BETTER AG

Top quality at manufacturer prices

Sejoy

COVID-19 Rapid Test Kit

For self-tests

With an integrated buffer solution

Sejoy 1T

Packaging

1 test per box

CARTON	500 tests per carton

Sejoy 5T

Packaging

5 tests per box

CARTON	720 tests per carton

Details

Listed for EU-wide recognition in the "EU common list" of the European Commission - Directorate General for Health and Food Safety

Click to check the validity of the CE certificate

SAMPLING	Nasal Swab
SENSITIVITY	94,50%
SPECIFICITY	99,90%
RESULT IN	10 Minutes
EC/CE CERTIFICATE NO	IVDD-474/2021 / CE 1434

Self Testing In

1 CE1434	CERTIFICATE	6 Lithuania	VALSTYBINĖ AKREDITAVIMO SVEIKATOS PRIEŽIŪROS VEIKLAI TARNYBA PRIE SVEIKATOS APSAUGOS MINISTERIJOS
2 Germany	Federal Institute for Drugs and Medical Devices	7 Malaysia	Medical Device Authority
3 France	MINISTÈRE DE L'EUROPE ET DES AFFAIRES ÉTRANGÈRES	8 Thailand	
4 Czech Republic	MINISTERSTVO ZDRAVOTNICTVÍ Palackého náměstí 375/4, 12801 Praha 2	9 Bulgaria	Ministry of Health
5 Austria	Austrian Federal Office for Safety in Health Care BASG	10 Croatia	HALMED Agency for Medicinal Products and Medical Devices of Croatia

Odem

White Listed In

1. Germany — Federal Institute for Drugs and Medical Devices
2. France — MINISTÈRE DE L'EUROPE ET DES AFFAIRES ÉTRANGÈRES
3. Belgium — fagg
4. Austria — Austrian Federal Office for Safety in Health Care BASG
5. Czech Republic — MINISTERSTVO ZDRAVOTNICTVÍ
6. Slovakia — PUBLIC HEALTH AUTHORITY OF THE SLOVAK REPUBLIC
7. Slovenia — REPUBLIC OF SLOVENIA GOV.SI
8. Bulgaria — Ministry of Health
9. Malaysia — Medical Device Authority
10. Chile — Ministerio de Salud
11. Ecuador — U.S. Embassy & Consulate in Ecuador
12. Lithuania
13. Thailand
14. Poland — gov.pl

Qdem

EN

SEJOY

SARS-CoV-2 Antigen Rapid Test Cassette Package Insert

REF COVG-602ST

Version: B

For self-testing

Code: 4.15.03.0141-0

Specimens: Nasal Swab

Effective Date: 2022.4.1

IVD

FREQUENTLY ASKED QUESTIONS

- When I am ready to start the test, what preparations do I need to do?

Regardless of whether you have symptoms or not, when you are ready to use this reagent, please do isolation and protection. Wear a face mask or cover your mouth and nose with a tissue when you are coughing and keep distance with other people.

- When can I test myself?

You can always test yourself whether you have symptoms or not. Please note that the test result is a snapshot that is valid for this point in time. Tests should be repeated according to the regulations of the responsible authorities.

- What should I pay attention to in order to obtain the most exact test result possible?

Always follow the instructions of use exactly. Perform the test immediately after collecting the sample. Dispense the drops from the test tube only into the designated well of the test cassette. Dispense two drops from the sample tube. Too many or too few drops can lead to an incorrect or invalid test result.

- The test strip is very discolored. What is the reason or what am I doing wrong?

The reason for a clearly visible discoloration of the test strip is that too large a quantity of drops has been dispensed from the sample tube into the test cassette well. The indicator strip can only hold a limited amount of liquid. If the control line does not appear or the test strip is very discolored, please repeat the test with a new test kit according to the instructions for use.

- What should I do if I took the test but didn't see a control line?

In this case, the test result is to be considered invalid. Please repeat the test with a new test kit according to the instructions for use.

- I am unsure of the interpretation of the results. What should I do?

If you cannot clearly determine the result of the test, contact the nearest medical facility applying the regulations of your local authority.

- My result is positive. What should I do?

If a horizontal-colored line is visible in the control area (C) as well as in the test area (T), your result is positive, and you should immediately contact the medical facility in accordance with the requirements of your local authorities. Y our test result may be checked, and the next steps will be explained to you.

- My result is negative. What should I do?

If only a horizontal-colored line is visible in the control area (C), this may mean that you are negative or that the viral load is too low to be recognized by the test. If you experience symptoms such as headaches, migraines, fever, loss of sense of smell and taste, contact the nearest medical facility applying the regulations of your local authority. In addition, you can repeat the test with a new test kit.

- Can this test cassette be reused or used by multiple people?

This test cassette is for one-time use and cannot be reused or used by multiple people.

- Why do I swab both nostrils?

Swabbing both nostrils give you the best chance of collecting sufficient sample to generate an accurate result. It has been observed in some cases that only one nostril has detectable virus, so it is important to collect from both nostrils. Correct swabbing is important to obtain a correct result.

PACKAGE SPECIFICATIONS

1 test/pack, 3 tests/pack, 5 tests/pack, 7 tests/pack, 25 tests/pack

INTENDED USE

This kit is used for in vitro qualitative determination of SARS-CoV-2 antigens in human anterior nasal swab samples. It can be used for rapid investigation of suspected COVID-19 cases and can be used as a reconfirmation method for nucleic acid detection in discharged cases.

