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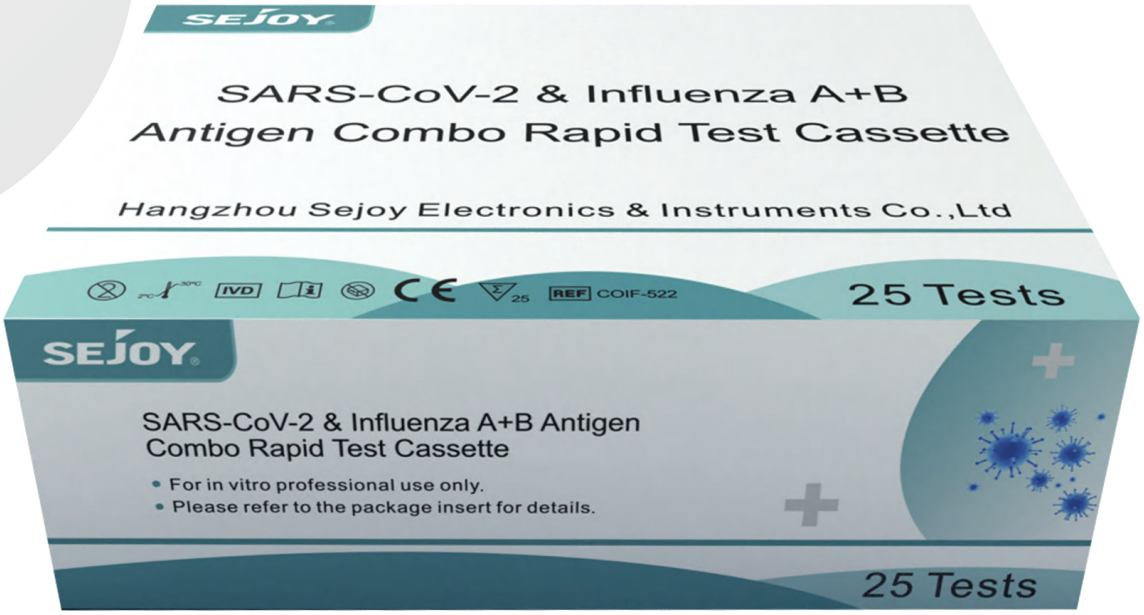
Sejoy

3in1 Combo Rapid Test Cassette

For professional use only

COVID-19, Influenza A, Influenza B



CE

25 Tests per Box | Oropharyngeal & Nasopharyngeal | 800 tests per box

Listed for EU-wide recognition in the "EU common list"

- Rapid detection of the 3 disease
- Reliable Test Result
- Fast test result in 20 min
- Simple Application
- 18 months Shelf life

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SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette Package Insert

Cat: COIF-522 **Specimens:** Nasopharyngeal Swab/ Oropharyngeal Swab (EN)

Version: A **Effective Date:** 2022. 10

Code: 4.15.03.90003-2 **For professional *in vitro* diagnostic use only.**

INTENDED USE

The SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2, influenza A and influenza B viral nucleoprotein antigens in nasopharyngeal swab/oropharyngeal Swab from individuals suspected of respiratory viral infection consistent with SARS-CoV-2 by their healthcare provider. Symptoms of Respiratory viral infection due to SARS-CoV-2 and influenza can be similar. The SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette is intended for the detection and differentiation of SARS-CoV-2, influenza A and influenza B viral nucleoprotein antigens. Antigens are generally detectable in nasopharyngeal /oropharyngeal specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical Correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not rule out SARS-CoV-2 or influenza Infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results must be combined with clinical observations, patient history and epidemiological information, and confirmed with a molecular assay, if necessary, for patient management. The SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette is intended for use by trained clinical laboratory personnel specifically instructed and trained in vitro diagnostic procedures.

