FASPIT™ SARS-CoV-2 Antigen Saliva Test Kit (Colloidal Gold Immunochromatography)

CE IVD Cat.No.: C2103

INTENDED USE

FASPIT™ SARS-CoV-2 Antigen Saliva Test Kit (Colloidal Gold Immunochromatography) is an immunochromatographic membrane assay that uses the double-antibody sandwich method to detect the SARS-CoV-2 nucleocapsid protein from saliva specimen from patients who are suspected of COVID-19 by a healthcare provider. Performance of the test is limited to certified laboratories that meet the requirements to perform moderate, high or waived complexity tests.

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.**

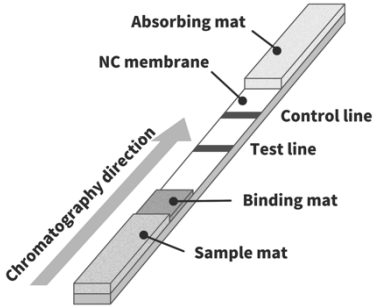
SUMMARY

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



FASPIT™ SARS-CoV-2 Antigen Saliva Test Kit (Colloidal Gold Immunochromatography) is an immunochromatographic membrane assay 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 Cassettes (20×)
- Assay Diluent (20×)
- Disposable Saliva Collector (20×)
- Disposable Extraction Droppers (20×)
- Instruction for Use (1×)

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

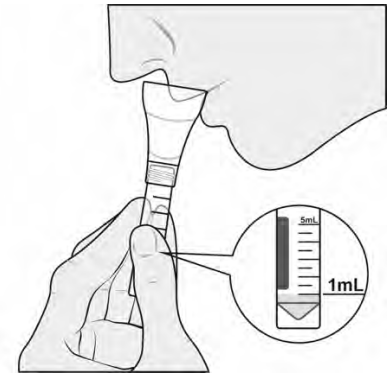
1.For *in vitro* diagnostic use.
2.To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.
3.When collecting a saliva sample, use the saliva collector supplied in the kit. Use of alternative collector or Virus Transport Medium (VTM) may result in false negative results.
4.Do not touch the reaction area of test strip.
5.Do not use test kit beyond the expiration date.
6.Do not use the kit if the pouch is punctured or sealed not well.
7.Performance of the test should be applied by professionally trained staff working in certified laboratories or clinics.
8.The test result should be interpreted by the physician along with clinical findings and other laboratory test results.
9. Dispose of cassette and items in contact with samples as medical waste after use.
10.Do not freeze the cassette or any other material.

STORAGE AND STABILITY

The kit is stored at 2 ~ 30 °C in sealed, preserve avoid light. The validity period is now at 18 months, can be extended if new stability data are available.
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 cassette 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.

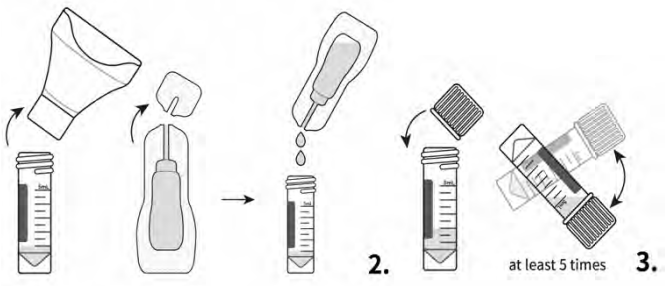
SPECIMEN COLLECTION

Attention: Do not eat, drink, smoke or use oral hygiene products for at least 10 minutes before the collection process



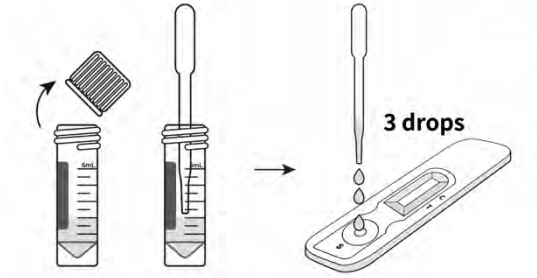
1.Rinse individual's mouth with clear water and discard before test is recommended.
2.Wait for 5 mins before saliva collection.
3.Instruct individual to place their lips over the collecting funnel and collect saliva until the saliva reaches the indicator line (about 1ml).