A positive test result indicates that the sample contains SARS-CoV-2 antigen. A negative test result does not rule out the possibility of infection.

This kit is for home use by laymen in a non-laboratory setting (such as person' s home or certain non-traditional sites such as offices, sporting events, airports, schools etc.). The test results of this kit are for clinical reference only. It is recommended to conduct a comprehensive analysis of the condition based on the patient's clinical manifestations and other laboratory tests.

Antigen testing is typically used in the acute phase of infection, when samples are tested within seven days of the onset of symptoms in a suspected population.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

- The kit is in vitro diagnostic use only. Do not use after the expiration date. See the foil bag spray code for the expiry date.
- The test should remain in the sealed pouch until ready to use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infection agent.
- The used test should be discarded according to local regulations.
- Avoid using bloody samples.
- Avoid touching the reagent membrane and sample well.
- Test for children and young people should be used with an adult.

KIT COMPONENTS

Materials Required and Provided

- Test Cassette
- Extraction Reagent with Integrated Extraction Tube
- Extraction tube cover
- Sterile Swabs
- Package Insert
- Tube Holder
- Biohazard Waste Bag
- Qualification Certificate

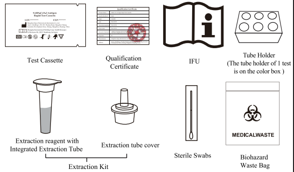
Note: Components of different batches cannot be mixed. Materials Required but not Provided

The timer and Disinfection products, such as hand sanitizer, rubbing alcohol, soap, etc.

DIRECTIONS FOR USE

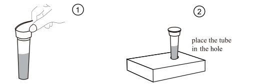
1. **Preparation before the beginning**

- Choose a location to do this test where it can sit UNDISTURBED for 15-30 minutes. Place the test cassette, sample extraction reagent and test components at room temperature for 15- 30 minutes, and equilibrate to room temperature {15~30°C (59°F-86°F)}
- Wash your hands with soap and water for at least 20 seconds before testing. If soap and water are not available, use hand sanitizer with at least 60% alcohol.
- It is not recommended to clean the nasal cavity before the test to prevent the virus content from being too low. Unless the nasal cavity is too wet or dry, after cleaning the nasal cavity, take a sample at least 30 minutes later.
- Open your test kit, and you should have:

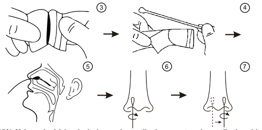


2. **Sample collection**

- Take out the extraction tube and the extraction tube cover, peel off the aluminum foil on the extraction buffer tube carefully and place the tube in the Tube Holder (see below).



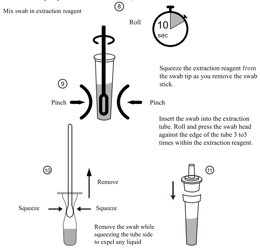
- Remove the swab from the container, being careful NOT to touch the soft end, which is the absorbent tip.
- Gently insert the swab into one nostril for 2-4cm (1-2cm for children) until you feel a bit of resistance.
- Using medium pressure, rub the swab slowly in a circular motion around the inside wall of your nostril 5 times within 7-10 seconds.
- Repeat the same process with the same swab in the other nostril.



CAUTION: If the swab stick breaks during specimen collection, repeat specimen collection with a new swab. When using swab, should pay attention to the safety of sampling. Avoid inserting too deep into the nasal cavity, causing pain and bleeding.

3. **Sample treatment**

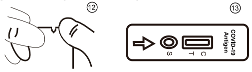
- Insert the swab into the Extraction tube and immerse the entire tip of swab into the extraction reagent.
- Soak the sampling swab below the liquid level of the extraction reagent. Rotate the swab and press for about 10 seconds. (Insert the swab into the extraction tube. Roll and press the swab head against the edge of the tube3 to 5 times within the extraction reagent)
- Squeeze the swab head against the inside of the extraction tube, then take out the swab and place the extraction tube cover firmly on the extraction tube. (Squeeze the extraction reagent from the swab tip as you remove the swab stick)



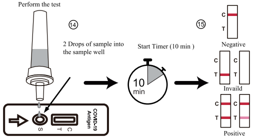
4. **Sample preservation:** The sample can be stored at room temperature {15~30°C (59°F-86°F)} for one hour.

TEST PROCEDURE

- Open the aluminum foil pouch of the test cassette, place the test cassette on a flat surface.



- Lay the cassette flat and add 2 drops of the treated sample into the sample well of the test cassette. Read the test result after adding the sample for 10 minutes. The result obtained after 30 minutes is invalid.



DISPOSAL THE SAMPLE AND CLEAN-UP

- The test cassette, sample extraction reagent and disposable virus sampling swab are collected into the biohazard waste bag and dispose it according to local regulations.
- Re-apply hand sanitizer.

INTERPRETATION OF RESULTS

NEGATIVE RESUI LT:

One colored line appears in the control line region(C). No line appears in the test region (T). A negative result indicates that SARS-CoV-2 antigen is not present in the specimen, or is present below the detectable level of the test.

