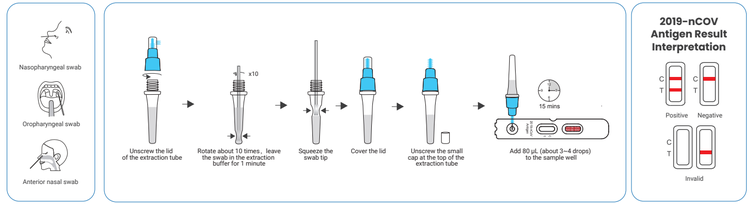
PRODUCT SPECIFICATIONS

PRODUCT COMPONENTS

Test cassette | Pre-installed extraction buffer | Swab

OPERATION PROCEDURE



PERFORMANCE

Reagents		PCR		Total
		Positive	Negative	
W196-2019-nCoV Antigen Test (Lateral Flow Method)	Positive	208	1	209
	Negative	4	361	365
Total		212	362	574

Sensitivity:
98.11% (95%CI: 95.24%~99.48%)
Specificity:
99.72% (95%CI: 98.47%~99.99%)
Total agreement:
99.13% (95%CI: 97.98%~99.72%)

Data for clinical evaluation*

Reagent		Confirmed by Referenced method PCR		Total
		Positive	Negative	
W634-2019-nCoV Antigen Test (Lateral Flow Method)	Positive	66	5	71
	Negative	5	335	340
Total		71	340	411
Sensitivity: 92.96%	Specificity: 98.53%		Total agreement:	97.57%

** NOTE : In field clinical evaluations conducted in Germany, US and UK by lay users.*

Data for asymptomatic patient

Reagent		Confirmed by Referenced method PCR		Total
		Positive	Negative	
W634-2019-nCoV Antigen Test (Lateral Flow Method)	Positive	43	0	43
	Negative	2	380	382
Total		45	380	425
Sensitivity: 95.56%	Specificity: 100%		Total agreement: 99.53%	

CT Value	CT ≤25	CT ≤30	CT ≤33	CT ≤35
Sensitivity	100%	98.02%	95.88%	92.83%

W630-Influenza/2019-nCoV Antigen Combo Test	2019-nCoV Antigen	Influenza A	Influenza B
Sensitivity	98.11%	95.81%	94.37%
Specificity	99.72%	91.03%	99.72%
Total Agreement	99.13%	91.86%	99.32%

ORDER INFORMATION

Catalog No.	Product Name	Classification	Packing Size	Sample Type	Storage Condition	Qualification
W196	2019-nCoV Antigen Test （Lateral Flow Method）	Professional Test	20T	Nasopharyngeal swab/oropharyngeal swab	2~30℃	CE
W634	2019-nCoV Antigen Test （Lateral Flow Method）	Self Test	1/5T	Nasal swab	2~30℃	CE 0123
W630	Influenza/2019-nCoV Antigen Combo Test	Professional Test	20T	Nasopharyngeal swab	2~30℃	CE
NEW W771	Flu A&B/2019-nCoV/RSV/ADV/MP Antigen Combo Test	Professional Test	10/20T	Nasopharyngeal swab/oropharyngeal swab	2~30℃	CE
NEW W770	Flu A&B/2019-nCoV/RSV/ADV Antigen Combo Test	Professional Test	10/20T	Nasopharyngeal swab/oropharyngeal swab	2~30℃	CE

Wondfo
Racing For Life

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Wondfo

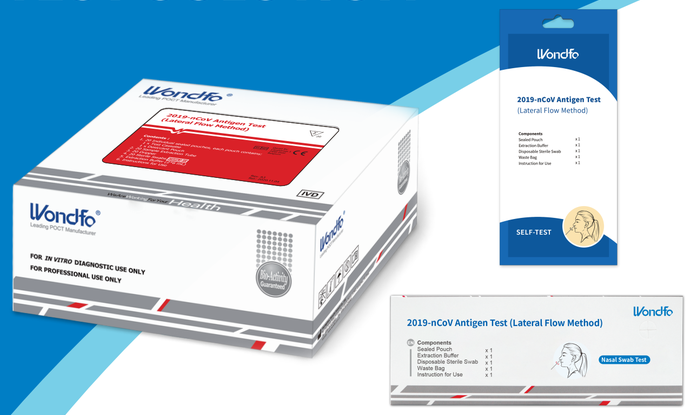
WONDFO 2019-nCoV ANTIGEN TEST SOLUTION

RAPID DEFENSE:
CONQUERING COVID-19 AND BEYOND!

