Tigsun COVID-19 Saliva Antigen Rapid Test

TG-1417 English

INTENDED USE

Tigsun COVID-19 Saliva Antigen Rapid Test is a lateral flow immunochromatographic assay intended for the rapid and qualitative detection of antigen from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in human saliva samples from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.

Results are for the identification of SARS-CoV-2 antigen. The antigen is generally detectable in upper respiratory samples during the acute phase of infection.

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 bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of the disease. Any positive result should be comprehensively evaluated by physicians based on clinical characteristics and symptoms and other diagnostic methods if necessary.

Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. Negative results do not rule out SARS-CoV-2 infection, neither can they be taken as the sole basis for treatment or other management 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. If a negative result appears, but the symptoms persist, other diagnostic methods should be used.

Tigsun COVID-19 Saliva Antigen Rapid Test is intended for use by medical professionals or trained operators proficient in performing tests using rapid lateral flow tests.

For in vitro diagnostic use only. For professional use only.

SUMMARY

2019 Novel Coronavirus, now known as SARS-CoV-2 (previously known as 2019-nCoV), is a new β-type coronavirus, which is a single-stranded RNA virus that can cause human respiratory infections. Its genetic characteristics are significantly different from severe acute respiratory syndrome (SARS)-associated coronavirus and the Middle East respiratory syndrome (MERS)-associated coronavirus. The primary infection site of the SARS-CoV-2 is the lower respiratory tract, which has a higher incidence in the elderly. The incubation period of infection is variable. Common symptoms after infection with SARS-CoV-2 include respiratory symptoms, fever, cough, shortness of breath, and difficult breathing. An infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death in more severe cases. The WHO has named the disease caused by SARS-CoV-2 as coronavirus disease 2019 (abbreviated "COVID-19"). SARS-CoV-2 is highly contagious and mainly transmitted through contact, droplet, or airborne routes.

PRINCIPLE

Tigsun COVID-19 Saliva Antigen Rapid Test employs immunochromatography technology to detect the SARS-CoV-2 antigen in human saliva specimens. SARS-CoV-2 specific antibodies and a control antibody are immobilized onto membrane support as two distinct lines and combined with other reagents/pads to construct a test strip. When specimens are processed and added to the test device, SARS-CoV-2 antigens present in the specimen bind to antibodies conjugated to detector particles in the test strip. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibodies bound on the membrane.

PRECAUTION

1. **This kit is for *in-vitro* diagnostic use only. For professional use only.**
2. This test has been authorized only to detect SARS-CoV-2 antigen, not for any other viruses or pathogens.
3. Do not use test kits beyond the expiration date; Do not use the kit if the pouch is punctured or not well sealed.
4. Check if the contents are complete before use. Reagent kits should be kept sealed and dry. The test cassette should be used within 1 hour after opened to avoid moisture.
5. Discard after first use. The test cannot be used more than once.
6. All specimens should be treated as capable of transmitting diseases. Use appropriate precautions in collecting, handling, storage, and disposal of patient samples and used kit contents. Biosafety level 2 or higher guidelines are suggested.
7. Testing should be applied by professionally trained staff working in certified laboratories or clinics at which the sample(s) is taken by qualified medical personnel.
8. The package insert instruction must be followed to obtain accurate results.
9. Proper specimen collection, storage, and transportation are critical to the performance of this test. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
10. INVALID RESULTS can occur when an insufficient volume of extraction reagent is added. To ensure delivery of adequate volume, hold the vial vertically and add drops slowly.
11. False Negative results can occur if the sample swab is not rotated (twirled).
12. Avoid repeatedly freezing and thawing the test samples. Before testing, please restore the test specimens to room temperature.
13. Do not touch the reaction area of the test strip.
14. Do not mix components from different kit lots.
15. Any positive result should be comprehensively evaluated by physicians based on clinical characteristics and symptoms, as well as other diagnostic methods.
16. If a negative result appears, but the symptoms persist, other diagnostic methods should be used.
17. Disposal of the agent: all specimens and the used kit has the infectious risk. The process of disposing of the diagnostic must follow the local infectious disposal law or laboratory regulation.

