SARS-Cov-2 Antigen Rapid Test Cassette (Swab)

SP-SW 106

SPRING HEALTHCARE

Package Insert

A RAPID TEST FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS ANTIGENS IN ANTERIOR NARES (NASAL)

For professional In Vitro Diagnostic Use Only.

CE IVD

INTENDED USE

SARS-Cov-2 Antigen Rapid Test Cassette (Swab) is a polymer immunochromatographic technology and double antibody sandwich principle that is intended for the qualitative detection of the Nucleocapsid (N-protein) antigen from SARS-CoV-2 in human anterior nares (Nasal) directly within the first 7 days of symptom onset.

Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
Negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
The SARS-Cov-2 Antigen Rapid Test Cassette (Swab) is intended for use by medical professionals or trained operators who are proficient in performing tests and trained clinical laboratory personnel or individuals trained in point of care settings.

SUMMARY

The SARS-Cov-2 Antigen Rapid Test Cassette (swab) is used for the in vitro qualitative detection of novel coronavirus in anterior nares (Nasal) of suspected pneumonia of suspected pneumonia patients infected by novel coronavirus, suspected clustering cases and others needing diagnosis or differential diagnosis for novel coronavirus. The definitions of "suspected cases" and "patients with suspected aggregated cases" and other groups are implemented with reference to the "Diagnosis and Treatment Plan for Novel Coronavirus-Infected Pneumonia" and "Monitoring Plan for Novel Coronavirus-Infected Pneumonia" and other documents (current version) issued by CDC (Centers for Disease Control and Prevention).
The product is only used for auxiliary diagnosis of related cases and emergency reserve for in vitro diagnosis during the pneumonia epidemic infected by SRAS-Cov-2 since December 2019 and it cannot be used as routine in vitro diagnostic reagents in clinical practice. The kit shall comply with the relevant requirements of the "Diagnosis and Treatment Plan for Pneumonia Infected in novel coronavirus" and "Prevention and Control Plan for Pneumonia Infected in novel coronavirus" and other documents in use.

PRINCIPLE

The SARS-Cov-2 Antigen Rapid Test Cassette (Swab) uses double antibody sandwich immunoassay. The NC membrane pre-immobilized with monoclonal antibodies against SARS-CoV-2 antigen and anti-mouse polyclonal antibodies, and the colloidal gold conjugated with monoclonal antibodies specific to SARS-CoV-2 antigen.
If SARS-CoV-2 antigen is present in the sample, a complex formed between the anti-SARS-CoV-2 conjugate and the antigen will be caught by the specific anti- SARS-CoV-2 monoclonal coated on the T region. Results appear in 10 to 15 minutes in the form of a red line that develops on the strip.
Whether the sample contains the SARS-CoV-2 antigen or not, the solution continues to migrate to encounter another reagent (an anti-mouse IgG antibody) that binds the remaining conjugates, thereby producing a red line on the region C.

REAGENTS

The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coronavirus; the reaction membrane contains the secondary antibodies for Novel coronavirus, and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.

WARNING AND PRECAUTIONS

- For prescription and in vitro diagnostic use only.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- Immediately use after opening the test device in the pouch. (Do not use opened Test device after 1 hour)
- In order to obtain accurate results, the test must follow this package insert.
- Do not interpret the test result before 10 minutes and after 15 minutes starting the test.

Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false-positive result. Avoid touching any bleeding areas of the anterior nares when collecting specimens.

- Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results. If specimen storage is necessary, swabs can be placed into extraction buffer for up to four hours. Specimens should not be stored dry.
- Do not use if the test device package is damaged.
- Do not use the kit contents beyond the expiration date.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
- If the extraction buffer contacts the skin or eye, flush with copious amounts of water.
- Handle all specimens as though they contain infectious agents.
- Do not interchange kit contents from different lots.
- Do not re-use any contents in the kit as they are single-use only.

MATERIALS

Materials provided

- Test Device
- Package Insert
- Sterilized Swab
- Tube Stand
- Extraction Tube with Filter Nozzle and Extractionbuffer

Materials required but not provided

- Timer
- Pair of Gloves
- Biohazard or Sharps container

STORAGE AND STABILITY

Store the SARS-Cov-2 Antigen Rapid Test Cassette (Swab) at room temperature or refrigerated (2-30°C). Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial. The test device must remain in the sealed pouch until use.

