

COVID-19 Antigen/Influenza A+B Antigen Combo Rapid Test

Introduction

COVID-19 Antigen/Influenza A+B Antigen Combo Rapid Test is a lateral flow immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigens and Influenza A and B virus antigens in nasal swab specimens from individuals suspected of COVID-19 and 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
- **Convenient:** Suitable for large-scale use
- **Simple:** No instrument required & simple procedure
- **Accuracy:** Highly sensitivity, specificity and accuracy

Nasal Swab		RT-PCR		Total
		Positive	Negative	
COVID-19 Antigen Test	Positive	97	0	97
	Negative	8	363	371
Total		105	363	468

Sensitivity=92.38% (95%CI: 85.09%-96.41%)
 Specificity=100% (95%CI: 98.69%-100%)
 Overall Agreement=98.29% (95%CI:96.66%-99.13%)

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: COVID-19 Antigen/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

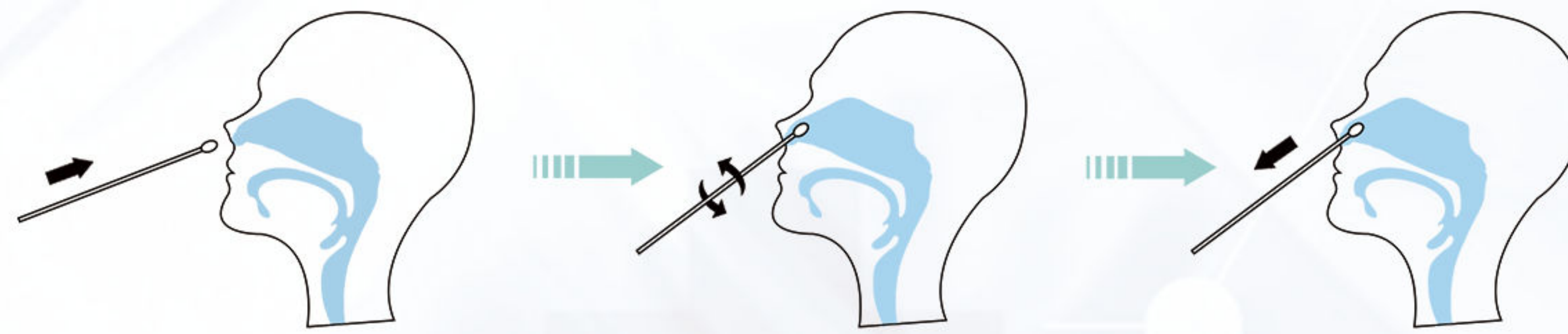
Components

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

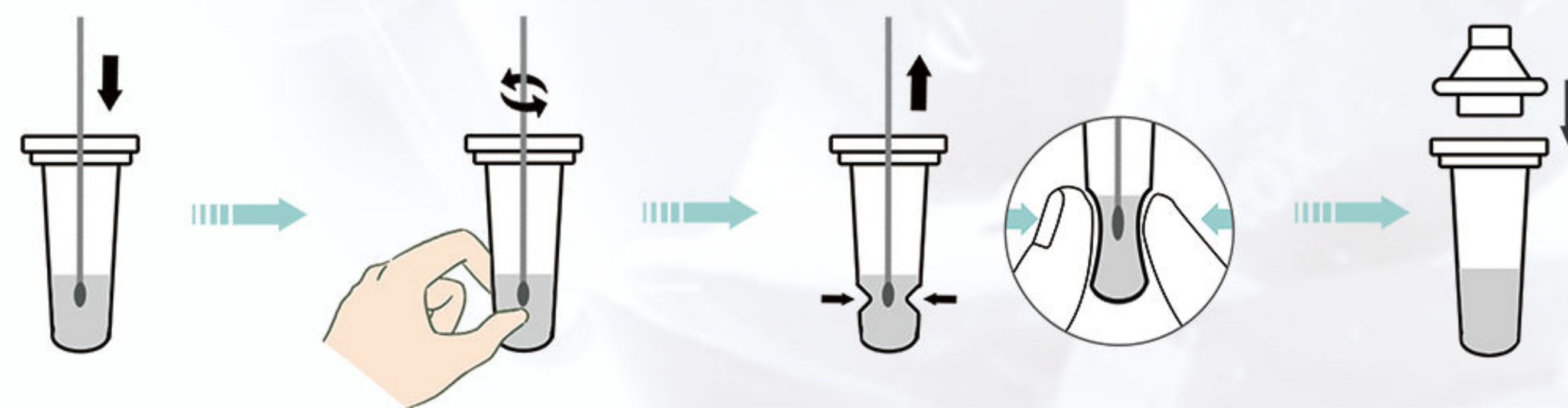
1. Carefully insert the entire absorbent tip of the swab in one nostril and rotate at least 5 times. Be sure that the absorbent tip of the swab scrapes against the nasal wall.



