



## COVID-19/Flu A&B Ag Combo Rapid Test

### ► Product Information

The COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) is an *in vitro* immunochromatographic assay for the qualitative and differential detection of nucleocapsid protein antigen from influenza A (including the subtype H1N1), influenza B and/or SARS-CoV-2 in nasal swab specimens. It is intended to aid in the rapid diagnosis of influenza A, influenza B and/or SARS-CoV-2 infections. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) must be confirmed with alternative testing method(s) and clinical findings. It is for *in vitro* Diagnosis use only.

### Benefits

- Rapid testing for Influenza A&B and SARS-CoV-2 antigen within 15 minutes
- Facilitates patient treatment decisions quickly
- Simple, time-saving procedure
- All necessary reagents provided & no equipment needed
- High sensitivity and specificity

### Specification

Information	Detail
Time to result	15 minutes
Storage	2-30°C
Shelf life	24 months
Specimen type	Nasal Swab

### Contents

- Test cassette
- Sterile swab
- Extraction tube with buffer
- Dropper tip
- Workstation (when applicable)
- Package insert

## Test Procedure & Interpretation

### Specimen Preparation



#### Step 1

Using the sterile swab provided in the kit, carefully insert the swab into one nostril of the patient. The swab tip should be inserted up to 2-4 cm until resistance is met.



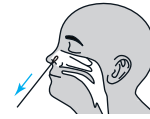
#### Step 2

Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.



#### Step 3

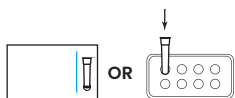
Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.



#### Step 4

Withdraw the swab from the nasal cavity. The specimen is now ready for preparation using the extraction buffer provided in the test kit.

### Sample Preparation



#### Step 1

For kit sizes of 1 test and 5 tests, Insert the extraction tube into the hole on the kit box as marked. For kit sizes of 20 tests, Insert the test extraction tube into the workstation provided in the kit. Make sure that the tube is standing upright and reaches the bottom of the workstation.



#### Step 2

Tear off the sealing film on the extraction tube gently to avoid spilling out the liquid.



#### Step 3

Insert the swab into the extraction tube which contains the extraction buffer (approximately 0.3 mL).



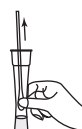
#### Step 4

Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.



#### Step 5

Leave the swab in the extraction tube for 1 minute.



#### Step 6

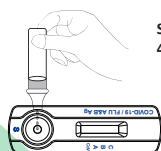
Squeeze the tube several times from the outside to immerse the swab. Remove the swab.



#### Step 7

Insert the tip into the extraction tube tightly.

### Test Procedure & Interpretation of Results



Squeeze here  
4 Drops of Solution

#### Step 1

Remove the test device from the pouch and lay it on a flat clean surface. Add 4 drops of the solution into the sample well of the test device by gently squeezing the tube.



15 Minutes

#### Step 2

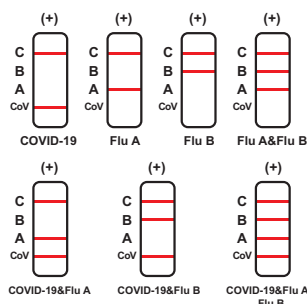
Start timer and wait 15 minutes. Do not read the test result after 20 minutes.

### Step 3

Read your results  
(See interpretation of results section).

#### Positive

- COVID-19 Positive** The presence of two lines as control line (C) and CoV test line
- Flu A Positive** The presence of two lines as control line (C) and A test line.
- Flu B Positive** The presence of two lines as control line (C) and B test line.
- Flu A+B Positive** The presence of three lines as control line (C), A test line and B test line.
- COVID-19 +Flu A Positive** The presence of three lines as control line (C), CoV test line and A test line.
- COVID-19 +Flu B Positive** The presence of three lines as control line (C), CoV test line and B test line.
- COVID-19 +Flu A & B Positive** The presence of Four lines as control line (C), CoV test line, A test and B test line.



#### Positive

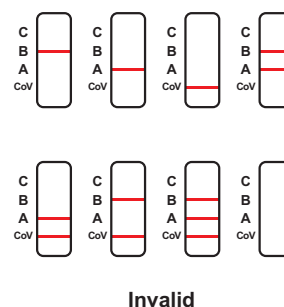
#### Negative

#### Negative

The presence of only control band (C) within the result window indicates a negative result.

#### Invalid

If the control band (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test.



#### Invalid

## Ordering Information

Product Description	Specimen	Catalog No.	Format	Kit Size
COVID-19/Flu A&B Ag Combo Rapid Test	Nasal Swab	GCFC-T502a/	Cassette	1/5/20 Test(s)/Kit

√ CE Marked

Zhejiang Orient Gene Biotech Co., Ltd  
Add: 3787#, East Yangguang Avenue, Dipu Street, Anji, Huzhou, Zhejiang, China  
Tel: +86-572-5303755/5303756  
Fax: +86-572-5226222  
Web: <http://www.orientgene.com>

Revision date: 2022-05-02