SAMPLE PREPARATION



1.Discard the funnel part as medical waste after saliva collection finished.
2.Twist off lip of Assay Diluent tube and dispense all extract solution into the collector.
3.**Close the cap of saliva collector**, blend collector massively at least 5 times to guarantee specimen well mixed with extract solution and place it on a flat platform for 1min.

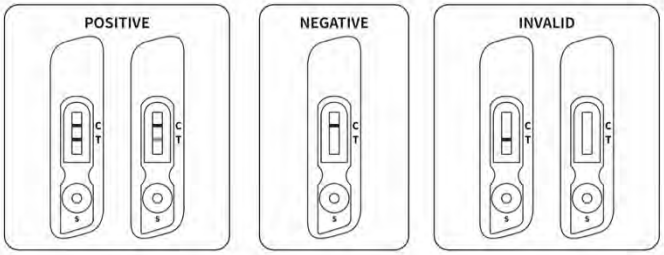
TEST PROCEDURES



Before the test, carefully read the kit instructions and strictly follow it.
1.Unpack the cassette aluminum foil bag, take out the cassette and lay it on the flat platform.
2.Twist off the cap of the collector prepared from the SAMPLE PREPARATION, transfer 3 drops of specimen processing solution (80-100μL) with extraction dropper vertically into the cassette sample well (S sign).
3.Place the cassette at room temperature for 15 minutes then read the test result.

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

INTERPRETATION OF RESULT



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 resampled for testing.

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. 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.
5. Positive test results do not rule out co-infections with other pathogens.
6. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.

ANALYTICAL PERFORMANCE

Limit of Detection

The Limit of Detection (LoD) of the FASPIT™ SARS-CoV-2 Antigen Saliva Test Kit 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 fold dilutions series. At each dilution, 1ml samples were used as specimen and tested in the FASPIT™ SARS-CoV-2 Antigen Saliva Test Kit 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.

Cross-Reactivity

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	cross-reactivity specimens	Concentration
Saliva	Negative saliva Pool	N/A
Virus	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	1.0×10^5 $TCID_{50}$/ml
	Influenza A	1.0×10^5 $TCID_{50}$/ml
	Influenza B	1.0×10^5 $TCID_{50}$/ml
	Enterovirus	1.0×10^5 $TCID_{50}$/ml
	Respiratory syncytial virus	1.0×10^5 PFU/ml

	Rhinovirus	1.0 x 10^5 PFU/ml
Bacteria	Haemophilus 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 date generated by this study, the organisms or viruses tested FASPIT™ SARS-CoV-2 Antigen Saliva Test Kit do not cross-react or interfere.

Endogenous Interference

A study was performed demonstrate that the potentially 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 Kit.

Endogenous 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

Based on the date generated by this study, the endogenous substances tested 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 (100μg/ml) was tested. There was no Hook effect detected.

PERFORMANCE CHARACTERISTICS

230 samples were collected from selected subjects, all samples were tested with FASPIT™ SARS-CoV-2 Antigen Saliva Test Kit and BD Veritor™ System for Rapid Detection of SARS-CoV-2 produced by BD Biosciences. Calculated the specificity and sensitivity, the results are as follows:

BD Biosciences	FASPIT™ SARS-CoV-2 Antigen Saliva Test Kit		Total
	Positive	Negative	
Positive	74	2	76
Negative	0	154	154
Total	74	156	230

Diagnostic Sensitivity:
74/(2+74)×100%=97.4% 95%CI(90.9%~99.3%)
Diagnostic Specificity:
154/(0+154)×100%=100.0% 95%CI(97.6%~100.0%)
Overall Agreement:
(74+154)/230×100%=99.1% 95%CI(96.9%~99.8%)

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

Atlas Link Technology Co., Ltd
Gu'an South 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
TEL: +49-0-6894581020
FAX: +49-0-6894581021
Email: ear@mt-procons.com

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