SPECIMEN COLLECTION AND PREPARATION

1. Specimen collection:

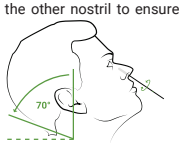
It is applicable to the diagnosis of the Novel coronavirus from the samples of anterior nares (Nasal). Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.
It is essential that correct specimen collection and preparation methods are followed. Inadequate specimen collection, improper specimen handling and/or transport may yield false results; therefore, specimen collection requires specific training and guidance due to the importance of specimen quality to obtain accurate test results. Specimens may be frozen at -80C and used up to 5 days and are stable for 4 hours in extraction buffer. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

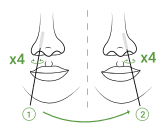
Procedural Notes

- ☑ Process the test sample immediately after collection.
- ☑ Use only provided or recommended anterior nares (Nasal) for specimen collection.
- ☑ Collect the specimen wearing safety gloves to avoid contamination.
- ☑ Do not touch the tip (specimen collection area) of the swab.
- ☑ Collect samples as soon as possible after the onset of symptoms.

1) Remove a anterior nares (Nasal) from the pouch.
2) Tilt the patient's head back 70 degrees. Carefully insert the swab into one nostril of the patient. The swab tip should be inserted no less than 2.5 cm (1 inch) from the edge of the nostril.
3) Roll the swab 3-4 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Leave the swab in the nostril for several seconds.
4) Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.
5) Withdraw the swab from the nasal cavity.

Caution: If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.

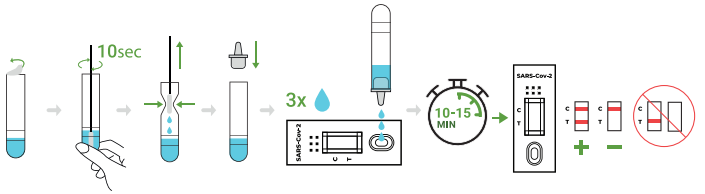




2. Test Procedures

- ☑ Allow test devices, reagents, specimens, and/or controls to equilibrate to room temperature (15~30°C) prior to testing.
- ☑ Remove The SARS-Cov-2 Antigen Rapid Test Cassette (swab) test device from its foil pouch immediately before testing.
- ☑ The SARS-Cov-2 Antigen Rapid Test Cassette (swab) IS INTENDED to be used only with a direct anterior nares (Nasal) specimen
- ☑ The SARS-Cov-2 Antigen Rapid Test Cassette (swab) kit IS NOT INTENDED for testing other liquid samples such as nasal wash or aspirate samples as results can be compromised by over dilution.

1) Remove the test device from the sealed foil pouch and use it as soon as possible. Place the test device on a clean and level surface. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2) Remove the sealed film of the specimen collection tube.
3) Place the sterilized swab specimen in the sample extraction buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
4) Remove the sterilized swab while squeezing the sterilized swab head against the inside of Buffer as you remove it to expel as much liquid as possible from the swab. Discard the sterilized swab in accordance with your biohazard waste disposal protocol.
5) Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the sample extraction buffer. See illustration 4.
6) Add 3 drops of the solution (approx.80ul) to the sample well and then start the timer. Read the result at 10~15 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

NOTE: The test results should be read and interpreted at 10 minutes after the sample application and the reading and interpretation of the results should not exceed 15 minutes. The test results should not be interpreted using any instruments.

POSITIVE: Two red lines appear. One red line appears in the control region"C", and one red line in the test region"T". The shade of color may vary, but it should be considered positive whenever there is even a faint line.

NEGATIVE: Only one red line appears in the control region"C", and no line in the test region"T". The negative result indicates that there are no Novel coronavirus particles in the sample or the number of viral particles is below the detectable range.

