GENESIS

EZER™ Flu & COVID-19 Antigen Duo Rapid Test

CE 1434 IVD ENGLISH Ver. 202102A_EN

INSTRUCTIONS FOR USE

Self-Testing

A rapid test for the detection of influenza A, influenza B and SARS-CoV-2 antigens in nasal specimens.

- For self-testing use.
- Use test only one time.
- Testing by adult only or under adult supervision.
- Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

Scan the QR code to access procedure video

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PREPARATION

1. Wash or sanitize your hand.
Make sure they are dry before starting the test.

2. Check your test kit.

Box (Tube holder)

Test device

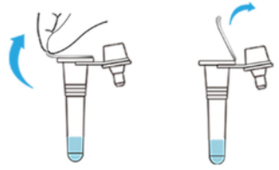
Swab

Timer (Not included)

Extraction tube

3. Open the pouch. Remove the test cassette on a flat and clean surface.

4. Peel off the aluminum foil seal from the top of the extraction buffer tube.

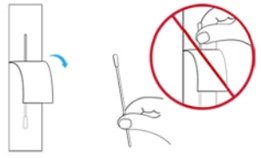


5. Punch through the perforated circle on the kit box to form a tube holder and being sure to keep the tube upright.

Tube holder

SAMPLE COLLECTION

6. Remove the swab from the pouch, being careful not to touch the swab head.



7. Swab both nostrils.
Be sure to rub BOTH nostrils with the SAME SWAB.

8. Gently insert the entire absorbent tip of the swab head into 1 nostril until resistance is felt (about ¾ of an inch).

Then, firmly rub the swab in a circular motion around the inside wall of the nostril at least 5 times. Take approximately 15 seconds to collect the specimen.

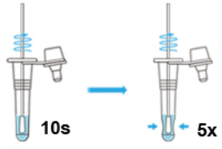
9. Remove Swab from nostril. Use the same swab, repeat step 8 in your other nostril.

NOTE: *If you are swabbing others, please wear a face mask.*
With children, you may not need to insert the swab as far into the nostril.
For very young children, you may need another person to steady the child's head while swabbing.

NOTE: *Failure to swab properly may cause false negative results.*

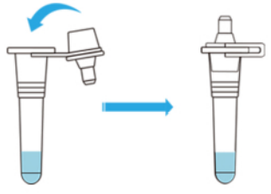
TEST PROCEDURE

10. Immediately place the swab into the tube swirl for 10 seconds and swirl in the fluid 5 or more times while pushing against the wall of the tube.



11. Remove the swab while squeezing the tube side to expel any liquid.
Discard the swab in trash.

12. Place the dropper tip firmly on the extraction tube.



13. Invert the extraction vial and hold bottle vertically, 1/2 inch above the sample well, and squeeze the vial gently. Allow **THREE(3)** drops of sample to fall into the sample well.

Note: *A false negative or invalid result may occur if less than 3 drops of fluid are added to the Sample Well.*

14. Start the timer: Read the result at 15 minutes. The test result should not be read after 30 minutes.

Note: *Do not move or lift the test cassette during this time.*

INTERPRETATION OF RESULTS

Positive

COVID-19 (+)

Flu B (+)

Flu A (+)

A reddish Control line (C position) and a reddish Test line (A,B / T) indicate that Influenza A, B and/or SARS-CoV-2 antigen has been detected.

Lines at the A and C positions indicate the presence of Influenza A viral antigen, lines at the B and C positions indicate the presence of Influenza type B viral antigen, and lines at the T and C positions indicate the presence of SARS-CoV-2 viral antigen in the specimen.

A positive result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype.

Note: *The Test line (reddish line) may vary in shade and intensity (light or dark, weak or strong) depending on the concentration of antigen detected. The intensity of the Control line should not be compared to that of the Test line for the interpretation of the test result. Even a light or faint Test line must be interpreted as a positive result.*

Negative

A reddish Control line (C position) only, with no Test line at the A, B, T positions, indicates that Influenza A, B antigen or SARS-CoV-2 antigen has not been detected. A negative result does not exclude influenza viral or SARS-CoV-2 viral infection.

Determination of negative results should not be made before 15 minutes.

Negative results are presumptive and may need to be confirmed with a molecular assay.

