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DDS SARS-COV-2 & INFLUENZA A & B COMBO RAPID TEST

FAST

EASY

PRECISE

ABOUT THE IMPORTER

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Advent Life is part of Advent Group - an established leader in health and education with a global presence on five continents through legal entities in Paris, Sofia, Montreal, as well as representatives based in London, Munich, Kuala Lumpur, Vienna and Budapest. Advent Group is a registered distributor of medical devices.

DDS SARS-COV-2 & INFLUENZA A & B COMBO RAPID TEST

A rapid test for qualitative detection of SARS-CoV-2 antigens and/or Influenza A and B antigens in human nasal swab samples. The test detects SARS-CoV-2 nucleoprotein. Covid-19 antigen and/ Influenza A + B antigen rapid combo test detects new SARS-COV-2 strains that have undergone mutations in the Spike protein.

PRINCIPLE

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The Coronavirus (SARS-Cov-2) Antigen Rapid Test is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies. The test device is composed of three parts, namely sample pad, reagent pad and reaction membrane. The whole strip is fixed inside a plastic device. The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against the coroinavirus; the reaction membrane contains the secondary antibodies for the coroinavirus, and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane. When the sample is added into the sample window, conjugates dried in the reagent pad are dissolved and migrate along with the sample.

The Influenza A&B Rapid Testis a qualitative, lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in nasal swab, throat swab or nasal aspirate specimens. In this test, antibody specific to the Influenza A and Influenza B nucleoproteins is separately coated on the test line regions of the test device.

During testing, the extracted specimen reacts with the antibody to Influenza A and/or Influenza B that are coated onto particles. The mixture migrates up the membrane to react with the antibody to Influenza A and/or Influenza B on the membrane and generate one or two colored lines in the test regions.

CHARACTERISTICS

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INFLUENZA A RAPID TEST

SPECIFICITY:	94.1%
ACCURACY:	98.4%
SENSITIVITY:	97.5%

INFLUENZA B RAPID TEST

SPECIFICITY:	91.7%
ACCURACY:	100%
SENSITIVITY:	98.8%

SARS-COV-2 ANTIGEN RAPID TEST

SPECIFICITY:	99.56%
ACCURACY:	99.66%
SENSITIVITY:	99.64%

Results after 10 minutes. Results are easy to interpret. Storage at room temperature (2°C to 30°C)

WHAT'S IN THE PACKAGE

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1 Test cassette

1 Sterilized swab

1 Tube with a dosing nozzle

1 Sample extraction buffer

1 Instructions for use

Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.

SAMPLING AND PREPARATION

1. Sampling
   The aim is to diagnose coronavirus or influenza A / B virus from nasopharyngeal swab samples. For optimal test performance, use freshly collected samples. Inadequate sampling or improper handling can lead to a falsely negative result.

1.1 Completely insert the sterilized swab supplied in this kit into the nasal basin and swab several times to collect the epidermal cells of the mucus. It is recommended to collect sample from the nasopharyngeal for more accurate results.

2. Specimen preparation:

2.1 Take out one sample extraction buffer, remove the bottle cap, and add the content into the ex traction tube.

2.2 Insert the swab into the tube and rotate in a circular motion, touching the inside of the tube. The solution will be used as a test sample.

3. Screw and tighten the nozzle on the tube containing the sample, then shake vigorously.

4. Remove the test device from its packaging and use it as soon as possible. Place the device on a clean, level surface. For optimal results, perform the test immediately after opening the package.

5. Add 3 drops of the solution (approximately 80 ul) to each of the specially adapted wells of the test device and then start the timer. See the result in 10 to 20 minutes, but no later.

RESULTS

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POSITIVE SARS-Cov-2: Two red lines appear. One red line appears in the control region (C), and one red line in the test region (T).

POSITIVE Influenza A: Two distinct colored lines appear. 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

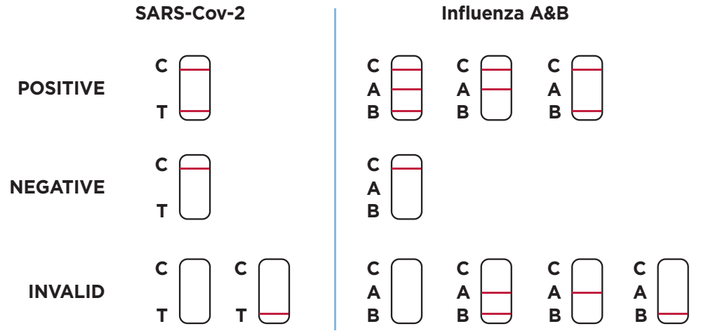
POSITIVE Influenza B: Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B). A positive result in the Influenza B region indicates that Influenza B antigen was detected in the sample.

POSITIVE Influenza A and Influenza B: Three distinct colored lines appear. 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 shade of color may vary**,** but it should be considered positive whenever there is even a faint line.

NEGATIVE Only one red line appears in the control region(C), and no line in the test region(T/A/B).

INVALID: No red line appears in the control region(C). The test is invalid even if there is a line on test region(T/A/B). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device.



IMPORTANT INFORMATION

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The test is for professional in-vitro diagnostic use only. The test should be used for the detection of Influenza A and/or B virus and/or coronavirus antigens in a nasopharyngeal swab.

Do not use after the expiration date.

Before opening, make sure that the foil package containing the test device is not damaged.
Perform the test at room temperature from 15°C to 30°C.

Wear gloves when handling samples and avoid touching the reagent membrane and sample window.
All samples and used accessories must be treated as infectious and disposed of in accordance with local regulations.

Avoid using bloody samples.

STORAGE AND STABILITY

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Store the rapid test cassette at room temperature or refrigerated (2-30°C). Do not freeze.

All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

Keep away from sunlight, moisture, and heat.