UK

Spring Healthcare
New Generation Lolly One

Spring SARS-CoV-2 Antigen Saliva B

SPRING HEALTHCARE

for home use

SP-SL502-1B, SP-SL502-3B, SP-SL502-5B, SP-SL502-15B, SP-SL502-20B.

INTENDED USE

"The SARS-CoV-2 antigen saliva B test is used for the rapid, qualitative detection of the nucleocapside protein antigen of SARS-CoV-2 in human saliva. The test is only for the In vitro diagnostics intended for self-testing. It only provides an initial screening test result. More specific alternative diagnostic methods (molecular diagnostics and / or CT) should be performed to obtain confirmation in case of SARS-CoV-2 infection. The decision on the diagnostic procedure should lie with a doctor. This test is for home use with self-collected saliva samples in people aged 16 -69. Sampling and testing of persons under the age of 16 and persons over the age of 69 should be carried out under the guidance of an adult. For people who are not able to take the test themselves, the test should be taken by the guardians or adults. Sick or disabled people (including people with color vision defects) should be assisted in the examination.
The World Health Organization (WHO) has designated the disease caused by the SARS-CoV-2 virus as coronavirus 2019 or COVID-19. The SARS-CoV-2 virus can cause mild to severe respiratory diseases and has spread worldwide. Cases of serious illnesses and deaths have been reported. Common symptoms of COVID-19 are fever, fatigue and dry cough. Some patients may experience pain, nasal congestion, headache, conjunctivitis, sore throat, diarrhea, loss of taste or smell, or rash or discoloration of the fingers or toes. The mean incubation period is estimated to be 1- 5 days with symptoms expected to appear within 12 days of infection. The SARS-CoV-2 antigen saliva B test is based on immunochromatography technology. Each test device has one line of monoclonal anti-SARS-CoV-2 antibodies on the detection line (T line) and one line of polyclonal anti-mouse IgG antibodies on the quality control line (C line). When the extracted sample is placed in the sample well, it reacts with the labeled antibody and forms a complex. The mixture then travels through the membrane by capillary action and interacts with the coated monoclonal anti-SARS-CoV-2 antibody on the detection line. If the sample contains SARS-CoV-2 antigen, the detection line appears purple-red and indicates that the SARS-CoV-2 antigen is positive. Otherwise, the test result will be negative. The test cassette also includes a quality control line C which should appear purple-red in all valid tests. If the quality control line C does not appear, the test result is invalid, even if the detection line appears."

PRINCIPLE

The Spring SARS-CoV-2 Antigen Saliva B is based on colloidal gold immunochromatography assay. During the test, specimens are applied to the test cartridges. If there are SARS-CoV-2 nucleocapsid antigens in the specimens, they will bind to colloidal gold-labeled antibodies against SARS-CoV-2 N protein on conjugation pad forming virus antigen-antibody-colloidal gold complex (complex T).
During lateral flow, the complex T move along nitrocellulose membrane toward one end of the absorbent paper. When passing the line T (coated with another monoclonal antibody against virus N protein), the complex T is captured by capture antibody resulting in coloring on line T; when passing the line C, residual colloidal gold-labeled is captured by quality-control antibody resulting in coloring on line C.

COMPONENT

1.Test cartridge
2.Instructions for use

STORAGE AND STABILITY

- Store the test kit in a cool, dry place between 36-86°F (2-30°C). Keep away from light. Exposure to temperature and / or humidity outside the specified conditions may cause inaccurate results.
- Do not freeze. Use the test kit at temperatures between 59-86°F (15-30°C).
- Use the test kit between 10-90% humidity.
- Do not use the test kit beyond the expiration date (printed on the foil pouch and box).

Note: All

WARNINGS AND PRECAUTIONS

1.Read the instructions for use carefully before using this product.
2.Use the test kit once only. Do not reuse the test strip.
3.This reagent is used for in vitro diagnosis only, please do not use expired products.
4.Do not use if the kit or any kit component past the indicated expiry date.
5.Do not open the sealed pouch, unless ready to conduct the assay.
6.Do not use the components of any other type of test kit as a substitute for the components in this kit.
7.Discard and do not use any damaged or dropped Test Cassette or material.
8.Use of Nitrile, Latex (or equivalent) gloves is recommended when handling patient samples. Wash hands thoroughly after performing the test.
9.Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10.Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
11.Using other sample types may cause inaccurate or invalid test results.
12.Saliva comes from respiratory tract. It is the type of sample recommended by WHO.
13.Keep the test kit away from children to reduce the risk of accidentally swallowing small parts.
14.This test is for presumptive screening only. Please consult a doctor to discuss your test result and to find out whether additional tests are needed. Please also consult a doctor if you have any concerns about your health, if you are experiencing prolonged symptoms, or if your symptoms are worsening.
15.Bring all reagents to room temperature (15~30℃) before use.
16.If the test line or control line is out of the test window, do not use the test cartridge . The test result is invalid and retest the sample with another one.
17.If your test result is positive you must have a confirmatory laboratory PCR test. Consult your doctor for any follow-up clinical care.
18.Dispose of used products, samples, and other consumables as medical wastes under relevant regulations.
19.Repeat testing is recommended (e.g. within 1-3 days) if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement.
20.Even if your test result is negative, continue to observe all applicable hygiene and safety measures. Even with a negative result, you may still be infectious. If you are showing symptoms you must seek immediate further testing by a laboratory PCR.