MATERIAL

Material Provided

1. 25 Individual sealed pouches; each contains 1 test cassette
2. Treatment Reagent (25 pcs)
3. Reagent Tube and Caps (25 pcs)
4. Specimen Collection Devices (25 pcs)
5. Dropper (25 pcs)
6. Instructions for use

Material Required but not Provided

1. Timers
2. Personal protective equipment, such as protective gloves, medical masks, goggles, and lab coats
3. Appropriate biohazard waste containers and disinfectants

STORAGE AND STABILITY

1. The original packaging should be stored in a cool and dry place at 2~30℃. Do Not Freeze.
2. Keep away from sunlight, moisture, heat, and frozen condition.
3. Kit contents are stable until the expiration date printed on the outer box.
4. Ensure all test components are at room temperature before use.
5. After opening the pouch, the cassette is effective to be used in 1 hour under room temperature (25℃) and humidity (<60%). Treatment reagent solution should be re-capped in time after use.

SPECIMEN COLLECTION

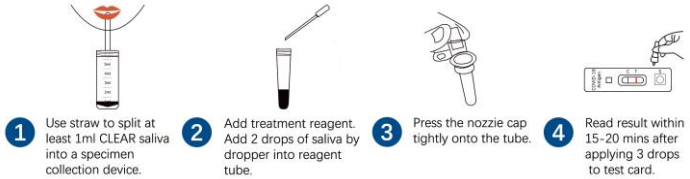
The test can be performed with human saliva specimens. It is essential that correct specimen collection and preparation methods must be followed. Saliva testing requires a volume of 1-1.5 milliliter sample of clear saliva. Do not eat, drink (even water), smoke, vape, chew gum, or tobacco or take medication for at least 30 minutes before your test.

1. Spit 1- 1.5ml of CLEAR saliva into a specimen collection device by using a provided straw. Foam doesn't count towards that saliva sample.
2. Take the cap, put the cap on top of the container, and screw it in until it feels nice and snug.

Please decontaminate the outside of your tube.

Specimens should be tested as soon as possible after collection. Specimens are stable for 4-hours at room temperature or 2° to 8°C within 12h.

TEST PROCEDURE



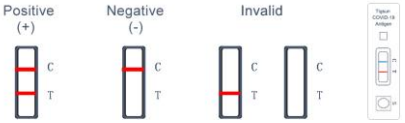
Please read the instruction carefully before testing.

Allow kit, buffer, and specimen to equilibrate to the room temperature.

1. Remove a test cassette from the foil pouch from the reagent box and place it on a level surface.
2. Hold the prefilled treatment reagent vertically. Break the tip and squeeze the bulb to dispense all buffer in the 1 piece of treatment reagent (~0.45ml) into the reagent tube.
3. Collect at least 1ml saliva into a specimen collection device.
4. Add 2 drops of saliva by dropper into the reagent tube with the treatment reagent. Mix well by swirling the reagent tube to dissolve its contents.
5. Press the nozzle cap tightly onto the tube, and wait for 1 or 2 minutes.
6. Add 3 drops of treated saliva to the sample well of the test cassette.
7. Read the result within 15 to 20 minutes after adding the sample. Do not observe the result after 20 minutes.

RESULT INTERPRETATION

1. Positive Result: Both control line (C) and test line(T) appear.
2. Negative Result: Only control line (C) appears
3. Invalid Result: Discard the test if no control line (C) or only test line (T) is visible. Repeat the test with a new cassette.



QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking, and correct procedural technique. Good laboratory practice recommends the use of the control materials. Users should follow appropriate federal state and local guidelines concerning the frequency of assaying external quality control materials.

LIMITATIONS OF PROCEDURE

1. This reagent is designed to detect SARS-CoV-2 antigen in human saliva samples.
2. This reagent is a qualitative assay. It is not designed to determine the quantitative concentration of SARS-CoV-2 antigen.
3. The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage, or repeated freezing and thawing will affect the test result.
4. The test result of this reagent is for clinical reference only. A confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated. Any positive result should be comprehensively evaluated by physicians based on clinical characteristics and symptoms, as well as other diagnostic methods.
5. Limited by the antigen detection reagents method, for negative test results, it is recommended to use nucleic acid detection or virus culture identification methods for review and confirmation.
6. Positive test results do not rule out co-infections with other pathogens. A negative result of this reagent can be caused by:
   1) Improper sample collection, improper sample transfer, or handing, the virus titer in the sample is too low.
   2) The level of SARS-CoV-2 antigen is below the detection limit of the test.
   3) Variations in viral genes may cause changes in antigen determinants.

PERFORMANCE CHARACTERISTICS

Limit of Detection (Analytical Performance)

The limit of detection (LoD) of Tigsun COVID-19 Ag Card was determined by evaluating different concentrations of inactivated SARS-CoV-2 viruses. Presumed negative saliva specimens were mixed thoroughly to be used as the clinical diluent. Inactivated SARS-CoV-2 viruses were diluted in this saliva matrix pool to generate virus dilutions for testing.

