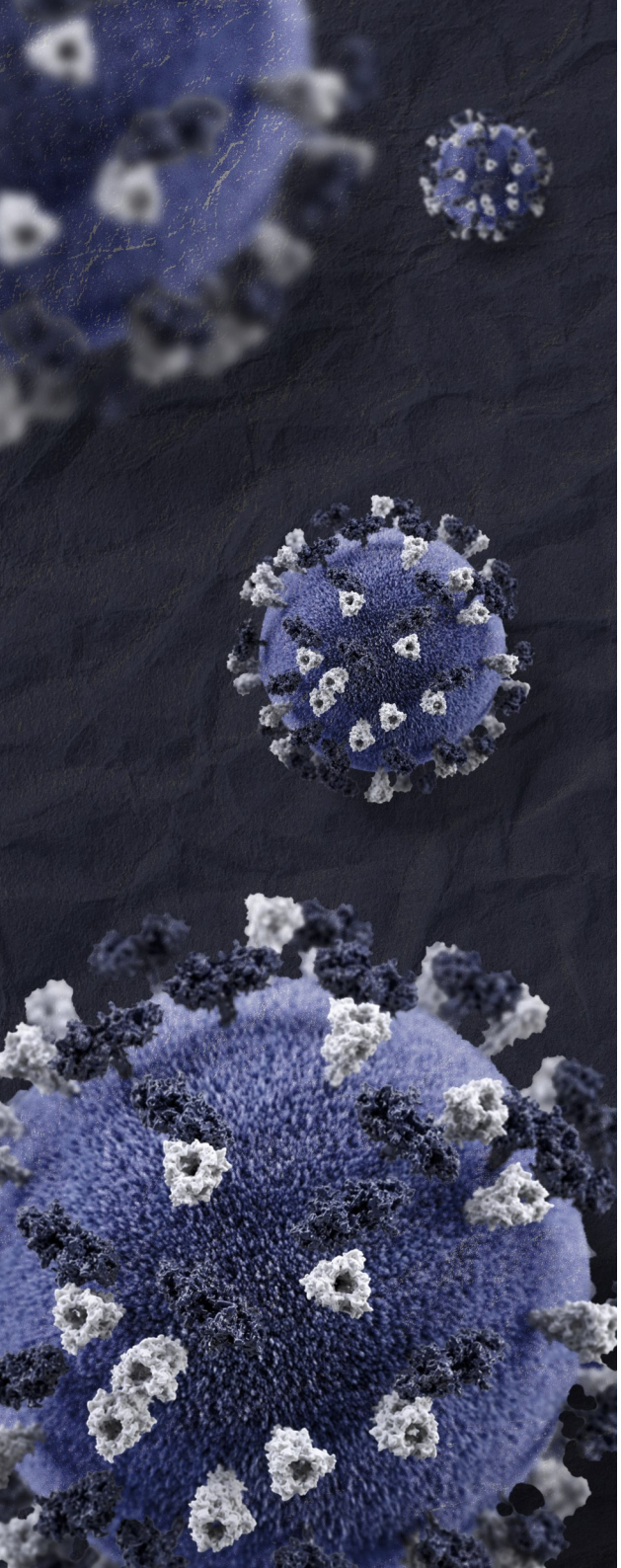


REF V16XX

RAPID TEST FLU_COVID

Lateral Flow Test | IVD

For the detection of SARS-CoV-2 and influenza antigens in human nasal or nasopharyngeal specimen.

This Lateral Flow test kit is manufactured by ProGnosis Biotech S.A. and complies with the specifications on the Standard EN ISO 13485:2016

Use only the current version of Product Data Sheet enclosed with the kit.

Rapid Test FLU_COVID, V16XX, is a qualitative Lateral Flow test for the detection of SARS-CoV-2 and Influenza A/B antigens in nasal or nasopharyngeal specimen.

The Lateral flow kit contains all reagents required for the immunoassay method.

Specimen: Nasal or nasopharyngeal swab.

