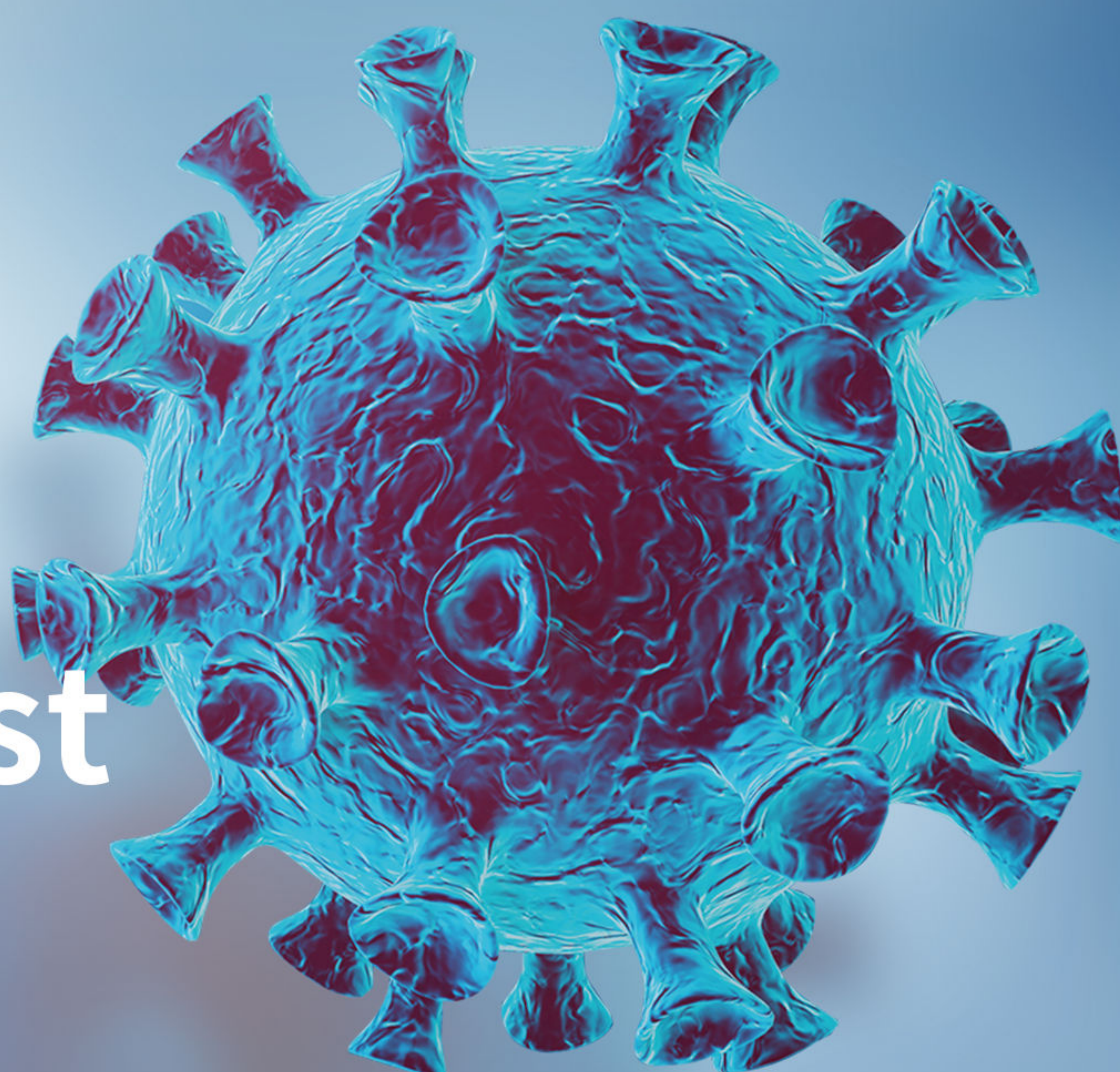


COVID-19 Antigen Rapid Test (Saliva Test)



Introduction

COVID-19 Antigen Rapid Test is a lateral flow immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in saliva samples 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.



