19 Antigen Rapid Test Cassette (For Self-testing) CE1434	Nasal Swab	Cassette	25 T

Hangzhou Biotest Biotech Co., Ltd.

17#, Futai Road, Zhongtai Town, Yuhang District, Hangzhou -311121 P.R. China

COVD-19 Antigen Rapid Test Cassette
Product Photos



检测试剂包装信息

Packing Information

ExactSign COVID-19 Antigen Rapid Test (Self-Testing)

产品名称 **Product name**	规格/盒 **Specifiifications**	单位 **Unit**	单位包装毛重 **Gross weight per unit package**
COVID-19 Antigen Rapid Test (Nasal Swab)	1T	袋/kit	0.029kg/袋 0.029kg / kit

试剂盒出口包装箱

Export Packing Cartons
ExactSign COVID-19 Antigen Rapid Test (Self-Testing)

包 装 箱 Packing Carton	长 length cm	宽 Width cm	高 height cm	每箱装袋数 量 Kit quantity per carton	单盒试剂净重 Net weight of single kit	整箱净重 Net weight of the whole carton	整箱毛重 Gross weight of the whole carton
纸箱 carton	69	39	55	800T	0.029Kg	23.2Kg	25kg

CERTIFICATE

EC Certificate No. 1434-IVDD-455/2021

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

Polish Centre for Testing and Certification certifies
that manufactured by:

HANGZHOU BIOTEST BIOTECH CO., LTD
17#, Futai Road, Zhongtai Street, Yuhang District, Hangzhou, P.R. China

in vitro diagnostic medical devices
for self-testing

The list of medical devices covered by this certificate is provided in the annex 1

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 01.09.2021 to 27.05.2024

The date of issue of the Certificate: 01.09.2021

The date of the first issue of the Certificate: 01.09.2021

CE 1434

Issued under the Contract No. MD-39/2021
Application No: 052/2021
Certificate bears the qualified signature.
Warsaw, 01.09.2021
Module A1

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.09.02 09:46:30 +02'00'
Vice-President

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

Product Service

Certificate

No. Q5 077434 0014 Rev. 02

Holder of Certificate: **HANGZHOU BIOTEST BIOTECH CO., LTD.**
17#, Futai Road, Zhongtai Street
Yuhang District
311121 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development,
Production and Distribution of
In Vitro Diagnostic Kit for the Detection of
Hormone, Drug of Abuse,
Infectious Disease,
Tumour Marker and Cardiac Marker,
Bacterial Vaginosis PH Panel(Vaginal Discharge)**

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.: SH2070801

Valid from: 2020-09-06
Valid until: 2023-09-05

Date, 2020-07-29

Christoph Dicks
Head of Certification/Notified Body

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

A4 / 07.17

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

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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 077434 0014 Rev. 02

Applied Standard(s):

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

Facility(ies):

HANGZHOU BIOTEST BIOTECH CO., LTD.
17#, Futai Road, Zhongtai Street, Yuhang District, 311121
Hangzhou, PEOPLE'S REPUBLIC OF CHINA

CITUS DIAGNOSTICS INC.
300-422 Richards street, Vancouver, British Columbia V6B 2Z4, CANADA

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

A4 / 07.17

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

TÜV®

EC DECLARATION OF CONFORMITY

EC DECLARATION OF CONFORMITY

博拓生物 BiotesT

EC Declaration of Conformity

Manufacturer:

Name：HANGZHOU BIOTEST BIOTECH CO., LTD

Address: No. 17, Futai Road, Zhongtai Street, Yuhang District, Hangzhou -311121 P.R. China

European Representative:

Name: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: COVID-19 Antigen Rapid Test Cassette(Nasal Swab)

Catalog Number: ICOVN-C81H(Brand Name: RightSign, ExactSign)
302282(Brand Name: Sienna)

Classification: Annex II, Self-testing Device of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC Annex III section 6

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. Hangzhou Biotest takes exclusive responsibility for this declaration of conformity.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO 13485:2016, EN ISO14971:2012, EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:2002/AC:2002, EN13532:2002, EN ISO 17511:2003, EN ISO 15193:2009, EN ISO 15223-1:2016, EN ISO 15194:2009, EN ISO 23640:2015, EC 1272/2008

Notified Body：

Name：POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.

Address：ul. Puławska 469 02-844 Warszawa Poland

Identification number: CE1434

(EC) Certificate(s): 1434-IVDD-455/2021

Expire date of the Certificate: 2024-05-27

Start of CE Marking: 2021-09-01

Place, Date of Issue: Hangzhou, P.R. China, Oct. 29, 2021

Signature: Super Liu

Name : Super Liu

Position : Quality Director

CE 1434