Self test **Professional test** **Combo test**

Guangzhou Wondfo Biotech Co., Ltd.

WONDFO 2019-nCOV ANTIGEN TEST SOLUTION



Direct detection of the virus

Instant results within 15mins

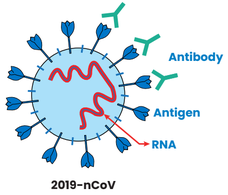
Easy to use, no equipment required

Room temperature storage(2~30°C)

Sample type: nasopharyngeal, oropharyngeal or nasal 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



2019-nCoV

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

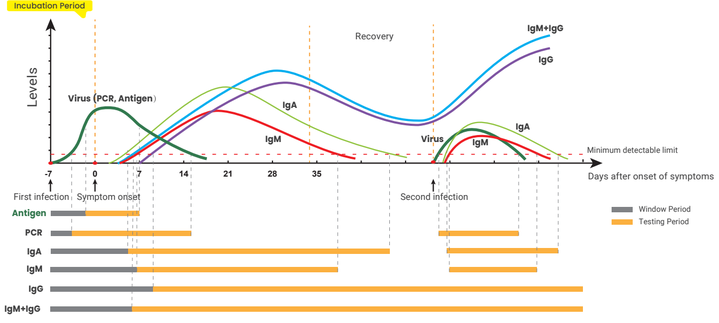
RT-PCR
Detect the RNA of virus, indicating the active viral infection.

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 2019-nCoV virus and antibodies after infection
*For illustrative purpose only



* Incubation Period: 1~14 days, mostly 3~7 days
* Antibody Window Period: 5-10 days after onset of symptoms
* The minimum detectable limit varies with methodology and sensitivity of test
* IgG antibody test can be referred as one of discharge criteria for recovering COVID-19 patients

ANTIGEN TEST ADVANTAGES

Antigen test OVER RT-PCR

- Short turn-around time
  (Antigen test: 15 min VS. RT-PCR: 2 hours)
- 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: swab VS. Blood)

ANTIGEN TEST APPLICATION

Similar to RT-PCR, the detection of antigen indicates the active infection. Under the circumstance that the area(s) is still undergoing widespread community transmission and/or the area 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

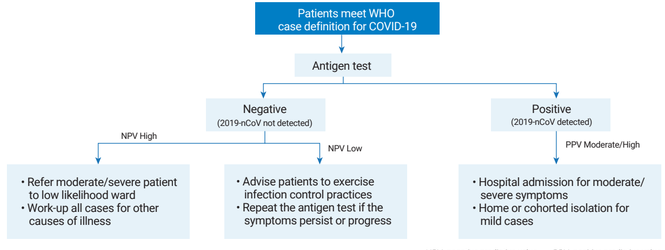
POSITIVE
The patient is undergo active 2019-nCoV infection. Further isolation is required.

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

World Health Organization

Antigen-detection in the diagnosis of novel coronavirus（2019-nCoV）infection using rapid immunoassays



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

Other antigen test related guidelines

- Interim Guidance for Rapid Antigen Testing for 2019-nCoV, American CDC (8-16-20)
- Considerations for Use of 2019-nCoV Antigen Testing in Nursing Homes, American CDC (8-27-20)
- Antigen-Detection in the Diagnosis of 2019-nCoV Infection Using Rapid Immunoassays, WHO (9-11-20)
- Considerations for Implementation of 2019-nCoV Rapid Antigen Testing, APHL (9-2-20)