Specification

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

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

Saliva		RT-PCR		Total
		Positive	Negative	
COVID-19 Antigen Rapid Test	Positive	95	1	96
	Negative	10	129	139
Total		105	130	235

Sensitivity=90.47% (95%CI: 82.77%-95.08%)
 Specificity=99.23% (95%CI: 95.15%- 99.96%)
 Overall Agreement=95.32% (95%CI:92.62%-98.02%)

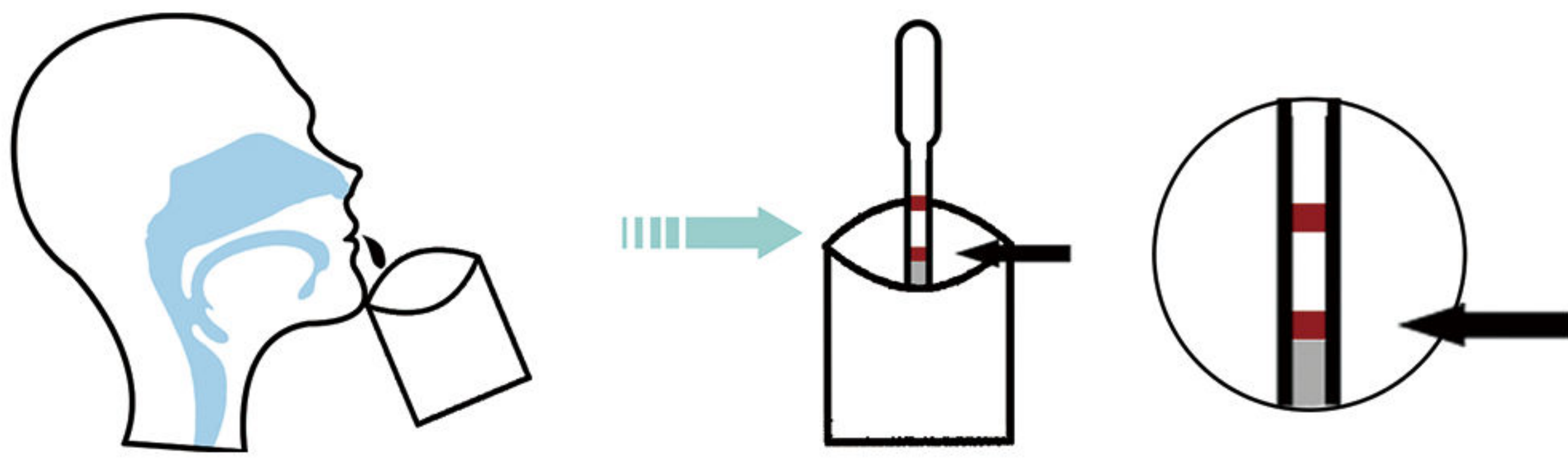
Components

1. Test cartridge
2. Pre-filled extraction buffer tube
3. Nozzles to extraction tube
4. Paper rack
5. Instructions for use
6. Paper Cup
7. Saliva transfer pipette

