SARS-Cov-2 Antigen Rapid Test Cassette (Saliva Spit)

REF: SP - SLS502

SPRING HEALTHCARE

CE IVD

Package Insert

For professional In Vitro Diagnostic Use Only.

INTENDED USE

SARS-Cov-2 Antigen Rapid Test Cassettee (Saliva Spit) is a polymer immunochromatographic technology and double antibody sandwich principle that is intended for the qualitative detection of the N protein antigen from SARS-CoV-2 in human saliva specimens directly.
The identification is based on SARS-CoV-2 N protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. It will provide information for clinical doctors to prescribe correct medications within the first seven 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 Cassettee (Saliva Spit) 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

Coronavirus is a single-stranded positive-sense RNA virus with an envelope of about 80 to 120 nm in diameter. Its genetic material is the largest of all RNA viruses and is an important pathogen of many domestic animals, pets, and human diseases. It can cause a variety of acute and chronic diseases. Common signs of a person infected with a coronavirus include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death. The 2019 new coronavirus, or "SARS-CoV-2 (COVID-19)" named by the World Health Organization can cause pneumonia epidemic.

The detection results of this kit are for clinical reference only. The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required.

PRINCIPLE

The SARS-Cov-2 Antigen Rapid Test Cassette (Saliva Spit) uses polymer immunochromatographic technology and double antibody sandwich principle were used to detect the novel coronavirus antigen in human saliva specimens with the use of capture method.

During the test, a specimen solution is added to the sample well of the kit. The specimen is first mixed with the colored polymer-labeled novel coronavirus monoclonal antibody 1 on the release pad, and then chromatographed on a nitrocellulose membrane. If the specimen contains novel coronavirus antigens, these antigens will first bind to colored polymer-labeled novel coronavirus monoclonal antibody 1, so that when the mixture is chromatographed on a nitrocellulose membrane, it will be immobilized with the novel coronavirus monoclonal antibody 2. The detection line (T line) was captured to form a colored polymer-labeled novel coronavirus monoclonal antibody 1-antigen novel coronavirus monoclonal antibody 2 immune complex. Therefore, a red line appeared on the T line, which was a positive result. If no novel coronavirus antigen is present in the specimens of the subject, a red line will not be formed on the test line (T line), which is a negative result. The quality control line (C line) on the test cassette is coated with goat anti-mouse antibody. Under normal circumstances, a red line should appear on the quality control line (C line) during the test to prove that the test cassette is working properly.

STORAGE AND STABILITY

Store The SARS-Cov-2 Antigen Rapid Test Cassette (Saliva Spit) at 2-30°C. Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

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 60 Minutes).
- In order to obtain accurate results, the tester must follow this package insert.
- Do not interpret the test result before 10 minutes and after 20 minutes after starting the test.
- 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.
- Perform test at room temperature 15 to 30 °C.
- 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.
- Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
- Nitrile or latex gloves should be worn when performing this test.
- If the extraction buffer contacts the skin or eye, flush with copious amounts of water.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Reagents contain sodium azide, which is harmful if inhaled, swallowed, or exposed to skin. Contact with acids produces a very toxic gas. If there is contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.
- Do not interchange kit contents from different lots.
- Do not re-use any contents in the kit as they are single-use only.
- Avoid using Blood Samples.

MATERIALIEN

Materials provided

- Test Device
- Collection Tube
- Pipette
- Extraction Buffer
- Saliva Collector
- Work Station
- Package Insert

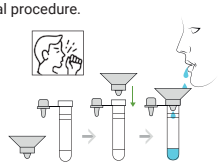
Materials required but not provided

- Pair of gloves
- Timer
- Biohazard or sharp container

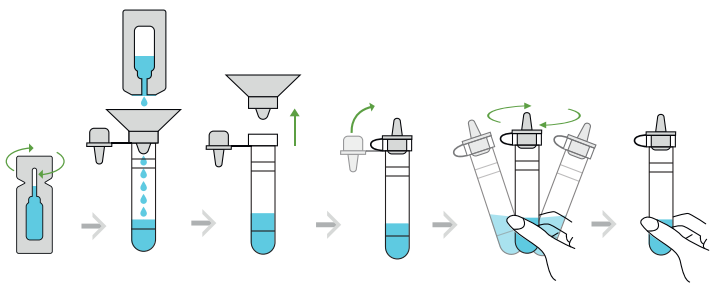
SPECIMEN COLLECTION AND PREPARATION

The SARS-Cov-2 Antigen Rapid Test Cassette (Saliva Spit) is designed for the use of buffered human fresh saliva as the specimen. Collecting specimen must follow standard clinical procedure.