The contrived saliva samples were tested according to the test procedure. The LoD was determined as the lowest virus concentration at which≥ 95% of all true positives replicates test positive(e.g. the concentration at which at least 19 out of 20 replicates tested positive).

Tigsun COVID-19 Ag Card LoD was confirmed as $1.0x10^3 TCID_{50}$/ml.

Hook Effect

As part of the LoD study, the highest concentration of inactivated SARS-CoV-2 stock available ($TCID_{50}$ of $3x10^8$ per mL) was tested. There was no Hook effect detected.

Cross-Reactivity (Analytical Specificity)

Cross-reactivity and potential interference of Tigsun COVID-19 Saliva Ag Card were evaluated by testing microorganisms that may be present in the upper respiratory tract. No cross-reactivity or interference was seen with the following microorganisms when tested at the concentration presented in the table below.

Potential Cross-Reactant	Concentration
Partial pulmonary virus	1.0 x $10^5 TCID_{50}$/ml
Rhinovirus	1.0 x $10^5 TCID_{50}$/ml
Enterovirus CA16	1.0 x $10^5 TCID_{50}$/ml
EB virus	1.0 x $10^5 TCID_{50}$/ml
Coronavirus OC43	1.0 x $10^5 TCID_{50}$/ml
Coronavirus 229E	1.0 x $10^5 TCID_{50}$/ml
Influenza A (H1N1) virus	1.2 x $10^5 TCID_{50}$/ml
Influenza A H3N2 virus	1.0 x $10^5 TCID_{50}$/ml
Influenza B virus (Y strain)	1.0 x $10^5 TCID_{50}$/ml
Influenza B virus (Victoria)	1.0 x $10^5 TCID_{50}$/ml
Respiratory Syncytial Virus A	1.0 x $10^5 TCID_{50}$/ml
Adenovirus type 3	1.0 x $10^5 TCID_{50}$/ml
Human parainfluenza virus2	1.0 x $10^5 TCID_{50}$/ml
Avian influenza virus H7N9	1.0 x $10^5 TCID_{50}$/ml
Avian influenza virus H5N1	1.0 x $10^5 TCID_{50}$/ml
Measles virus	1.0 x $10^5 TCID_{50}$/ml
Mumps virus	1.0 x $10^5 TCID_{50}$/ml
Parapertussis	1.0 x 10^6 CFU/ml
Streptococcus pyogenes (group A)	1.0 x 10^6 CFU/ml
streptococcus pneumoniae	1.0 x 10^6 CFU/ml

Endogenous Interference Substances Studies

A study was performed to demonstrate that fourteen (14) potentially interfering substances that may be found in the upper respiratory tract do not interfere with the detection of SARS-CoV-2 in the Tigsun COVID-19 Saliva Antigen Rapid Test.

Interfering Substance	Active Ingredient	Concentration
Afrin – nasal spray	Oxymetazoline	10mg/ml
Blood (human)	Blood	2%
Chloraseptic, Cepacol	Benzocaine, Menthol	0.7g/L
Flonase	Fluticasone	5%
Halls Relief Cherry Flavor	Menthol	0.8 g/mL
Nasocort Allergy 24 hour	Triamcinolone	5%
Neo-Synephrine	Phenylephrine hydrochloride	100mg/ml
Oseltamivir	Oseltamivir	2.2 μg/mL
Purifiedmucin protein	Mucin protein	2.5 mg/mL
Rhinocort	Budesonide (Glucocorticoid)	5%
Saline nasal spray	Saline	25%
Tobramycin	Tobramycin	1.25mg/ml
Zanamivir	Zanamivir	282.0 ng/mL
Zicam Cold Remedy	Galphimia glauca, Luffa operculata, Sabadilla	5%

Sensitivity and Specificity

102 clinical case samples, which include 27 confirmed case samples and 75 confirmed excluded case samples, were obtained for testing and then compared the test results between Tigsun COVID-19 Saliva Antigen Rapid Test and the confirmed case samples. The results of sensitivity and specificity between the two methods are shown below.

		PCR		
		Positive	Negative	Total
Tigsun COVID-19 Saliva Antigen Rapid Test	Positive	25	1	26
	Negative	2	74	76
	Total	27	75	102

* Confirmed cases were the patients diagnosed according to the treatment plan.
* Confirmed excluded cares were identified by negative PCR results.

Results analysis:
Sensitivity: 92.59% (76.63%～97.94%)
Specificity: 98.67% (92.83%～99.76%)
Accuracy: 97.06% (91.71%～98.99%)

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