POSITIVE RESULT:

Two lines appear. One colored line should be in the control region (C) and another apparent colored line should be in the test region (T). A positive result indicates that SARS-CoV-2 was detected in the specimen.

INVALID RESULT:

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE:

The intensity of the color in test line region (T) will vary depending on the concentration of SARS-CoV-2 Antigen present in the specimen. Therefore, any shade of color in the test line region(T) should be considered positive.

PRINCIPLE OF THE ASSAY

The SARS-CoV-2 Antigen Rapid Test Cassette is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in human Nasal swabs. In this test, antibody specific to the N protein of SARS-CoV-2 is separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibody to N protein of SARS-CoV-2 that are coated onto particles. The mixture migrates up the membrane to react with the antibody to N protein of SARS-CoV-2 on the membrane and generate one colored line in the test regions. The presence of this colored line of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use.

DO NOT FREEZE.

The manufacture date and expiration date was labelled in the sealed pouch. Do not use beyond the expiration date.

LIMITATIONS OF THE TEST

1. The test result of this kit is not the only confirmation indicator of clinical indication. The infection should be confirmed by a specialist along with other laboratory results, clinical symptoms epidemiology, and additional clinical data.
2. The test results are related to the quality of sample collection, processing, transportation and storage. Any errors may lead to inaccurate results. If cross-contamination is not controlled during the sample processing, false positive results may occur.
3. In the early stages of infection, low levels of antigen expression can result in negative results.
4. A negative result obtained from this kit should be confirmed by PCR.A negative result may be obtained if the concentration of the SARS-CoV-2 present in the swab is not adequate or is below the detectable level of the test.
5. The negative results are not intended to exclude other non 2019-nCov virus infections.
6. A negative test result does not rule out a coronavirus infection and does not exempt you from the applicable rules for spread control (e.g., contact restrictions and protective measures).
7. Excess blood or mucus on the swab specimen may interfere with performance and may yield a false positive result.

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD)

SARS-CoV-2 Antigen Rapid Test Cassette has been confirmed can be detect SARS-CoV-2 at 400TCID$_{50}$/ml.

Study on Interfering Substances

Test results will not be interfered by following substances at certain concentrations:

Interfering substance	Conc.	Interfering substance	Conc.
Whole Blood	4%	Compound Benzoin Gel	1. 5mg/ml
Ibuprofen	1mg/ ml	Cromolyn glycate	1 5%
tetracycline	3ug/ml	chloramphenicol	3ug/ml
Mucin	0.5%	Mupirocin	10mg/ml
Erythromycin	3ug/ml	Oseltamivir	5mg/ml
Tobramycin	5%	Naphazoline Hydrochlo-ride Nasal Drops	15%
menthol	15%	Fluticasone propionate spray	15%
Afrin	15%	Deoxyepinephrine hydrochloride	15%

Cross-Reactivity

Test results will not be affected by other respiratory viruses and commonly encountered microbial flora and low pathogenic coronaviruses listed in table below at certain concentrations.

Name	Concentration
HCOV-HKU1	10^5TCID$_{50}$ /ml
Staphylococcus aureus	10^6TCID$_{50}$ /ml
Measles virus	10^5TCID$_{50}$ /ml
Mumps virus	10^5TCID$_{50}$ /ml
Mycoplasmal pneumonia	10^6TCID$_{50}$ /ml
Paraimfluenzavirus, type2	10^5TCID$_{50}$ /ml
Human coronavirus OC43	10^5TCID$_{50}$ /ml
Human coronavirus 229E	10^5TCID$_{50}$ /ml
Influenza B Victoria STRAIN	10^5TCID$_{50}$ /ml
Influenza B YSTRAIN	10^5TCID$_{50}$ /ml
Influenza A H1N1 2009	10^5TCID$_{50}$ /ml
Influenza A H3N2	10^5TCID$_{50}$ /ml
H7N9	10^5TCID$_{50}$ /ml
H5N1	10^5TCID$_{50}$ /ml
Epstein- Barr virus	10^5TCID$_{50}$ /ml
Enterovirus CA16	10^5TCID$_{50}$ /ml
Human coronavirus NL63	10^5TCID$_{50}$ /ml
MERS coronavirus	10^5TCID$_{50}$ /ml
MERS CoV Florida/ USA-2_ Saudi Arabia 2014	1.17 x 10^4TCID$_{50}$ /ml
Respiratory syncytial virus	10^5TCID$_{50}$ /ml
RSV-A 2006 Isolate	5.01 x 10^4TCID$_{50}$ /ml
RSV-B CH93-18(19)	1.55 x 10^3TCID$_{50}$ /ml

Clinical Performance

Clinical performance of SARS-CoV-2 Antigen Rapid Test Cassette has been determined by testing 102 positive and 300 negative specimens for SARS-CoV-2 antigen.Analytical Resultswith correlation to Ct-values of the positive samples:

Ct-value	PCR confirmed	Correct sample number	Identified RATE
≤30	82	82	100 % (Sensitivity)
≤32	94	92	97.9 % (Sensitivity)
≤34	102	98	96. 1% (Sensitivity)
Negative	300	300	99.9%(Specificity)
total	402	398	99.0% (Total Accuracy)

The correlation between the Ct-values of the analyzed samples and the sensitivity reveals a sensitivity of 100% (95%CI* 95.5%-100.0%) for samples with a Ct-value of up to 30.the sensitivity reveals a sensitivity of97.9 % (95%CI* 92.6%-99. 4%) for samples with a Ct-value of up to 32. the sensitivity reveals a sensitivity of 96.1% (95%CI* 90.4%-98.5%) for samples with a Ct-value of up to 34. This is in line with expectations regarding viral detection by antigen rapid testing compared to PCR analysis.

