

Influenza A/B Antigen Rapid Test

Introduction

Influenza A/B Antigen Rapid Test is a lateral flow immunoassay for the qualitative detection of Influenza A and B virus antigens in nasal swab specimens from individuals suspected of Flu A/B.

As a high-tech manufacturer of IVD, UDX Bio focuses on the R&D, and quality control of the product. UDX Bio produces according to the ISO 13485:2016 standard strictly and now has obtained the CE, FDA certifications.



Benefits

- **Fast:** Read result in 15 minutes, rapid point-of-care diagnostic test
- **Simple:** No instrument required & simple procedure
- **Convenient:** Suitable for large-scale use
- **Accuracy:** Highly sensitivity, specificity and accuracy

Nasal Swab		RT-PCR		Total
		Positive	Negative	
Influenza A Antigen Test	Positive	185	9	194
	Negative	19	602	621
Total		204	611	815

Sensitivity=90.68% (95%CI: 85.63%-94.15%)
 Specificity=98.53% (95%CI: 97.12%-99.28%)
 Overall Agreement=96.56% (95%CI:95.31%-97.81%)

Nasal Swab		RT-PCR		Total
		Positive	Negative	
Influenza B Antigen Test	Positive	96	6	102
	Negative	9	382	391
Total		105	388	493

Sensitivity=91.43% (95%CI: 83.93%-95.76%)
 Specificity=98.45% (95%CI: 96.49%-99.37%)
 Overall Agreement=96.96% (95%CI:95.44%-98.47%)

Specification

Product: Influenza A+B Antigen Combo Rapid Test

Package size: 1 test/kit, 5 tests/kit, 20 tests/kit, 25 tests/kit, 50 tests/kit

Specimen type: Nasal Swab

Test time: 15 minutes

Storage: 2°C-30°C

Method: Colloidal Gold Method

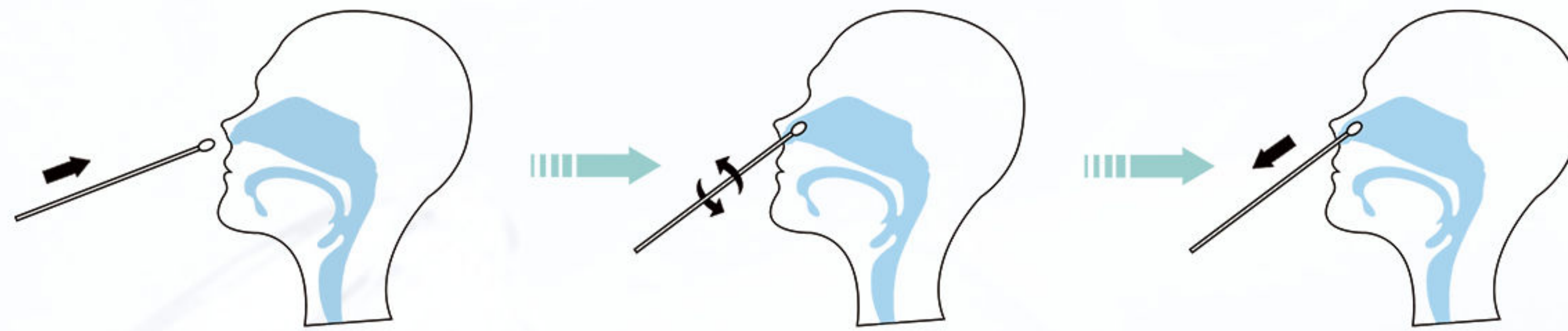
Components

1. Test cartridge
2. Pre-filled extraction buffer tube
3. Nasal swab
4. Nozzles to extraction tube
5. Paper rack
6. Instructions for use