Invalid

A reddish purple line should always appear at the Control line position (C position). If a line does not form at the Control line position in 15 minutes, the test result is invalid and the test should be repeated with a new EZER Flu & COVID-19 Antigen Duo rapid test device.

EZER™ Flu & COVID-19 Antigen Duo Rapid Test

INTENDED USE

For Self-Testing

The *EZER*™ Flu & COVID-19 Antigen Duo Rapid Test is a lateral flow immunoassay intended for the in vitro rapid, simultaneous qualitative detection and differentiation of nucleocapsid antigen from SARS-CoV-2, influenza A and influenza B from nasal swab specimens obtained from individuals, who are suspected of respiratory viral infection, within the first three days of onset of symptoms. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

This test is for laymen with self-collected nasal (nares) swab samples from individuals aged 14 years or older, or adult collected nasal swab samples from individuals aged 2 years or older.

Results are for the simultaneous identification of nucleocapsid antigens of SARS-CoV-2, influenza A and influenza B, but does not differentiate between SARS-CoV and SARS-CoV-2 viruses.

These viral antigens are generally detectable in nasal swab samples during the acute phase of infection. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of the disease. Positive result is advised to consult with a medical practitioner, and follow local authorities' recommendations, and not take any decision of medical relevance without first consulting their medical practitioner.

Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

Negative influenza A and B test results should be treated as presumptive. It is recommended these results be confirmed an influenza A and B molecular assay. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

User should contact medical practitioner if symptoms or other infection suspicion persist.

CONTENTS

REF	Size	Contents
P213106	1 Test	Test device (1), Sterilized swab (1), Extraction tube (with extraction buffer) (1), Package insert (1).
P213107	5 Tests	Test devices (5), Sterilized swabs (5), Extraction tubes (with extraction buffer) (5), Package insert (1).
P213109	20 Tests	Test devices (20), Sterilized swabs (20), Extraction tubes (with extraction buffer) (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. Proper sample collection and handling are essential for correct results. Inadequate or improper nasal swab sample collection may yield false negative test results.
2. Keep test kit and materials out of the reach of children and pets before and after use.
3. INVALID RESULTS can occur when an insufficient volume of extraction reagent is added to the test card. To ensure delivery of adequate volume, hold bottle vertically, 1/2 inch above the sample well, and add drops slowly.
4. The test is intended to be read at 15 minutes. If the test is read before 15 minutes or after 30 minutes, false negative or false positive results may occur, and the test should be repeated with a new test cassette.
5. 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.
6. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false-positive result. Avoid touching any bleeding areas of the nasal cavity when collecting specimens.
7. Avoid exposure of your skin, eyes, nose, or mouth to the solution in the extraction tube. The chemicals in the reagent solution are hazardous to the skin and eye.
8. Note：Add 3 drops of samples individually in both sample wells.

DO

1. Children between 2~14 years of age must be tested by a parent or legal guardian.
2. Wear a safety mask or other face-covering and medical gloves when collecting the sample from another individual.
3. Wash hands thoroughly for before and after handling the sample.
4. In order to obtain accurate results, you must follow the instructions for use.
5. Blow their nose several times before collecting specimen.
6. Only open the kit when you are ready to complete the test.
7. Complete the test immediately after opening the test device in the pouch.
8. Keep the test device on a flat surface during the testing.
9. When collecting a sample, use only the nasal swab provided in the kit.
10. Handle all specimens and any components contacted with the specimens as though they contain infectious agents, and disinfect them, even if the test is negative.

DON'Ts

1. Do not use on anyone under two years of age.
2. Do not open the kit contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.
3. Do not touch the sample drop and the judgment part of the test board directly by hand.
4. Do not use kit components beyond the expiration date.
5. Do not use the test if the pouch is damaged or open.
6. Do not reuse any kit components. Do not use with multiple specimens.
7. Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
8. Do not use on anyone who is prone to nosebleeds.
9. Do not dip the swab into the liquid reagent or other liquid before inserting the swab into the nose.
10. Do not touch swab tip when handling the swab sample.

ANALYTICAL PERFORMANCE

Analytical sensitivity (Limit of Detection, LoD)

The LoD of COVID-19 for the *EZER*™ Flu & COVID-19 Antigen Duo Self-Test is 140 $TCID_{50}$/mL.

The LoD of Flu A for the *EZER*™ Flu & COVID-19 Antigen Duo Self-Test was established based on a total of 8 influenza A.

