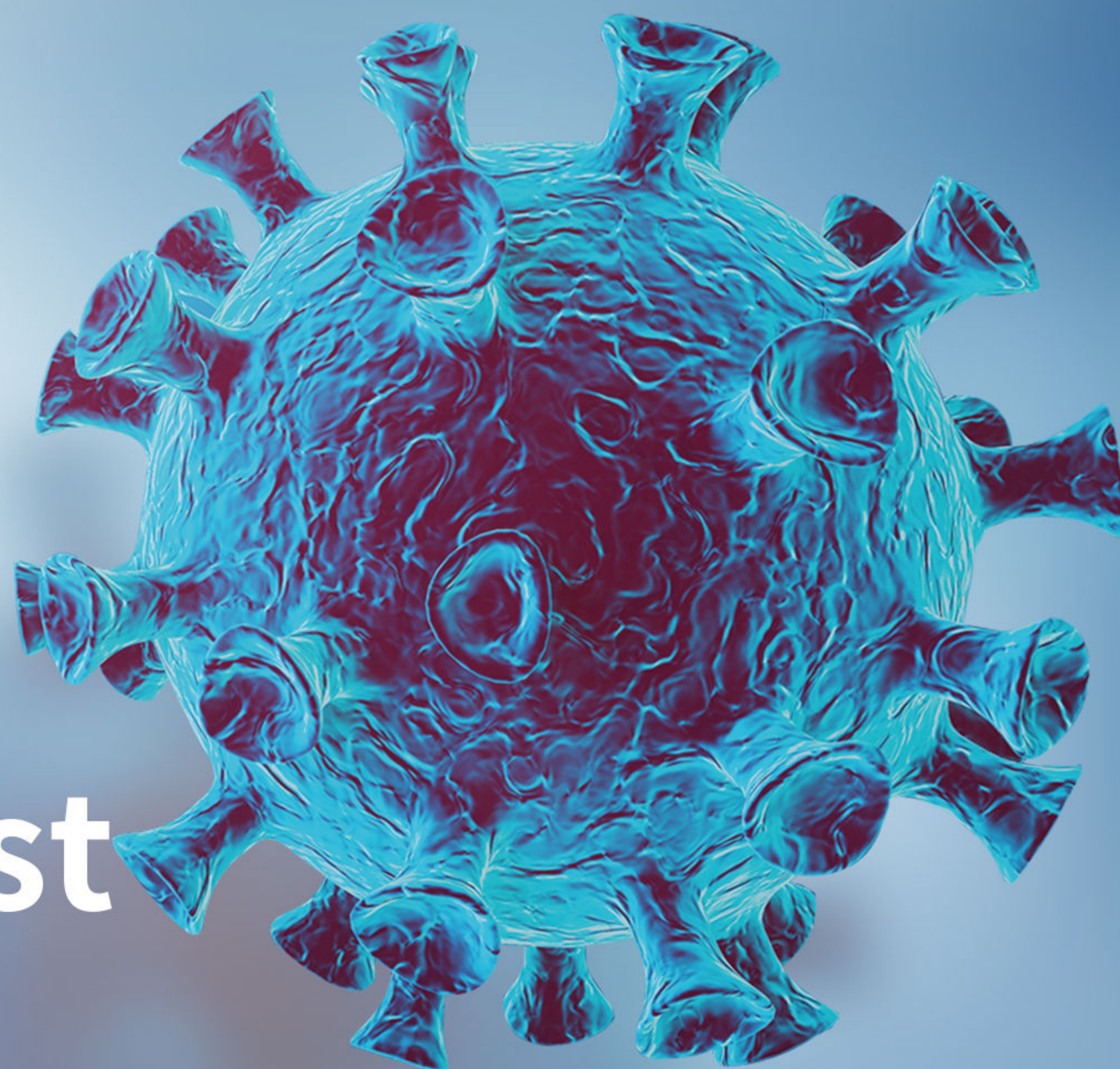


# COVID-19 Antigen Rapid Test (Nasal Swab Test)



## Introduction

COVID-19 Antigen Rapid Test is a lateral flow immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab specimens from individuals suspected of COVID-19.

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 certifications.

## Benefits

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



Nasal Swab		RT-PCR		Total
		Positive	Negative	
COVID-19 Antigen Rapid 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%)

## Specification

<b>Product</b>	<b>COVID-19 Antigen Rapid Test</b>	<b>Test time</b>	<b>15 minutes</b>
<b>Method</b>	<b>Colloidal Gold Method</b>	<b>Package size</b>	<b>1 pc/box; 5 pcs/box; 20 pcs/box; 25pcs/box; 50 pcs/box</b>
<b>specimen type</b>	<b>Nasal swab</b>	<b>Storage</b>	<b>2°C~30°C</b>