INVALID: No red line appears in the control region"C". The test is invalid even if there is a line on test region"T". Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

- The SARS-Cov-2 Antigen Rapid Test Cassette (Swab) is an acute-phase screening test for qualitative detection. Sample collected may contain antigen titles below the reagent's sensitivity threshold, so a negative test result does not exclude infection with novel coronavirus
- The SARS-Cov-2 Antigen Rapid Test Cassette (Swab) detects viable and non-viable novel coronavirus antigen. Test performance depends on antigen load in the sample and may not correlate with cell culture performed on the same sample. A positive test does not rule out the possibility that other pathogens may be present. Therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
- 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.
- Performance of the test has not been established for monitoring antiviral treatment of novel coronavirus.
- 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 List.
- 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 a molecular assay or ELISA.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

This clinical evaluation by Spring Healthcare Services was conducted from March 5th 2021 to March 25th 2021. In this trial, 316 clinical samples were selected. There were 114 PCR-positive and 202 PCR-negative samples that were tested from lot 20211012, 20211014, 20211015 with expiration date 03/2023, 03/2023, 04/2023. The SARS-Cov-2 Antigen Rapid Test Cassette (Swab) and SARS-CoV-2 PCR were detected by means of immunochromatography and the positive and negative match rates were calculated.

Results overview

The SARS-Cov-2 Antigen Rapid Test Cassette (swab) and the SARS-CoV-2 PCR test were detected simultaneously, and the positive coincidence rate, negative coincidence rate, and total coincidence rate were calculated.

1) 114 cases of positive samples confirmed by Nucleic Acid Test (RT-PCR): tested with SARS-Cov-2 Antigen Rapid Test Cassette (swab), 112 cases were positive, 2 case were negative.

2) 202 cases of negative samples confirmed by Nucleic Acid Test (RT-PCR): tested with SARS-Cov-2 Antigen Rapid Test Cassette (swab), 202 cases were negative, 0 cases were positive.

Method		RT - PCR		Total Results
The SARS -Cov-2 Antigen Rapid Test Cassette(Swab)	Results	Positive	Negative	
	Positive	112	0	112
	Negative	2	202	204
Total Results		114	202	316

Analysis
Clinical sensitivity = **100 x 112/114 = 98,25% (95% KI: 96,80%-99,70%)**
Clinical specificity = **100 x 202/202 = >99,99% (95% KI: 97,90%-100%)**
Accuracy = **100 x (112+202)/316 = 99,37 (95% KI: 98,50%-100%)**
Pe = (114*202+112*204)/ (316*316) = 0,46
*:95% confidence interview

Limit of Detection (LoD)

2019-nCoV Strain Tested	C-TAN-nCOV wuhan strain 01				
Stock 2019-nCoV Concentration	1 X 106 TCID50/mL				
Dilution	1/100	1/200	1/400	1/800	1/1600
Concentration in Dilution tested (TCID50/ml)	$1X10^4$	$5X10^3$	$2.5X\ 10^3$	$1.25X10^3$	$6.25X10^2$
Call rates of 20 replicates near cut-off	100(20/20)	100(20/20)	100(20/20)	95(19/20)	10(2/20)
Limit of Detection (LoD) per Virus Strain	1.25 X 103 TCID50/mL				

Cross Reactions & Microbial Interference

Cross-reactivity was evaluated by testing various viruses and microorganisms that potentially may cross-react with the positive or negative test results. The final concentration of each organism is documented in the table below. Each microorganism and virus was prepared in the absence and presence of SARS-CoV-2 at 3 x LoD concentration. Both the cross-reactivity and microbial interference studies were conducted in triplicate.

