COVID-19 Antigen Saliva Test Card

(Immunochromatography)

012G521

Rapid test for the qualitative detection of COVID-19 Antigens in human saliva

For professional in vitro diagnostic use only

ultimed

www.ultimed.org

INTENDED USE

The ulti med COVID-19 Antigen Saliva Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from 2019-nCoV in saliva specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset. Results are for the identification of 2019-nCoV nucleocapsid protein antigen. Positive results indicate the presence of viral antigens, but 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 disease. Negative results should be treated as presumptive, and do not rule out 2019-nCoV 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, and confirmed with a molecular assay, if necessary, for patient management.
The Test Card is intended for use by medically trained personnel who have been specifically instructed and trained in vitro diagnostic procedures.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The ulti med COVID-19 Antigen Saliva Test uses double-antibody sandwich to detect the antigen of novel coronavirus (2019-nCoV) in saliva samples. During detection, the gold labeled anti-2019-nCoV monoclonal antibody in the labeling pad binds to the 2019-nCoV antigen in the sample to form a complex, and the reaction complex moves forward along the nitrocellulose membrane under the action of chromatography. It is captured by the anti-2019-nCoV monoclonal antibody pre-coated on the detection zone (T) on the nitrocellulose membrane, and finally a red color reaction line is formed in the T zone. If the sample does not contain 2019-nCoV antigen, a red color reaction line cannot be formed in the T zone. Regardless of whether the sample to be tested contains 2019-nCoV antigens, a red reaction line will always form in the quality control area (C).

ATTENTION:

1) Only intended for in-vitro diagnostics.
2) Read the instructions for use carefully.
3) Do not use after the expiry date stated on the packaging.
4) Do not use if the protective foil on the test cassette or swab is damaged.
5) Do not smoke, eat or drink in the vicinity of the test and sample collection. The premises should be at the well ventilated when performing the test.

6) Protective clothing such as lab coats, disposable gloves (nitrile, latex or equivalent material) and wear protective goggles.
7) The test cassette should remain in the sealed pouch until use. To get an accurate result, an open and unprotected test cassette is not to be used,
8) Do not reuse the test cassette and swab.
9) Do not use damaged or fallen material and dispose of it in according to regulations.
10) Observe proven precautionary measures against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of samples.
11) All samples should be handled as if they contained infectious agents.
12) Inadequate or improper sample collection, storage or transport can lead to incorrect test results.
13) Use not visibly bloody or viscous sample material.
14) Please wash your hands thoroughly after performing the test.

STORAGE AND STABILITY

The ulti med COVID-19 Antigen Saliva Test can be stored at room temperature or refrigerated (2-30°C). The test cassette must remain in the sealed pouch until use. The test cassette and the saliva collector are stable through the expiration date printed on the box.

- Do not freeze.
- Do not use beyond the expiration date.

MATERIALS PROVIDED

- 20 Test Cassettes
- 20 Saliva Collectors
- 1 Instruction for Use
- 1 Quick Reference Instrcution

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Timer

PREPARATION

Allow the test cassette to reach room temperature (18-26°C) before the test is carried out. Please refrain from consuming food, drinks, chewing gum, tobacco and other substances for 30 minutes before testing in order to avoid incorrect results.

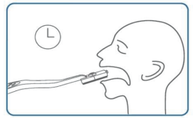
SPECIMEN COLLECTION

1. Insert the sponge end of the collector into mouth. Actively swab carefully the inside of the mouth and along the tongue to collect oral fluid for 90 seconds. Allow the saliva to absorb on the sponge naturally.
2. Remove the collector from the mouth when the sponge is saturated and soft or the indicator located on the back of the saliva collector turns blue.
3. The samples should be used as soon as possible after collection.
4. Samples should be tested immediately after collection.
5. Samples should not be inactivated.

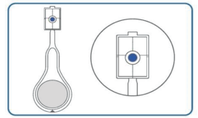
****NOTE***

When sampling, gently hold the saliva collector in mouth and let the saliva naturally adsorb in the sponge. Do not bite the sponge with the teeth. Any saliva specimen is appropriate for testing but the saliva specimen collected in the morning, before brushing, mouth rinsing, eating and drinking is recommended.