Do not place anything into the mouth including food, drink, gum, or tobacco products for at least 30 minutes prior to collection of saliva specimen.



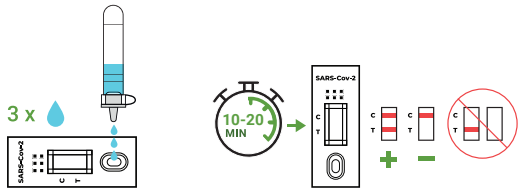
1. Use the collection tube and saliva collector to collect saliva.
2. **Cough deeply twice before collecting the samples.**
3. Insert the saliva collector into the collection tube, then put the saliva collector close to lips and let the saliva flow into the collection tube. The volume of saliva needs to be at the scale mark (approx.300µL).
4. If the volume of saliva is too much, use a dropper to remove the excess saliva until the final solution at the scale mark (approx. 300µL).
5. Tighten the lid of the collection tube and mix the liquid of the chamber well before using (Shaking up and down for about 20 times).



TEST PROCEDURE

Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.

1) Please read the instruction manual carefully before testing.
2) Place the collection tube with saliva collector which has saliva in the work station. Unscrew the lid of an extraction buffer. Add all of the extraction buffer into the collection tube.
3) Discard the saliva collector. Cover the collection tube with the dropper tip onto the collection tube. Shake the collection tube more than 3 times vigorously to mix the saliva and the extraction buffer, then squeeze the mixed solution 10 times to allow the saliva to be thoroughly mixed.
4) Remove the test cassette from the sealed pouch.
5) Specimen adding: Reverse the collection tube, holding the tube upright, transfer 3 drops (approximately 100 µL) slowly to the specimen well (S) of the test cassette, then start the timer.
6) Timing observation: judge the result 10 minutes after specimen adding, do not observe the result 20 minutes later.



INTERPRETATION OF RESULTS

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

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

INVALID: No red band appears in the control region (C). The test is invalid even if there is a band 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.

LIMITATIONS

- The SARS-Cov-2 Antigen Rapid Test Cassettee (Saliva Spit) is an initial 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 (Saliva Spit) 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.
- Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- Extracted specimens may be frozen at -80°C and used up to 5 days after freezing and are stable for 4 hours in extraction buffer at room temperature.
- The detection of SARS-CoV-2 nucleocapsid antigen is dependent upon proper specimen collection, handling, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
- Results from the device should be correlated with the clinical history, epidemiological data and other data available to the clinician evaluating the patient.
- This device has been evaluated for use with human specimen material only.
- This device is a qualitative test and does not provide information on the viral concentration present in the specimen.
- The prevalence of infection will affect the test's predictive values.
- Positive and negative predictive values are highly dependent on prevalence. False-negative test results are more likely during peak activity when the prevalence of the disease is high. False-positive test results are more likely during the periods of low SARS-CoV-2 activity when prevalence is moderate to low.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

Clinical evaluation was performed to compare the results obtained by SARS-Cov-2 Antigen Rapid Test Cassette (Saliva Spit) and PCR. The results were summarized below:

		SARS-CoV-2 Molecular PCR		Total
		Positive	Negative	
SARS-Cov-2 Antigen Rapid Test Cassette (Saliva Spit)	Positive	151	0	151
	Negative	4	304	308
Total		155	304	459

Relative Sensitivity: 97.41% (95% CI= 95.96% ~ 98.86%)
Relative Specificity: 99.99% (95% CI= 97.90% ~ 100.00%)
Accuracy: 99.13% (95% CI= 98.28% ~ 99.98%)

Cross Reactivity

SARS-Cov-2 Antigen Rapid Test Cassette (Saliva Spit) was evaluated with a total of 47 other viruses and bacteria. The results show that SARS-Cov-2 Antigen Rapid Test Cassette (Saliva Spit) has no cross-reactivity with other viruses or microorganisms.