Virus/Bacteria/Parasite	Strain	Source/Specimen type	Concentration
MERS-coronavirus	N/A	SINO/recombinant protein	72ug/ml
Adenovirus	Type 1	AMMS/Inactivated virus	1.5 x 10^6TCID$_{50}$/ml
	Type 3	AMMS/Inactivated virus	7.5 x 10^6TCID$_{50}$/ml
	Type 5	AMMS/Inactivated virus	4.5 x 10^6TCID$_{50}$/ml
	Type 7	AMMS/Inactivated virus	1.0 x 10^6TCID$_{50}$/ml
	Type 8	AMMS/Inactivated virus	1.0 x 10^6TCID$_{50}$/ml
	Type 11	AMMS/Inactivated virus	2.5 x 10^6TCID$_{50}$/ml
	Type 18	AMMS/Inactivated virus	2.5 x 10^6TCID$_{50}$/ml
	Type 23	AMMS/Inactivated virus	6.0 x 10^6TCID$_{50}$/ml
	Type 55	AMMS/Inactivated virus	1.5 x 10^6TCID$_{50}$/ml
Influenza A	H1N1 Denver	AMMS/Inactivated virus	3.0 x 10^8TCID$_{50}$/ml
	H1N1 WS/33	AMMS/Inactivated virus	2.0 x 10^8TCID$_{50}$/ml
	H1N1 A/Mal/302/54	AMMS/Inactivated virus	1.5 x 10^8TCID$_{50}$/ml
	H1N1 New Caledonia	AMMS/Inactivated virus	7.6 x 10^8TCID$_{50}$/ml
	H3N2 A/ Hong Kong/8/68	AMMS/Inactivated virus	4.6 x 10^8TCID$_{50}$/ml
Influenza B	Nevada/03/2011	AMMS/Inactivated virus	1.5 x 10^8TCID$_{50}$/ml
	B/Lee/40	AMMS/Inactivated virus	8.5 x 10^8TCID$_{50}$/ml
	B/Taiwan/2/62	AMMS/Inactivated virus	4.0 x 10^8TCID$_{50}$/ml
Respiratory syncytial virus	N/A	AMMS/Inactivated virus	2.5 x 10^8TCID$_{50}$/ml
Legionella pneumophila	Bloomington-2	AMMS/Inactivated Bacteria	1 x 10^6PFU/ml
	Los Angeles-1	AMMS/Inactivated Bacteria	1 x 10^6PFU/ml
	82A3105	AMMS/Inactivated Bacteria	1 x 10^6PFU/ml
Rhinovirus A16	N/A	AMMS/Inactivated virus	1.5 x 10^6TCID$_{50}$/ml
Mycobacterium tuberculosis	K	AMMS/Inactivated Bacteria	1 x 10^5PFU/ml
	Erdman	AMMS/Inactivated Bacteria	1 x 10^5PFU/ml
	HN878	AMMS/Inactivated Bacteria	1 x 10^5PFU/ml
	CDC1551	AMMS/Inactivated Bacteria	1 x 10^5PFU/ml
	H37Rv	AMMS/Inactivated Bacteria	1 x 10^5PFU/ml
Streptococcus pneumoniae	4752-98 [Maryland (D1)6B-17]	AMMS/Inactivated Bacteria	1 x 10^5PFU/ml
	178 [Poland 23F-16]	AMMS/Inactivated Bacteria	1 x 10^5PFU/ml
	262 [CIP 104340]	AMMS/Inactivated Bacteria	1 x 10^5PFU/ml
	Slovakia 14-10 [29055]	AMMS/Inactivated Bacteria	1 x 10^5PFU/ml
	Typing strain T1 [NCIB 11841, SF 130]	AMMS/Inactivated Bacteria	1 x 10^5PFU/ml
Mycoplasma pneumoniae	Mutant 22	AMMS/Inactivated Bacteria	1 x 10^5PFU/ml
	FHstrainofEatonAgent [NCTC 10119]	AMMS/Inactivated Bacteria	1 x 10^5PFU/ml
	36M129-B7	AMMS/Inactivated Bacteria	1 x 10^5PFU/ml
Coronavirus	229E	AMMS/Inactivated virus	1.5 x10^6TCID$_{50}$/ml
	OC43	AMMS/Inactivated virus	1.5 x10^6TCID$_{50}$/ml
	NL63	AMMS/Inactivated virus	1.5 x10^6TCID$_{50}$/ml
	HKU1	AMMS/Inactivated virus	1.5 x10^6TCID$_{50}$/ml
Human Metapneumovirus (hMPV) 3 Type B1	Peru2-2002	AMMS/Inactivated virus	1.5 x10^6TCID$_{50}$/ml
Human Metapneumovirus (hMPV) 16 Type A1	IA10-2003	AMMS/Inactivated virus	1.5 x10^6TCID$_{50}$/ml
Parainfluenza virus	Type 1	AMMS/Inactivated virus	1.5 x10^6TCID$_{50}$/ml
	Type 2	AMMS/Inactivated virus	1.5 x10^6TCID$_{50}$/ml
	Type 3	AMMS/Inactivated virus	1.5 x10^6TCID$_{50}$/ml
	Type 4A	AMMS/Inactivated virus	1.5 x10^6TCID$_{50}$/ml
Enterovirus	N/A	AMMS/Inactivated virus	4.0 x 10^5TCID$_{50}$/ml
Haemophilus influenzae	N/A	AMMS/Inactivated virus	1 x 10^6CFU/ml
Streptococcus pyogenes	N/A	AMMS/Inactivated virus	1.6 x 10^6CFU/ml
Streptococcus aureus	N/A	AMMS/Inactivated virus	2 x 10^6CFU/ml
Streptococcus epidermidis	N/A	AMMS/Inactivated virus	2 x 10^6CFU/ml
Candida albicans	N/A	AMMS/Inactivated virus	1.8 x 10^6CFU/ml
Bordetella pertussis	N/A	AMMS/Inactivated virus	1.4 x 10^6CFU/ml
Chlamydia pneumoniae	N/A	AMMS/Inactivated virus	1 x 10^6IFU/ml
Pooled Human Nasal Wash	N/A	N/A	100%