SUMMARY

The novel corona viruses (SARS-CoV-2) belong to the β genus. SARS-CoV-2 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel corona virus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, Fatigue and dry cough. Nasal congestion, runny nose, sore throat, malignant diarrhea is found in a few cases. Influenza (flu) is a contagious respiratory illness caused by influenza Viruses. It can cause mild to severe illness. Serious outcomes of flu infection can result in hospitalization or death. Some people, such as older people, young children, and people with certain health conditions, are at high risk of serious flu complications. There are two main types of influenza (flu) virus: Types A and B. The influenza A and viruses that routinely spread in people (human influenza viruses) are responsible for seasonal flu epidemics each year.

PRINCIPLE

The SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2, Influenza A and Influenza B nucleoproteins in Nasopharyngeal swab /oropharyngeal swab. In this test, antibody specific to the N protein of SARS-CoV-2, Influenza A and Influenza B nucleoproteins 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, Influenza A and/or Influenza B that are coated onto particles. The mixture migrates up the membrane to react with the antibody to N protein of SARS-CoV-2, Influenza A and/or Influenza B 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.

REAGENTS

The test cassette contains anti-SARS-CoV-2 Nucleocapsid, anti-Influenza A and B protein particles, and anti-SARS-CoV-2 Nucleocapsid, anti-Influenza A and B protein coated on the membrane.

PRECAUTIONS

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

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infection agent.
4. The used test should be discarded according to local regulations.
5. Avoid using bloody samples.
6. Wear gloves wen handing the samples, avoid touching the reagent membrane and sample well.

STORAGE AND STABILITY

1. Store as packaged in the sealed pouch at the temperature (2-30℃). The kit is stable within the expiration date printed on the labeling.**DO NOT FREEZE**.
2. Once open the pouch, the test should be used within 15 min. Prolonged exposure to hot and humid environment will cause product deterioration. The LOT and the expiration date were printed on the labeling.

SPECIMEN COLLECTION, TRANSPORT AND STORAGE

Specimen Collection:

Nasal secretion collection:

1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
2. Swab over the surface of the posteriornasopharynx.
3. Withdraw the sterile swab from the nasal cavity.

Throat secretion collection:

1. Insert a sterile swab into the throat completely from the mouth, centering on the throat wall and the reddened area of the palate tonsils, wipe the bilateral pharyngeal tonsils and posterior pharyngeal wall with moderate force, avoid touching the tongue and take out the swab.

Specimen transport and storage:

1. Specimens should be tested as soon as possible after collection.
2. If swabs are not processed immediately, it is highly recommended the swab sample is placed into a dry, sterile, and tightly sealed plastic tube for storage. It can be stored at 2-8℃ for 8 hours and can be stored for a long time at -70℃.Do not store specimens in viral transport media.
3. Samples collected from swabs that are too viscous or agglomerated are not recommended for testing of this product. If the swabs are contaminated with a large amount of blood, they are not recommended for testing. It is not recommended to use the samples that are processed with sample extraction solution not provided in this kit for testing of this product.

SPECIMEN PREPARATION

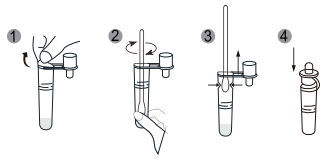
Only the extraction buffer and tubes provided in the kit is to be used for swab specimen preparation.

1.Take out the tube, peel off the aluminum foil on the extraction buffer tube carefully avoid liquid spills and place the tube in the Tube Holder.

2.Place the swab specimen in the Extraction Tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.

3.Remove the swab while squeezing the swab head against the inside of the Extraction Tube as you remove it to expel as much liquid as possible form the swab. Discard the swab in accordance with your biohazard waste disposal protocol.

4.Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface.



*NOTE: The storage of the specimen after extraction is stable for 2 hours at room temperature or 24 hours at 2-8°C.

KIT COMPONENTS

Materials provide.

Test cassettes Extraction Buffer with Integrated Extraction Tube, 0.5ml per Tube
Sterile Swabs Package Insert Workstation

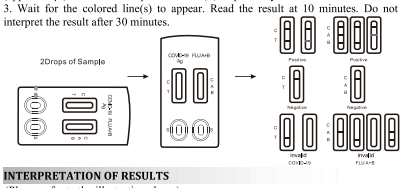
Materials required but not provide.