MATERIAL

Materials provided

- Test Device
- Package Insert

Materials required but not provided

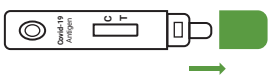
- Pair of gloves
- Timer

TEST PROCEDURES

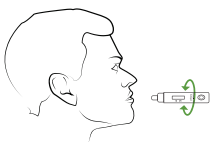
Prepare for the test
1.Before collecting oral fluid, please do not placed anything in the mouth including food, drink, gum, alcohol and tobacco for at least 10 minutes prior to collection.
2.Restore the test devices to room temperature (15-30°C) for around 10 min prior to testing.
3.Prepare a time device (e.g. watch, clock or timer)

Perform the test
1. Deeply cough 3~5 times. Note: Please cover your mouth and nose with a mask or tissue paper and keep distance from other people.

2. Remove the cassette device from the sealed pouch and take the cap off gently by holding the sides to expose the collection pad.

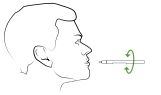


3. Hold the device on the part opposite to the collection pad and place the collection pad into the mouth.



4. Rub the collection pad against the cheek and tongue gently in a circular motion 10 times. Then keep the collection pad in the mouth with plenty of saliva for about 2 minutes.

A: Gently rub the collection pad against each cheek several times.



B: Gently rub the collection pad on top of the tongue.

C: Place the collection pad underneath the tongue.

D: Cover the rectangular hole with the lip.

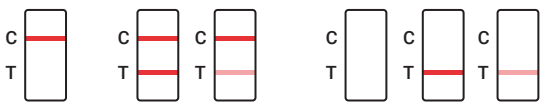
E: Blow vigorously into the pad several times until the liquid rises.

5.Check if the C line appears at the C region in the result reading window. If not, please repeat step 4 until a C line is visible or the total in-mouth time of the collection pad exceed 10 minutes.
6.Lay the device on a clean, flat surface with the result reading window upward and keep the collection pad untouched for 10-15 minutes. Please use a time device for timing.
7.Read the results between 10-15 minutes. Note: The result might be visible after a shorter time, however, it should only be interpreted between 10-15 minutes.

After the test
1. Collect all used items (Test cassette, and potentially used gloves, tissue paper or masks) into the Biohazard Specimen Bag. Close the bag and dispose in a biohazard trash can.

RESULTS INTERPRETATION

1. Negative results: coloring on C line appear only.
2. Positive results: coloring on both T line and C line. (Note: Faint line should be regard as coloring)
3. Invalid results: no coloring appear on C line regardless of T line coloring.



Negative Positive Invalid

PRODUCT PERFORMANCE

The limit of detection (LoD)
The limit of detection (LoD) of the Spring SARS-CoV-2 Antigen Saliva B was established using serial dilutions of concentrated inactivated virus samples. The specimens were diluted with the prescribed diluent in triplicate. Each series of diluted specimen was evaluated with twenty separate test cassettes. The LoD was determined as the lowest virus concentration that equal to or greater than 95% of the results were positive.(i.e., the concentration at which at least 19 out of 20 replicates tested positive).
The LoD of testing Gamma-Irradiated SARS-CoV-2 virus lysate is 60 TCID50/mL.

Clinical sensitivity, specificity and total agreement

The product performance was evaluated with clinical specimens, taking commercial RT-PCR kit as the gold standard.

Saliva		RT - PCR		Total Results
Spring SARS-CoV-2 Antigen Saliva B	Results	Positive	Negative	
	Positive	99	1	100
	Negative	5	135	140
Total Results		104	136	240

Sensitivity=94.47% (95%CI: 85.77%-98.08%)
Specificity=99.23% (95%CI: 95.15%- 99.96%)
Overall Agreement=98.32% (95%CI:94.62%-99.02%)

Cross-reactivity

The analytical specificity of the Spring SARS-CoV-2 Antigen Saliva B was evaluated by testing commensal and pathogenic microorganisms that may be present in the mouth cavity. No cross-reactivity (except SARS-coronavirus) or interference were seen with the following microorganisms when tested at the concentration presented in the table below:

Microorganism	Concentration	Cross-reactivity
MERS-CoV	1.17×10^6 $TCID_{50}$/mL	No
SARS-CoV	2.3×10^5 $TCID_{50}$/mL	Yes
HCoV-HKU1	1.8×10^5 $TCID_{50}$/mL	No
Influenza type A	1.98×10^6 $TCID_{50}$/mL	No
Influenza type B	2.32×10^6 $TCID_{50}$/mL	No
Human coronavirus 229E	1.77×10^6 $TCID_{50}$/mL	No
Human coronavirus OC43	1.05×10^6 $TCID_{50}$/mL	No
Human coronavirus NL63	1.17×10^6 $TCID_{50}$/mL	No
Adenovirus	7×10^{10} NIU/mL	No
Human Metapneumovirus (hMPV) Type B1	1.55×10^4 $TCID_{50}$/mL	No
Parainfluenza virus Type 1	5.01×10^5 $TCID_{50}$/mL	No
Parainfluenza virus Type 2	1.6×10^6 $TCID_{50}$/mL	No
Parainfluenza virus Type 3	1.6×10^8 $TCID_{50}$/mL	No
Parainfluenza virus Type 4b	1.15×10^7 $TCID_{50}$/mL	No
Enterovirus D68	1.0×10^6 $TCID_{50}$/mL	No
Respiratory syncytial virus	2.88×10^5 $TCID_{50}$/mL	No
Rhinovirus 1A	2.2×10^7 PFU/mL	No
Haemophilus influenzae type b	5.2×10^7 CFU/mL	No
Streptococcus pneumoniae (262)	$>2\times10^4$ CFU/mL	No
Streptococcus pyogenes	3.6×10^7 CFU/mL	No
Candida albicans	4.5×10^8 $TCID_{50}$/mL	No
Bordetella pertussis	3.9×10^9 CFU/mL	No
Mycoplasma pneumoniae	4.4×10^7 CFU/mL	No
Chlamydia pneumoniae	1.4×10^8 IFU/mL	No
Legionella pneumoniae	7.8×10^6 CFU/mL	No
Mycobacterium tuberculosis H37Ra	$>2\times10^4$ CFU/mL	No
Pneumocystis jirovecii (PJP)	3.45×10^8 CFU/mL	No

Interfering substances

The following substances were evaluated with the Spring SARS-CoV-2 Antigen Saliva B at the concentrations listed in the following table and were found not to affect test performance.

Interfering substance	Concentration	Interference
Biotin	200 ng/dL	No
Whole Blood	5 %	No
Menthol	0.8 g/mL	No
Saline	15 %	No
Acetylsalicylic Acid	3 mg/dL	No
Zanamivir	282 ng/mL	No
Budesonide	0.63 µg/dL	No
Ribavirin	1 mg/mL	No
Acetaminophen	199 µM	No
Tobramycin	1.25 mg/mL	No
Oseltamivir	2.2 µg/mL	No
Diphenhydramine	77.4 µg/dL	No
Dextromethorphan	1.56 µg/dL	No
Mucin protein	2.5 mg/mL	No
OTC Nasal Drops (Phenylephrine)	15 %	No
OTC Nasal Gel (Sodium Chloride)	5 %	No
OTC Nasal Spray 3 (Fluconazole)	5 %	No
Throat Lozenge (Benzocaine,Menthol)	0.15 %	No
Antibiotic,Nasal Ointment (Mupirocin)	0.25 %	No

High dose hook effect

The Spring SARS-CoV-2 Antigen Saliva B was tested up to 106 TCID50/mL of inactivated SARS-CoV-2. There was no high-dose hook effect observed.

Endogenous Interference

The Spring SARS-CoV-2 Antigen Saliva B 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
Fluticasone 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 Spring SARS-CoV-2 Antigen Saliva B.

Food/beverage Interference

Food/beverage interference study was performed to evaluate the potential interference of food/beverage in saliva samples on Spring SARS-CoV-2 Antigen Saliva B.

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 Spring SARS-CoV-2 Antigen Saliva B.

LIMITATIONS

1.This product is intended for assisted diagnosis of viral infections only. A final clinical diagnosis should also consider factors like symptoms, results of other tests as well.
2.A negative result indicates that the viral load in tested sample is below the limit of detection of this product. It can not completely exclude the possibility of viral infection of patient.
3.A positive result indicates that the tested sample has viral load higher than the limit of detection of this product. However, the color intensity of test line may not correlate with the severity of infection or disease progression of the patient.

BIBLIOGRAPHY

Wang C, Horby PW, Hayden FG, Gao GF. A novel coronavirus outbreak of global health concern. The Lancet. 24 January 2020.

SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device	2°C 30°C	Store at 2-30 °C
	Manufacturer	EC REP	European authorized representative
	Date of Manufacture		Expiry date
	Do not re-use		Consult instruction for use
LOT	Lot number		Keep dry
REF	Catalogue number		Keep away from sunlight
CE	CE Mark		Biological risks

COMPOSITION

REF No.	SP-SL502-1B	SP-SL502-3B	SP-SL502-5B	SP-SL502-15B	SP-SL502-20B
Components	1 test/box	3 test/box	5 test/box	15 test/box	20 test/box
Test device	1	3	5	15	20
Package insert	1	1	1	1	1

GENERAL INFORMATION

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Number: SP-SL502
Effective Date:2021-10-02