The results show neither observed cross-reactivity nor microbial interference with the organisms at the concentrations tested.

Interfering Substances Effect

To assess substances with the potential to interfere with the performance of the SARS-Cov-2 Antigen Rapid Test Cassette (swab), positive and negative samples were tested with the addition of potentially interfering substances. The SARS-CoV-2 target concentration in the positive samples was approximately 2x LoD. All samples tested produced expected results, demonstrating that the SARS-Cov-2 Antigen Rapid Test Cassette (swab) performance was not affected by any of the 32 potentially interfering substances listed in the table below at the concentrations tested.

Potential Interfering Substances	Concentration	Potential Interfering Substances	Concentration
Acetaminophen	10 mg/ml	Mometasone	1 mg/ml
Acetylsalicylic	15 mg/ml	Mucin	2%
Beclomethasone	0.5 mg/ml	Mupirocin	1 mg/ml
Benzocaine	5 mg/ml	OTC Throat drop (Halls)	15%
Budesonide	2 mg/ml	OTC Throat drop (Ricola)	15%
Chlorpheniramine maleate	5 mg/ml	OTC Nasal spray (Afrin)	15%
Dexamethasone	1 mg/ml	OTC Nasal spray (VicksSinex)	15%
Dextromethorphan HBr	2 mg/ml	OTC Nasal spray (Zicam)	15%
Diphenhydramine HCl	5 mg/ml	Oxymetazoline HCl	10 mg/ml
Ephedrine HCl	10 mg/ml	Phenylephrine HCl	5 mg/ml
Flunisolide	5 mg/ml	Phenylpropanolamine	5 mg/ml
Fluticasone	1 mg/ml	Tobramycin	1 mg/ml
Guaiacol Glyceryl Ether	20 mg/ml	Triamcinolone	1 mg/ml
Histamine Dihydrochloride	10 mg/ml	Whole Blood	4%
Menthol	10 mg/ml	Zanamivir	1 mg/ml
Homeopathic (Alkalol)	5% v/v	Tamiflu (Oseltamivir Phosphate)	10 mg/ml

The interfering effects of biotin concentrations ranging between 625 ng/mL and 10 µg/mL were tested in a separate study. Biotin concentrations up to 1.25 µg/ml did not lead to false results. Biotin concentrations ≥2.5 µg/ml can cause false-negative COVID-19 results with the SARS-Cov-2 Antigen Rapid Test Cassette (Swab).

High-dose Hook Effect

The SARS-Cov-2 Antigen Rapid Test Cassette (Swab) was tested and no high-dose hook effect was observed **for the virus concentration is 1.0×107TCID50/ml or below.**

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SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device	2℃ 30℃	Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction for use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC
REF	Catalogue number	Σ	The number of tests

PACKAGING SPECIFICATIONS

Product Code	Material	Quantity
SP-SW 106-25	Test Device	25
	Sterilized Swab	25
	Extraction Tube With Filter Nozzle	25
	Sample Extraction Buffer	25
	Tube Stand	1
	Package Insert	1
SP-SW 106-01	Test Device	1
	Sterilized Swab	1
	Extraction Tube With Filter Nozzle	1
	Sample Extraction Buffer	1
	Tube Stand	-
	Package Insert	1

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