Timer For timing use.

DIRECTIONS FOR USE

Allow the test, extracted specimen and/or controls to equilibrate to room temperature (15-30℃ or 59-86℉) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it within 15 min. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Invert the specimen extraction tube and add 2 drops of extracted specimen (approx.65μl) to each of the specimen well(S) respectively and then start the timer.
3. Wait for the colored line(s) to appear. Read the result at 10 minutes. Do not interpret the result after 30 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE SARS-CoV-2:*Two distinct colored lines appear in the left window. One colored line should be in the control region (C) and another colored line should be in the Test region (T). Positive result in the Test region indicates detection of SARS-CoV-2 antigens in the sample.

POSITIVE Influenza A:*Two distinct colored lines appear in the right window. One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A). A positive result in the Influenza A region indicates that Influenza A antigen was detected in the sample.

POSITIVE Influenza B: *Two distinct colored lines appear in the right window. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B). A positive result in the Influenza B region indicates that Influenza B antigen was detected in the sample.

POSITIVE Influenza A and Influenza B: *Three distinct colored lines appear in the right window. One colored line should be in the control region (C) and two-colored line should be in the Influenza A region (A) and Influenza B region (B). A positive result in the Influenza A region and Influenza B region indicates that Influenza A antigen and Influenza B antigen were detected in the sample.

***NOTE:** The intensity of the color in the test line region (T) will vary based on the amount of SARS-CoV-2 antigen, Flu A and/or B antigen present in the sample. So, any shade of color in the test region (T/A/B) should be considered positive.

NEGATIVE:One colored line appears in the control region (C). No apparent colored line appears in the test line region (T/A/B).

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

QUALITY CONTROL

- A procedural control is included in the test. A colored line appearing in the control region(C) is considered an internal procedural control. It confirms adequate membrane wicking.
- Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The test Procedure and the Interpretation of test Result must be followed closely when testing for the presence of SARS-CoV-2/Influenza A/Influenza B antigens in the human nasopharyngeal/oropharyngeal specimens from suspected individuals. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. The performance of the SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test. Viral Transport Media (VTM) specimen and extracted specimens for PCR tests cannot be used for the test.
3. The SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette is for in vitro diagnostic use only. This test should be used for detection of SARS-CoV-2/Influenza A/Influenza B Antigens in human nasopharyngeal /oropharyngeal specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2, Influenza A or Influenza B infection in conjunction with clinical presentation and the results of other laboratory tests. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2/Influenza A/Influenza B antigens can be determined by this qualitative test.
4. The SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette will only indicate the presence of SARS-CoV-2/Influenza A/Influenza B Antigens in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2/Influenza A/Influenza B infections.
5. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
6. If the test result is negative or non-reactive and clinical symptoms persist. It is recommended to re-sample the patient a few days later and test again or test with a molecular diagnostic device to rule out infection in these individuals.
7. The test will show negative results under the following conditions: The concentration of the novel coronavirus antigens, Influenza A or Influenza B virus in the sample is lower than the minimum detection limit of the test.
8. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
9. A negative result for Influenza A or Influenza B obtained from this kit should be confirmed by RT-PCR/culture.
10. Excess blood or mucin on the swab specimen may interfere with test performance and may yield a false positive result.
11. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
12. Positive results of SARS-CoV-2 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors. A positive result for influenza A and/or B does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered

EXPECTED VALUES

The SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette has been compared with leading commercial RT-PCR tests. The correlation between these two systems is no less than 97%.

PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

The SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette has been evaluated with specimens obtained from the patients'-PCR is used as the reference method for the SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette. Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT- PCR indicated a negative result.