- For professional use only
- For in vitro diagnostic use only
- Rapid Test FLU_COVID is a sensitive screening assay for the detection of SARS-CoV-2 and/or Influenza A and B virus. Results should not be used as the only source to diagnose or to determine infection status.
- Negative result do not rule out SARS-CoV-2 or Influenza infection
- Test should only be conducted by medical personnel
- Test time (incubation time after specimens preparation): 15 min
- Shelf life: 2 years
- Storage: 4-30°C

1. Description

Rapid Test FLU_COVID is a qualitative, lateral flow immunoassay designed to detect the presence or absence SARS-CoV-2 and Influenza A or B virus antigens in nasal or nasopharyngeal swab specimens directly collected.

2. Principal of the assay

In this test, antibodies specific to Influenza A and B nucleoproteins are coated on the test line region FluA and FluB of the nitrocellulose membrane. Antibodies specific to SARS-CoV-2 nucleocapsid protein are coated on the test line region CoV of the nitrocellulose membrane. During testing, antigens in the specimen react with the antibodies that are coated onto gold nanoparticles. The mixture migrates up the membrane to react with the antibodies immobilized on the membrane and generate a colored line in the test region FluA, FluB and or CoV. The presence of one of these colored lines indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has been performed properly.

3. Introduction

A novel coronavirus (identified as 2019-nCoV) emerged in the Chinese province of Hubei (Wuhan) in December 2019, which has resulted in hundreds of thousands of confirmed human infections worldwide. Cases of severe illness and deaths have been reported. On February 11, 2020 the International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2. The median incubation time is estimated to be approximately 5 days with symptoms estimated to be present within 12 days of infection. The most common symptoms of COVID-19 (according to WHO), are similar to other viral respiratory diseases and include fever, dry cough and tiredness. The virus spreads primarily through droplets of saliva or discharge from the nose when an infected person coughs or sneezes.

Influenza, commonly knows as "the flu", is an infectious respiratory disease caused by influenza viruses type A,B or C. It spreads from person to person through the air via coughs or sneezes, is highly contagious and most common symptoms are fever or chills, cough, sore throat, runny nose, headaches and fatigue. Influenza viruses cause seasonal flu epidemics each year but once in a few decades a new flu strain could lead to pandemic.

4. Reagents Provided

	V1601	V1605	V1620
Reaction device	1	5	20
Prefilled extraction tube with Running Buffer	1	5	20
Sterile swabs	1	5	20
Carton case	-	-	1
Positive Control*	-	-	1
Negative Control*	-	-	1
Manual	1	1	1

5. Materials required but not provided

- Clock or Timer
- Gloves and face protection shield
- Container for biohazardous waste

*Note: Positive and Negative control are in prefilled bottles with purple screw cap.

6. Storage Instructions

Store kit components between 4 and 30°C (39.2 - 96°F). Do not freeze any components provided. Expiry of the kit and reagents is stated on their labels and no quality guarantee is accepted after the expiration date. The expiry of the kit components can only be guaranteed if the components are stored properly and the reagent is not contaminated prior handling.

7. Safety and Precautions for use

7.1 Health and safety precautions

- Use gloves, protective clothing and eye/face protection and handle appropriately with the requisite Good Laboratory Practices. The product must only be used by qualified personnel.
- WASTE MANAGEMENT: Dispose of all specimens and materials used to perform the test as biohazard waste. Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
- During the specimen collection human source material spills should be also treated as potentially infectious. Spills should be immediately decontaminated, including the spill area, materials and any contaminated surfaces, with an appropriate chemical disinfectant and should be wiped away.
- Do not re-use any of the kit components as they are single-use only.
- Sterile swabs must be used only for nasal or nasopharyngeal specimen. Avoid to touch the tip of the swab.
- Do not eat, drink or smoke in the area where the specimens and the kit are stored and handled.
- All positive results should be processed following local news and regulations.

