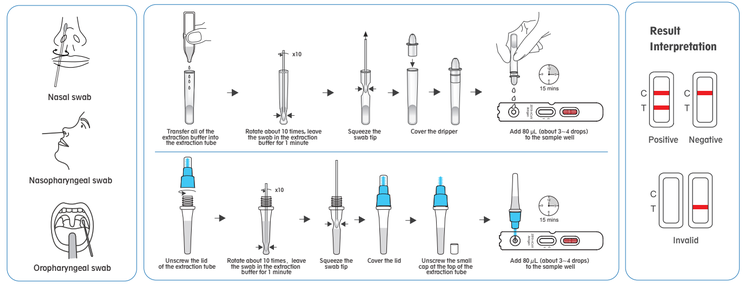
Rev. A9 Rel.: 2021/02/05

PRODUCT SPECIFICATIONS

Product Components

Test cassette | Capsule extraction buffer | Pre-installed extraction buffer | Extraction tube | NP/OP/Nasal swab

Operation procedure



Performance

Reagents	Specimen		PCR		Total
			Positive	Negative	
Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	Nasopharyngeal / opharyngeal swab	Positive	208	1	209
		Negative	4	361	365
		Total	212	362	574
	Nasal swab	Positive	135	2	137
		Negative	3	216	219
		Total	138	218	356

Nasopharyngeal/Oropharyngeal Swab:
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%)

Nasal Swab:
Sensitivity: 97.83% (95%CI: 93.78%~99.55%)
Specificity: 99.08% (95%CI: 96.73%~99.89%)
Total agreement: 98.60% (95%CI: 96.75%~99.54%)

Order information

Catalog No.	Product Name	Packing Size	Sample Type	Storage Condition	Shelf Life	Qualification
W196/ W634	2019-nCoV Antigen Test (Lateral Flow Method)	1T/5T/20T	Nasopharyngeal swab/ Oropharyngeal swab/ **Nasal swab**	2~30 ℃	12 months	CE

WONDFO BIOTECH
WeAreWorkingForYourHealth

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WONDFO 2019-nCoV ANTIGEN TEST

3 sample types are available: **NP/OP/NASAL !**

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

Guangzhou Wondfo Biotech Co., Ltd.

WONDFO 2019-nCoV ANTIGEN TEST

Direct detection of the virus

Instant results within 15mins

Easy to use, no equipment required

Room temperature storage(2~30°C)

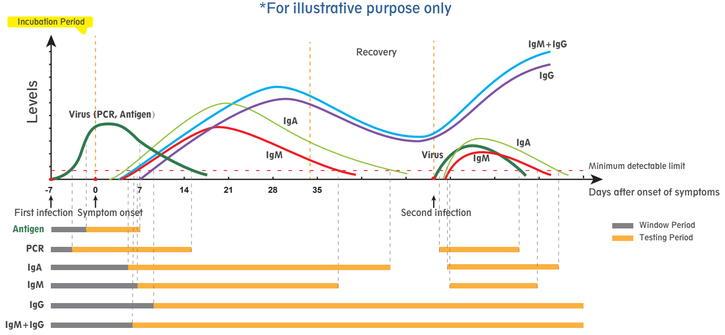
Multiple sampling types
(sample type: NP/OP/Nasal swab)

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

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

COMPARISON OF NASAL VS NASOPHARYNGEAL/OROPHARYNGEAL SWAB

- NP swab samples must be collected by trained personnel with protective equipment. Evidence supports the use of alternative sampling methods, including nasal swabs collected by patients, and some tests have received regulatory approval with nasal samples.
- Our study suggests that supervised Nasal sampling leads to results comparable to NP sampling for the Ag-RDT. A possible reduction in VL present in the nasal region compared to the NP region may be counter balanced by the ease-of-sampling.
- The evaluation results from FIND of Wondfo 2019-nCoV Antigen Test showed no significant difference among NP and Nasal swab in clinical specificity and sensitivity compared with RT-PCR result.

* Detailed information about comparition of NP/OP & Nasal swab could be found at: https://doi.org/10.1007/s00430-021-00710-9
FIND Evaluation of Guangzhou Wondfo Biotech Co., Ltd Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)
Public Report-Version 1.0, 30 September 2021

ANTIGEN TEST APPLICATION

Rapid antigen detection tests (RADT) can contribute to overall COVID-19 testing capacity, offering advantages in terms of shorter turnaround times and reduced costs, especially in situations in which PCR capacity is limited.

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

ecdc EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

Options for the use of rapid antigen detection tests for COVID-19 in the EU/EEA

WHO TO TEST?

	Testing symptomatic		Screening asymptomatic		Recurring screening
	Prevalence ≥10%	Prevalence <10%	Prevalence ≥10%	Prevalence <10%	Prevalence ≥10%
Use of RADT	Yes	Yes	Yes	No	Yes
Timing	within 5 days after onset of symptoms		within 7days after exposure or as soon as possible	**if RADTs are used:** within 7 days after exposure or as as soon as possible	within 7 days after exposure or as soon as possible

* Detailed information about Antigen Test could be found at: https://www.ecdc.europa.eu/en

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Wondfo

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Wondfo Racing For Life

2019-nCoV Antigen Test

Sample type: Saliva/Sputum

Antigen test with Saliva / Sputum sample, no more discomfort during the test.