SARS-CoV-2 Test:

SARS-CoV-2 Antigen Rapid Test		RT-PCR		Total Results
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	113	2	115
	Negative	3	212	215
Total		116	214	330
Relative Sensitivity		97.41%(95%CI*:92.67%-99.12%)		
Relative Specificity		99.07%(95%CI*:96.66%-99.74%)		
Accuracy		98.48% (95%CI*: 96.50%~99.35%)		

Influenza A+B Test:

Influenza A+B Antigen Combo Rapid Test		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
Flu A+B	Positive	100	2	102	85	2	87
	Negative	1	180	181	2	200	202
Total		101	182	283	87	202	289
Relative Sensitivity		99.0% (95%CI*: 94.6%~99.8%)			97.7% (95%CI*: 92.0%~99.4%)		
Relative Specificity		98.9% (95%CI*: 96.1%~99.7%)			99.0% (95%CI*: 96.5%~99.7%)		
Accuracy		98.9% (95%CI*: 96.9%~99.6%)			98.6% (95%CI*: 96.5%~99.5%)		

*Confidence Intervals

Specificity Testing with Various Viral Strains

The SARS-CoV-2 & Influenza A+B Antigen Combo Rapid Test Cassette was tested with the following viral strains. No discernible line at either of the test-line regions was observed at these concentrations listed:

SARS-CoV-2 Test:

Description	Concentration
HCOV-HKU1	10^5TCID$_{50}$ /ml
Staphylococcus aureus	10^6TCID$_{50}$ /ml
Group A streptococci	10^6TCID$_{50}$ /ml
Measles virus	10^5TCID$_{50}$ /ml
Mumps virus	10^5TCID$_{50}$ /ml
Adenovirus type 3	10^5TCID$_{50}$ /ml
Mycoplasmal pneumonia	10^6TCID$_{50}$ /ml
Parainfluenza virus, type2	10^5TCID$_{50}$ /ml
Human metapneumovirus	10^5TCID$_{50}$ /ml
Human coronavirus OC43	10^5TCID$_{50}$ /ml
Human coronavirus 229E	10^5TCID$_{50}$ /ml
Bordetella parapertusis	10^6TCID$_{50}$ /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
Rhinovirus	10^5TCID$_{50}$ /ml
Respiratory syncytial virus	10^5TCID$_{50}$ /ml
Streptococcus pneumoni-ae	10^6TCID$_{50}$ /ml
Candida albicans	10^6TCID$_{50}$ /ml
Chlamydia pneumoniae	10^6TCID$_{50}$ /ml
Bordetella pertussis	10^6TCID$_{50}$ /ml
Pneumocystis jiroveci	10^6TCID$_{50}$ /ml
Mycobacterium tubercu- losis	10^6TCID$_{50}$ /ml
Legionella pneumophila	10^6TCID$_{50}$ /ml

Influenza A+B Test:

Description	Cross reaction
Human adenovirus 3	N/A
Human adenovirus 7	N/A
Human coronavirus OC43	N/A
Parainfluenza virus 1	N/A
Parainfluenza virus 2	N/A
Parainfluenza virus 3	N/A
Measles	N/A
Mumps	N/A
Human respiratory syncytial virus	N/A
Human Rhinovirus 1A	N/A
Human herpesvirus 5	N/A
Herpes simplex virus 1	N/A
Human herpesvirus 2	N/A
Rubella	N/A
Varicella-Zoster	N/A

TCID$_{50}$ = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

Precision

Intra-Assay & Inter-Assay

Within-run and Between-run precision has been determined by using seven specimens of SARS-CoV-2 and Influenza A/B standard control. Three different lots of SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test Cassette have been tested using negative, SARS-COV-2 Antigen weak, SARS-CoV-2 Antigen Strong, Influenza A weak, Influenza B Weak, Influenza A Strong and Influenza B Strong. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified>99% of the time.