7.2 Precautions related to the procedure

- In accordance with Article 1, Paragraph 2b of European Directive 98/79/EC, the use of in-vitro diagnostic medical devices is envisaged by the manufacturer to ensure the suitability, performance, and safety of these products. Consequently, the testing procedure, information, precautions, and warnings in the instructions for use must be followed rigorously. No changes to the test procedure are permitted, nor is any use in combination with other products not approved by the manufacturer. The user is solely responsible for any such changes. The manufacturer is not responsible for false results nor incidents arising as a result of these.
- Do not use the kit if the packaging of components is damaged, if there is an expired reagent or if the desiccant bag is absent.
- All reagents should be warmed in room temperature before use.
- Cover or cap all reagents when not in use.
- Do not mix and interchange different specimens.
- Do not interchange individual reagents between kits of different lot numbers.

8. Specimen collection

8.1 Nasal Mid-Turbinate specimen collection

Tilt the patient's head back 70 degrees. Remove a sterile swab from the pouch. While gently rotating it, insert the swab less than one inch (about 2 cm) into patient's nostril (until resistance is met at the turbinates). Rotate the swab five times against the nasal wall then slowly remove from the nostril. Using the same swab repeat the collection procedure with the second nostril. (Figure 1.)

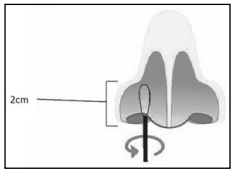


Figure 2. Nasal swab procedure

8.2 Nasopharyngeal specimen collection

Tilt the patient's head back 70 degrees. Remove a sterile swab from the pouch. Place the swab into one of the patient's nostrils. When it reaches the posterior nasopharynx rotate 3 to 5 times over the surface and then remove it slowly while rotating it (Figure 2.)

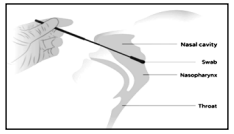


Figure 3. Nasopharyngeal swab

9. Method Procedure

9.1 Calculate the number of swabbing sticks and tubes needed, according to the number of samples to collect.

9.2 After the specimen collection (see Chapter 8), place the swab in the extraction tube, rotate the swab forcefully against the side of the tube for 1min. Best results are obtained when the specimen is vigorously extracted in the solution.

9.3 Remove the swab, squeezing the sides of the tube to extract as much liquid as possible.

9.4 Discard the swab.

9.5 Close the extraction tube with the dropper cup. Add 3 drops in the circular window of the cassette.

9.6 After 15 minutes, the test stick can be visually read and interpreted according to the corresponding figure.

Note: The test result should not be read and interpreted after 30 minutes.

POSITIVE/ NEGATIVE CONTROL: add 2 drops directly form the prefilled tube in the circular window of the cassette

10. Interpretation of results

Note*: *For internal procedure purposes four colored lines are present on the result window of the Rapid Test FLU_COVID. The colored lines have no effect on the product's performance since they are washed away during the experiment.*

FLU A Positive: Two visible colored bands appear at both FluA and Control (C) line. It indicates a positive result for the Influenza A virus nucleoprotein antigen in the specimen.

FLU B Positive: Two visible colored bands appear at both FluB and Control (C) line. It indicates a positive result for the Influenza B virus nucleoprotein antigen in the specimen.

FLU A and B Positive: Three visible colored bands appear at FluA, FluB and Control (C) line. It indicates a positive result for the Influenza A and B nucleoprotein antigen in the specimen.

FLU A and SARS-CoV-2 Positive: Three visible colored bands appear at FluA, CoV and Control (C) line. It indicates a positive result for the Influenza A and SARS-CoV-2 antigen in the specimen.

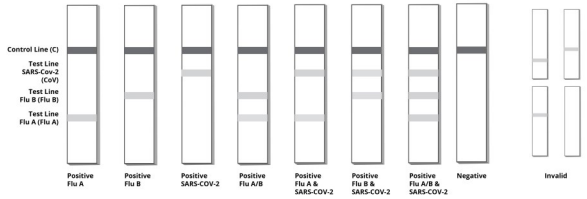
FLU B and SARS-CoV-2 Positive: Three visible colored bands appear at FluB, CoV and Control (C) line. It indicates a positive result for the Influenza B and SARS-CoV-2 antigen in the specimen.

