

## PRODUCT SPECIFICATIONS

### Product Components



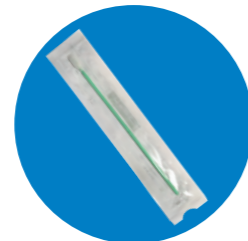
Test cassette



Extraction buffer

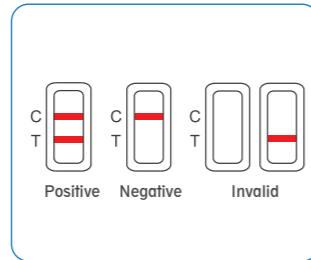
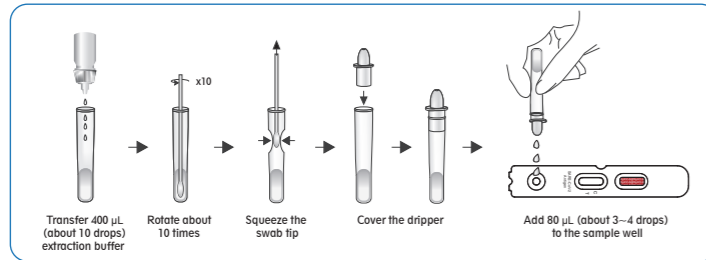
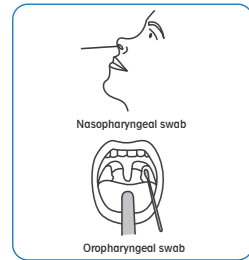


Extraction tube



Swab

### Operation procedure



### Performance

Reagents		PCR		Total
		Positive	Negative	
Wondfo SARS-CoV-2 Antigen Test (Lateral Flow Method)	Positive	478	1	479
	Negative	19	361	380
<b>Total</b>		497	362	859

Sensitivity: 96.18% (95%CI: 96.43%~98.49%)  
 Specificity: 99.72% (95%CI: 98.45%~99.95%)  
 Total agreement: 97.67% (95%CI: 94.11%~97.54%)

### Order information

Catalog No.	Product Name	Packing Size	Sample Type	Storage Condition	Shelf Life	Qualification
W196	SARS-CoV-2 Antigen Test (Lateral Flow Method)	20T	Nasopharyngeal swab or oropharyngeal swab	2~30 °C	12 months	CE

WONDFO BIOTECH  
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# WONDFO SARS-COV-2 ANTIGEN TEST

Speed Up the **COVID-19** Control !

# WONDFO SARS-COV-2 ANTIGEN TEST



Direct detection of the virus



Instant results within 15mins



Easy to use, no equipment required



Room temperature storage (2~30°C)

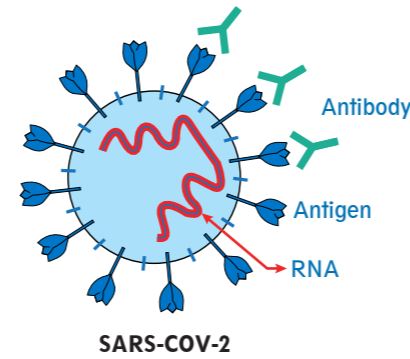


Non-invasive sampling (sample type: nasopharyngeal or oropharyngeal swab)



Early detection of COVID-19 (WHO recommends the testing period is from 3 days before to 5-7 days after symptoms onset)

## CURRENT DIAGNOSTIC METHODS FOR COVID-19



### Antigen test

Detect the antigen of the virus, indicating the active viral infection.

### RT-PCR

Detect the RNA of virus, indicating the active viral infection.

### Antibody test

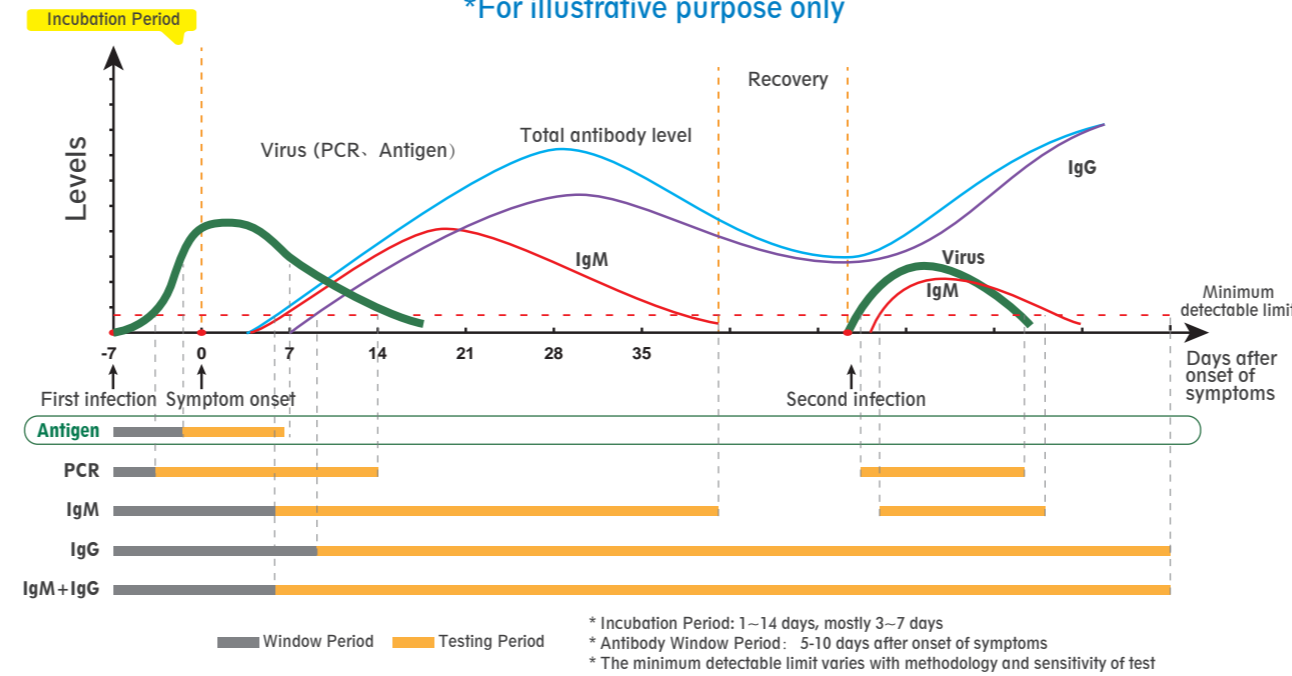
Detect the antibody generated by immune response after viral infection, indicating the active or past viral infection.