99.9% (95%CI* 98.7%-100%) Specificity: In total 300 PCR confirmed negative samples: 300 PCR confirmed negative samples were correctly detected by the SARS-CoV-2 Antigen Rapid Test Cassette. There are no false positive cases.

99.0% (95%CI* 97.5%-99.6%) Accuracy: In total 402 PCR confirmed samples: 398 PCR confirmed samples were correctly detected by the SARS-CoV-2 Antigen Rapid Test Cassette.

The observed accuracy may vary depending on the prevalence of the virus in the population.

BIBLIOGRAPHY

1.Weiss SR,Leibowitz JZ.Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164

2.Cui J,Li F,Shi ZL.Origin and evolution of pathogenic coronaviruses.Nat Rev Microbiol 2019;17:181-192.

3.Su S,Wong G,Shi W ,et al.Epidemiology,genetic recombination,and pathogenesis of coronaviruses. TrendsMicrobiol 2016;24:490-502.

Index of Symbols

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by date		Do not reuse
	Temperature limitation	LOT	Lot Number	REF	Catalogue number
CE 1434	For self-testing		Manufacturer		Manufacturing date

EC REP **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestrasse 80, 20537 Hamburg, Germany

Hangzhou Sejoy Electronics & Instruments Co.,Ltd.
Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone,311100 Hangzhou City,Zhejiang, China
Website: www.sejoy.com

Importer (Switzerland) Better AG, General-Guisan-Str. 8, 6300 Zug, Switzerland Tel: +353 1 513 75 11 E-Mail: info@OdemShop.com Shop: www.OdemShop.com

Importer (EU) Importex Logistics OÜ Narva mnt 5, 10117 Tallinn, Estonia

CE 1434

ACCESSORIES:

Accessory	Manufacturer	EC Representative	CE-Mark
Swab A	Hangzhou Yiguoren Biotechnology Co., Ltd Room 402, Building 2, No. 2628, Yuhangtang Road, Cangqian Street, Yuhang District, Hangzhou City, Zhejiang, People' s Republic of China	Zoustech S.L. Paseo de la Castellana, 141 28049 Madrid	CE 0197
Swab B	Jiangsu Changfeng Medical Industry Co., Ltd. Touqiao Town, Guangling District, Yangzhou, 225109 Jiangsu, P.R. China	Llins Service & Consulting GmbH Obere Seegasse 34/2, 69124 Heidelberg, Germany	CE 0197
Swab C	Jiangsu Rongye Technology Co., Ltd. Touqiao Town, Yangzhou City, 225109, Jiangsu, P.R. China	Riomavix S.L. Calle de Almansa 55, 1D, Madrid 28039 Spain	CE 0197
Swab D	BioTeke Corporation(wuxi)Co.,Ltd 4th Floor, D5 & 2nd Floor, D3 & 1st and 2nd Floor, D16, No.1719, Huishan Avenue, Wuxi, Jiangsu, 214174, China	SUNGO Europe B.V. Olympisch Stadion 24 1076DE Amsterdam Netherlands	CE 2797
Swab E	Zhejiang Gongdong Medical Technology Co., Ltd. No.10 Beiyuan Ave., Huangyan, 318020 Taizhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA	Shanghai International Holding Corp. GmbH (Europe) EiffestraBe 80 20537 Hamburg GERMANY	CE 0123

Date: 2022-7-1

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 "Sejoy" branded goods in Europe, Asia and Africa.

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

Yours sincerely,

_____

Name: Yunhua Ren

Position: General Manager

Company stamp:

杭州世佳电子有限公司
HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO.,LTD.

Add: AREA C, BUILDING 2, NO.365, WUZHOU ROAD, YUHANG ECONOMIC DEVELOPMENT ZONE, HANGZHOU, 311100, CHINA
Tel: 0086 571 81957767
Fax: 0086 571 81957750
Web-site: www.sejoy.com

Statement on the monitoring of SARS-CoV-2 variants

Recently,the SARS-CoV-2 has discovered the newest SARS-CoV-2 variant "Omicron", whose Pango lineage is B.1.1.529.The Sejoy urgently established a special verification team to monitor and analyze the genetic data of the newly discovered SARS-CoV-2 variant; The Peptide probe sequence comparison results of the marketed products confirmed that the SARS-CoV-2 Antigen Rapid Test Cassette (Ref.:COVG-602ST) that has been marketed by Hangzhou Sejoy Electronics & Instruments Co.,Ltd. has no missed detection against the above-mentioned variant and still ensure the accuracy and sensitivity of the detection reagents.

Up to now, our company has monitored and analyzed the genetic data of major epidemic SARS-CoV-2 variants, including Alpha variant (B.1.1.7), Beta variant (B.1.351),Gamma variant(P.1) and Delta variant(B.1.617.2), Omicron variant (B1.1.529),our company will continue to pay attention to the variant of the SARS-CoV-2 to ensure that our company's SARS-CoV-2 Antigen Rapid Test Cassette (Ref.:COVG-602ST) will not miss detection and ensure the sensitivity, accuracy and specificity are not affected.