SARS-CoV-2 Positive: Two visible colored bands appear at both CoV and Control (C) line. It indicates a positive result for the SARS-CoV-2 nucleocapsid protein antigen in the specimen.

FLU A Flu B and SARS-CoV-2 Positive: Four visible colored bands appear at Flu A, FluB, CoV and Control (C) line. It indicates a positive result for the Influenza A, Influenza B and SARS-CoV-2 antigen in the specimen.

Negative: One visible colored band appears at Control line. It indicates that the concentration of the Influenza and/or SARS-CoV-2 antigen is zero or below the detection limit of the test.

Invalid: No colored band appears at Control line no matter whether it appears at Test lines or not.



Interpretation of results

11. Limitations

- The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
- After specimen collection the swab must be extracted as soon as possible. Otherwise they may be stored dry in their original packaging for up to 2 hours at RT. When using a viral transport medium, extract AGAIN the swab in the extraction tube that contains Prognosis Running Buffer. When using the transport media, the test sensitivity can be reduced due to excessive dilution of specimen.
  Note: the transport medium should not contain chaotropic substances such as Guanidinium thiocyanate.
- After the extraction specimens should be tested as soon as possible. Otherwise they can be stored at room temperature 20-25°C (68-77°F) for two hours.
- The test should be used for the detection of INFLUENZA A/B and SARS-CoV-2 antigen ONLY in nasal or nasopharyngeal swab specimens.
- Failure to follow the guidelines for proper specimen collection, test procedure and interpretation of test results may adversely affect test performance and/or produce invalid result.
- USE ONLY the sterile swabs that are provided in the kit for the specimen collection.
- During specimen collection avoid contact with bleeding areas and excess of mucus as both of them may give a false positive result due to interference with the test performance.
- Positive results indicate the presence of Influenza A/B and/or SARS-CoV-2 antigens but a diagnosis of an infection should only be made by a physician evaluating all clinical and laboratory findings and must be based in the correlation of the results with further clinical observations.
- A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor quality specimen is obtained.
- Positive test results do not rule out co-infection with other pathogens.
- The Rapid Test FLU_COVID will indicate the presence of Influenza A/B and/or SARS-CoV-2 in the specimen from both viable and non-viable virus.

12. Immunoassay Performance

12.1 Cross-reactivity

In order to determine the cross reactivity of Rapid Test FLU_COVID, an evaluation was performed; no cross reactivity against organism, pathogens that could cause infections was observed.

Rapid Test FLU_COVID could have some cross reaction with SARS and very low with MERS.

Microorganism	Concentration	Result
Adenovirus Type 1 (Species C)	2.57 x 10^8 $TCID_{50}$/mL	Negative
Adenovirus Type 3 (Species B)	3.39 x 10^7 $TCID_{50}$/mL	Negative
Adenovirus Type 7A (Species B)	1.02 x 10^8 $TCID_{50}$/mL	Negative
Alpha coronavirus 229E	4.68 x 10^4 $TCID_{50}$/mL	Negative
Alpha coronavirus NL63	1.70 x 10^5 $TCID_{50}$/mL	Negative
Beta coronavirus OC43	5.01 x 10^5 $TCID_{50}$/mL	Negative
Escherichia Coli O157	6.4x10^6 CFU/ml	Negative
Influenza A virus*	1.51 x 10^6 $TCID_{50}$/mL	Negative
Influenza B virus*	5.01 x 10^5 $TCID_{50}$/mL	Negative
Listeria monocytogenes	2.5x10^6 CFU/ml	Negative
Salmonella enteritidis	3.6x10^6 CFU/ml	Negative
SARS-Cov-2*	1.15 x 10^7 $TCID_{50}$/mL	Negative
Streptococcus pneumococcal	4.2x10^6 CFU/ml	Negative
Streptococcus pyogenes	3.6x10^6 CFU/ml	Negative

***Note:** No cross reaction was observed in Test line FluA when Influenza B and SARS-CoV-2 virus was evaluated. No cross reaction was observed in Test line FluB when Influenza A and SARS-CoV-2 virus was evaluated. No cross reaction was observed in Test line CoV when Influenza A and Influenza B virus was evaluated.