## WHEN TO USE ANTIGEN TEST?

### Releasing profile

Levels of SARS-CoV-2 virus and antibodies after infection

\*For illustrative purpose only



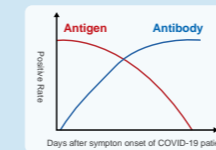
## ANTIGEN TEST ADVANTAGES

### Antigen test OVER RT-PCR

- Short turn-around time (Antigen test: 20mins vs. RT-PCR: 2hours)
- Inexpensive cost, no equipment required and simple operation make antigen test suitable for point-of-care (POC) setting usage.

### Antigen test OVER Antibody test

- Detect the virus directly, allowing the early detection of COVID-19
- Non-invasive sampling (sampling type: blood vs. swab)



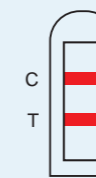
## ANTIGEN TEST APPLICATION

Similar to RT-PCR, the detection of antigen indicates the active infection. Under the circumstance that the area(s) still undergo widespread community transmission with limited RT-PCR resources, antigen can be used for aiding in the diagnosis of COVID-19 suspect patients.



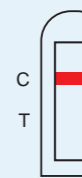
\* American CDC also recommends to use rapid antigen tests for screening testing in high-risk congregate settings where the immediate result is required.

### Result interpretation



#### POSITIVE

The patient is undergo active SARS-CoV-2 infection. Further isolation is required.



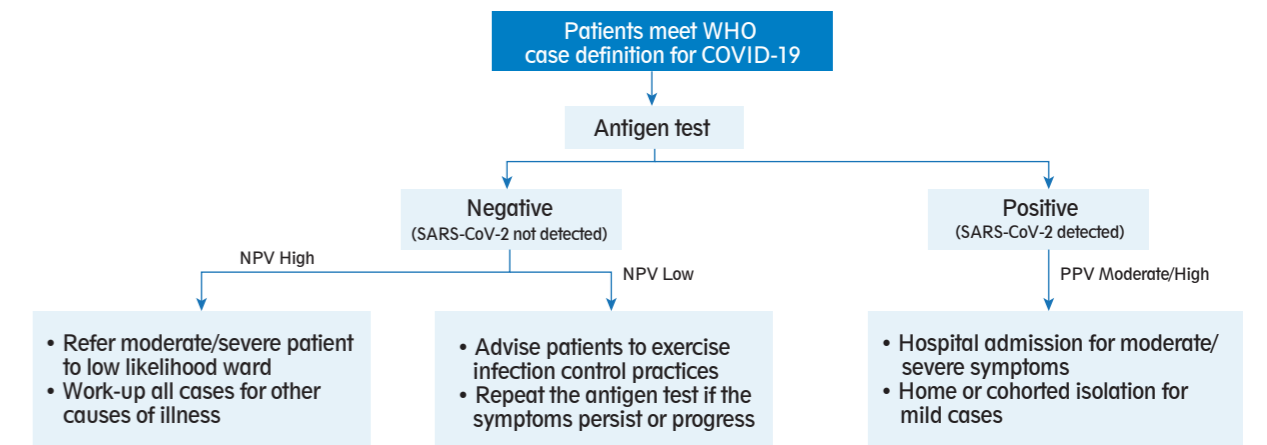
#### NEGATIVE

The patient should be further evaluated by RT-PCR, especially if the result of the antigen test is inconsistent with the clinical context.

## ANTIGEN TEST OFFICIAL GUIDELINES



Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays



NPV- negative predictive value PPV- positive predictive value  
 \*The value for NPV and PPV is decided based on products performance and disease prevalence in applied scenarios.

### Other antigen test related guidelines

- Interim Guidance for Rapid Antigen Testing for SARS-CoV-2, American CDC (8-16-20)
- Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes, American CDC (8-27-20)
- Antigen-Detection in the Diagnosis of SARS-CoV-2 Infection Using Rapid Immunoassays, WHO (9-11-20)
- Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing, APHL (9-2-20)