

ALL IN  
TRIPLEX®autotest  
santé

## INSTRUCTIONS FOR USE

- ALL IN TRIPLEX® is a self-test used to screen for the virus causing COVID-19, Influenza and Bronchiolitis in a nasal swab.
- ALL IN TRIPLEX® is a single-use in-vitro diagnostic device.
- ALL IN TRIPLEX® is designed for use by non-healthcare professionals in a private setting or under the supervision of a healthcare professional.
- ALL IN TRIPLEX® can be carried out by an adult in children over 1 month old\*.
- ALL IN TRIPLEX® can be used independently by children over 6 years old under adult supervision\*\*.
- The self-test takes approximately 1 minute and the results are delivered in 15 minutes.
- Make sure you have a timer available.
- Read all of the instructions carefully before starting the test.

\*Study carried out in a French pediatric emergency department on a panel of 263 children.

\*\*Study conducted in 4 paediatric emergency units and 37 paediatric clinics in France involving a cohort of 500 children.

## SUITABLE FOR CHILDREN

### CONTENTS OF THE BOX

(REFERENCES AS-CGR-001/AS-CGR-002/AS-CGR-003)

1 sachet **A**Humidity  
absorber  
(discard)**B**

Self-test

**C**Swab  
included**D**Protective  
cap**E**Holder with buffer  
sachet included**F**

AAZ-LMB  
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92100 Boulogne-Billancourt - France

CE 0459

#### Key to symbols:



: read the instructions carefully



: CE marking



: store between +2 and +30°C



: do not reuse



: expiry date



: in-vitro diagnostic medical device



: Device for self-testing

AAZ AWT 32-A (20240711) Instructions for use ALL IN TRIPLEX® EN  
NON-CONTRACTUAL PHOTO

### STEP 1

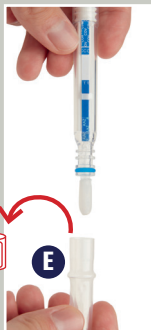
Allow the self-test kit to reach room temperature (15 - 30°C), then wash and dry your hands.

Remove the self-test kit from the sealed sachet **A** immediately before carrying out the test.

Blow your nose before carrying out the self-test.

1. Place the self-test kit on the table.  
Remove the self-test kit **C** from the holder **F** by pulling upwards.

2. Remove the protective cap **E** and discard it.

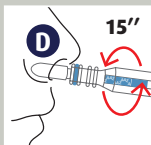
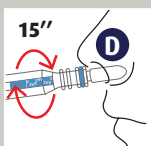


### STEP 2

1. Gently insert the swab **D** into the left nostril until you feel resistance (insert 1 to 2 cm into the nostril).

Rotate the swab several times in the nostril for 15 seconds by wiping the swab **D** against the inner wall of your nostril.

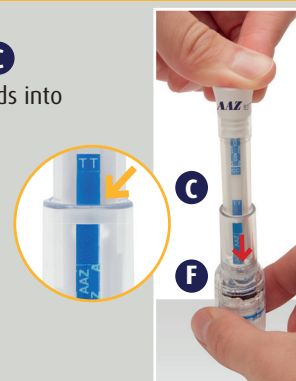
2. Repeat the same procedure in the right nostril for 15 seconds.



### STEP 3

1. Insert **immediately** the self-test kit **C** with the swab **D** pointing downwards into the holder **F** placed on the table.

a. Press firmly on the self-test to pierce the buffer sachet and push it to the bottom of the holder.



b. Check that a pink line appears within one minute.

If a pink line does not appear, press firmly once again to fully insert the self-test kit.



### STEP 4

1. Make a note of the time and wait 15 minutes before reading the result.



**DO NOT LEAVE MORE THAN 20 MIN BEFORE READING**

**INTERPRETING THE RESULTS - SEE OVERLEAF**

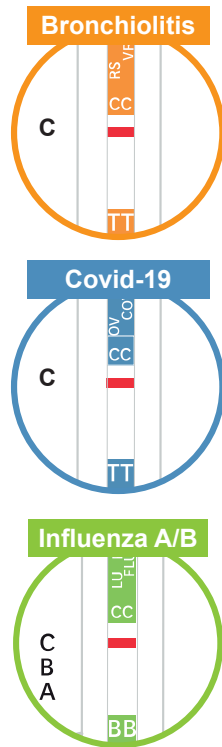
# INTERPRETING THE RESULTS

## NEGATIVE SELF-TEST

If your self-test result corresponds to the three images opposite, your result is negative.

1 coloured line present on each test strip, Control line (C)

You are probably not infected with the Bronchiolitis, COVID-19 or Influenza virus.



PLACE YOUR SELF-TEST KIT HERE

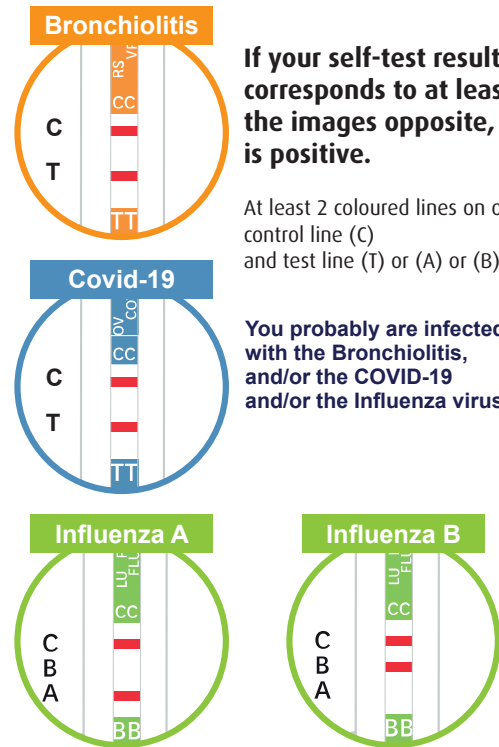


## POSITIVE SELF-TEST

If your self-test result corresponds to at least one of the images opposite, your result is positive.

