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"See Now" Coronavirus nCoV Antigen Cassette Test

For in vitro Diagnosis Use

Product Code: SN 8.7

INTENDED USE

The *"See Now"* **Coronavirus nCoV Antigen test** is used for the qualitative detection of SARS-CoV-2 antigens in nasopharyngeal swab.

SN Coronavirus nCoV Antigen test cannot be used as the basis to diagnose or exclude SARS-CoV-2 infection.

PRINCIPLE

The *"See Now"* **Coronavirus (SARS-CoV-2) Antigen test** is an immunochromatographic lateral flow device that employs the principle of double antibody sandwich method. Colloidal gold conjugated anti-SARS-CoV-2 antibodies are dry-immobilized on the test device. When the specimen is added, it migrates by capillary diffusion through the strip to re-hydrate the gold conjugate complexes. If present at or above the limit of detection, SARS-CoV-2 viral antigens will react with the gold conjugate complexes to form particles, which will continue to migrate along the strip until the **Test Zone (T)** where they are captured by the immobilized anti-SARS-CoV-2 antibodies to form a visible red line. If there are no SARS-CoV-2 viral antigens in the specimen, no red line will appear in the **Test Zone (T).** The gold conjugate complexes will continue to migrate alone until being captured by immobilized antibody in the **Control Zone (C**) to form a red line, which indicates the validity of the test.

MATERIALS SUPPLIED

1. See Now Coronavirus Antigen test cassette
2. Sample extraction buffer
3. Instructions for use

MATERIALS REQUIRED BUT NOT SUPPLIED

- Sterilized swab, Extraction tube, Timer;

STORAGE AND STABILITY

- The *"See Now"* **Coronavirus Ag. test** should be stored between 4-30 ºC in the sealed pouch or desiccated container.
- Do not use it after the expiration date.
- Do not freeze.

PRECAUTIONS

- *FOR PROFESSIONAL AND IN VITRO DIAGNOSTIC USE ONLY.*
- The test device should remain in the sealed pouch until use.
- There should be no smoking or eating where antigen containing materials are being handled. Wear disposable gloves and lab coat while handling specimens. Wash hands thoroughly afterwards.
- Decontaminate and dispose of specimens and all potentially contaminated materials if they contain infectious agent.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory have been evaluated.
- *Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. Standard precautions and institutional guidelines should always be followed in handling, storing, and disposing of all specimens and all items contaminated with blood or other body fluids.*

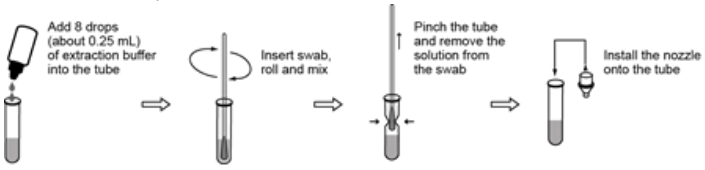
SPECIMEN COLLECTION AND STORAGE/ PREPARATION

It is applicable to the diagnosis of the influenza virus A and B from the samples of nasal swabs, throat swabs or nasal aspirates. Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

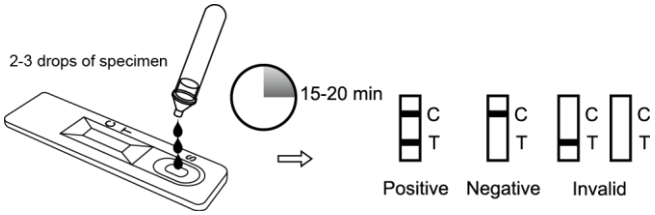
Nasal Swabbing

Insert the sterilized swab into the nasal basin, reaching the surface of posterior nasopharynx that presents the most secretion and swab several times to collect the epidermal cells of the mucus. **It is recommended to collect sample from nasal basin for more accurate results.**

1. Add **8 drops (about 0.25 mL)** of extraction buffer into the extraction tube.
2. Place the swab with specimen into the extraction tube. Roll the swab three to five (3-5) times. Leave the swab in the extraction buffer for 1 minute.
3. Pinch the extraction tube with fingers and remove the solution from the swab as much as possible. Dispose of the used swab in accordance with your biohazard waste disposal protocol.
4. Install the nozzle cap onto the sample extraction tube tightly. Use extraction solution as test specimen.