杭州世佳电子有限公司
HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO.,LTD.

Hangzhou Sejoy Electronics & Instruments Co.,Ltd.

2021-11-30

CERTIFICATE

EC Certificate No. 1434-IVDD-265/2022

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

Polish Centre for Testing and Certification certifies
that manufactured by:

Hangzhou Sejoy Electronics & Instruments Co., Ltd
Area C, Building 2, No. 365, Wuzhou Road, Yuhang Economic Development Zone, 311100 Hangzhou City, Zhejiang, China

in vitro diagnostic medical devices
for self-testing

The list of medical devices covered by this certificate is provided in the Annex no.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 25.05.2022 to 27.05.2025

The date of issue of the Certificate: 25.05.2022

The date of the first issue of the Certificate: 22.10.2021

CE 1434

Issued under the Contract No. MD-100/2021
Application No: 192b/2021
Certificate bears the qualified signature.
Warsaw, 25/05/2022
Module A1

Director
Medical Device Certification
Department

ANNEX no. 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-265/2022

List of medical devices covered by the certificate:

SARS-CoV-2 Antigen Rapid Test Cassette
Ref. No. COVG-602ST

Under brands:

CAMERON MEDICAL
CEDAR MED
Core+ hygienics
EurekaCARE
EUROSIREL
GENnasal™
LIMITLESS ® MEDICAL
Norgenics.
NOVAMA®
Sejoy®
TERMAX OTC
femometer®

CE 1434

Issued under the Contract No. MD-100/2021
Application No: 192b/2021
Certificate bears the qualified signature.
Warsaw, 25/05/2022

Director
Medical Device
Certification Department

EU DECLARATION OF CONFORMITY

(SARS-CoV-2 Antigen Rapid Test Cassette)

EU DECLARATION OF CONFORMITY

Manufacturer:	Hangzhou Sejoy Electronics& Instruments Co.,Ltd. Area C, Building 2, No.365, Wuzhou Road,YuhangEconomic Development Zone,Hangzhou City 311100 Zhejiang China
European Authorized Representative:	Shanghai International Holding Corp.GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Product Name:	SARS-CoV-2 Antigen Rapid Test Cassette
Specification:	1 test/box， 5tests/box， 25tests/box
Classification:	Other device not listed under Annex II and self-testing of Directive 98/79/EC
Conformity assessment route:	Annex III,except Point 6,of Directive 98/79/EC
Applicable Standards:	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 23640:2015, EN ISO 13612:2002, EN ISO 17511:2003, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN 13641:2002

CE

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.

Hangzhou, March 22, 2021
Place,date

General Manager
Legally binding signature, Position

杭州世佳电子有限公司
HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO.,LTD.

The test results of the COVID-19 N antibody against the N antigen of different mutant strains

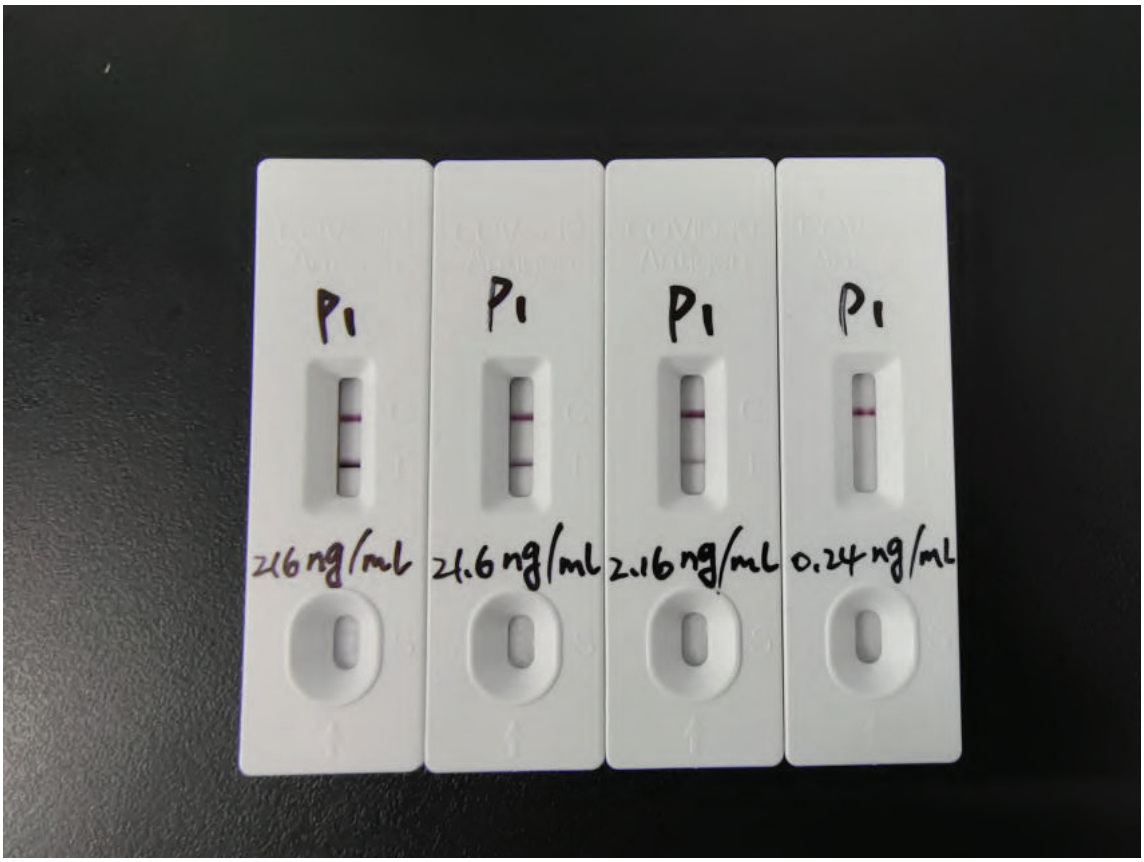
Experimental purposes: Verification of the detection of the COVID-19 N antibody against the N antigen of different mutant strains

