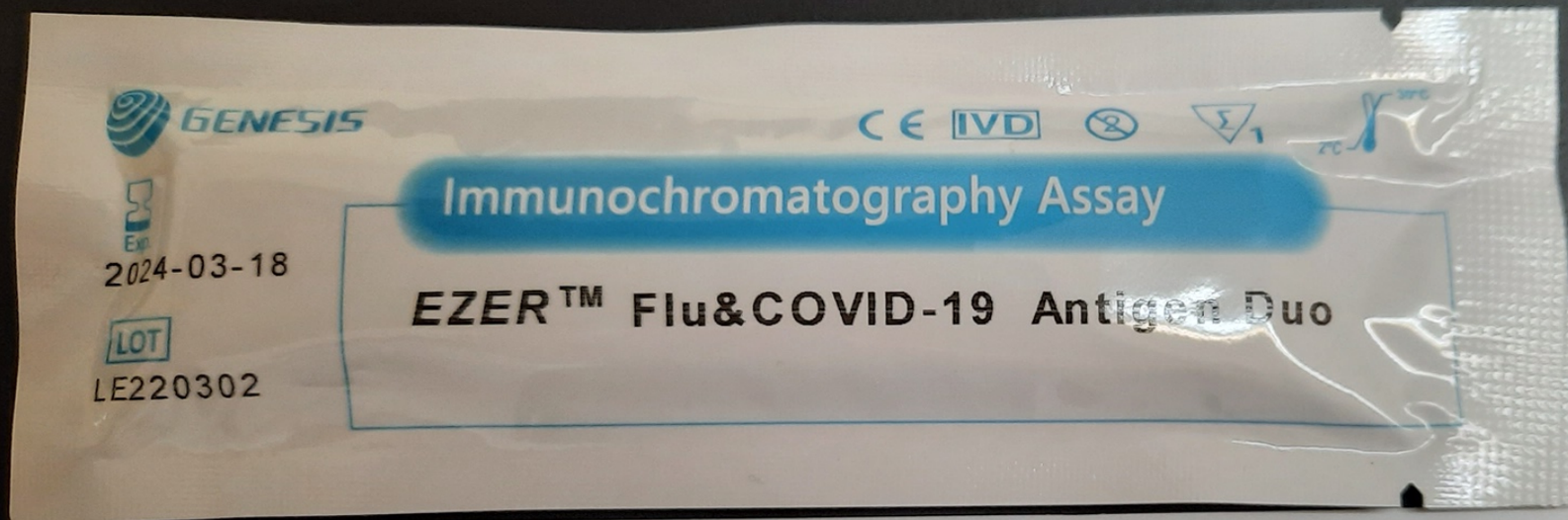

RAPID
TEST
5.00€
ΔΙΑΤΙΘΕΤΑΙ
ΤΕΣΤ ΓΡΙΠΗΣ
A+B ΜΑΖΙ ΜΕ
COVID-19



GENESIS

CE IVD

Sep. 2021, Ver. 01

P213110 EZER™ Flu & COVID-19 Antigen Duo

This kit is designed for testing freshly collected swab samples.

INTENDED USE

EZER™ Flu & COVID-19 Antigen Duo Rapid Test is intended for the simultaneous qualitative detection and differentiation of the nucleocapsid protein antigens from SARS-CoV-2, influenza A and influenza B in direct nasal

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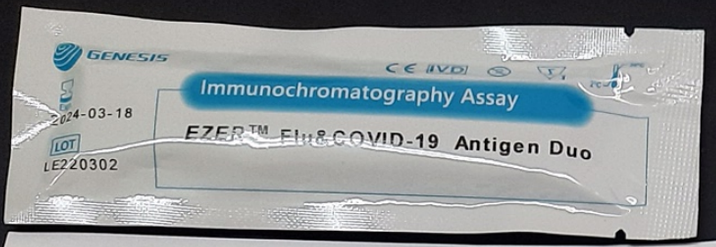

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The detection is based on the antibodies which were developed specifically recognizing and reacting with the nucleoprotein of virus.

Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. SARS-CoV-2, influenza A and influenza B viral antigens are generally detectable in upper respiratory 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.

BACKGROUND

Influenza virus belongs to the family of Orthomyxoviridae, and immunologically diverse, single-stranded RNA viruses. There influenza A and B virus is the main pathogen that severe illnesses both in human and in many animal species. Based on the current epidemiological investigation, the incubation period is 1 to 4 days. The main manifestations include acute fever, general aching and respiratory symptoms. Both Type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season.1

COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The *EZER™* Flu & COVID-19 Antigen Duo rapid test *is for influenza antigen rapid test and COVID-19 antigen rapid test, is an immunochromatographic assay for the qualitative detection of 2019 Novel Coronavirus, influenza A and B antigens.*

The EZER™ Flu & COVID-19 Antigen Duo rapid test has four letters on the surface of the strips indicating test line (S), (A), (B) and control line (C). Test line and control line in the result window are not visible before applying any samples. The control line is a reference line which indicates the test is performing properly. The control line must appear every time when the test is performed.

