COVID-19 & Influenza A+B Antigen Combo Rapid Test
For Self-Testing
Package Insert

CE 2934 IVD REF FCO-6032H English

INTENDED USE

The COVID-19 & Influenza A+B Antigen Combo Rapid Test is a single-use test kit intended for qualitative detection of nucleocapsid protein antigen of influenza A and B viral antigens and COVID-19 Antigen from nasal swab specimens.
This test is intended for home use with self-collected nasal swab samples in individuals aged 12 and older. Sampling from anyone under the age of 12 and over the age of 70 should be performed under the guidance and assistance of their guardian. People who are unable to carry out the test on their own should seek support
The test is intended for symptomatic individuals within 7 onset days or asymptomatic individuals contact with persons who have been diagnosed positive or with individuals suspected to be infected.
Positive results are indicative of the presence of Influenza andSARS-CoV-2. Individuals who test positive should self-isolate and seek additional care from their healthcare provider. Positive results do not rule out bacterial infection or co-infection with other viruses.
Negative results do not preclude Influenza andSARS-CoV-2 infection. Individuals who test negative and continue to experience Influenza or COVID-like symptoms should seek follow up care from their healthcare provider.

PRINCIPLE

The COVID-19 & Influenza A+B Antigen Combo Rapid Test is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2, Influenza A and B nucleocapsid protein from nasal swab specimens.
SARS-CoV-2, Influenza A and B specific antibodies are immobilized onto the test region of the membrane and combined with other reagents/pads to construct a test strip.
The test is designed to detection of nucleocapsid protein antigens in nasal swab specimens, which is different from the mutation sites have occurred in the spike protein, so it is theoretically able to detect variants including those in UK, India, South Africa and Brazil.

KIT COMPONENTS

Component	1Test /Kit	5 Tests /Kit	10 Tests /Kit	20 Tests /Kit	25 Tests /Kit
COVID-19 & Influenza A+B Antigen combo Test	1	5	10	20	25
Extraction tube with buffer	1	5	10	20	25
Sterilized nasal swab	1	5	10	20	25
Waste bag	1	5	10	20	25
Workstation	/	/	1	1	1
Package insert	1	1	1	1	1

ADDITIONAL SPECIAL EQUIPMENT

Timer

WARNINGS AND PRECAUTIONS

- Do not use after expiration date. Do not use if kit is damaged or open. Do not reuse the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Discard the using testing materials in accordance with local regulations.
- The extraction buffer contains a salt solution if the solution contacts the skin or eyes, flush with copious amounts of water.Don't swallow the buffer.When swallowing the buffer, rinse the mouth thoroughly with water and give plenty of water to dilute the substance.If any discomfort, seek medical attention immediately.
- Children and elder please use the test under the guardian.

STORAGE AND STABILITY

Store unused test devices unopened at 4°C-30°C. If stored at 4°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

TEST PROCEDURE

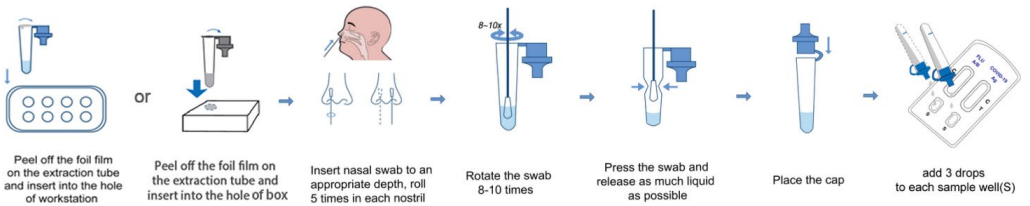
Open the kit box. Check the components before use.

Please read all instructions carefully before you begin.
[Preparation before sampling]
1. Get a flat area ready, like a table. Make sure it is clear, clean and dry.
2. Take off hand jewellery.
3. Wash your hands for 20 seconds. Use soap and water, or hand sanitiser. Dry your hands using towels.

clean disposable paper

For better protection and avoid cross-contamination, disposable gloves, masks and eye protection (not provided in the package) are recommended.
[Specimen Preparation]
1. Peel off the foil film on the extraction tube and insert into the hole of workstation. (For 1 test/kit and 5 tests/kit, Insert the extraction tube into the hole of the box.)
2. Open nasal swab package at the sticky end and take the nasal swab out.
3. Gently insert the soft tip of the nasal swab into left nostril about 2.5cm (1 inch) for adult.
Note: For child, the maximum depth of insertion into the nostril may be less than 2.5 cm and should be carefully and appropriately adjusted by the person, who collects sample.
4. Firmly brush against the inside of the nostril in a circular motion 5 times or more.
5. Move the nasal swab to the right nostril and repeat the previous action. Make sure an adequate sample is collected.
6. Insert the nasal swab into the tube which contains extraction buffer.
7. Rotate nasal swab at least 8-10 times while pressing nasal swab tip against the bottom and the side of the tube.
8. Remove the nasal swab while squeezing and rolling the nasal swab against the sides of the tube to release as much liquid as possible .
9. Cover the tube with cap tightly and insert the tube back into the workstation or box.