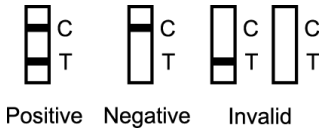


TEST PROCEDURE



- Remove the test device from pouch when ready to perform the test. Label the test device with patient or control identification
- Return the white cap assembly to the extraction tube.
- Reverse the sample extraction tube and add 2-3 drops (about 50-75 µl) of test sample by squeezing the extracted solution tube into the sample window.
- Read the results at 15-20 minutes. **The results after 20 minutes may not be accurate.**

INTERPRETATION OF RESULTS



POSITIVE

If two colored bands appear within 15-20 minutes with one colored band in the Control Zone (C) and another in the Test Zone (T), the test result is positive and valid. No matter how faint the colored band is in the Test Zone (T), the result should be considered as positive. A positive result does not rule out co-infections with other pathogens.

NEGATIVE

If one colored band appears in the Control Zone (C) and no colored band appears in the Test Zone (T) within 15-20 minutes, the test result is negative and valid. A negative result does not exclude SARS-CoV-2 viral infection and should be confirmed by molecular diagnostic method if COVID-19 disease is suspected.

INVALID

The test result is invalid if there is no colored band in the Control Zone (C) within 15-20 minutes. Repeat the test with a new test device.

LIMITATION OF PROCEDURE

1.The *"See Now"* **Coronavirus nCoV Antigen test** test is limited to the qualitative detection of SARS-CoV-2 viral antigen in nasopharyngeal swab specimens. The exact concentration of SARS-CoV-2 viral antigen cannot be determined by this assay.

2. Proper specimen collection is critical, and failure to follow the procedure may give inaccurate results. Improper specimen collection, storage or repeated freezing and thawing of specimens can lead to inaccurate results.

3. A negative test result may occur if the level of antigen in a specimen is below the limit of detection of the test.

4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.

5. Negative test results do not rule out other potential non-SARS-CoV-2 viral infections. Negative results should be confirmed by molecular diagnosis if COVID-19 disease is suspected.

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

7. Monoclonal antibodies may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.

8. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5-7 of illness are more likely to be tested negative compared to a RT-PCR assay.

9. The **SN Coronavirus nCoV Antigen test** can detect both viable and non-viable SARS-CoV-2 material. The **SN Coronavirus nCoV Antigen test** for rapid detection of SARS-CoV-2 performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.

10. The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.

11. The kit was validated with the assorted swabs. Use of alternative swabs may result in false negative results.

12. Specimen stability recommendations are based upon stability data from influenza testing and performance may be different with SARS-CoV-2. Users should test specimens as quickly as possible after specimen collection, and within two hours after specimen collection.

13. The validity of **SN Coronavirus nCoV Antigen test** has not been proven for dentification/confirmation of tissue culture isolates and should not be used in this capacity.

PERFORMANCE CHARACTERISTICS

A. Analytical Sensitivity

The limit of detection (LOD) for the SN Coronavirus Antigen test was established in an analytical sensitivity study performed with one virus strain and one recombinant nucleocapsid protein.

The LOD is mentioned as below:

No.	Item	Limit of Detection
1	SARS-CoV-2, Virus	1.3 x102 TCID50/mL
2	SARS-CoV-2, Recombinant nucleocapsid protein	1 ng/mL

Accuracy

The accuracy of **SN Coronavirus nCoV Antigen test** was established with 236 nasopharyngeal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. The following table summarizes the accuracy of the **SN Coronavirus nCoV Antigen test** compared to RT-PCR.

		RT-PCR		
		Positive	Negative	Total
SN Coronavirus Antigen Test	Positive	30	4	34
	Negative	2	200	202
	Total	32	204	236

The **sensitivity** was **93.75%** (95%CI: 85.36%~99.99%).

The **specificity** was **98.04%** (95%CI: 96.14%~99.94%).

The **accuracy** was **97.46%** (95%CI: 95.45%~99.47%).

B. Cross reactivity

The cross reactivity of the **SN Coronavirus nCoV Antigen test** was evaluated with a total of 27 microorganisms. None of microorganisms tested in the below table gave a positive result.