Specimen collection

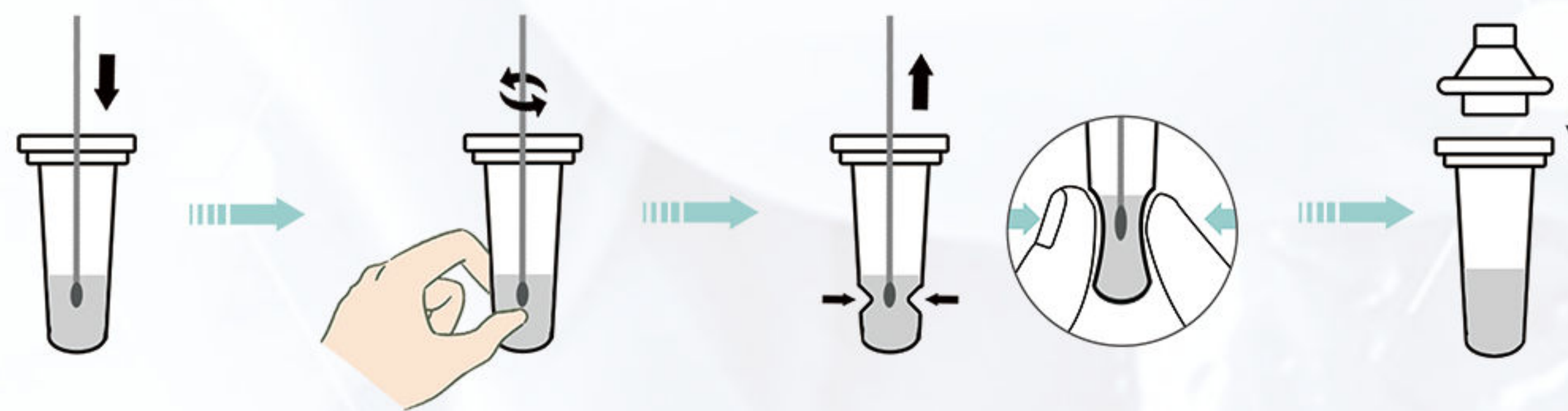
1. Carefully insert the entire absorbent tip of the swab in one nostril and rotate at least 5 times. Be sure that the absorbent tip of the swab scrapes against the nasal wall.



2. Remove swab from nostril and, using the same swab, repeat step 1 in the other nostril.

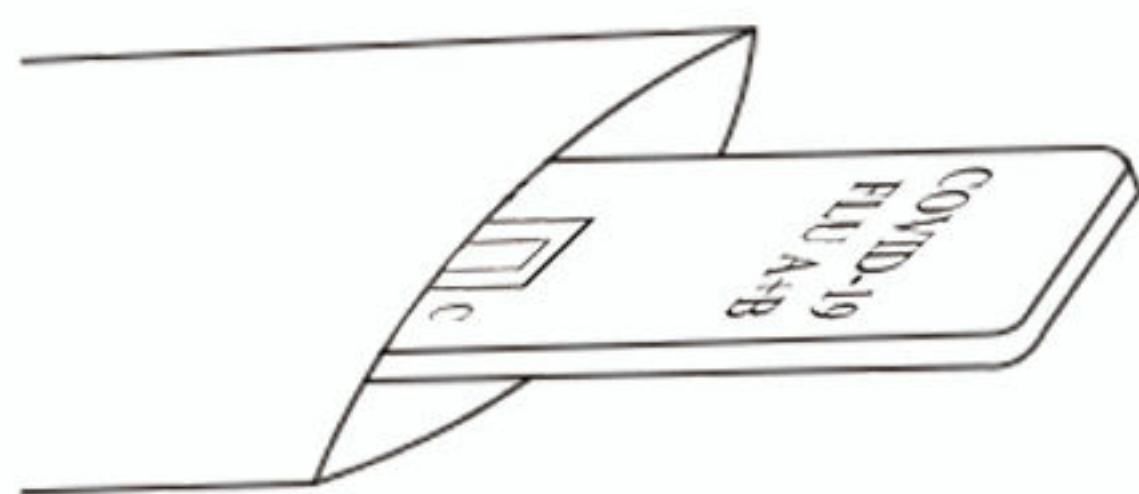


3. Insert the absorbent tip of the swab into the extraction buffer tube and swirl the swab at least 5 times.
4. Squeeze the tube against the submerged swab several times to facilitate extraction of the specimen. Remove the swab, place it back in its original wrapping and dispose into the waste bag.
5. Place the nozzle onto the extraction tube and ensure it is attached firmly.

