

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

CE2934 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 antigens 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 specimens in individuals aged 12 and older. Sampling from the anterior nares under the age of 17 should be performed by a parent or guardian. This test is not intended for use in clinical settings. It is not intended for use as a diagnostic tool for clinical guidance and assistance of their guardian. People who are unable to carry out the test on their own should seek support.

Invalid: The test is intended for asymptomatic individuals within 7 onset days or asymptomatic individuals in contact with persons who have been diagnosed positive or with individuals suspected to be infected. Positive results are indicative of the presence of influenza and SARS-CoV-2. Individuals who are tested without a new test cassette, if the problem persists, discontinue using the test kit immediately and contact your local distributor.

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.

Negative results do not preclude influenza and SARS-CoV-2 infection. Individuals who test negative and continue to experience influenza or COVID-19 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 antigens 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 to construct a test strip.

The test is designed to detect nucleocapsid protein antigens in nasal swab specimens, which is different from the mutation sites have occurred. In the spike protein, it is theoretically able to detect variants including those in UK, India, South Africa and Brazil.

KIT COMPONENTS

Component	1 Test Kit	5 Tests Kit	10 Tests Kit	20 Tests Kit	25 Tests Kit
COVID-19 Influenza A+B Antigen 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
Package insert	1	1	1	1	1

ADDITIONAL SPECIAL EQUIPMENT

Timer

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 used testing materials in accordance with local regulations.

The extraction buffer contains a salt solution if the solution contains the skin or eyes, flush with copious amounts of water. Do not swallow the buffer when it is entering the buffer into the nostril. Thoroughly with water and give plenty of water to dilute the substance. If any discomfort, seek medical attention immediately.

Children and older 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 clean, clean and dry.

2. Take of hand jewellery.

3. Wash your hands for 20 seconds. Use soap and water, or hand sanitizer. Dry your hands using clean disposable paper towels.

4. Before preparation and avoid cross-contamination, disposable gloves, masks and eye protection (not provided in the package) are recommended.

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 1x10⁷ TCID₅₀/ml for viruses and 1x10⁷ CFU/ml for bacteria.

[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, the extraction tube is the hole of the workstation.)

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 cm or more. Insert the swab gently and appropriately adjusted by the person, who collects sample.

4. Firmly brush against the inside of the nostril in a circular motion for 5 seconds or more.

5. Move the nasal swab to the right nostril and repeat. The previous action. Make sure an adequate sample is collected.

6. Rotate the nasal swab about 180 degrees while pressing nasal swab against the bottom and the side of the nostril.

7. Cover the tube with cap lightly and insert the tube 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. Insert 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 tube with 75% alcohol or sanitizer. Wash your hands between each test.

3. The performance was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the test results.

4. A negative result does not exclude the possibility of COVID-19 and/or influenza A and/or influenza B.

5. The results obtained with this assay, especially in the case of weak test lines which are difficult to interpret, should relate only to a medical institution for testing.

6. The test is intended for infection detection and not for definitive infection status. The test is used for the auxiliary diagnosis and can not be used as a definitive diagnostic tool.

7. False negative result may occur if a specimen of an individual in a sample is below the detection limit of the test.

8. False negative result may occur if the specimen is improperly collected, transported, or handled.

9. False positive test results are more likely during periods of low COVID activity when prevalence is increasing 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, may false positive results may be returned.

INDEX OF SYMBOLS

2 No use IVD For in vitro diagnostic use only

3 Stored between 4-30°C IVD Consult instruction for use

4 Keep away from sunlight LOT Lot number

5 Use-by date Date of Manufacture

6 Manufacturer Date of Manufacture

7 Sterilized using ethylene oxide BSTERILE Sterilized using irradiation

8 Catalog No. CE Mark

9 Authorized Representative in the European Union Contains biological material of animal origin

10 Share Info GmbH Heerdt-Löhweg 83, 40549 Düsseldorf

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