Sample collection:

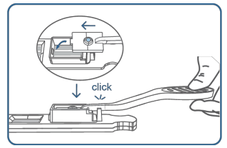


Saliva collector (with blue indicator):



TEST PROCEDURE

1. Remove the test cassette which equilibrated to room temperature from the foil bag, place it horizontally on the table and mark it with the patient's data.
2. Insert the saturated saliva collector with the with the sponge side down into the test card holder. The bump at the end of the collector must fit into the hole of the test card holder. Push the collector gently down until it locks into place. (see picture below)
3. As the test starts to work, a colored line moves across the result window in the center of the cassette.
4. Interpret test results at **10 minutes**. (Less than 10 minutes could produce a false negative; more than 10 minutes could produce a false positive)



Reproductions may vary from original!

INTERPRETATION OF RESULTS

Positive		POSITIVE COVID-19*: If both C and T lines are visible after 10 minutes, the test result is positive and valid.
Negative		NEGATIVE*: If test area (T line) has no color and the control area displays a colored line, the result is negative and valid.
Invalid		INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**** NOTE:***

The intensity of the red color in the test line region (T) will vary based on the amount of COVID-19 antigens present in the sample.
Any shade of color in the test regions (T) should be considered positive. Positive results have to be checked with a PCR test.
Negative results should not be used as the sole diagnose method for the presence of Covid-19 infection.

INTERNAL QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

LIMITATIONS

1. The result of the ulti med COVID-19 Antigen Saliva Test should not be taken as a confirmed diagnosis, it serves as a clinical reference only. Judgement should be made along with RT-PCR results, clinical symptoms, epidemiological information and further clinical data.
2. Test Card performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
3. The test card must be equilibrated to room temperature (18-26°C) before used, otherwise the results may be incorrect
4. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
5. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
6. Positive test results do not rule out co-infections with other pathogens.
7. Negative test results are not intended to rule in other viral or bacterial infections.
8. Negative results should be treated as presumptive and confirmed with a molecular assay.
9. Clinical performance was evaluated with fresh samples.
10. Users should test specimens as quickly as possible after specimen collection.

PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity and Accuracy

The performance of the ulti med COVID-19 Antigen Saliva Test was established with 243 sample collected from symptomatic patients, with symptoms onset within 7 days. RT-PCR is used as the reference method for the ulti med COVID-19 Antigen Saliva Test. Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

COVID-19 Test:

COVID-19 Antigen Saliva Test		Comparative RT-PCR		
		Positive	Negative	Total
COVID-19 Antigen	Positive	110	2	112
	Negative	5	126	131
Total		115	128	243
Sensitivity		95.65% (95%CI*: 90.22%-98.13%)		
Specificity		98.44% (95%CI*: 94.48%-99.57%)		
Accuracy		97.12% (95%CI*: 94.17%-98.60%)		

**** Confidence Intervals***

The performance of ulti med COVID-19 Antigen Saliva Test with positive results stratified by the comparative method cycle threshold (Ct) counts were collected and assessed to better understand the correlation of assay performance to the cycle threshold. As presented in the table below, the positive agreement of the ulti med COVID-19 Antigen Saliva Test is higher with samples of a Ct count <25.

COVID-19 Test:

COVID-19 Antigen Saliva Test	Comparative RT-PCR Method (Positive by Ct value)	
	Positive (Ct ≤25)	Positive (Ct>25)
Positive	91	19
Total	92	23
Positive agreement	98.91%	82.60%

2. Limit of Detection

The experimental results show that for the virus culture concentration above 100 $TCID_{50}$/ml, the positive rate of detection is greater than or equal to 95%. For the virus culture concentration of 50 $TCID_{50}$/ml and below, the positive rate of detection is lower than 95%. So, the limit of detection of the ulti med COVID-19 Antigen Saliva Test is 100 $TCID_{50}$/ml.

3. Cross-reactivity with Various Viral Strains

Cross-reactivity of the test card was evaluated. The results showed no cross reactivity with the following specimen.