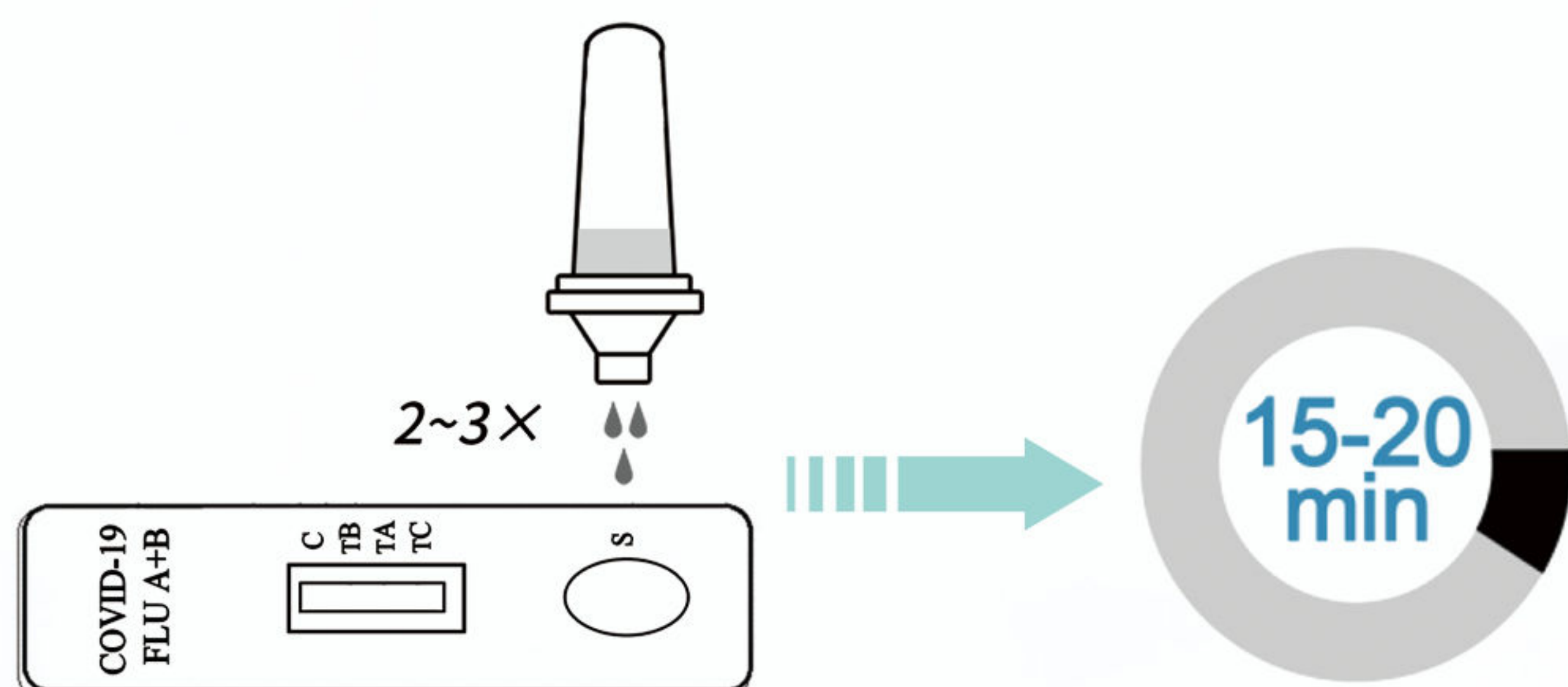


Running the Test

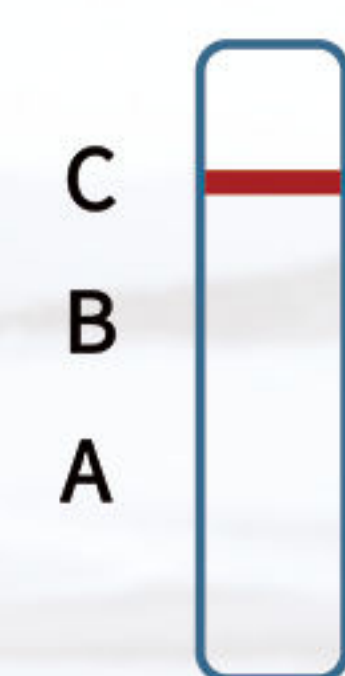
Remove the cassette device from the sealed pouch just prior to testing. Lay the device on a clean, flat surface and label with specimen ID/name.