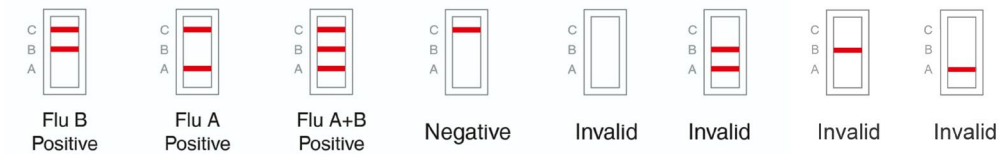
[Test Procedure]
1.Open the sealed pouch and take out the test cassette. For best results, the test should be performed in one hour.
2. Hold the tube vertically upside down over the sample well.
3. Add 3 drops specimen into the each sample well by gently squeezing the sides of the tube, then start the timer.



4.Wait for colored lines to appear.The test result can be read in 10-15 minutes, DO NOT read after 20 minutes.

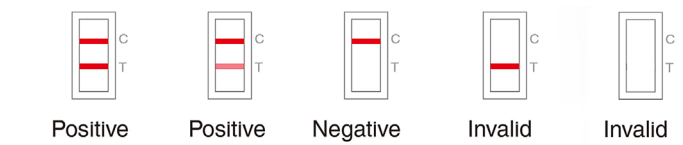
[After the testing]
1. After you have done the test, put all parts of the kit in the waste bag. Discard the waste bag in accordance with local regulations.
2. If you are doing more than 1 test, clean the table with 75% alcohol or sanitiser. Wash your hands between each test.

INTERPRETATION OF TEST RESULT For Flu A+B



- **Positive Influenza A:***
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 Influenza A region (A).
- **Positive Influenza B:***
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 Influenza B region (B).
- **Positive Influenza A and Influenza B:***
Three distinct colored lines appear in the left 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).
- **Negative:**
One colored line appears in the control region (C) of the left window. No apparent colored line appears in the test line region (B/A).
- **Invalid:**
Control line fails to appear in the left window. 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.

INTERPRETATION OF TEST RESULT For COVID-19



- **Positive COVID-19:***
  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 Test region (T).
- **Negative:**
  One colored line appears in the control region (C) of the right window. No apparent colored line appears in the test line region (T).
- **Invalid:**
  Control line fails to appear in the right window. 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.

***NOTE:** The intensity of the color in the test line region will vary depending on the concentration of the analyses in the specimen. Therefore, any shade of color in the test line region should be considered positive.

BUILT-IN CONTROL

This test contains a built-in control feature, the C line on the test. The C line develops after adding sample solution. Otherwise, review the whole procedure and repeat test with a new device.

WHAT SHOULD I DO AFTER TEST

If the test result is positive	There is currently a suspicion of a COVID-19 or Flu A or Flu B infection ➢ Contact your doctor / general practitioner or the local health department immediately ➢ Comply with local guidelines for self-isolation ➢ To have a PCR confirmatory test performed
If the test result is negative	Continue to comply with all applicable rules regarding contact with others and protective measures ➢ An infection may also be present if the test is negative ➢ If it is suspected, repeat the test after 1 - 2 days, as the virus cannot be accurately detected in all phases of an infection
If the test result is invalid	Possibly caused by incorrect test execution ➢ Repeat the test ➢ If the test results remain invalid, contact a doctor or a COVID-19 test center

Note: Do not take any decision of medical relevance without first consulting your medical practitioner

