

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

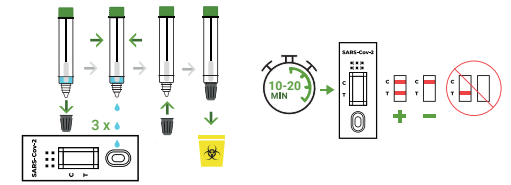
REF: SP - SL502

S P R I N G
HEALTHCARE

CE IVD

Package Insert

For professional In Vitro Diagnostic Use Only.



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 Cassette (Saliva) 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) 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) and PCR. The results were summarized below:

Table: SARS-Cov-2 Antigen Rapid Test Cassette vs. PCR

		Rapid Test Device		Total Results
		+	-	
PCR	+	127	3	130
	-	0	200	200
Total Results		127	203	330

Relative sensitivity: $127/130 = 97.69\%$ (95% CI 96.07% ~ 99.31%)

Relative specificity: $200/200 = 100\%$ (95% CI 99.56% ~ 100%)

Overall agreement: $(127+200) / (127+0+3+200) * 100\% = 99.09\%$ (95% CI 98.07% ~ 99.99%)

CI: Confidence Interval

INTENDED USE

SARS-Cov-2 Antigen Rapid Test Cassette (Saliva) 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 saliva specimens 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 (Saliva) 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) 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 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 20 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.

STORAGE AND STABILITY

Store The SARS-Cov-2 Antigen Rapid Test Cassette (Saliva) 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 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. 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.
- 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 though 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
- Saliva Swab
- Extraction Vial with buffer
- Package Insert

Materials required but not provided

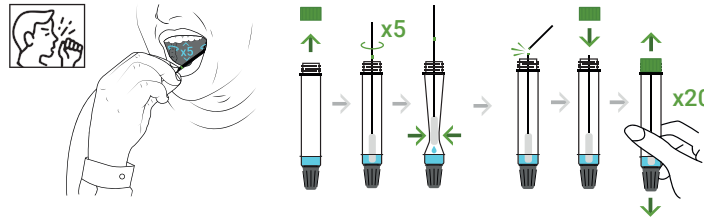
- Pair of gloves
- Timer
- Biohazard or sharp container

SPECIMEN COLLECTION AND PREPARATION

The SARS-Cov-2 Antigen Rapid Test Cassette (Saliva) 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 10 minutes prior to collection of saliva specimen.

- Remove the swab from the sealed pouch.
- Cough deeply twice before collecting the samples.**
- Insert the sponge end of the collector into the mouth. Then swab back and forth along the gum line from one end to the other end of the upper and lower gum, both side of the cheek, and top of the tongue 3 to 5 times.
- Open the lid of the collection tube. Remove the saturated collector pad out of the mouth and place it into the tube which contains 1 ml sample extraction buffer, and then fully stirred along the wall of the tube. Break off the collector, leaving the sponge end of the collector in the chamber.
- 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.

- Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
- Put the test device on a clean and level surface.
- Shake the swab specimen in the extraction vial to well mix.
- To run test, twist open the bottom screw cap of the extraction vial to expose dropper tip. Transfer 3 drops of the specimen to the sample well of the test device. Close the nozzle and dispose of the extraction tube containing the used swab according to your local regulations and biohazard waste disposal protocol.
- Start timer. Read the result at 10~20 minutes. Do not interpret the result after 20 minutes.

Cross Reactivity

SARS-Cov-2 Antigen-Schnelltestkassette (Speichel) wurde mit insgesamt 47 anderen Viren und Bakterien ausgewertet. Die Ergebnisse zeigen, dass die SARS-Cov-2-Antigen-Schnelltestkassette (Speichel) keine Kreuzreaktivität mit anderen Viren oder Mikroorganismen aufweist.