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

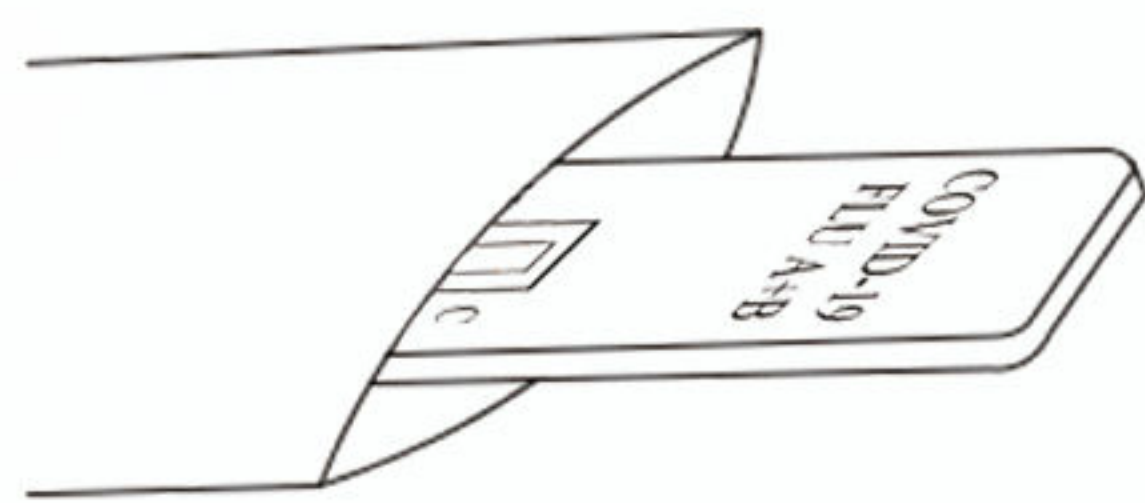


3. Insert the absorbent tip of the swab into the extraction buffer tube and swirl the swab at least 5 times.
4. Squeeze the tube against the submerged swab several times to facilitate extraction of the specimen. Remove the swab, place it back in its original wrapping and dispose into the waste bag.
5.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

