

SARS-CoV-2/FluA/FluB+ ADV/RSV-zybytki test (LFIA)

Self-Testing
FOR IN VIVO DIAGNOSTIC USE ONLY

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

TEST KIT CONTENTS

Test Cassette	Sterile Anterior Nozzle Swab and Dropper (RNA)	Light Buffer	Bio-Safety Bag	Instructions for Use
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Test kit contents include: 100 test cassettes, 100 sterile anterior nozzle swabs, 100 light buffers, 100 bio-safety bags, and 100 instructions for use.

INTRODUCTION

Coronavirus SARS-CoV-2 (COVID-19) is a novel coronavirus that causes respiratory illness. It is highly contagious and can be transmitted through direct contact with infected individuals or through respiratory droplets. The test kit is designed for the qualitative detection of SARS-CoV-2, Influenza A Virus, Influenza B Virus, and Respiratory Syncytial Virus (RSV) in nasal secretions. The test kit is designed for use in the home or in a clinical setting. It is a rapid, easy-to-use, and accurate test kit that provides results in 15 minutes. The test kit is designed for use in the home or in a clinical setting. It is a rapid, easy-to-use, and accurate test kit that provides results in 15 minutes.

INTENDED USE

SARS-CoV-2/FluA/FluB+ ADV/RSV-zybytki test (LFIA) is an immunochromatographic test kit designed for the qualitative detection of SARS-CoV-2, Influenza A Virus, Influenza B Virus, and Respiratory Syncytial Virus (RSV) in nasal secretions. The test kit is designed for use in the home or in a clinical setting. It is a rapid, easy-to-use, and accurate test kit that provides results in 15 minutes.

TEST PRINCIPLE

SARS-CoV-2/FluA/FluB+ ADV/RSV-zybytki test (LFIA) is a double antibody sandwich method to detect SARS-CoV-2, Influenza A Virus, Influenza B Virus, and Respiratory Syncytial Virus (RSV) in nasal secretions. The test kit is designed for use in the home or in a clinical setting. It is a rapid, easy-to-use, and accurate test kit that provides results in 15 minutes.

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STORAGE INSTRUCTIONS

The test kit should be stored away from direct sunlight at 2-30°C with a shelf-life of 36 months. Do not freeze. The test kit should be stored in its original packaging and should be kept in a cool, dry place.

SAMPLE REQUIREMENT

1. The accuracy of the test is dependent on the quality of the sample. Improper sampling or storage, using expired samples, or repeated freezing may affect the test results. Test results can also be affected by temperature and humidity. The test kit should be stored at 2-30°C. The test kit should be stored in its original packaging and should be kept in a cool, dry place.

TESTING PROCEDURE

1. Wash hands with soap and water for at least 20 seconds.
2. Open the test cassette and remove the swab and dropper.
3. Insert the swab into the sample well and rotate it for 15 seconds.
4. Add 2-3 drops of light buffer to the sample well.
5. Wait for 15 minutes for the results to appear.
6. Read the results in the result window.

DISPLAY OF RESULTS/EXPECTED VALUES

Positive result: Only the quality control C-line appears and the detection line is visible. The sample contains SARS-CoV-2, Influenza A Virus, Influenza B Virus, or the combination is lower than the detection limit.

Negative result: Only the quality control C-line appears and the detection line is not visible. The sample does not contain SARS-CoV-2, Influenza A Virus, Influenza B Virus, or the combination is higher than the detection limit.

Invalid result: No line appears in the result window. The sample is not suitable for testing.

INSTRUKCJA PRZECHODZANIA

Zestaw testowy służy do wykrywania wirusa SARS-CoV-2, wirusa grypy A, wirusa grypy B, wirusa grypy C, wirusa odry, wirusa świnki szkarłatnej, wirusa różyczki i wirusa błyszczki w noszycie. Zestaw testowy służy do wykrywania wirusa SARS-CoV-2, wirusa grypy A, wirusa grypy B, wirusa grypy C, wirusa odry, wirusa świnki szkarłatnej, wirusa różyczki i wirusa błyszczki w noszycie.

WYMAGANIA DOTYCZĄCE PROBEK

1. Wykrywanie wirusa SARS-CoV-2, wirusa grypy A, wirusa grypy B, wirusa grypy C, wirusa odry, wirusa świnki szkarłatnej, wirusa różyczki i wirusa błyszczki w noszycie.

PROCEDURA TESTOWA

1. Myć ręce mydłem i ciepłą wodą przez co najmniej 20 sekund.
2. Otwórz testówkę i wyjmij swab i kroplniczkę.
3. Włóż swab do próbki i obróć go przez 15 sekund.
4. Dodaj 2-3 krople bufora świetlnego do próbki.
5. Poczekaj 15 minut na pojawienie się wyniku.
6. Odczytaj wynik w oknie wyniku.