Microorganisms	Concentrations	Microorganisms	Concentrations
Human coronavirus	2.0 x 10^6 $TCID_{50}$/mL	MERS-coronavirus	1.0 x 10^6
Human coronavirus	2.0 x 10^6 $TCID_{50}$/mL	Chlamydia pneumoniae	2.0 x 10^6 IFU/mL
Human coronavirus	2.0 x 10^6 $TCID_{50}$/mL	Streptococcus	2.0 x 10^6
Parainfluenza virus 1	2.0 x 10^6 $TCID_{50}$/mL	Streptococcus pyogenes	2.0 x 10^6
Parainfluenza virus 2	2.0 x 10^6 $TCID_{50}$/mL	Bordetella pertussis	2.0 x 10^6
Parainfluenza virus 3	2.0 x 10^6 $TCID_{50}$/mL	Mycobacterium	2.0 x 10^6
Enterovirus EV71	2.0 x 10^6 $TCID_{50}$/mL	Legionella pneumophila	2.0 x 10^6
Respiratory syncytial	2.0 x 10^6 $TCID_{50}$/mL	Mycoplasma	2.0 x 10^6 U/mL
Rhinovirus	2.0 x 10^6 $TCID_{50}$/mL	Haemophilus influenzae	2.0 x 10^6
Influenza A virus (H1N1)	2.0 x 10^6 $TCID_{50}$/mL	Candida albicans	2.0 x 10^6
Influenza A virus (H3N2)	2.0 x 10^6 $TCID_{50}$/mL	Staphylococcus aureus	2.0 x 10^6
Influenza B virus	2.0 x 10^6 $TCID_{50}$/mL	Pseudomonas	2.0 x 10^6
Influenza B virus	2.0 x 10^6 $TCID_{50}$/mL	Escherichia coli	2.0 x 10^6
Adeno virus	2.0 x 10^6 $TCID_{50}$/mL		

C. Interference

1. Microorganism

SN Coronavirus nCoV Antigen test has tested samples with common microorganism. The results showed that these microorganisms had no affect on the specificity of the assay up to the listed concentration.

Microorganisms	Concentrations	Microorganisms	Concentrations
Human coronavirus	2.0 x 10^6 $TCID_{50}$/mL	MERS-coronavirus	1.0 x 10^6
Human coronavirus	2.0 x 10^6 $TCID_{50}$/mL	Chlamydia pneumoniae	2.0 x 10^6 IFU/mL
Human coronavirus	2.0 x 10^6 $TCID_{50}$/mL	Streptococcus	2.0 x 10^6 CFU/mL
Parainfluenza virus 1	2.0 x 10^6 $TCID_{50}$/mL	Streptococcus pyogenes	2.0 x 10^6 CFU/mL
Parainfluenza virus 2	2.0 x 10^6 $TCID_{50}$/mL	Bordetella pertussis	2.0 x 10^6 CFU/mL
Parainfluenza virus 3	2.0 x 10^6 $TCID_{50}$/mL	Mycobacterium	2.0 x 10^6 CFU/mL
Enterovirus EV71	2.0 x 10^6 $TCID_{50}$/mL	Legionella pneumophila	2.0 x 10^6 CFU/mL
Respiratory syncytial	2.0 x 10^6 $TCID_{50}$/mL	Mycoplasma	2.0 x 10^6 U/mL
Rhinovirus	2.0 x 10^6 $TCID_{50}$/mL	Haemophilus influenzae	2.0 x 10^6 CFU/mL
Influenza A virus (H1N1)	2.0 x 10^6 $TCID_{50}$/mL	Candida albicans	2.0 x 10^6 CFU/mL
Influenza A virus (H3N2)	2.0 x 10^6 $TCID_{50}$/mL	Staphylococcus aureus	2.0 x 10^6 CFU/mL
Influenza B virus	2.0 x 10^6 $TCID_{50}$/mL	Pseudomonas	2.0 x 10^6 CFU/mL
Influenza B virus	2.0 x 10^6 $TCID_{50}$/mL	Escherichia coli	2.0 x 10^6 CFU/mL
Adeno virus	2.0 x 10^6 $TCID_{50}$/mL		

2. Endogenous Substances

SN Coronavirus nCoV Antigen test has tested samples with common endogenous substances. The results showed that these substances had no affect on the specificity of the assay up to the listed concentration.

Substances	Concentrations	Substances	Concentration
Whole Blood	1% v/v	Homeopathic (Alkalol)	10% v/v
Mucin	2% w/v	CVS Nasal Drops	15% v/v
Tobramycin	0.0004% w/v	Afrin (Oxymetazoline)	15% v/v
Ricola (Menthol)	0.15% w/v	CVS Nasal Spray	15% v/v
Chloraseptic	0.15% w/v	Fluticasone Propionate	5% v/v
Mupirocin	0.25% w/v	Zicam	5% w/v
Tamiflu (Oseltamivir	0.5% w/v		

REFERENCES

1. Wu C, Liu Y, Yang Y, Zhang P, Zhong W, Wang Y, et al. (February 2020). "Analysis of therapeutic targets for SARS-CoV-2 and discovery of potential drugs by computational methods". Acta Pharmaceutica Sinica B. doi:10.1016.