Influenza Viral Strain	Calculated LoD ($TCID_{50}$/mL)
A/New Caledonia/20/1999_H1N1	$4.25x10^3$
A/California/04/2009_H1N1	$2.11x10^3$
A/PR/8/34_H1N1	$7.31x10^2$
A/Bean Goose/Hubei/chenhu XVI35-1/2016_H3N2	$2.47x10^2$
A/Guizhou/54/89_H3N2	$1.98x10^2$
A/Human/Hubei/3/2005_H3N2	$1.46x10^4$
A/Bar-headed Goose/QH/BTY2/2015_H5N1	$9.88x10^4$
A/Anhui/1/2013_H7N9	$1.98x10^5$

The LoD of Flu B for the *EZER*™ Flu & COVID-19 Antigen Duo Self-Test was established based on a total of 2 influenza B.

Influenza Viral Strain	Calculated LoD ($TCID_{50}$/mL)
B52-Victoria	39.5
B5-Yamagata	$5.31x10^2$

Clinical performance

Performance of the *EZER*™ Flu & COVID-19 Antigen Duo Rapid Test was established with 502 nasal swabs collected from individual symptomatic patients in Locus Medicus Medical SA, Greece.

All samples were tested in parallel with the *EZER*™ Flu & COVID-19 Antigen Duo and a SARS-CoV-2 RT-PCR assay. In this study, 97.2% (173/178) of positive individuals in SARS-CoV-2 specific PCR test are positive when tested by EZER Flu & COVID-19 Antigen Duo Rapid Test.

		RT-PCR assay (SARS-CoV-2)		
		+	−	Total
EZER Flu & COVID-19 Antigen Duo (COVID-19 Antigen)	+	173	2	175
	−	5	322	327
	Total	178	324	502

Relative Sensitivity：97.2% (95%CI：93.6%-99.1%)
Relative Specificity：99.4% (95%CI：97.8%-99.9%)
Positive Predictive Value：98.9% (95%CI：95.9%-99.9%)
Negative Predictive Value：98.5% (95%CI：96.5%-99.5%)
Accuracy：98.6% (95%CI：97.2%-99.4%)

Among the 502 specimens, by using Influenza RT-qPCR, it was confirmed that either Influenza A or Influenza B were negative. However, 2 Influenza A and 3 Influenza B samples were tested positive by Flu Antigen rapid test. The specificity of Influenza A Antigen rapid test is 99.6%, and Influenza B Antigen rapid test is 99.4%.

During the study, with inability to obtain fresh positive influenza samples, retrospective method was used to evaluate the performance of the kit. Specimens stored/frozen in viral transport media (VTM) confirmed positive by Influenza RT-qPCR were used.
In this study, 88.7%(102/115) of Flu A positive sample in Influenza specific PCR test are Flu A positive when tested by EZER Flu & COVID-19 Antigen Duo Rapid Test. 86.6%(103/119) of Flu B positive sample in Influenza specific PCR test are Flu B positive when tested by EZER Flu & COVID-19 Antigen Duo Rapid Test.

Co-infection (Competitive Interference)

For Co-infection, SARS-CoV-2 at levels near LoD was tested in the presence of high levels of influenza A or influenza B as well as near LoD influenza A and influenza B in the presence of high levels of SARS-CoV-2. No competitive interference was seen between SARS-CoV-2 and Influenza A and B in this testing at the concentration listed in the table below.

Competitive Virus	Concentration ($TCID_{50}$/mL)	Competitive Target Virus	Concentration ($TCID_{50}$/mL)	Competitive Target Percent Positivity
Influenza A H1N1	$1.0 x10^5$	SARS-CoV-2	$4.2x10^2$	100%
Influenza A H3N2	$1.0 x10^5$	SARS-CoV-2	$4.2x10^2$	100%
Influenza B	$1.0 x10^5$	SARS-CoV-2	$4.2x10^2$	100%
SARS-CoV-2	$5.6x10^5$	Influenza A H1N1	$4.25x10^3$	100%
SARS-CoV-2	$5.6x10^5$	Influenza A H3N2	$2.47x10^2$	100%
SARS-CoV-2	$5.6x10^5$	Influenza B	$5.31x10^2$	100%