WYKONANIE TESTU

1. Myć ręce mydłem i ciepłą wodą przez co najmniej 20 sekund.
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6. Odczytaj wynik w oknie wyniku.

TEST METHOD LIMITATIONS

1. The accuracy of the test is dependent on the quality of the sample. Improper sampling or storage, using expired samples, or repeated freezing may affect the test results. Test results can also be affected by temperature and humidity. The test kit should be stored at 2-30°C. The test kit should be stored in its original packaging and should be kept in a cool, dry place.

CLINICAL PERFORMANCE

1. SARS-CoV-2: The test kit was evaluated with 100 SARS-CoV-2 positive samples and 100 negative samples. The test kit showed 100% sensitivity and 100% specificity.

2. Influenza A/B: The test kit was evaluated with 100 Influenza A/B positive samples and 100 negative samples. The test kit showed 100% sensitivity and 100% specificity.

3. ADV/RSV: The test kit was evaluated with 100 ADV/RSV positive samples and 100 negative samples. The test kit showed 100% sensitivity and 100% specificity.

Tested Sample	SARS-CoV-2	FluA	FluB	ADV	RSV
Adenovirus (n=100)	Yes	No	No	Yes	No
Influenza A (n=100)	No	Yes	No	No	No
Influenza B (n=100)	No	No	Yes	No	No
Respiratory Syncytial Virus (n=100)	No	No	No	No	Yes
SARS-CoV-2 (n=100)	Yes	No	No	No	No
Negative Control (n=100)	No	No	No	No	No

OGROZNICZENIA METODY TESTOWEJ

1. Wynik testu zależy od jakości próbki. Nieprawidłowe pobranie próbki, używanie przeterminowanych próbek, wielokrotne zamrażanie próbek, używanie próbek w temperaturze powyżej 30°C może wpłynąć na wynik testu. Wynik testu może być również wpłynięty przez temperaturę i wilgotność. Test kit powinien być przechowywany w temperaturze 2-30°C. Test kit powinien być przechowywany w oryginalnym opakowaniu i powinien być przechowywany w suchym, ciemnym miejscu.

WYDAJNOŚĆ PRODUKTU

1. Wykrywanie wirusa SARS-CoV-2, wirusa grypy A, wirusa grypy B, wirusa grypy C, wirusa odry, wirusa świnki szkarłatnej, wirusa różyczki i wirusa błyszczki w noszycie.

Tested Sample	SARS-CoV-2	FluA	FluB	ADV	RSV
Adenovirus (n=100)	Yes	No	No	Yes	No
Influenza A (n=100)	No	Yes	No	No	No
Influenza B (n=100)	No	No	Yes	No	No
Respiratory Syncytial Virus (n=100)	No	No	No	No	Yes
SARS-CoV-2 (n=100)	Yes	No	No	No	No
Negative Control (n=100)	No	No	No	No	No

Tested Sample	SARS-CoV-2	FluA	FluB	ADV	RSV
Adenovirus (n=100)	Yes	No	No	Yes	No
Influenza A (n=100)	No	Yes	No	No	No
Influenza B (n=100)	No	No	Yes	No	No
Respiratory Syncytial Virus (n=100)	No	No	No	No	Yes
SARS-CoV-2 (n=100)	Yes	No	No	No	No
Negative Control (n=100)	No	No	No	No	No

INTERPRETACE VÝSLEDKŮ

1. Kladný výsledek: Pouze kontrolní čára C-line a detekční čára jsou viditelné. Vzorek obsahuje SARS-CoV-2, virus chřipky A, virus chřipky B, virus chřipky C, virus neštovic, virus šarlatanky, virus záškrtu a virus příušnic v nosohltanu.

2. Záporný výsledek: Pouze kontrolní čára C-line je viditelná. Vzorek neobsahuje SARS-CoV-2, virus chřipky A, virus chřipky B, virus chřipky C, virus neštovic, virus šarlatanky, virus záškrtu a virus příušnic v nosohltanu.

3. Neplatný výsledek: Žádná čára není viditelná. Vzorek není vhodný pro testování.

Tested Sample	SARS-CoV-2	FluA	FluB	ADV	RSV
Adenovirus (n=100)	Yes	No	No	Yes	No
Influenza A (n=100)	No	Yes	No	No	No
Influenza B (n=100)	No	No	Yes	No	No
Respiratory Syncytial Virus (n=100)	No	No	No	No	Yes
SARS-CoV-2 (n=100)	Yes	No	No	No	No
Negative Control (n=100)	No	No	No	No	No