PERFORMANCE CHARACTERISTICS

1. Clinical study: A comparison was conducted with RT-PCR, according the test data listed below table.

Safecare Test		Influenza A			Influenza B			COVID-19		
		Reference test result		Total	Reference test result		Total	PCR		Total
		Positive	Negative		Positive	Negative		Positive	Negative	
Influenza A+B	Positive	39	1	40	27	0	27	212	0	212
	Negative	0	179	179	0	180	180	8	200	208
Total		39	180	219	27	180	207	220	200	420
Relative Sensitivity		39/39=100.00% 95%CI: 90.97%～100.00%			27/27=100% 95% CI: 87.23%～100.00%			212/220=96.36% 95%CI: 92.96%～98.42%		
Relative Specificity		179/180=99.44% 95%CI: 96.94%～99.99%			180/180=100.00% 95%CI: 97.97%～100.00%			200/200=100% 95%CI: 98.17%～100.00%		
Overall Agreement		(39+179)/219=99.54% 95% CI: 97.48%～99.99%			(27+180)/207=100% 95%CI: 98.23%～100.00%			(212+200)/420=98.1% 95% CI: 96.28%～99.17%		

2. Cross-reactivity: Cross-reactivity studies are performed to demonstrate that the test does not react with the following microorganisms in the table below at concentration of $1x10^5$ $TCID_{50}$ /mL for viruses and $1x10^5$ CFU/mL for bacteria.

Human metapneumovirus (hMPV)	Human parainfluenza virus 1	Rhinovirus	*Bordetella pertussis*	*Streptococcus pneumoniae*
Human coronavirus OC43	Human parainfluenza virus 2	Enterovirus	*Chlamydia pneumoniae*	*Streptococcus pyogenes*
Human coronavirus 229E	Human parainfluenza virus 3	Adenovirus	*Haemophilus influenzae*	*Mycobacterium tuberculosis*
Human coronavirus NL63	Human parainfluenza virus 4	MERS	*Legionella pnuemophila*	*Staphylococcus aureus*
Human coronavirus HKU1	Respiratory Syncytial Virus		*Mycoplasma pneumoniae*	*Candida albicans*

5. Interference: The following endogenous interference substances were evaluated at the concentrations listed and no effect was found.

Whole blood (2%), three OTC nasal sprays (10%), three OTC nasal drop (25%), three nasal mouthwashes (25%), 4-Acetamidophenol (10mg/mL), Acetylsalicylic acid (20mg/mL), Chlorpheniramine (5 mg/mL), Dextromethorphan (10mg/mL), Diphenhydramine (5mg/mL), Ephedrine (20mg/mL), Guaiacol glyceryl ether (20mg/mL), Oxymetazoline (10mg/mL), Phenylephrine (100mg/ml), Phenylpropanolamine (20mg/mL) ,Oseltamivir Phosphate (10mg/mL), Mupirocin (10mg/mL),Vitamin A (10%), D-Panthenol (10%)

LIMITATIONS AND POSSIBLE ERRORS

1. The COVID-19 & Influenza A+B Antigen Combo Rapid Test is intended for use as a self-test and may only be used for qualitative detection of SARS-CoV-2, Influenza A and B antigens. The colour intensity of a positive line shall not be evaluated as quantitative or semi-quantitative.
2. The COVID-19 & Influenza A+B Antigen Combo Rapid Test should be only for the detection of SARS-CoV-2, Influenza A and B antigens,not for any other viruses or pathogens.The test does not differentiate between SARS-CoV and SARS-CoV- 2.
3. The performance was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
4. A negative result does not exclude the possibility of COVID-19 and /or Influenza A and /or Influenza B infection.
5. The results obtained with this assay, especially in the case of weak test lines which are difficult to interpret, should retest or go to a medical institution for testing.
6. The test is intended for infection detection and not for determine infection status.The test is used for the auxiliary diagnosis and can not be used as the sole diagnostic indicator of whether the test subject is infected with the COVID-19 and /or Influenza A and /or Influenza B.
7. False negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
8. False negative results may occur if a specimen is improperly collected, transported, or handled.
9. False positive test results are more likely during periods of low COVID activity when prevalence is moderate to low
10. Testing of individuals without COVID-19 symptoms and/or individuals who live in areas with low numbers of COVID-19 infections and without known exposure to COVID-19, more false positive results may be returned.

INDEX OF SYMBOLS

	Do not reuse	IVD	For in vitro diagnostic use only
4℃ 30℃	Stored between 4-30℃		Consult instruction for use
	Keep away from sunlight	LOT	Lot number
	Use-by date	Σ	Contains sufficient for <n> tests
	Manufacturer		Date of Manufacture
STERILE EO	Sterilized using ethylene oxide	STERILE R	Sterilized using irradiation
REF	Catalog No.	CE 2934	CE Mark
EC REP	Authorized Representative in the European Community	BIO	Contains biological material of animal origin

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