Table 2: Cross-reactivity results

Virus/Bacteria/Parasite	Strain	Concentration	Results
Mers-Coronavirus	N/A	36 ug/mL	No Cross-Reactivity
Adenovirus	Type 1	1.5×10^5 $TCID_{50}$/mL	No Cross-Reactivity
	Type 3	7.5×10^5 $TCID_{50}$/mL	No Cross-Reactivity
	Type 5	4.5×10^4 $TCID_{50}$/mL	No Cross-Reactivity
	Type 7	1.0×10^4 $TCID_{50}$/mL	No Cross-Reactivity
	Type 8	1.0×10^4 $TCID_{50}$/mL	No Cross-Reactivity
	Type 11	2.5×10^3 $TCID_{50}$/mL	No Cross-Reactivity
	Type 18	2.5×10^3 $TCID_{50}$/mL	No Cross-Reactivity
	Type 23	6.0×10^3 $TCID_{50}$/mL	No Cross-Reactivity
	Type 55	1.5×10^3 $TCID_{50}$/mL	No Cross-Reactivity
Influenza A	H1N1 Denver	3.0×10^7 $TCID_{50}$/mL	No Cross-Reactivity
	H1N1 WS/33	2.0×10^7 $TCID_{50}$/mL	No Cross-Reactivity
	H1N1 A/Mal/302/54	1.5×10^7 $TCID_{50}$/mL	No Cross-Reactivity
	H1N1 New Caledonia	7.6×10^7 $TCID_{50}$/mL	No Cross-Reactivity
	H3N2A/Hong Kong/8/68	4.6×10^7 $TCID_{50}$/mL	No Cross-Reactivity
Influenza B	Nevada/03/2011	1.5×10^7 $TCID_{50}$/mL	No Cross-Reactivity
	B/Lee/40	8.5×10^7 $TCID_{50}$/mL	No Cross-Reactivity
	B/Taiwan/2/62	4.0×10^7 $TCID_{50}$/mL	No Cross-Reactivity
Respiratory syncytial virus	N/A	2.5×10^7 $TCID_{50}$/mL	No Cross-Reactivity
Legionella pneumophila	Bloomington-2	1×10^5 PFU/mL	No Cross-Reactivity
	Los Angeles-1	1×10^5 PFU/mL	No Cross-Reactivity
	82A3105	1×10^5 PFU/mL	No Cross-Reactivity
Mycobacterium tuberculosis	K	1×10^5 PFU/mL	No Cross-Reactivity
	Erdman	1×10^5 PFU/mL	No Cross-Reactivity
	HN878	1×10^5 PFU/mL	No Cross-Reactivity
	CDC1551	1×10^5 PFU/mL	No Cross-Reactivity
	H37Rv	1×10^5 PFU/mL	No Cross-Reactivity
Streptococcus pneumoniae	4752-98 [Maryland (D1)6B-17]	1×10^5 PFU/mL	No Cross-Reactivity
	178 [Poland 23F-16]	1×10^5 PFU/mL	No Cross-Reactivity
	262 [CIP 104340]	1×10^5 PFU/mL	No Cross-Reactivity
	Slovakia 14-10 [29055]	1×10^5 PFU/mL	No Cross-Reactivity
Streptococcus pyogens	Typing strain T1 [NCIB 11841, SF 130]	1×10^5 PFU/mL	No Cross-Reactivity
Mycoplasma pneumoniae	Mutant 22	1×10^5 PFU/mL	No Cross-Reactivity
	FH strain of E atom Agent [NCTC10119]	1×10^5 PFU/mL	No Cross-Reactivity
	36M129-B7	1×10^5 PFU/mL	No Cross-Reactivity
Coronavirus	229E	1.5×10^5 $TCID_{50}$/mL	No Cross-Reactivity
	OC43	1.5×10^5 $TCID_{50}$/mL	No Cross-Reactivity
	NL63	1.5×10^5 $TCID_{50}$/mL	No Cross-Reactivity
	HKU1	1.5×10^5 $TCID_{50}$/mL	No Cross-Reactivity
Human Metapneumovirus (hMPV) 3 Type B1	Peru2-2002	1.5×10^5 $TCID_{50}$/mL	No Cross-Reactivity
Human Metapneumovirus (hMPV) 16 Type A1	IA10-2003	1.5×10^5 $TCID_{50}$/mL	No Cross-Reactivity
Parainfluenza virus	Type 1	1.5×10^5 $TCID_{50}$/mL	No Cross-Reactivity
	Type 2	1.5×10^5 $TCID_{50}$/mL	No Cross-Reactivity
	Type 3	1.5×10^5 $TCID_{50}$/mL	No Cross-Reactivity
	Type 4A	1.5×10^5 $TCID_{50}$/mL	No Cross-Reactivity
Rhino VIRUS A16	N/A	1.5×10^5 $TCID_{50}$/mL	No Cross-Reactivity
SARS-Cov-2	C-TAN-nCOV wuhan strain 01	1.5×10^5 $TCID_{50}$/mL	No Cross-Reactivity

Microbial Interference

Microbial interference study was performed to evaluate microbial interference effect, using samples spiked at 3×LoD SARS-CoV-2 concentration and a high interferent level.