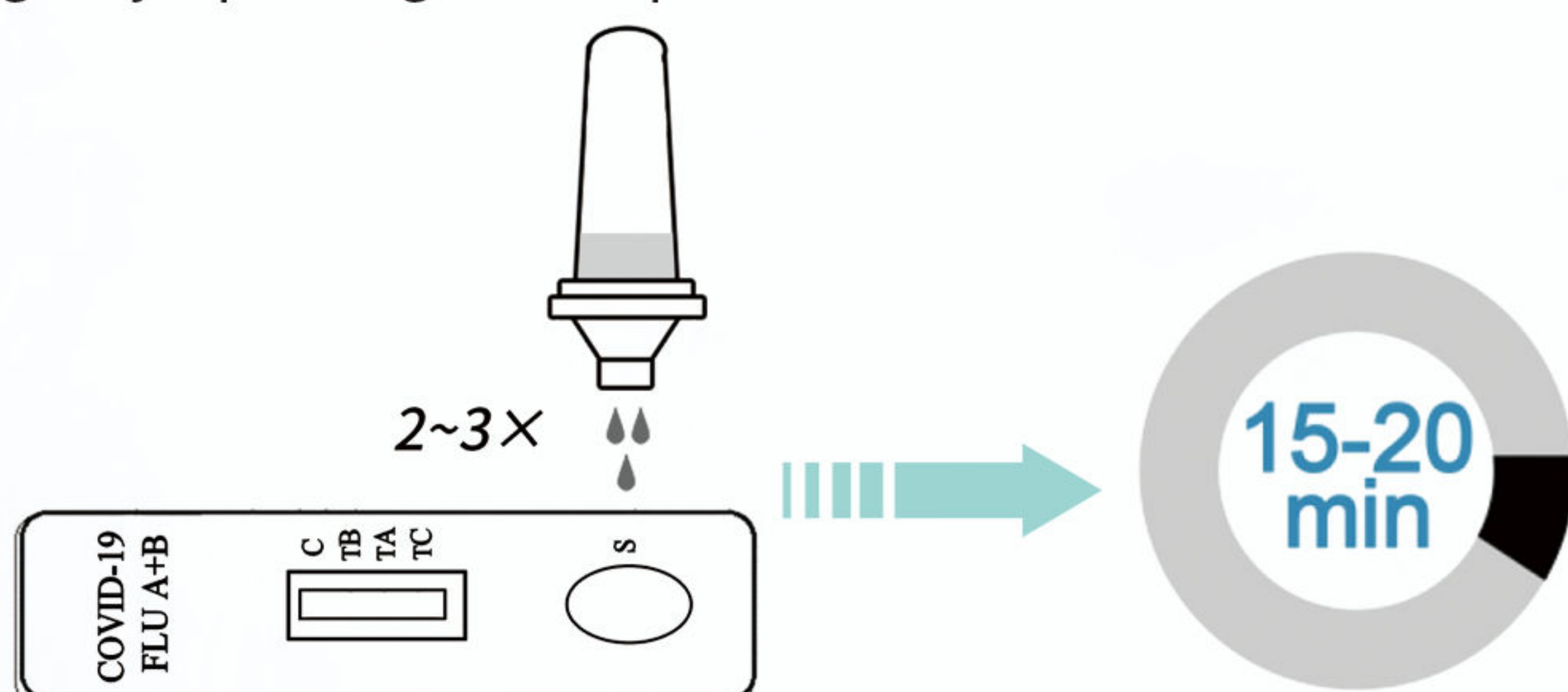


Running the Test

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.

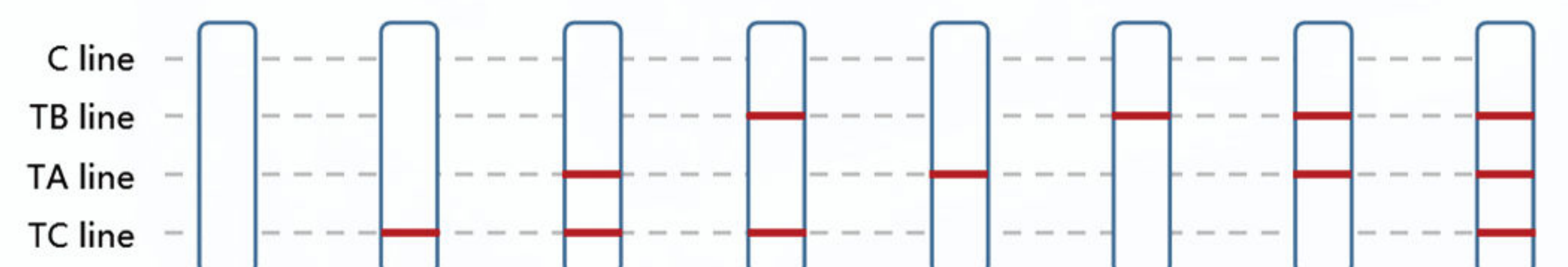


Test result



Influenza B test results:	Neg	Neg	Neg	Pos	Neg	Pos	Pos	Pos
Influenza A test results:	Neg	Neg	Pos	Neg	Pos	Neg	Pos	Pos
COVID-19 test results:	Neg	Pos	Pos	Pos	Neg	Neg	Neg	Pos

Valid results



Invalid results