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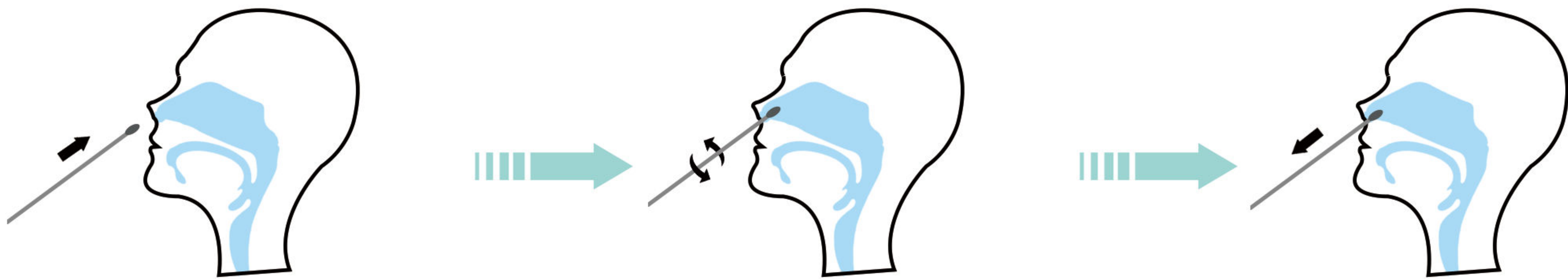
## Components

1. Test cartridge 20/kit
2. Pre-filled virus extraction buffer tubes 20 tubes/kit.
3. Nozzles to extraction tubes 20/kit
4. Paper rack 1/kit
5. Nasal swabs 20/kit
6. Instructions for use 1 copy/kit