Table 3: Microbial interference Results

No.	Microorganism	Concentration	Results
1.	Streptococcus hemolyticus	1×10^5 cfu/ml	No Interference
2.	Pseudomonas aeruginosa	1×10^5 cfu/ml	No Interference
3.	Staphylococcus aureus	1×10^5 cfu/ml	No Interference
4.	Escherichia coli	1×10^5 cfu/ml	No Interference
5.	Candida albicans	1×10^5 cfu/ml	No Interference
6.	Aspergillus Niger	1×10^5 cfu/ml	No Interference

The results show that microorganism listed above has no microbial interference on the negative and positive test results, and these substances do not cross-react with SARS-Cov-2 Antigen Rapid Test Cassette (Saliva Spit).

Endogenous Interference

SARS-Cov-2 Antigen Rapid Test Cassette (Saliva Spit) was evaluated with a total of 38 Endogenous Interference Substances.

Substance	Concentration	Substance	Concentration
Acetaminophen	10 mg/ml	OTC Throat drop (Ricola)	15%
Acetyl salicylic acid	15 mg/ml	OTC Nasal spray (Afrin)	15%
Beclomethasone	0.5 mg/ml	OTC Nasal spray (VicksSinex)	15%
Benzocaine	1.5 mg/mL	OTC Nasal spray (Zicam)	15%
Budesonide	2 mg/ml	Oxymetazoline HCl	10 mg/ml
Chlorpheniramine maleate	5 mg/ml	Phenylephrine HCl	5 mg/ml
Dexamethasone	1 mg/ml	Phenylpropanolamine	5 mg/ml
Dextromethorphan HBr	2 mg/ml	Tobramycin	1 mg/ml
Diphenhydramine HCl	5 mg/ml	Triamcinolone	1 mg/ml
Ephedrine HCl	10 mg/ml	Whole Blood	4%
Flunisolide	5 mg/ml	Zanamivir	1 mg/ml
Fluticasone	1 mg/ml	Homeopathic (Alkalol)	5% v/v
Guaiacol Glyceryl Ether	20 mg/ml	Tamiflu (Oseltamivir Phosphate)	10 mg/ml
Histamine Dihydrochloride	10 mg/ml	biotin	10 ug/ml
Menthol	1.5 mg/mL	biotin	5 ug/ml
Mometasone	1 mg/ml	biotin	2.5 ug/ml
Mucin	0.50%	biotin	1.25 ug/ml
Mupirocin	1 mg/ml	biotin	625 ng/ml
OTC Throat drop (Halls)	15%	biotin	312.5 ng/ml

The results show that endogenous interference substances listed in above table has no inference effect on the negative and positive test results, and these substances do not cross-react with SARS-Cov-2 Antigen Rapid Test Cassette (Saliva Spit).

Food/beverage Interference

Food/beverage interference study was performed to evaluate the potential interference of food/beverage in saliva samples on SARS-Cov-2 Antigen Rapid Test Cassette (Saliva Spit).

Table 5: Food/beverage interference Results

Substance	Concentration	Results
Mouth Wash	1%	No Interference
Orange Juice	1%	No Interference
Alcohol	1%	No Interference
MSG	1%	No Interference
Salt	1%	No Interference
Gum	1%	No Interference
Cough Syrup	1%	No Interference
Sugar	1%	No Interference
Tee	1%	No Interference
Food Color: red	1%	No Interference
Food Color: blue	1%	No Interference
Food Color: green	1%	No Interference
Cranberry Juice	1%	No Interference
Carbonated Cola	1%	No Interference
Baking Soda	1%	No Interference
Cigarette	1%	No Interference
Toothpaste	1%	No Interference

The results show that 1% substance listed in above Table has no inference effect on the negative and positive test results, and these substances have no interference on SARS-Cov-2 Antigen Rapid Test Cassette (Saliva Spit).

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SYMBOLS

Symbols	Meaning	Symbols	Meaning
IVD	For in vitro diagnostic use only	2°C 30°C	Store between 2-30°C
	Manufacturer	EC REP	European union authorized representative
	Don't use the product		Use by date
	Do not reuse		Consult instructions for use
LOT	Lot Number	Σ	Tests per kit
REF	Catalog No.		Keep dry
	Biological risks	CE	The product meets the basic requirements of European in vitro diagnostic medical

PACKAGING SPECIFICATIONS

Product Code	Material	Quantity	Product Code	Material	Quantity
SP – SLS 502-20	Test Device	20	SP – SLS 502-01	Test Device	1
	Saliva Collectors	20		Saliva Collectors	1
	Extraction buffer	20		Extraction buffer	1
	Collection Tubes	20		Collection Tubes	1
	Work Station	1		Work Station	–
	Droppers	20		Droppers	1
	Package Insert	1		Package Insert	1

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