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 ⁷ TCID ₅₀ /mL	No Cross-Reactivity
	Type 3	7.5 × 10 ⁷ TCID ₅₀ /mL	No Cross-Reactivity
	Type 5	4.5 × 10 ⁷ TCID ₅₀ /mL	No Cross-Reactivity
	Type 7	1.0 × 10 ⁷ TCID ₅₀ /mL	No Cross-Reactivity
	Type 8	1.0 × 10 ⁷ TCID ₅₀ /mL	No Cross-Reactivity
	Type 11	2.5 × 10 ⁷ TCID ₅₀ /mL	No Cross-Reactivity
	Type 18	2.5 × 10 ⁷ TCID ₅₀ /mL	No Cross-Reactivity
	Type 23	6.0 × 10 ⁷ 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 ⁸ PFU/mL	No Cross-Reactivity
	Los Angeles-1	1 × 10 ⁸ PFU/mL	No Cross-Reactivity
	82A3105	1 × 10 ⁸ PFU/mL	No Cross-Reactivity
Mycobacterium tuberculosis	K	1 × 10 ⁸ PFU/mL	No Cross-Reactivity
	Erdman	1 × 10 ⁸ PFU/mL	No Cross-Reactivity
	HN878	1 × 10 ⁸ PFU/mL	No Cross-Reactivity
	CDC1551	1 × 10 ⁸ PFU/mL	No Cross-Reactivity
	H37Rv	1 × 10 ⁸ PFU/mL	No Cross-Reactivity
Streptococcus pneumoniae	4752-98 [Maryland (D1)6B-17]	1 × 10 ⁸ PFU/mL	No Cross-Reactivity
	178 [Poland 23F-16]	1 × 10 ⁸ PFU/mL	No Cross-Reactivity
	262 [CIP 104340]	1 × 10 ⁸ PFU/mL	No Cross-Reactivity
	Slovakia 14-10 [29055]	1 × 10 ⁸ PFU/mL	No Cross-Reactivity
Streptococcus pyogenes	Typing strain T1 [NCIB 11841, SF 130]	1 × 10 ⁸ PFU/mL	No Cross-Reactivity
Mycoplasma pneumoniae	Mutant 22	1 × 10 ⁸ PFU/mL	No Cross-Reactivity
	FH strain of E atom Agent [NCTC10119]	1 × 10 ⁸ PFU/mL	No Cross-Reactivity
	36M129-B7	1 × 10 ⁸ PFU/mL	No Cross-Reactivity
Coronavirus	229E	1.5 × 05TCID ₅₀ /mL	No Cross-Reactivity
	OC43	1.5 × 05TCID ₅₀ /mL	No Cross-Reactivity
	NL63	1.5 × 05TCID ₅₀ /mL	No Cross-Reactivity
	HKU1	1.5 × 05TCID ₅₀ /mL	No Cross-Reactivity
Human Metapneumovirus (hMPV) 3 Type B1	Peru2-2002	1.5 × 05TCID ₅₀ /mL	No Cross-Reactivity
Human Metapneumovirus (hMPV) 16 Type A1	IA10-2003	1.5 × 05TCID ₅₀ /mL	No Cross-Reactivity
Parainfluenza virus	Type 1	1.5 × 05TCID ₅₀ /mL	No Cross-Reactivity
	Type 2	1.5 × 05TCID ₅₀ /mL	No Cross-Reactivity
	Type 3	1.5 × 05TCID ₅₀ /mL	No Cross-Reactivity
	Type 4A	1.5 × 05TCID ₅₀ /mL	No Cross-Reactivity
Rhino VIRUS A16	N/A	1.5 × 05TCID ₅₀ /mL	No Cross-Reactivity
SARS-Cov-2	C-TAN-nCOV wuhan strain 01	1.5 × 05TCID ₅₀ /mL	No Cross-Reactivity

Microbial Interference

Microbial interference study was performed to evaluate microbial interference effect, using samples spiked at 3xLoD 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).

Endogenous Interference

SARS-Cov-2 Antigen Rapid Test Cassette (Saliva) was evaluated with a total of 13 Endogenous Interference Substances.

Table 4: Endogenous Interference

Substance	Concentration	Results
Whole Blood	4%	No Interference
Mucin	0.5%	No Interference
Benzocaine	1.5 mg/mL	No Interference
Neil Med	5% v/v	No Interference
CVS Nasal Drops (Phenylephrine)	15% v/v	No Interference
Oxymetazolin	15% v/v	No Interference
CVS Nasal Spray (Cromolyn)	15% v/v	No Interference
Zicam	5% v/v	No Interference
Sore Throat Phenol Spray	15% v/v	No Interference
Tobramycin	4 µg/mL	No Interference
Mupirocin	10 mg/mL	No Interference
Fluflucason Propionate	5% v/v	No Interference
Tamiflu	5 mg/mL	No Interference

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).

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).

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).

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SYMBOLS

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

PACKAGING SPECIFICATIONS

Product Code	Material	Quantity
SP – SL 502-20	Test Device	20
	Saliva Swab	20
	Extraction Vial with buffer	20
	Package Insert	1
SP – SL 502-01	Test Device	1
	Saliva Swab	1
	Extraction Vial with buffer	1
	Package Insert	1



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