CE IVD

FOR PROFESSIONAL USE

ND COVID-19 Ag test

NDR002

[PERFORMANCE CHARACTERISTIC]

1. CLINICAL EVALUATION

Performance characteristic for the ND COVID-19 Ag Test for rapid detection of SARS-CoV-2 antigen was established in prospective, single institute, randomized, single- blinded study conducted at a trial site in South Korea during the 2020 SARS-CoV-2 pandemic situation. A total of 84 prospective specimens were tested using the ND COVID-19 Ag Test. These specimens consisted of nasopharyngeal swabs and oropharyngeal swabs from symptomatic patients. The performance of the ND COVID-19 Ag Test was compared to a commercialized molecular assay.

		RT-PCR		
		POS	NEG	TOTAL
ND COVID-19 Ag	POS	32	0	32
	NEG	2	50	52
	TOTAL	34	50	84

Positive agreement: 94.1% (32/34) (95% Confidence Interval: 80.3% to 99.27%)
Negative agreement: 100% (50/50) (95% Confidence Interval: 92.89% to 100.00%)
Categorical agreement: 97.6% (82/84)
Positive predictive value: 100% (32/32) (95% Confidence Interval: 89.11% to 100.00%)
Negative predictive value: 96.2% (50/52) (95% Confidence Interval: 87.11% to 99.52%

2. ANALYTICAL PERFORMANCE

Limit of Detection (LoD):
The study used "SARS-CoV-2 (2019-nCOV) NCCP 43326/2020 / Korea" strain. The titer of cultured virus was confirmed by PCR. The cell is inactivated and spiked into Nasopharyngeal swab specimen. The LoD is 1.25 X $10^{3.2}$ $TCID_{50}$/ml.

Cross-Reactivity:
There was no cross-reaction with potential cross-reactive substances except SARS-coronavirus.

Endogenous/Exogenous Interference Substances Studies:
There was no interference for potential interfering substances.

No.	Bacteria/Virus	Division	Concentration
1	Respiratory Syncytial Virus	Ag	0.49mg/mL
2	Influenza A H1N1 NP	Ag	2.21mg/mL
3	Influenza B	Ag	2.5mg/mL
4	Influenza A H1N1(Native)	Ag	40320HA Units/mL
5	Campylobacter jejuni	Bacteria	>10^7 CFU/mL
6	Serratia marcescens	Bacteria	>10^7 CFU/mL
7	Staphylococcus aureus	Bacteria	>10^7 CFU/mL
8	Enterococcus faecalis	Bacteria	>10^7 CFU/mL
9	Escherichia coli	Bacteria	>10^7 CFU/mL
10	Klebsiella pneumoniae	Bacteria	>10^7 CFU/mL
11	Lactobacillus casei	Bacteria	>10^7 CFU/mL
12	Listeria monocytogenes	Bacteria	>10^7 CFU/mL
13	Vibrio parahaemolyticus	Bacteria	>10^7 CFU/mL
14	Human hepesvirus 1 HF	Virus	10^6 PFU/mL
15	Coxsackievirus A9 P.B	Virus	10^6 PFU/mL
16	Coxsackievirus B5 Faulkner	Virus	10^6 PFU/mL
17	Echovirus 6 D'Amori	Virus	10^6 PFU/mL
18	Echovirus 6 Harris	Virus	10^6 PFU/mL
19	Adenovirus Type 18	Virus	10^5 PFU/mL
20	Rubella virus	Virus	10^4 PFU/mL
21	Dengue virus type 4	Virus	10^5 PFU/mL

High-dose Hook Effect:
SARS-CoV-2 cultured virus was spiked into specimen. SARS-CoV-2 cultured virus did not show hook-effect at 1 X $10^{6.2}$ $TCID_{50}$/ml.

[LIMITATION OF THE TEST]

The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.

The test should be used for the detection of SARS-CoV-2 antigen in human nasopharyngeal swab specimens.

Neither the quantitative value nor the rate of SARS-CoV-2 antigen concentration can be determined by this qualitative test.

Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.

A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor quality specimen is obtained.

For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.

The test result must always be evaluated with other data available to the physician.

A negative result may occur if the concentration of antigen or antibody in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS- CoV-2 infection, and should be confirmed by viral culture or an molecular assay or ELISA.

Positive test results do not rule out co-infections with other pathogens.

Negative test results are not intended to rule in other coronavirus infection except the SARS-CoV-1.

Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.

[REFERENCES]

Clinical management of severe acute respiratory infection when novel coronavirus(nCoV) infection is suspected. Interim guidance. WHO.2020

Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR.2020

Diagnosis and treatment of pneumonia caused by new coronavirus (trial version 4) National Health Commission. 2020

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[PURPOSE OF USE]

ND COVID-19 Ag Test is a rapid chromatographic immunoassay for the qualitative detection of specific antigens to SARS-CoV-2 present in human nasopharynx. This test is for administration by healthcare workers and labs only, as an aid to early diagnosis of SARS-CoV-2 infection in patient with clinical symptoms with SARS-CoV-2 infection. It provides only an initial screening test result. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of SARS-CoV-2 infection.