Interfering Substances

The test results do not be interfered with the substance at the following concentration:

Interfering substance	Conc.	Interfering substance	Conc.
Whole Blood	4%	Compound Benzoin Gel	1.5mg/ml
Ibuprofen	1mg/ml	Cromolyn glycate	15%
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 hydro-chloride	15%

BIBLIOGRAPHY

1. Williams, KM, Jackson MA, Hamilton M. (2002) Rapid Diagnostic Testing for URIs in Children; Impact on Physician Decision Making and Cost. Infec. Med. 19(3): 109-111.
2. Betts, R.F. 1995. Influenza virus, p. 1546-1567. In G.L. Mandell, R.G. Douglas, Jr. and J.E. Bennett (ed.), Principle and practice of infectious diseases, 4th ed. Churchill Livingstone, Inc., New York, N.Y.
3. WHO recommendations on the use of rapid testing for influenza diagnosis, World Health Organization, July 2005.
4. Westgard JO, Barry PL, Hunt MR, Groth T. A multi-rule Shewhart for quality control in clinical chemistry, Clinical Chemistry 1981;27:493-5011.

Index of Symbols

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use-by date		Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	Catalogue number
	Manufacturer		Keep dry		Keep away from sunlight
	Do not use if package is damaged		Date of manufacture		

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10117 Tallinn, Estonia

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20537 Hamburg, Germany

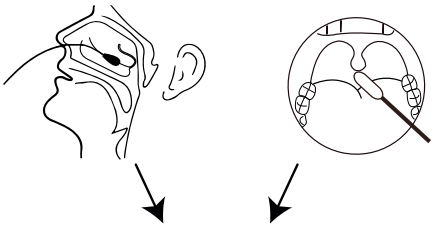
Manufacturer
Hangzhou Sejoy Electronics & Instruments Co.,Ltd.
Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone,Hangzhou City 311100 Zhejiang China

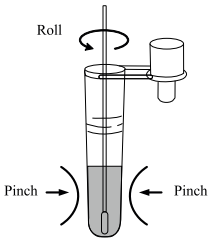
CE

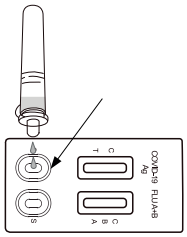
Specification

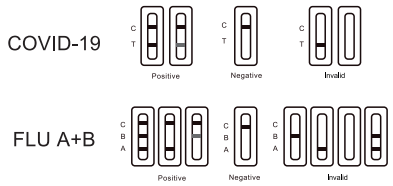
Principle	Chromatographic Immunoassay
Format	Cassette
Certificate	CE
Package specifications	1 test/pack, 25 tests/pack
Sample Type	Oropharyngeal/Nasopharyngeal
Operation Temperature	15-30°C
Storage Temperature	2-30°C
Test Time	20 min
Shelf Life	18 months

Test Procedure Steps









Sensitivity and Specificity

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SARS-CoV-2 Test:

SARS-CoV-2 Antigen Rapid Test		RT-PCR		Total Results
		Positive	Negative	
SARS-CoV-2 Antigen	Positive	113	2	115
	Negative	3	212	215
Total		116	214	330
Relative Sensitivity		97.4%(95%CI*:90.39%-98.61%)		
Relative Specificity		99.1%(95%CI*:98.20%-99.87%)		
Accuracy		98.5% (95%CI*: 94.9%~99.1%)		

Influenza A+B Test:

Influenza A+B Antigen Combo Rapid Test		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
Flu A+B	Positive	100	2	102	85	2	87
	Negative	1	180	181	2	200	202
Total		101	182	283	87	202	289
Relative Sensitivity		99.0% (95%CI*: 71.3%~99.9%)			97.7% (95%CI*: 61.5%~99.8%)		
Relative Specificity		98.9% (95%CI*: 91.5%~>99.9%)			99.0% (95%CI*: 95.7%~100.0%)		
Accuracy		98.9% (95%CI*: 91.3%~99.7%)			98.6% (95%CI*: 93.2%~>99.9%)		

EU DECLARATION OF CONFORMITY

Manufacturer:	Hangzhou Sejoy Electronics& Instruments Co.,Ltd. Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic 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 & Influenza A+B Antigen Combo Rapid Test Cassette
Specification:	COIF-522
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 14971:2019, 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 15223-1:2021, EN 13641:2002

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.

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

Hangzhou, August 12, 2022
Place,date

General Manager
Legally binding signature, Position