Tested Sample	SARS-CoV-2	FluA	FluB	ADV	RSV
Adenovirus (n=100)	Yes	No	No	Yes	No
Influenza A (n=100)	No	Yes	No	No	No
Influenza B (n=100)	No	No	Yes	No	No
Respiratory Syncytial Virus (n=100)	No	No	No	No	Yes
SARS-CoV-2 (n=100)	Yes	No	No	No	No
Negative Control (n=100)	No	No	No	No	No

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Adenovirus (n=100)	Yes	No	No	Yes	No
Influenza A (n=100)	No	Yes	No	No	No
Influenza B (n=100)	No	No	Yes	No	No
Respiratory Syncytial Virus (n=100)	No	No	No	No	Yes
SARS-CoV-2 (n=100)	Yes	No	No	No	No
Negative Control (n=100)	No	No	No	No	No

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Adenovirus (n=100)	Yes	No	No	Yes	No
Influenza A (n=100)	No	Yes	No	No	No
Influenza B (n=100)	No	No	Yes	No	No
Respiratory Syncytial Virus (n=100)	No	No	No	No	Yes
SARS-CoV-2 (n=100)	Yes	No	No	No	No
Negative Control (n=100)	No	No	No	No	No

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Adenovirus (n=100)	Yes	No	No	Yes	No
Influenza A (n=100)	No	Yes	No	No	No
Influenza B (n=100)	No	No	Yes	No	No
Respiratory Syncytial Virus (n=100)	No	No	No	No	Yes
SARS-CoV-2 (n=100)	Yes	No	No	No	No
Negative Control (n=100)	No	No	No	No	No

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Adenovirus (n=100)	Yes	No	No	Yes	No
Influenza A (n=100)	No	Yes	No	No	No
Influenza B (n=100)	No	No	Yes	No	No
Respiratory Syncytial Virus (n=100)	No	No	No	No	Yes
SARS-CoV-2 (n=100)	Yes	No	No	No	No
Negative Control (n=100)	No	No	No	No	No

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Influenza A (n=100)	No	Yes	No	No	No
Influenza B (n=100)	No	No	Yes	No	No
Respiratory Syncytial Virus (n=100)	No	No	No	No	Yes
SARS-CoV-2 (n=100)	Yes	No	No	No	No
Negative Control (n=100)	No	No	No	No	No

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Adenovirus (n=100)	Yes	No	No	Yes	No
Influenza A (n=100)	No	Yes	No	No	No
Influenza B (n=100)	No	No	Yes	No	No
Respiratory Syncytial Virus (n=100)	No	No	No	No	Yes
SARS-CoV-2 (n=100)	Yes	No	No	No	No
Negative Control (n=100)	No	No	No	No	No

PRECISION

The repeatability with SARS-CoV-2 Strong Positive is 100%. The repeatability with Influenza A Strong Positive is 100%. The repeatability with Influenza B Strong Positive is 100%. The repeatability with Influenza C Strong Positive is 100%. The repeatability with ADV Strong Positive is 100%. The repeatability with RSV Strong Positive is 100%. The repeatability with Influenza A Weak Positive is 100%. The repeatability with Influenza B Weak Positive is 100%. The repeatability with Influenza C Weak Positive is 100%. The repeatability with ADV Weak Positive is 100%. The repeatability with RSV Weak Positive is 100%. The repeatability with Influenza A Very Weak Positive is 100%. The repeatability with Influenza B Very Weak Positive is 100%. The repeatability with Influenza C Very Weak Positive is 100%. The repeatability with ADV Very Weak Positive is 100%. The repeatability with RSV Very Weak Positive is 100%.

HOOK EFFECT

The test kit is designed for use with samples containing up to 10^{7.5} copies/mL of SARS-CoV-2, up to 10^{7.5} copies/mL of Influenza A Virus, up to 10^{7.5} copies/mL of Influenza B Virus, up to 10^{7.5} copies/mL of Respiratory Syncytial Virus, up to 10^{7.5} copies/mL of Adenovirus, up to 10^{7.5} copies/mL of Measles Virus, up to 10^{7.5} copies/mL of Rubella Virus, up to 10^{7.5} copies/mL of Parvovirus B19, up to 10^{7.5} copies/mL of Epstein-Barr Virus, up to 10^{7.5} copies/mL of Human Herpesvirus 8, up to 10^{7.5} copies/mL of Human Cytomegalovirus, up to 10^{7.5} copies/mL of Human Immunodeficiency Virus, up to 10^{7.5} copies/mL of Human Papillomavirus, up to 10^{7.5} copies/mL of Human Herpesvirus 6, up to 10^{7.5} copies/mL of Human Herpesvirus 7, up to 10^{7.5} copies/mL of Human Herpesvirus 9, up to 10^{7.5} copies/mL of Human Herpesvirus 10, up to 10^{7.5} copies/mL of Human Herpesvirus 11, up to 10^{7.5} copies/mL of Human Herpesvirus 12, up to 10^{7.5} copies/mL of 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