[DESCRIPTION]

ND COVID-19 Ag Test has two pre-coated lines, "C" Control line, "T" Test line on the surface of the nitrocellulose membrane. Both the control line and test line in the result window are not visible before applying any specimens. Mouse monoclonal anti-SARS-CoV-2 antibody is coated on the test line region and Rabbit anti-chicken IgY antibody is coated on the control line region. Mouse monoclonal anti-SARS-CoV-2 antibody conjugated with gold particles are used as detectors for SARS-CoV-2 antigen device, as well as Chicken IgY conjugated with gold particles. During the test, SARS-CoV-2 antigen in the specimen interact with monoclonal anti-SARS-CoV-2 antibody conjugated with gold particles making antigen-antibody gold particles complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by the mouse monoclonal anti-SARS-CoV-2 antibody. A colored test line would be visible in the result window if SARS-CoV-2 antigens are present in the specimen. The intensity of colored test line will vary depending upon the amount of SARS-CoV-2 antigen present in the specimen. If SARS-CoV-2 antigens are not present in the specimen, then no color appears in the test line. The control line is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

[MATERIALS PROVIDED]

25 test devices
25 Extraction buffer tubes
25 Flocked swabs (2 different type of swabs)
1 Rack & 1 IFU

[STORAGE & STABILITY]

1. Store the kit at room temperature, 1~30°C / 34-86°F, out of direct sunlight.
2. Kit materials are stable until the expiration date printed on the outer box.
3. Do not freeze the kit.

[PRECAUTIONS]

1. For Professional in vitro diagnostic use only.
2. Do not use the product beyond the expiration data.
3. Do not use the product if the pouch is damaged or the seal is broken.
4. Handle all specimens as potentially infections.
5. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infectious material. When the assay procedure is completed, Dispose specimens after autoclaving at 121℃ for at least 20 min or treating with 0.5% Sodium Hypochlorite for 1-2 hours.
6. Refer to 'Guidelines for COVID-19 Response', 'Guidelines for the Laboratory Diagnosis of COVID-19' and 'Q&A for COVID19(SARS-CoV-2 or 2019-nCoV) testing' when using this product.
7. Use of samples is limited to samples described in the Purpose of Use and 'Guidelines for COVID-19 Response', 'Guidelines for the Laboratory Diagnosis of COVID-19'.
8. Testing should be performed on the bio safety workbench class II.
9. Wear suitable protective gloves, clothing, and eye/face protection when handling the contents of this kit.

[COLLECTION & PREPARATION OF SAMPLE]

To collect a nasopharyngeal swab specimen, insert a sterile swab into the nostril of the patient reaching the surface of the posterior nasopharynx.

Using gentle rotation, push the swab until resistance is met at the level of the turbinate.

Rotate the swab a few times against the nasopharyngeal wall.

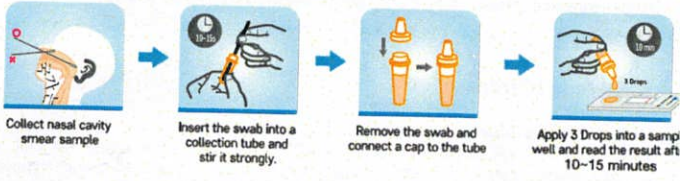
Remove the swab from the nostril carefully.

Specimen should be tested as soon as possible after collection.

Do not use transport media, use the collected specimen and extraction buffer immediately. Be careful of contamination.

Specimens may be stored at room temperature for up to 1 hours or at 2-8°C/ 36-46°F for up to 4 hours prior to testing.

[TEST PROCEDURE]



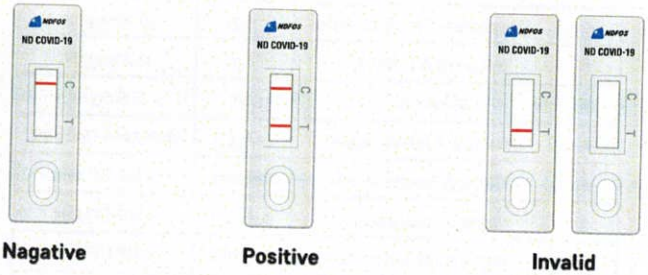
Before using the kit, carefully read the kit instructions and strictly follow the kit instructions:

Take out the test card, balance it to room temperature, unpack the test card aluminum foil bag and lay it flat.

Put 3 drops of the treated sample processing solution vertically into the sample card's sample hole.

The test card is placed at room temperature for 10-15 minutes to observe the test result, and the observation result after 20 minutes is invalid.

[INTERPRETATION OF RESULT]



Nagative **Positive** **Invalid**

1. Positive: Two red bands, the test line (T line) and the quality control line (C line) are colored.

2. Negative: a red strip, the quality control line (C line) color development;

3. Invalid: No color appears in the position of the quality control line (C line) in the observation window, indicating that this test is invalid and should be resampled for testing.