When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. Results appear at 15 minutes in the form of a red line in the S region (S), A region (A) or B region (B) that develops on the membrane. If SARS CoV-2 is present in the sample, the test line would appear. The highly selective antibodies to SARS CoV-2 are used as capture and detector in the assay. These antibodies can detect SARS CoV-2 antigens directly. If influenza A presents in the sample, a complex formed between the anti-influenza A conjugate and the virus will be captured by the specific anti-influenza A monoclonal antibodies coated on the A region (A). If the sample contains influenza B, a complex formed between the anti-influenza B conjugate and the virus will be captured by the specific anti-influenza B monoclonal antibodies coated on the B region (B).

CONTENTS

Test devices (20), Sterilized swabs (20), Extraction tubes (20), Nozzles (20), Tube stand (1), Package insert (1).

STORAGE CONDITIONS

Test devices must be stored at 2~30°C. DO NOT FREEZE. Devices must be brought back to room temperature at time of testing.

WARNINGS AND PRECAUTIONS

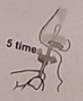
1. For *in vitro* diagnostic use only.
2. Use the sterilized swab supplied in the kit for collection nasal.
3. Proper specimen collection, storage and transport are critical to the performance of this test.
4. Do not use kit components beyond the expiration date.
5. The test plate should be used immediately after opening the packaging. When it absorbs moisture, the quality deteriorates and an accurate result cannot be obtained.
6. Please do not touch the sample drop and the judgment part of the test board directly by hand.
7. Do not reuse the device.
8. If the test is invalid, one should consider the possible improper handling, inaccurate operation procedure, or device quality. Repeat the test with a new device ensuring that the test procedure has been followed accurately.
9. Assessment must be conducted exactly 15 minutes after starting the reaction. Given the nature of the measurement, the reaction and color development may slightly continue and progress even after 15 minutes.
10. The color tone of the line may vary depending on the color tone and specimen properties. However, the test result is valid as long as a red line is present.
11. If the line is not red at all (e.g. black), the test result is invalid and another test should be performed.
12. A highly viscous specimen may affect sample migration and/or the reaction, resulting in weak coloration, delayed or no formation of the line, or a nonspecific reaction because of specimen retention.

SAMPLE COLLECTION AND PREPARATION

DOs and DON'Ts of Sample Collection

- Do use freshly collected samples of nasal swabs for optimum test performance.
- Do test sample immediately.
- Use only swabs provided with the kit.

Prepare test samples with sample extraction buffer for immediate testing after collection. If immediate testing is not possible, collected samples can be held refrigerated (2~8°C) for up to 48 hours prior to testing. Inadequate sample collection or improper sample handling may yield a false-negative result.



Nasal Swabbing

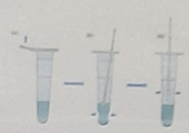
Insert nasal swab into one nostril, and the tip should be inserted up to 2.5 cm from the edge of the nostril. Gently rotate the swab 5 times or more against the nasal wall for collecting cells and mucus. Using the same swab, repeat sample collection in the other nostril.

PROCEDURE

Reagents, specimens and devices must be at room temperature (15~30 °C) for testing. Please read the instruction completely before beginning to test specimens.

1. Sample Extraction

Insert swab with collected sample into extraction tube containing 0.5 ml of sample extraction buffer. Squeeze the swab several times by compressing the outside walls of the tube end against the swab to mix well. Finally squeeze the swab to make most of the solution stays in the extraction tube and remove the swab. Use extraction solution as test sample. (step a~c)



2. Test Reaction

(1) Remove test device from sealed foil pouch prior to testing and lay flat on work bench.

(2) Insert filtered nozzle into the extraction tube with test sample. (step d)

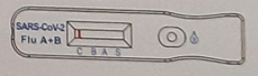
(3) Invert extraction tube and add 3 drops of test sample into the sample wells of COVID-19 and Flu A+B Duo by gently squeezing extraction tube. (step e)

(4) Read results at 15 minutes and disregard after 30 minutes. A positive result may be visible at 3 minutes. However, the complete reaction time of 15 minutes is required to confirm a negative result.

INTERPRETATION OF RESULTS

Allow the samples to run according to the instruction and read the test result in the reading area.

Negative Result



Only one reddish band appears on control region (C) of the device. No reddish line is visible next to the test region (S、A、B). This indicates that there is no detectable SARS-CoV-2 antigen and influenza A or influenza B antigen in the sample.