Experimental Materials

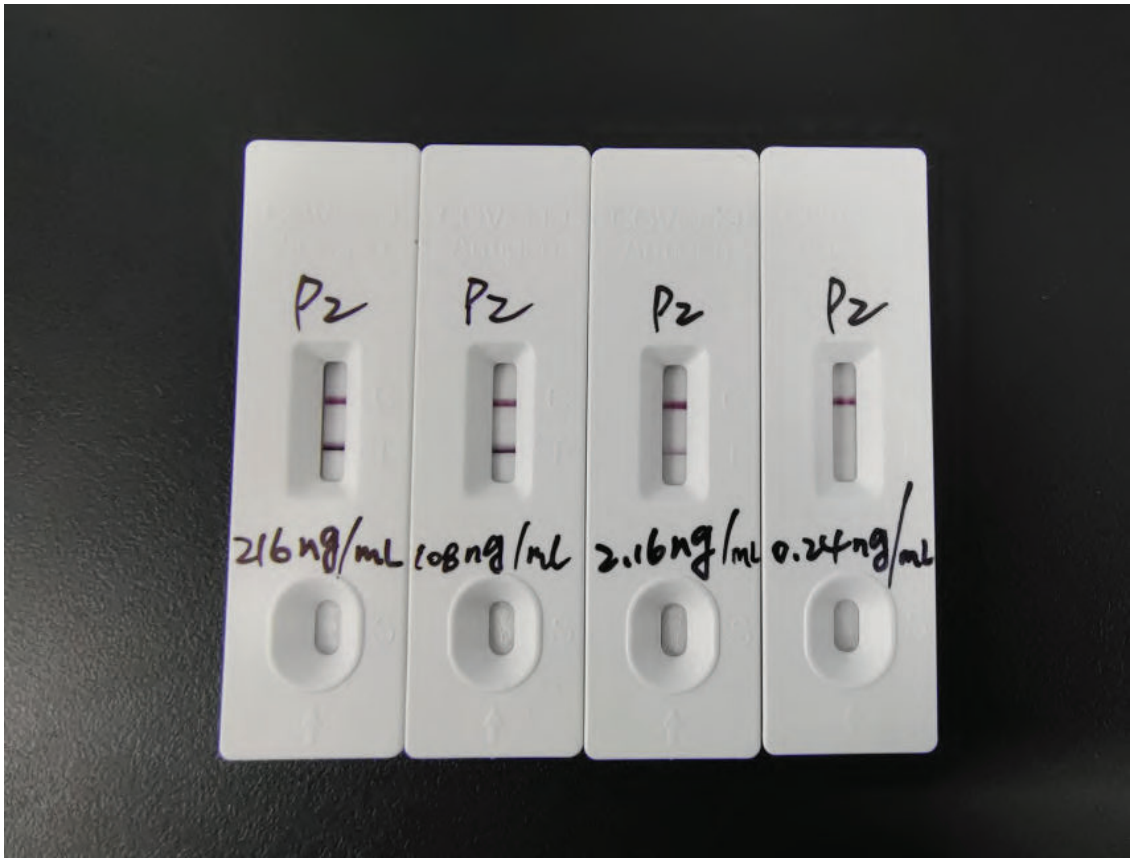
1. Utilize COVID-19 antibody test strips made by double antibody sandwich method.
2. N Recombinant Protein of wild strain; α-mutant N recombinant protein; Detla-mutant N recombinant protein; Lambda-mutant N recombinant protein; Omircon-mutant N recombinant protein;
3. Covid-19 Antigen detection sample extraction liquid;

Experimental method: Test strips made of Covid-19 N antibody verify the detection effects of different mutant strains at different concentrations