12.2 Interference Data

The following substances showed no significant interference on the test results of Rapid Test FLU_COVID.

No	Interfering Substances	Final Test
1	Azithromycin	84 mg/ml
2	Amoxicillin	54 mg/L
3	Albuterol	0.05 mg/L
4	Acarbose	0.3 mg/L
5	Chlorpheniramine	0.8 mg/L
6	Chlorothiazide	27 mg/L
7	Rheumatoid factor	200 IU/ml
8	Triglycerides	1.5 mg/L
9	Hemoglobin	100 mg/L
10	Human Chorionic Gonadotropin Hormone	10-fold dilution
11	Ibuprofen	219 mg/L
12	Xylometazoline (Otriven)	10%
13	Acetylsalicylic Acid	3 mg/ml
14	Mucin	0.5%

12.3 High Dose Hook Effect

No high dose hook effect was observed up to 1.15 x 10^7 $TCID_{50}$/mL of heat inactivated SARS-CoV-2, 1.51 x 10^6 $TCID_{50}$/mL of heat inactivated Influenza A virus, 5.01 x 10^5 $TCID_{50}$/mL of heat inactivated Influenza B virus, with the Rapid Test FLU_COVID.

12.4 Limit of Detection

The lowest detectable concentration of an analyte in a method is known as LOD. In this case, serial dilution of heat inactivated viruses were used in order to determine the limit of detection in Rapid Test FLU_COVID. The LOD is the level at which 95% of the replicates are characterized as positive. The results of 20 replicates are shown below.

LOD for SARS-COV-2 : 358.75 $TCID_{50}$/mL

LOD for Influenza A virus : 75.5 $TCID_{50}$/mL

LOD for Influenza B virus : 12.5*10^2 $TCID_{50}$/mL

12.5 Clinical performance characteristics

In order to determine the clinical performance of the Rapid Test FLU_COVID, a total amount of 956 specimens both with nasopharyngeal and nasal specimen collection were tested.

12.5.1 Nasopharyngeal specimens

Influenza A

878 negative and 78 Influenza A positive specimens (total amount 956) confirmed with RT-PCR assay [**SARS-CoV-2/Influenza A/B multiplex Real-TM (Sacace)]** were tested. The results are presented below.

Rapid Test FLU_COVID	Real-time RT PCR		
	Positive	*Negative*	*Total*
Positive	76	2	78
Negative	2	876	878
Total	78	878	956

Clinical Diagnostic Specificity: 99.77%
Clinical Diagnostic Sensitivity: 97.44%

Influenza B

943 negative and 13 Influenza B positive specimens (total amount 956) confirmed with RT-PCR assay [**SARS-CoV-2/Influenza A/B multiplex Real-TM (Sacace)]** were tested. The results are presented below.

Rapid Test FLU_COVID	Real-time RT PCR		
	Positive	*Negative*	*Total*
Positive	13	3	16
Negative	0	940	940
Total	13	943	956

Clinical Diagnostic Specificity: 99.68%
Clinical Diagnostic Sensitivity: 100%

SARS-CoV-2

582 negative and 374 positive specimens (total amount 956) confirmed with RT-PCR assay [**SARS-CoV-2/Influenza A/B multiplex Real-TM (Sacace)]** were tested. The results are presented below.

Rapid Test FLU_COVID	Real-time RT PCR		
	Positive	*Negative*	*Total*
Positive	371	1	372
Negative	3	581	584
Total	374	582	956

Clinical Diagnostic Specificity: 99.83%
Clinical Diagnostic Sensitivity: 99.20%

12.5.2 Nasal specimens

Influenza A

878 negative and 78 Influenza A positive specimens (total amount 956) confirmed with RT-PCR assay [**SARS-CoV-2/Influenza A/B multiplex Real-TM (Sacace)]** were tested. The results are presented below.