Commonly used sample types for antigen test

Nasopharyngeal (NP) / Oropharyngeal (OP)

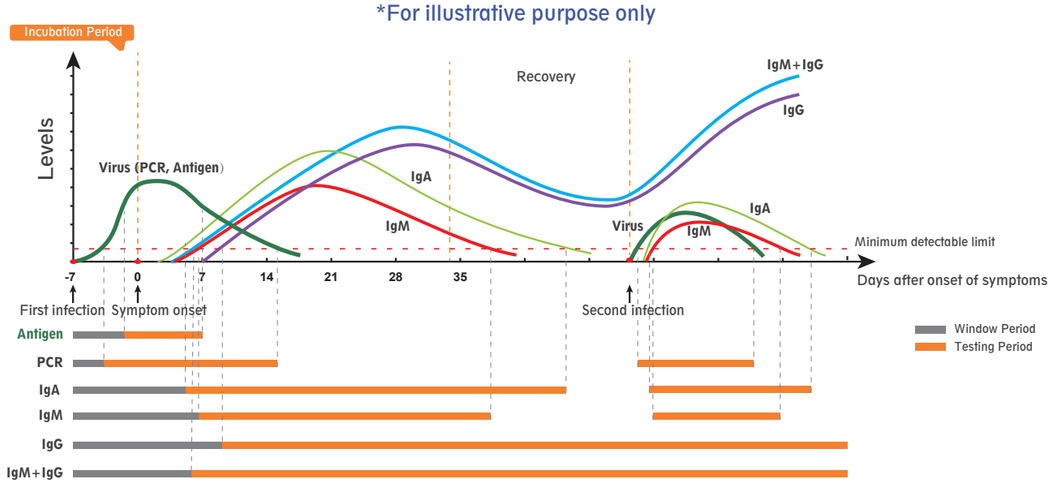
- Professional training needed for sampling
- Discomfort for testee when sampling
- Higher viral load

Saliva/Sputum

- No professional training needed for sampling
- No more discomfort during sampling

When to use antigen test?

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



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* 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

Application

Saliva/Sputum antigen test can be applied for initial screening of COVID-19, the positive result indicates the active infection.

Application Scenarios

High-risk congregates

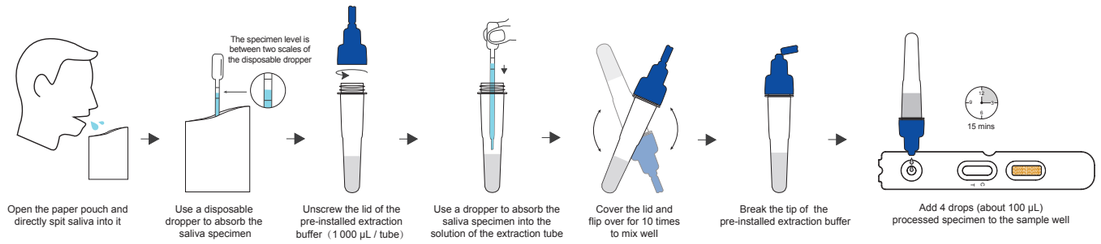
Designated hospital

Primary care triage

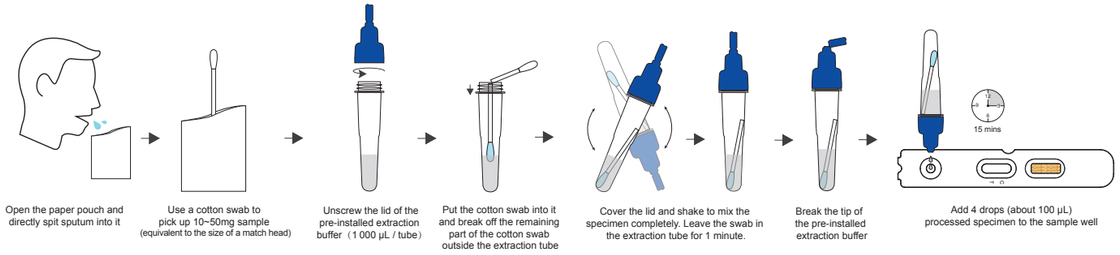
Product Specifications

OPERATION

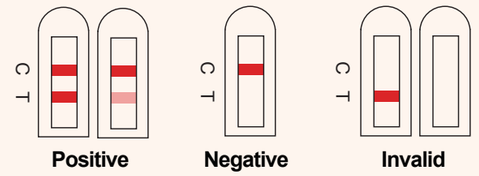
(Option A) Saliva specimen collection



(Option B) Sputum specimen collection



RESULT INTERPRETATION



*C=Control Line
T= Test Line

PRODUCT PERFORMANCE

2019-nCoV Antigen Test	PCR		Total
	Positive	Negative	
2019-nCoV Positive	246	2	248
2019-nCoV Negative	6	381	387
Total	252	383	635

Sensitivity:
97.62%（95%CI: 94.89%～99.12%）
Specificity:
99.48%（95%CI: 98.13%～99.94%）
Total Agreement:
98.74%（95%CI: 97.53%～99.45%）

ORDER INFORMATION

Catalog No.	Paking Size	Reaction Time	Shelf Life	Sample Type	Storage Temperature
W633P0001～W633P0008	1/5/10/20 T/kit	15～20 minutes	24 months	Saliva/Sputum Test	2～30ºC