FASPIT™ SARS-CoV-2 Antigen Saliva Test

CE IVD REF :C2112

INTENDED USE

FASPIT™ SARS-CoV-2 Antigen Saliva Test is an immunoassay that uses the double-antibody sandwich method to detect the SARS-CoV-2 nucleocapsid protein from saliva specimen from patients who are suspected of SARS-CoV-2 infection by a healthcare provider. **Performance of the test is limited to professional use.**

SARS-CoV-2 Antigen Saliva Test Kit provides preliminary test results, with negative results don't preclude SARS-CoV-2 infection. The test kit cannot be used as the sole basis for treatment or other management decision. **For *in vitro* diagnostic use only.**

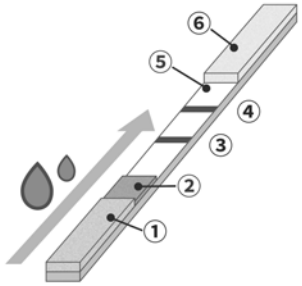
SUMMARY

Novel coronavirus pneumonia (Coronavirus disease 19, COVID-19) is an infectious disease caused by SARS- CoV-2 infection. On February 11, 2020 the International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.

Since the massive COVID-19 pandemic, the application of antigen testing for large-scale screening has become popular. Currently, the most commonly used method is to use Nasopharyngeal Swab (NPS) and Oropharyngeal Swab (OPS) for nucleic acid detection. There are many reports that use of saliva samples for detection has the same level of detection as NPS[1][2]. Furthermore, collecting saliva samples can effectively reduce risk of virus transmission to healthcare provider and causes less individuals discomfort compared with NPS/OPS specimen.

SARS-CoV-2 Virus is a positive single-strand RNA virus, which could mutate rapidly, there have been a large number of gene sequencing reports on mutant viruses. Using Spike protein for detection has potential risk to be unable to identify mutant viruses. SARS-CoV-2 Antigen Saliva Test Kit takes the nucleocapsid protein of the SARS-CoV-2 virus as the antigen marker throughout, which will technically guarantee its specificity and keep off influence by the mutation of the virus.

PRINCIPLES OF THE TEST



①Sample Pad ②Conjugate Pad ③Test Line
④Control Line ⑤NC Membrane ⑥Absorbing Pad

FASPIT™ SARS-CoV-2 Antigen Saliva Test is an immunoassay that uses the double-antibody sandwich method to detect the novel coronavirus (SARS-CoV-2) nucleocapsid protein from saliva specimen. SARS-CoV-2 specific antibodies and a control antibody are immobilized onto a membrane support as two distinct lines and combined with other materials to construct a test strip.

If SARS-CoV-2 viral antigen is present, it will migrate on membrane, reach to test area and caught by specific antibody to form a complex result in a visible red ribbon on Test line (T line). If the quality control line (C line) does not appear, it means that the test result is invalid. This sample needs to be tested again.

MATERIAL PROVIDED

- Test Sticks (1x)
- Instruction for Use (1x)
- Biohazard Waste Bag (1x)

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer/Watch
- Personal protective equipment, such as protective gloves, medical mask, goggles and lab coat
- Appropriate biohazard waste container and disinfectants

WARNINGS AND PRECAUTIONS

1.For *in vitro* diagnostic use.
2.To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.
3.Do not touch the any area of test stick except handle.
4.Do not use test kit beyond the expiration date.
5.Do not use the kit if the pouch is punctured or sealed not well.
6.Performance of the test should be applied by professionally trained staff working in certified laboratories or clinics.
7.The test result should be interpreted by the physician along with clinical findings and other laboratory test results.
8.Dispose of device and items in contact with samples as medical waste after use.
9.Do not freeze the device or any other material.
10.Keep away from children when using and storing.

STORAGE AND STABILITY

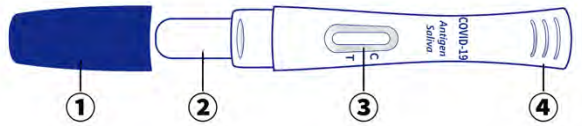
The kit is stored at 2 ~ 30 °C in sealed, preserve avoid light. The validity period is at 18 months.
Reagents and devices must be used at room temperature (15~30 °C).
Saliva specimen can be stored and transported after mixed with extraction solution under 2 ~8°C within 10 hours and -20°C within 4 days.
The unsealed device is valid for 1 hour. It is recommended to use the testing kit immediately after opening, especially the test environment humidity is more than 60%. The expiration date is printed on the package.