At least 2 coloured lines on one test strip, control line (C) and test line (T) or (A) or (B)

You probably are infected with the Bronchiolitis, and/or the COVID-19 and/or the Influenza virus.



Contact your doctor to inform them of the result so that they can advise you of the next step.

ALL IN TRIPLEX® is a reliable self-test, however:

- 1 Repeat the test if symptoms appear that suggest COVID-19, Influenza or Bronchiolitis.
- 2 If you develop any symptoms, contact your treating physician who will then assess the need for further tests.

**I WILL FOLLOW PROTECTIVE AND DISTANCING MEASURES, REGARDLESS OF MY TEST RESULT.**

If your self-test does not correspond to any of the scenarios outlined here, the result is invalid and your test has not worked. The results are inconclusive. You must repeat the test. Please contact your doctor if you have several invalid self-tests.

## PRINCIPLE AND PERFORMANCE

ALL IN TRIPLEX® is a lateral flow, multiplex, triple immunochromatographic self-test using highly sensitive monoclonal antibodies to detect the specific target antigens for each virus (Bronchiolitis, SARS-CoV-2, Influenza A and B) in a nasal swab. This is a qualitative, non-automated test.

**Reliability:** a comparative clinical study conducted at the CHR d'Orléans [Orleans Regional Hospital Centre] highlighted a 98.3% correlation between the ALL IN TRIPLEX® result and RT-PCR laboratory testing on a nasopharyngeal swab.

### Specificity:

- **For Bronchiolitis:** 100% specificity has been confirmed for this self-test. No false-positive result has been documented\*.
- **For COVID-19:** 100% specificity has been confirmed for this self-test. No false-positive result has been documented\*.
- **For Influenza A/B:** 100% specificity has been confirmed for this self-test. No false-positive result has been documented\*.

### Sensitivity:

- **For Bronchiolitis:** the sensitivity of this self-test has been assessed as 87.2%, i.e. 12.8% false negatives\*\*.
- **For COVID-19:** the sensitivity of this self-test has been assessed as 95.1%, i.e. 4.9% false negatives\*\*.
- **For Influenza A/B:** the sensitivity of this self-test has been assessed as 92.3%, i.e. 7.7% false negatives\*\*.

**Practicability:** the practicability study demonstrating the use of this self-test kit by non-healthcare professionals showed that 97.9% of self-tests are interpreted correctly.

**Interference:** examination of samples containing substances or collected from individuals with medical conditions likely to skew these test results, did not reveal any signs of significant interference.

\* False positive: a sample known to be negative for the target marker and incorrectly classed as positive by the device.  
\*\* False negative: a sample known to be positive for the target marker and incorrectly classed as negative by the device.

## PRECAUTIONS AND WARNINGS - STORAGE - STABILITY - DISPOSAL

- **ALL IN TRIPLEX®** is a single-use self-test kit designed to screen for the Bronchiolitis, COVID-19 or Influenza A and Influenza B virus. It cannot be used for any other diagnosis or for any other purpose.
- Store the self-test kit in its original packaging, in a cool, dry place between 2°C and 30°C.
- If the box is stored in the refrigerator (between 2°C and 8°C), allow the kit to come to room temperature (between 15°C and 30°C) prior to use.
- The self-test kit is intended for single-use only. It cannot be reused under any circumstances.
- Open the packaging as soon as you are ready to carry out the test.
- Do not use the self-test kit after the expiry date.
- Do not use the self-test kit if the packaging is open or damaged.
- Do not wait or store the test after sampling.
- The test must be inserted into its holder immediately after sample collection.
- Do not carry out the test in a room with a strong air current, e.g. with a fan or powerful air conditioning system.
- Storage outside the specified conditions or failure to comply with the limitations regarding use may generate incorrect results.

- Despite test performance, false negative and false positive results may be generated. Seek medical advice if you are not sure about your self-test result.
- The user of the self-test kit must not make any medical decision without first consulting their doctor, regardless of whether the result is positive or negative.
- Do not mix the components of various batches of the ALL IN TRIPLEX® kit.
- Strict compliance with the various testing steps is essential in order to obtain a correct result.
- Do not use nasal sprays in the 12 hours before carrying out the test.
- The buffer contains a solution with a preservative. Rinse with copious quantities of water if the solution comes into contact with the skin or eyes.
- AAZ-LMB accepts no liability for the use, distribution or dispensing of ALL IN TRIPLEX® or its components outside the indications and limitations for use specified in the current instructions for use.
- Once the self-test has been completed, dispose of all of the items in the kit as per local recommendations.
- Any serious incident should be reported to AAZ-LMB and to the competent authority of the Member State in which the user and/or patient is established.

Additional information and a demonstration video are available at [www.autotest-sante.com](http://www.autotest-sante.com)

[www.autotest-sante.com](http://www.autotest-sante.com)

email: [contact@azlab.fr](mailto:contact@azlab.fr)