Rapid Test FLU_COVID	Real-time RT PCR		
	Positive	*Negative*	*Total*
Positive	75	2	77
Negative	3	876	879
Total	78	878	956

Clinical Diagnostic Specificity: 99.77%
Clinical Diagnostic Sensitivity: 96.15%

Influenza B

943 negative and 13 Influenza B positive specimens (total amount 956) confirmed with RT-PCR assay [**SARS-CoV-2/Influenza A/B multiplex Real-TM (Sacace)]** were tested. The results are presented below.

Rapid Test FLU_COVID	Real-time RT PCR		
	Positive	*Negative*	*Total*
Positive	13	3	16
Negative	0	940	940
Total	13	943	956

Clinical Diagnostic Specificity: 99.68%
Clinical Diagnostic Sensitivity: 100%

SARS-CoV-2

582 negative and 374 positive specimens (total amount 956) confirmed with RT-PCR assay [**SARS-CoV-2/Influenza A/B multiplex Real-TM (Sacace)]** were tested. The results are presented below.

Rapid Test FLU_COVID	Real-time RT PCR		
	Positive	*Negative*	*Total*
Positive	370	1	371
Negative	4	581	585
Total	374	582	956

Clinical Diagnostic Specificity: 99.83%
Clinical Diagnostic Sensitivity: 98.93%

13. Method Summary

Total procedure time (after specimens preparation): 15 min.

Specimen collection (nasal or nasopharyngeal) according to specific instruction (chapter 8)

⇩

Insert the swab into the extraction tube and rotate it forcefully against the side of the tube for 1min

⇩

Remove the swab, squeezing the sides of the tube to extract as much liquid as possible

⇩

Close the extraction tube with the dropper cup. Add 3 drops in the circular window of the device.

⇩

(Wait 15 mins)

FLU A positive: Formation of 2 lines FluA and Control (C)
FLU B positive: Formation of 2 lines FluB and Control (C)
FLU A and B positive: Formation of 3 lines FluA, FluB and Control (C)
FLU A and SARS-CoV-2 positive: Formation of 3 lines FluA, CoV and Control (C)
FLU B and SARS-CoV-2 positive: Formation of 3 lines FluB, CoV and Control (C)
SARS-CoV-2 positive: Formation of 2 lines CoV and Control
FLU A, FLU B and SARS-CoV-2 positive: Formation of 4 lines FluA, FluB, CoV and Control (C)
Negative: Formation of Control line ONLY
Invalid: No Control line even if there is a line in FluA/FluB/CoV

14. References

1. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html
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IVD In Vitro Diagnostics Medical Device
Content sufficient for tests
REF Catalog number
Manufacturer
Storage Conditions
Instructions for use
EXP Expiration Date

CE

VERSION 4/ 2023-05-25

REF V16XX

RAPID TEST FLU_COVID

Lateral Flow Test | IVD

For the detection of Influenza A/B and SARS-CoV-2 antigens in human nasal or naso-pharyngeal specimen.

This Lateral Flow test kit is manufactured by ProGnosis Biotech S.A. and complies with the specifications on the Standard EN ISO 13485:2016

Use only the current version of Product Data Sheet enclosed with the kit.

Rapid Test FLU_COVID, V16XX, is a qualitative Lateral Flow test for the detection of Influenza A/B and SARS-CoV-2 antigens in nasal or nasopharyngeal specimen.

The Lateral flow kit contains all reagents required for the immunoassay method.

Specimen: Nasal or nasopharyngeal swab.

The extracted specimen can be used with the kit codes V15XX, V16XX, V17XX, V18XX

- For professional use only.
- For in vitro diagnostic use only
- Rapid Test FLU_COVID is a sensitive screening assay for the detection of Influenza A/B and/or SARS-CoV-2. Results should not be used as the only source to diagnose or to determine infection status.
- Negative result do not rule out INFLUENZA A/B or SARS-CoV-2 infection
- Test should only be conducted by medical personnel
- Test time (incubation time after specimens preparation): 15 min
- Shelf life: 2 years
- Storage: 4-30°C

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