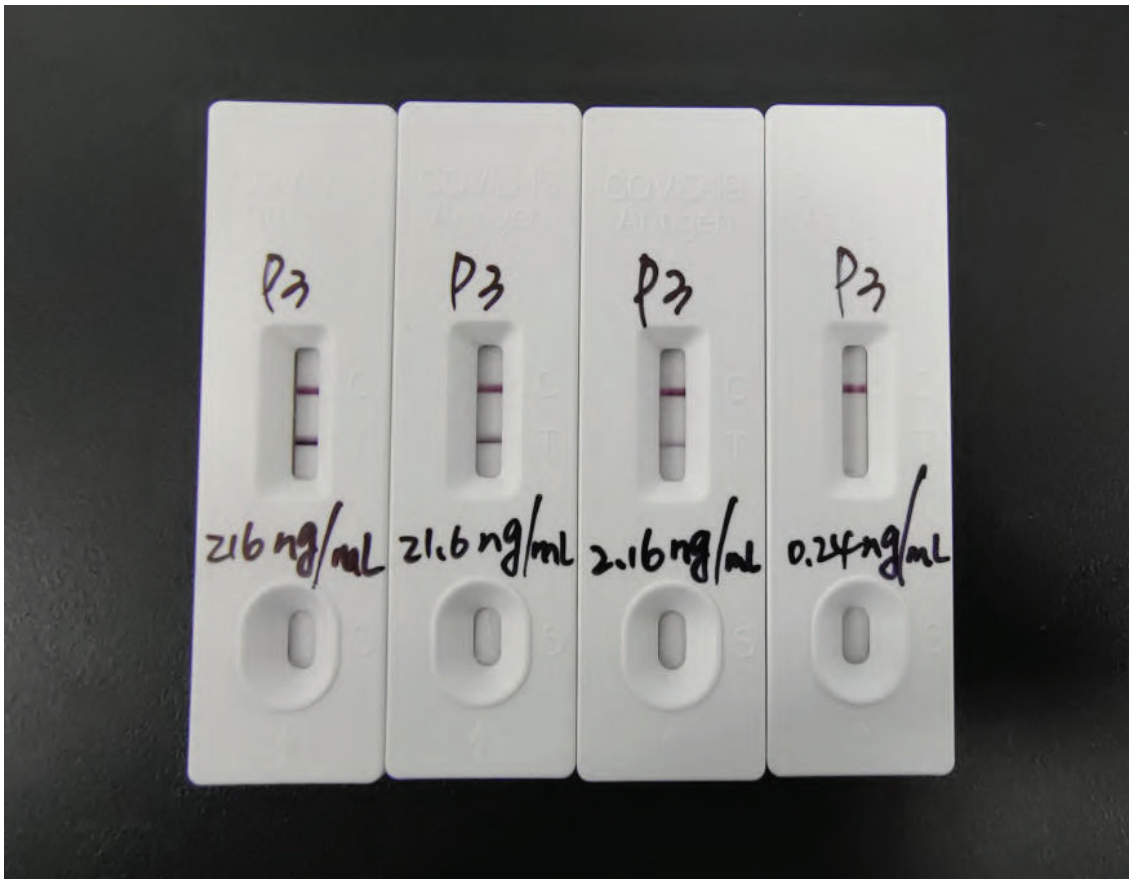
Experimental result:



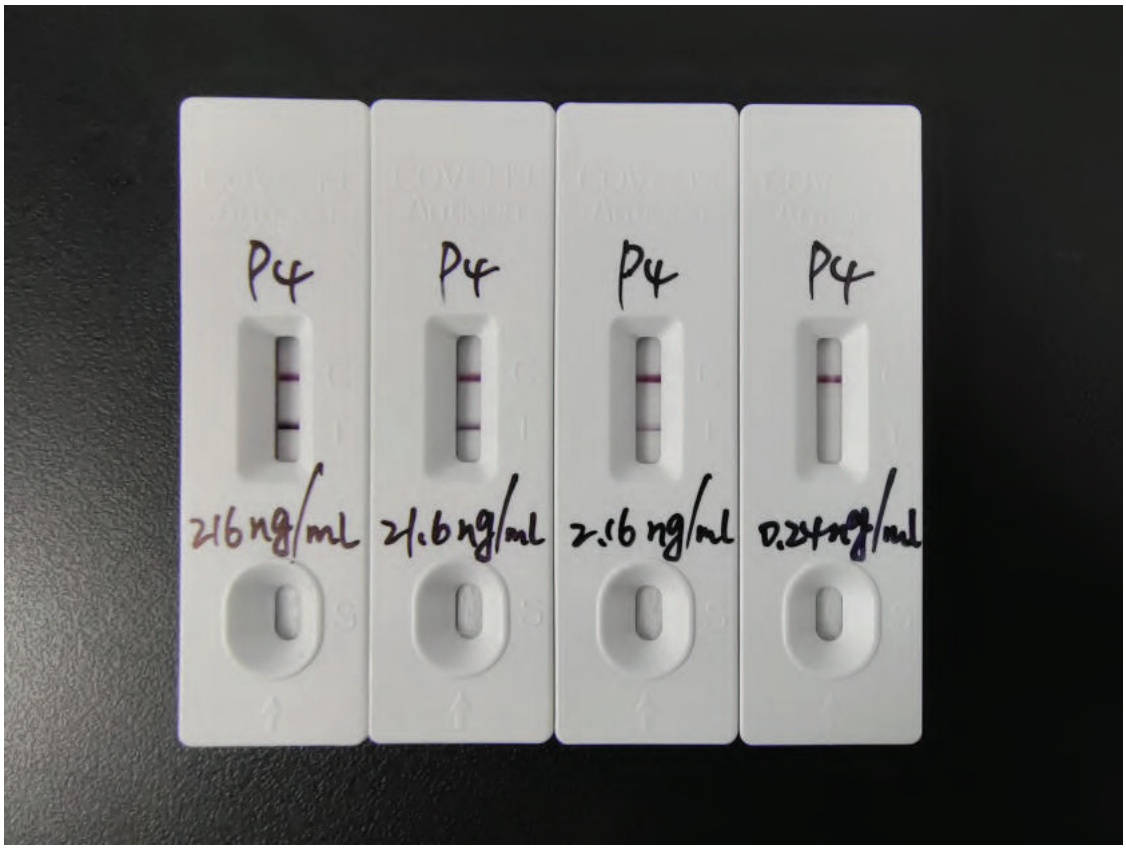
N Recombinant Protein of wild strain



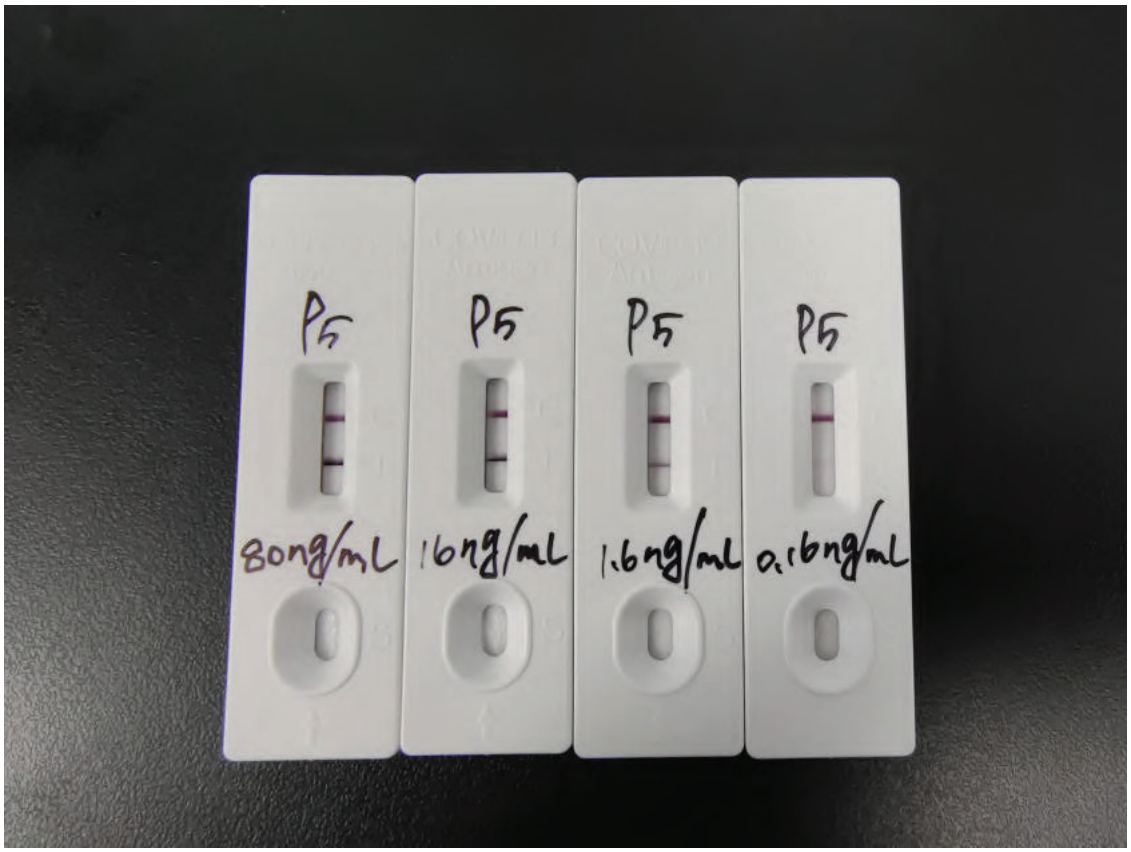
α-mutant N recombinant protein



Detla-mutant N recombinant protein



Lambda-mutant N recombinant protein



Omircon-mutant N recombinant protein

Experimental conclusion:

COVID-19 N Antibody is tested by different concentrations of wild-type COVID-19 N protein recombinant antigen, α-COVID-19 N protein recombinant antigen, Delta-COVID-19 N protein recombinant antigen, Lambda-COVID-19 N protein recombinant antigen, Omircon-COVID-19 N protein recombinant antigen and all the results are detectable.

CONFIRMATION OF EU PRODUCT NOTIFICATIONS

FROM AUTHORIZED REPRESENTATIVE

Shanghai International Holding Corporation GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg Germany

Confirmation

of EU product notifications

Herewith we confirm that

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraase 80, 20537 Hamburg, Germany

has taken over the function of an European Authorised Representative according to the requirements of IVD Directive 98/79/EC for:

Hangzhou Sejoy Electronics& Instruments Co., Ltd.
Area C, Building 2, No.365, Wuzhou Road, Yuhang Economic Development Zone
311100 Hangzhou City, Zhejiang, China

for their in-vitro diagnostic device:
SARS-CoV-2 Antigen Rapid Test Cassette

and has submitted the product notifications at the relevant German Competent Authority according to Article 10(3) of the above mentioned IVD Directive and all supporting technical documents showing the devices' conformity with the Directive are deposited in our office.

15.04.2021

Mr. Liang Jin
-- on behalf of --
Shanghai International Holding
Corp. GmbH (Europe)

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Amtsgericht Hamburg
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