Analytical specificity

Cross-reactivity and microbial Interference of COVID-19 antigen test

Each organism and virus were tested in the absence or presence of SARS-CoV-2 virus at low positive level.
No cross-reactivity or interference was observed with the following microorganisms:

Bacteria and Yeast：
Streptococcus pneumoniae, *Haemophilus influenzae*, *Staphylococcus aureus*, *Streptococcus pyogenes*, *Staphylococcus epidermidis*, *Mycobacteria tuberculosis*, *Legionella pneumophila*, *Candida albicans*, *Bordetella pertussis*, *Mycoplasma pneumoniae*, *Chlamydia pneumoniae*

Virus：
Influenza A(H1N1), Influenza A(H3N2), Influenza B(Victoria), Influenza B(Yamagata), RSV, Adenovirus, Enterovirus, Human metapneumovirus, Human coronavirus OC43, Human coronavirus 229E, Human coronavirus NL63, Rhinovirus, Parainfluenza virus Type 1, Parainfluenza virus Type 2, Parainfluenza virus Type 3, Parainfluenza virus Type 4

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for 'wet' testing, in silico analysis was used to assess the degree of protein sequence homology.

- Human coronavirus HKU1：Homology is relatively low, at 36.7% across 82% of sequences, but cross-reactivity cannot be ruled out.
- SARS-coronavirus：Homology is relatively high, at 91% homology across 100% of sequences.
- MERS-coronavirus：Homology is relatively low, at 50% homology across 88% of sequences, but cross-reactivity cannot be ruled out.

Endogenous/Exogenous interference substances

The following potential interfering substances have been tested using the *EZER*™ Flu & COVID-19 Antigen Duo Rapid Test and no interference was observed：
Whole Blood(4%), Mucin(0.3%), Naso GEL (NeilMed)(5% v/v), Chloraseptic (Menthol/Benzocaine) (1.5 mg/mL), Nasal Drops (Phenylephrine) (15% v/v), Nasal Spray (Cromolyn)(15% v/v), Afrin (Oxymetazoline)(15% v/v), Zicam(5% v/v), Homeopathic (Alkalol)(1:10 dilution), Sore Throat Phenol Spray(15% v/v), Tobramycin(4 μg/mL), Mupirocin(10 mg/mL), Fluticasone Propionate(1% v/v), Tamiflu (Oseltamivir Phosphate)(5 mg/mL).

LIMITATIONS

1. This kit is a qualitative test and cannot determine the amount of antigen in the sample.
2. Users should test specimens as quickly as possible after specimen collection.
3. Positive test results do not rule out co-infections with other pathogens.
4. A false-negative test result may occur if the sample collected may contain antigen titers below the reagent's sensitivity threshold or if the sample was collected improperly.
5. Specimen obtained early with sudden onset of symptoms will contain the highest viral titers, the amount of antigen in a sample may decrease as the duration of illness increases.
6. A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.
7. A negative test result does not rule out other viral or bacterial infections.
8. Negative results should be treated as presumptive only and may not mean you are not infectious. If you are experiencing any COVID symptoms you must seek immediate further laboratory PCR testing and follow up clinical care.
9. User should not take any decision of medical relevance without first consulting his or her medical practitioner.
10. Influenza testing is beneficial for a small group of patients.

Index of Symbols

	Attention, see instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2~30°C	LOT	Lot Number	REF	Catalog #

EC REP **Lotus NL B.V.**
Koningin Julianaplein 10, le Verd, 2595AA, The Hague, Netherlands.
e-mail：peter@lotusnl.com

Hangzhou Genesis Biodetection and Biocontrol Co., Ltd.
ADD：No.139, 10th Street (East), Hangzhou Economic & Technological Development Zone, Hangzhou, China, 310018
TEL：+86-571-87818163 FAX：+86-571-8782-4695
Web：https://www.genesis-ivd.com

Nasal Swab Manufacturers

Jiangsu HanHeng Medical Technology Co., Ltd. CE 0197
16-B4, #1 North Qingyang Road, Tianning District, Changzhou, 213017 Jiangsu P.R. China

EC REP **Luxus Lebenswelt GmbH**
Kochstr. 1, 47877, Willich, Germany

Jiangsu Rongye Technology Co., Ltd. CE 0197
Touqiao Town, Yangzhou City 225109 Jiangsu P.R. China

EC REP **Riomavix S.L.**
Calle de Almansa 55, 1D, Madrid 28039 Spain