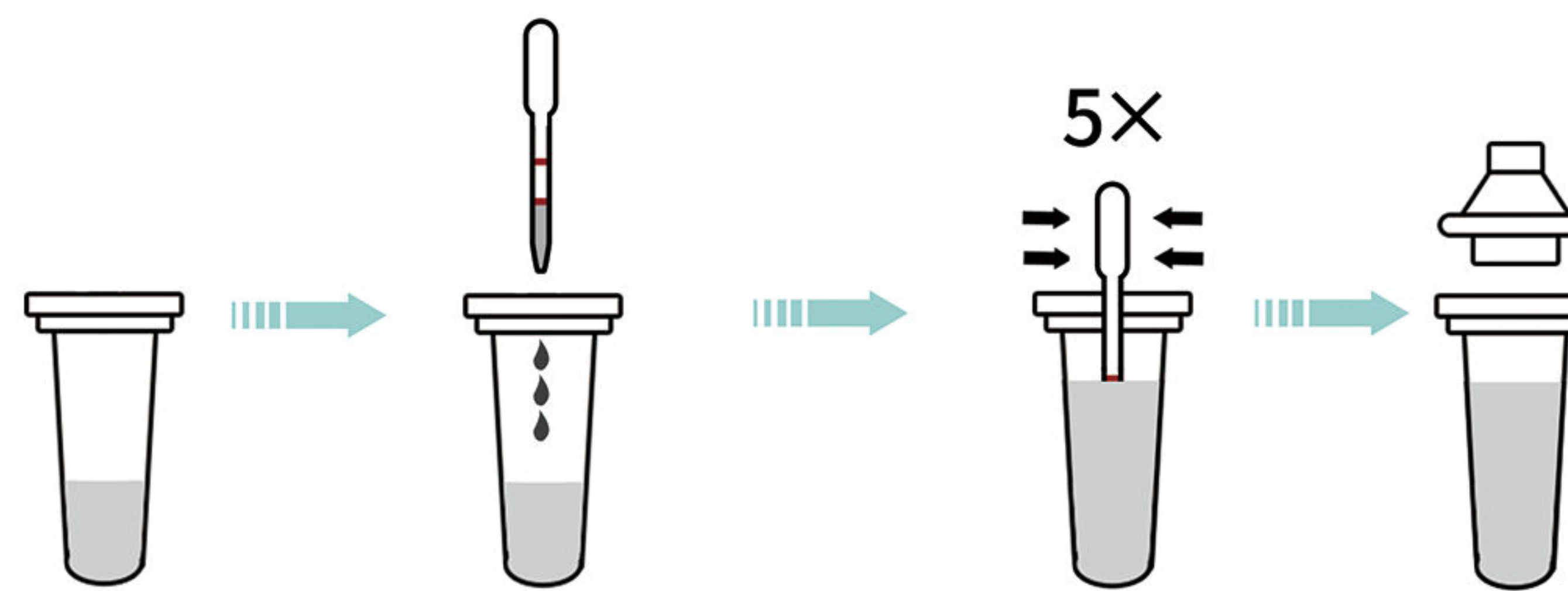


Test Procedure

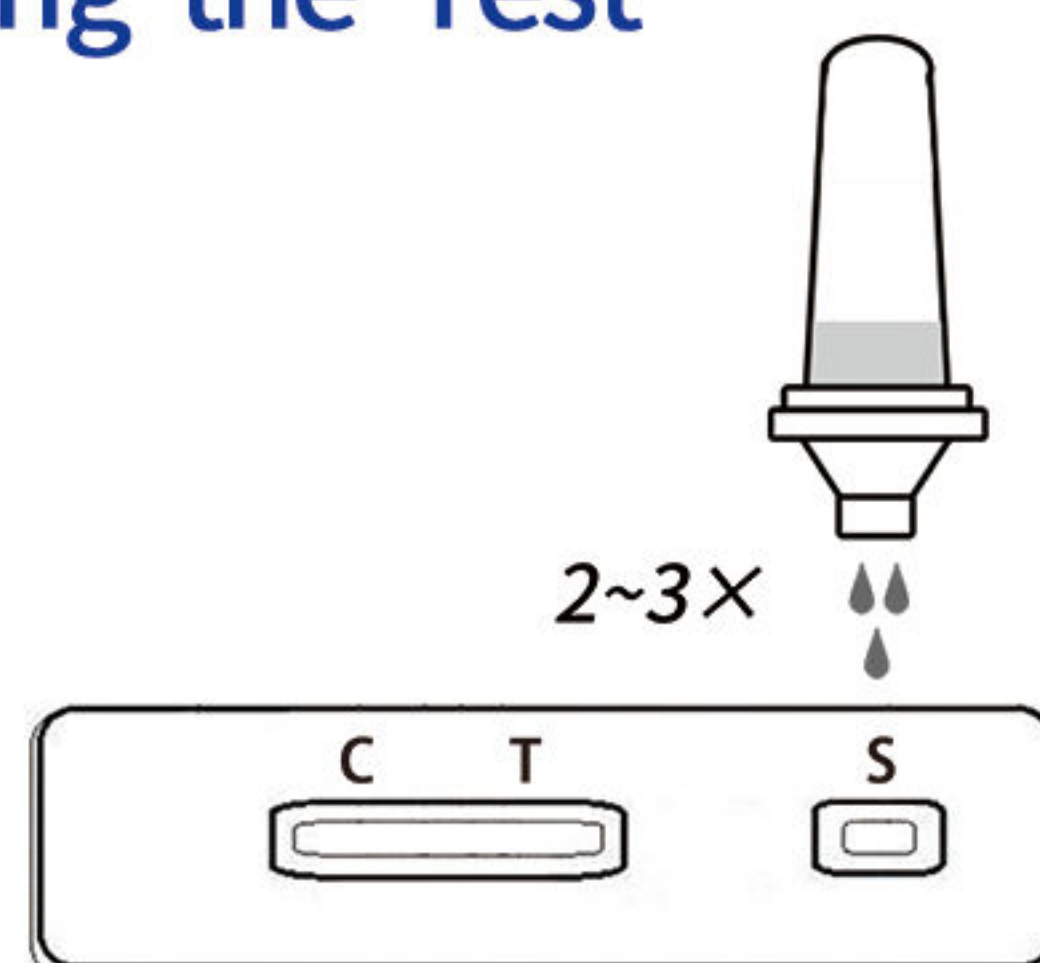
① Specimen collection



② Sample preparation



③ Running the Test



④ Test result