TEST PROCEDURE

Read following attention before starting a test:

Attention: Do not eat, drink, smoke or use oral hygiene products for at least 20 minutes before the collection process

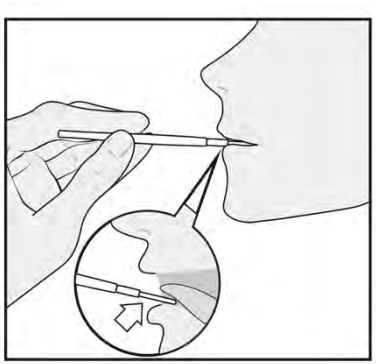
1.Rinse individual's mouth with clear water and discard before test.
2.Wait for 5 mins for naturally produce saliva and keep saliva in oral cavity.
3.Unpack the aluminum foil bag, take out the saliva stick and familiar with structure of saliva stick by reading figure below.



①Cap ②Absorbent Pad ③Test Window ④Handle

4.Hold the handle and immerse stick in saliva below the tongue, hold for several seconds until burgundy color shows in test window.**DO NOT SWALLOW ANY SALIVA AFTER TEST STARTED.**
Note: The reaction time is affected by the amount of saliva

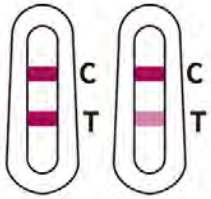
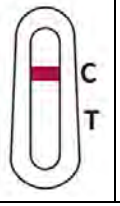
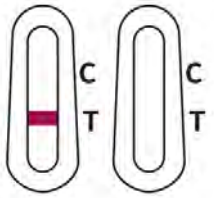
and the ambient temperature. Only color shows in test window ensures that sufficient saliva is obtained.



5.Close the cap of saliva stick and place the stick in the flat platform at room temperature for 15 minutes then interpretate the result. **Rinse individual's mouth again with clean water. Collect all component and sealed in biohazard waste bag. Treat it as potential infectious substances and discard accord with local legislation.**

Warning: Results must be interpreted in 20 minutes after completing the test procedure.

INTERPRETATION OF RESULT

POSITIVE	NEGATIVE	INVALID
		

1.Positive: Two red ribbon, the test line (T line) and the quality control line (C line) are colored.
2.Negative: One red ribbon, just quality control line (C line) is colored;
3.Invalid: No color appears in the position of the quality control line (C line) in the observation window, indicating that this test is invalid and should be repeat the test.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATION

1. The contents of this kit is restricted for the qualitative detection of SARS antigens from saliva specimens.
2. Test results must be evaluated in conjunction with other clinical data available to the physicians.
3. Failure to follow the Test Procedure may adversely affect test performance and / or invalidate the test result.
4. Mucus in the oral cavity, such as thick sputum, may cause false positive results. Fresh saliva should be taken when sampling.
5. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected improperly.
6. Positive test results do not rule out co-infections with other pathogens.
7. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
8. Lay person is not allowed to perform the test without guidance and supervision from professionals.

PERFORMANCE CHARACTERISTICS

Clinical Performance

260 samples were collected from selected subjects, all samples were tested with FASPIT™ SARS-CoV-2 Antigen Saliva Test and TaqPath™ COVID-19 Fast PCR Combo Kit produced by Life Technologies Corporation. Calculated the specificity and sensitivity, the results are as follows:

RNA Test	FASPIT™ SARS-CoV-2 Antigen Saliva Test		Total
	Positive	Negative	
Positive	125	5	130
Negative	3	127	130
Total	128	132	260

Diagnostic Sensitivity:
125/(5+125)×100%=96.2% 95%CI(91.3%~98.3%)
Diagnostic Specificity:
127/(3+127)×100%=97.7% 95%CI(93.4%~99.2%)
Overall Agreement:
(125+127)/260×100%=96.9% 95%CI(94.0%~98.4%)

Analytical Performance

Analytical Sensitivity (Limit of Detection, LoD)

The Limit of Detection (LoD) of the FASPIT™ SARS-CoV-2 Antigen Saliva Test was determined using limiting dilutions of heat-inactived SARS-CoV-2, that has been inactivated by heating at 65°C for 30 minutes. The virus material was supplied at a concentration of $2.5x10^5$ $TCID_{50}$/ml.

In this study, designed to estimate the LoD of the assay when using a direct saliva specimen, the starting material was spiked into a volume of saliva matrix obtained from healthy donors and confirmed negative for SARS-CoV-2. The specimen samples were prepared into to 3-4 folds dilutions series. At each dilution, 1ml samples were used as specimen and tested in the FASPIT™ SARS-CoV-2 Antigen Saliva Test using the test procedure according to instruction for use.

Starting Material Concentration	Diluent Concentration				
$2.5×10^5$ $TCID_{50}$/mL	200	150	100	50	25
Positive/Total	20/20	20/20	20/20	20/20	13/20

Results indicate that the LoD of FASPIT™SARS-CoV-2 Antigen Saliva Test Kit (Colloidal Gold Immunochromatography) is 50 $TCID_{50}$/ml.