COVID-19 Test:

Description	Test Level
Adenovirus type 3	1 x 10^5 TCID50/ml
Bordetella parapertussia	1 x 10^6 CFU/ml
Bordetella pertussis	1 x 10^6 CFU/ml
Candida albicans	1 x 10^6 CFU/ml

Chlamydia pneumoniae	1 x 10^6 CFU/ml
Enterovirus CA16	1 x 10^5 TCID50/ml
Epstein-Barr virus	1 x 10^5 TCID50/ml
Human coronavirus OC43	1 x 10^5 TCID50/ml
Human coronavirus 229E	1 x 10^5 TCID50/ml
Human coronavirus NL63	1 x 10^4 TCID50/ml
Human coronavirus HKU1	1 x 10^5 TCID50/ml
Human metapneumovirus (hMPV)	1 x 10^5 TCID50/ml
Influenza A H1N1/2009	1 x 10^5 TCID50/ml
Influenza A H3N2	1 x 10^5 TCID50/ml
Influenza B (Victoriacstrain)	1 x 10^5 TCID50/ml
Influenza B (Y strain)	1 x 10^5 TCID50/ml
Legionella pneumophila	1 x 10^6 CFU/ml
Measles	1 x 10^5 TCID50/ml
MERS coronavirus EMC/2012	1 x 10^4 TCID50/ml
Mycobacterium tuberculosis	1 x 10^6 CFU/ml
Mycoplasma pneumoniae	1 x 10^6 CFU/ml
Parainfluenzavirus 2	1 x 10^5 TCID50/ml
Paramyxovirus parotitis	1 x 10^5 TCID50/ml
Pneumocystis jirovecii	1 x 10^6 CFU/ml
Respiratory Syncytial virus	1 x 10^5 TCID50/ml
Rhinovirus	1 x 10^5 TCID50/ml
Staphylococcus aureus	1 x 10^6 CFU/ml
Streptococcus pneumoniae	1 x 10^6 CFU/ml
Streptococcus pyogenes	1 x 10^6 CFU/ml
Avian Influenza virus (H7N9)	1 x 10^5 TCID50/ml
Avian Influenza virus (H5N1)	1 x 10^5 TCID50/ml

4. Interference Substances

The substances at the following concentrations do not interfere with the test results.

Substance	Concentration
Whole Blood	4%
Ibuprofen	1 mg/ml
Mucin	0.50%
Tetracycline	3 µg/ml
Chloramphenicol	3 µg/ml
Erythromycin	3 µg/ml
Tobramycin	5%
Throat spray (Menthol)	15%
Mupirocin	10 mg/ml
Throat lozenge (Menthol)	1.5 mg/ml
Tamiflu (Oseltamivir)	5 mg/ml
Naphthoxoline hydrochloride nasal drops	15%
Fisherman's Friend	1.5 mg/ml

Compound Benzocain Gel	1.5 mg/ml
Cromoglycate	15%
Sinex (Phenylephrine Hydrochloride)	15%
Afrin (Oxymetazoline)	15%
Fluticasone propionate spray	15%

5. Precision

1. The testing of 10 replicates of negative and positive samples with standard controls was performed. The negative agreement and the positive agreement were 100%.
2. The testing of sets from three different lots with positive and negative standard controls was performed. The negative agreement and the positive agreement were 100%.

6. Hook Effect

The ulti med COVID-19 Antigen Saliva Test was tested with up to 1.6 × 10^5 $TCID_{50}$/ml of heat-inactivated 2019-nCoV strain and no high-dose effect was observed.

KEY TO SYMBOLS USED

	Manufacturer	Σ n	Contents sufficient for <n>tests
IVD	For in vitro diagnostic use only	LOT	Lot. no.
	For single use only		Expiration date
	Read instructions for use	REF	Ordering number
	Keep away from direct sunlight		Store at
	Keep Dry		

NOTE

This operating manual conforms to the latest technology / revision. Subject to change without prior notice!

ulti med Products (Deutschland) GmbH
Reeshoop 1 • 22926 Ahrensburg
Telefon: 04102 - 80090
Fax: 04102 - 50082
E-Mail: info@ultimed.org
www.ultimed.org

May 2021 G / ME
Rev: C

CE