## Test Procedure

### ① Specimen collection

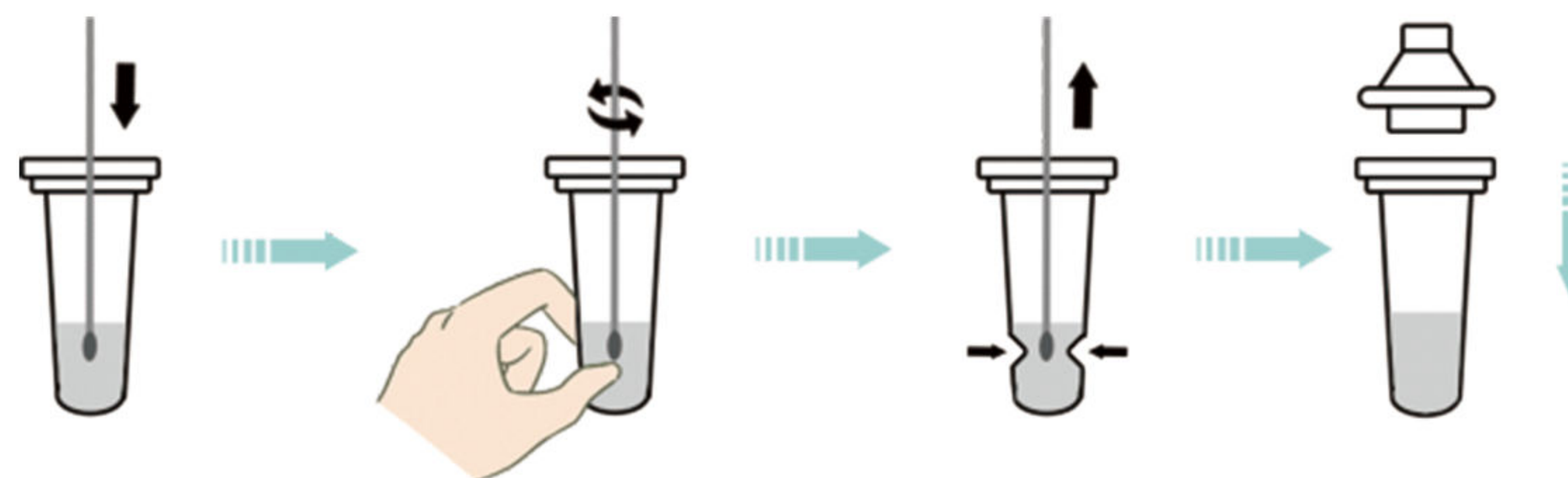


Carefully insert the entire absorbent tip of the swab in one nostril

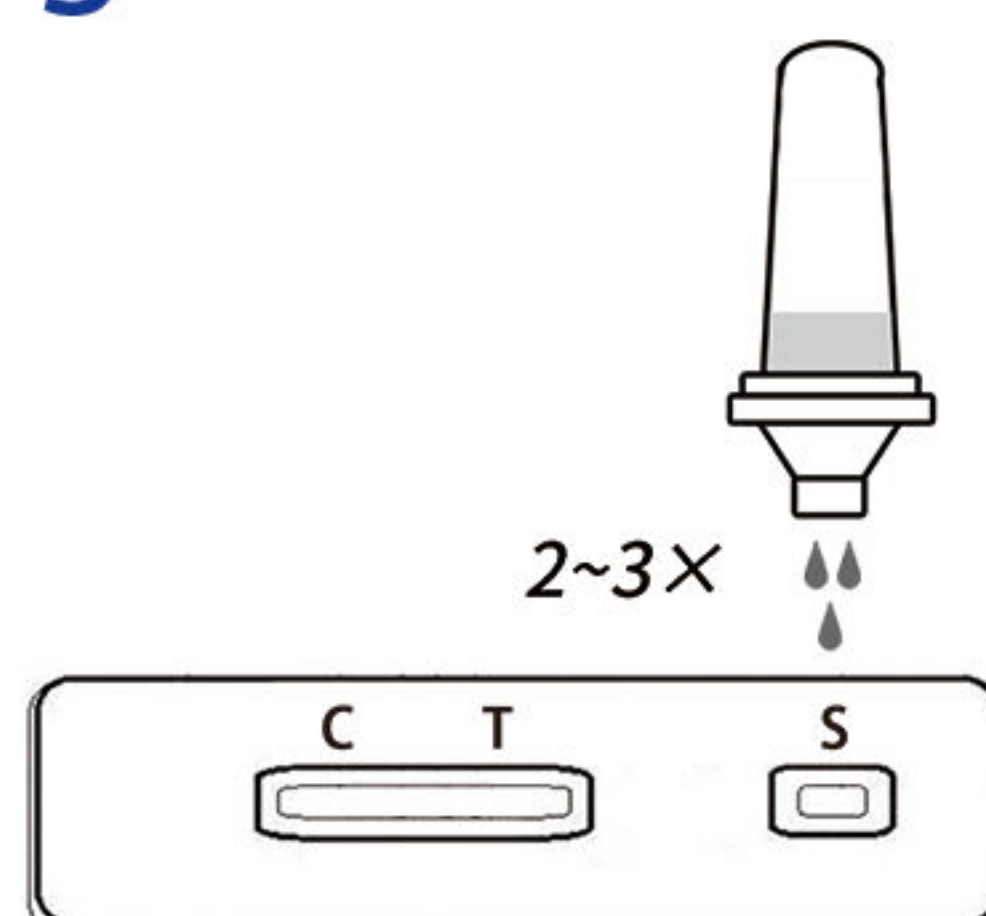
And rotate at least 5 times. Be sure that the absorbent tip of the swab scrapes against the nasal wall.

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

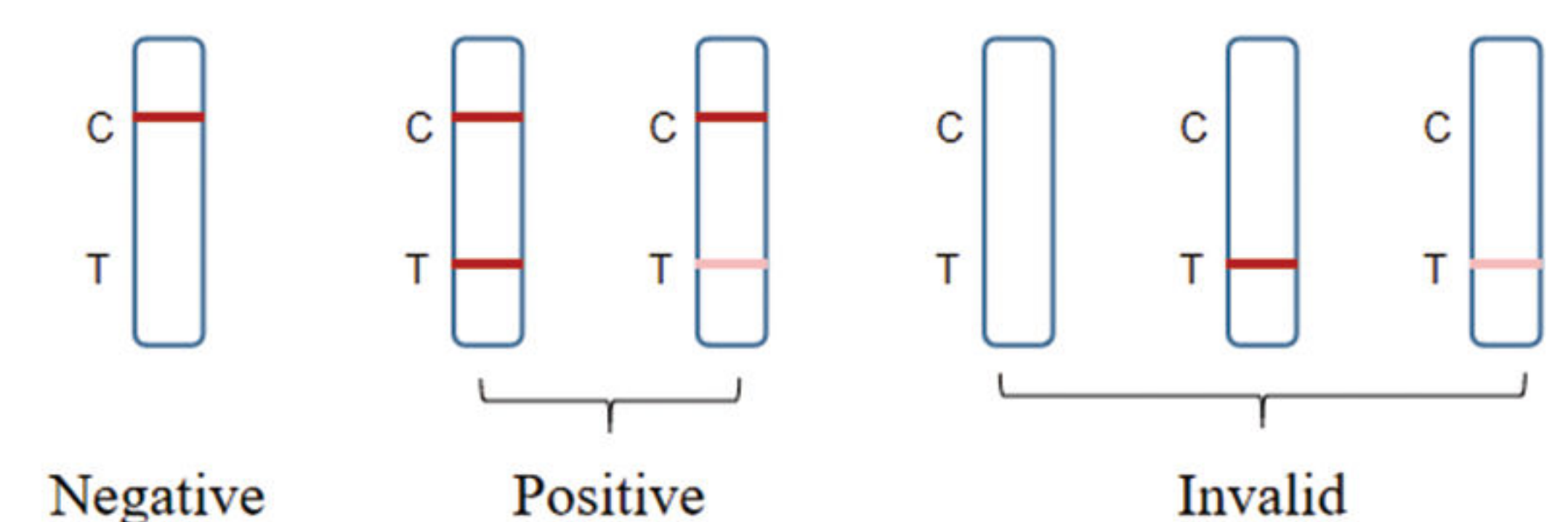
### ② Sample preparation



### ③ Running the Test



### ④ Test result



Negative

Positive

Invalid