Analytical Specificity (Cross-Reactivity and Microbial Interference)

Cross-reactivity and potential interference of FASPIT™ SARS-CoV-2 Antigen Saliva Test Kit (Colloidal Gold Immunochromatography) was evaluated by testing the pathogenic microorganisms listed in the table below.

Type	Pathogens	Concentration
Saliva	Negative Saliva Pool	N/A
Protein	SARS N-Protein	5 μg/ml
Virus	MERS	1.0×10^5 $TCID_{50}$/ml
	Human metapneumovirus (hMPV)	1.0×10^5 $TCID_{50}$/ml
	Human coronavirus 229E	1.0×10^5 $TCID_{50}$/ml
	Human coronavirus OC43	1.0×10^5 $TCID_{50}$/ml
	Human coronavirus NL63	1.0×10^5 $TCID_{50}$/ml
	Adenovirus	1.0×10^5 $TCID_{50}$/ml
	Parainfluenza virus 1	1.0×10^5 $TCID_{50}$/ml
	Parainfluenza virus 2	1.0×10^5 $TCID_{50}$/ml
	Parainfluenza virus 3	1.0×10^5 $TCID_{50}$/ml

	Parainfluenza virus 4	1.0 x 10^5 $TCID_{50}$/ml
	Influenza A	1.0 x 10^5 $TCID_{50}$/ml
	Influenza B	1.0 x 10^5 $TCID_{50}$/ml
	Enterovirus	1.0 x 10^5 $TCID_{50}$/ml
	Respiratory syncytial virus	1.0 x 10^5 PFU/ml
	Rhinovirus	1.0 x 10^5 PFU/ml
Bacteria	Hemophilus influenzae	1.0 x 10^6 CFU/ml
	Streptococcus pneumoniae	1.0 x 10^6 CFU/ml
	Streptococcus pyogenes	1.0 x 10^6 CFU/ml
	Candida albicans	1.0 x 10^6 CFU/ml
	Bordetella pertussis	1.0 x 10^6 CFU/ml
	Mycoplasma pneumoniae	1.0 x 10^6 U/ml
	Chlamydia pneumoniae	1.0 x 10^6 CFU/ml
	Legionella pneumophila	1.0 x 10^6 CFU/ml

Testing was performed in triplicate.

Based on the data generated by this study, the organisms or viruses tested by FASPIT™ SARS-CoV-2 Antigen Saliva Test Kit do not cross-react or interfere except SARS recombinant N-protein under concentration of 5 μg/ml.

Interfering Substances

Interference substances	**Concentration**
Mucin: bovine submaxillary gland, type I-S	2.5 mg/mL
White blood cells/ leukocytes	5 × 10^6 cells/mL
Afrin® Original nasal spray	15% v/v
Cepacol® (benzocaine/ menthol lozenges)	3 mg/mL
Chloraseptic® Sore Throat spray/solution	5% v/v
Toothpaste (Colgate®)	5% v/v
Crest mouthwash	20 mg/dL
Nicotine	0.03 mg/mL
Flonase®allergy relief (Fluticasone furoate)	500 ng/mL
Zicam® cold remedy	10% v/v
Tobramycin	500 ng/mL
Mupirocin	500 ng/mL

A study was performed demonstrate that the potential interfering substances that may be found in the oral cavity do not cross-react or interfere with the detection of SARS-CoV-2 in the FASPIT™ SARS-CoV-2 Antigen Saliva Test.

Based on the data generated by this study, the endogenous substances tested by FASPIT™SARS-CoV-2 Antigen Saliva Test Kit do not cross-react or interfere.

Hook Effect

The highest concentration of heat-inactivated SARS-CoV-2 stock available 2.5x10^5 $TCID_{50}$/ml was tested. There was no Hook effect detected.

REFERENCE

[1]Yoon JG, Yoon J, Song JY, *et,al*. Clinical Significance of a High SARS-CoV-2 Viral Load in the Saliva. ***J Korean Med Sci.*** 2020 May 25;35(20):e195.
[2]Azzi L, Carcano G, Gianfagna F,*et,al*. Saliva is a reliable tool to detect SARS-CoV-2. ***J Infect.*** 2020 Jul;81(1):e45-e50.

INDEX OF SYMBOLS

	Attention, see instructions for use
	For In-Vitro Diagnostic Use only
	Authorized Representative
	Use-by date
	Lot Number
	Catalogue Number
	Store between 2 – 30 centigrade
	Contains sufficient for <n> tests
	Do Not use if package is damaged
	Do Not Reuse
	CE Mark

Atlas Link Technology Co., Ltd
Gu'AnSouth Industry Zone, 065500 Langfang City,
Hebei Province, the People's Republic of China
TEL: +86-10-8890 9113 FAX: +86-10-8890 9115
WEB: https://www.invitro-test.com

EC REP

MT Promedt Consulting GmbH
Altenhofstrasse 80, 66386 St. Ingbert Germany
Email: ear@mt-procons.com

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