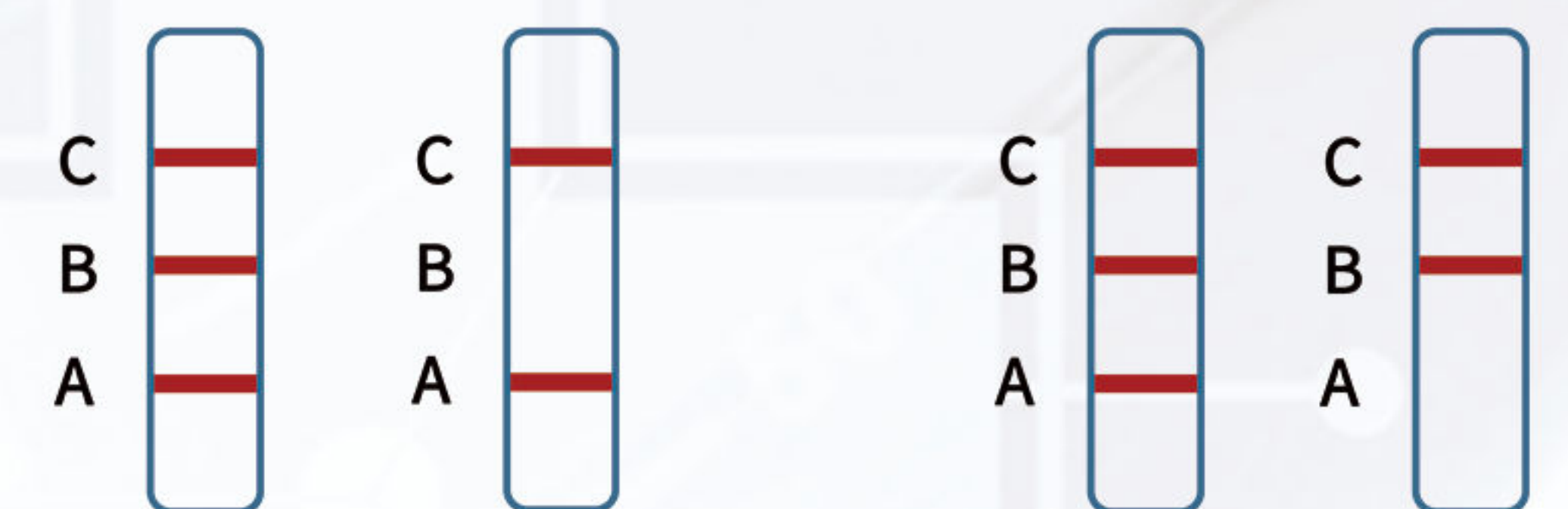
Invert the sample extraction tube and slowly add 2~3 drops of the extracted specimen into the sample well of the cassette device by gently squeezing the sample tube.



Test result

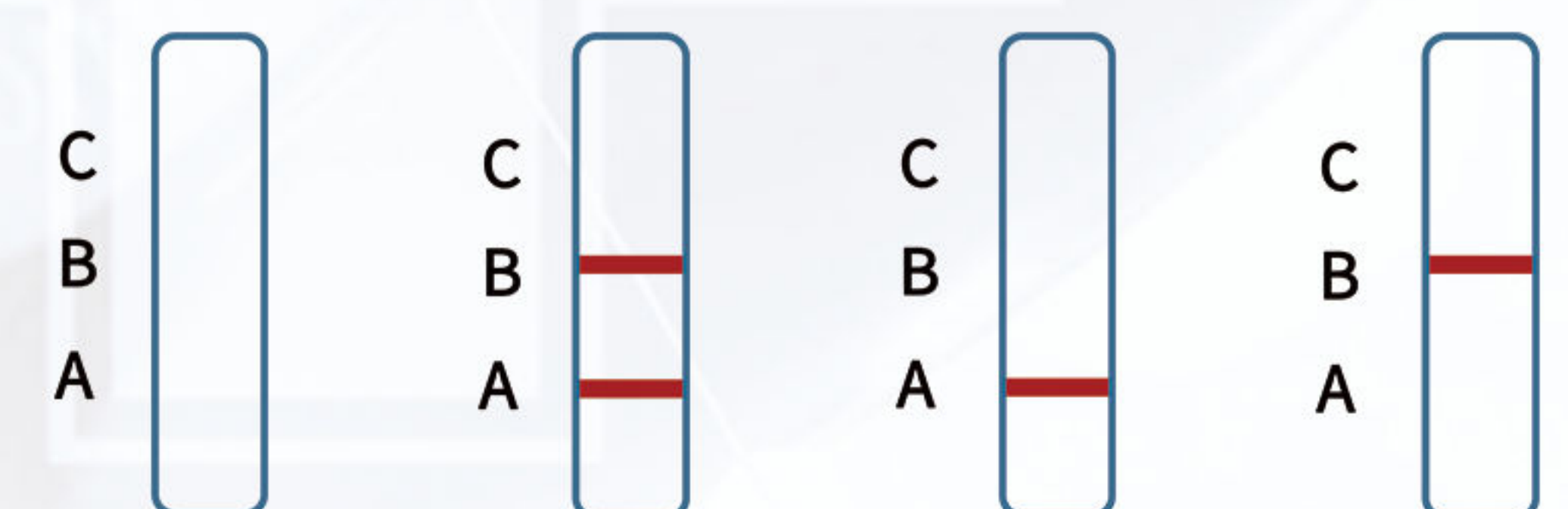


Negative results



Flu A positive results

Flu B positive results



Invalid results