SARS-CoV-2 Antigen Saliva Lolly Test

Package Insert

Cat: COVG-603
Version: Z
Specimens: Saliva
Effective Date: 2021.07

For professional *in vitro* diagnostic use only.

INTENDED USE

The Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in saliva specimens directly collected from individuals who are suspected of SARS-CoV-2.

Results are for the identification of SARS-CoV-2 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 SARS-CoV-2 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 SARS-CoV-2 and confirmed with a molecular assay.

PACKAGE SPECIFICATIONS

1test/pack, 5tests/pack, 25 tests/pack, 50 tests/pack, 100 tests/pack

INTRODUCTION

The novel coronaviruses belong to the β genus. SARS-COV-2 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

This test uses double-antibody sandwich to legally detect the antigen of novel coronavirus (SARS-CoV-2) in saliva samples. During detection, the gold labeled anti-SARS-CoV-2 monoclonal antibody in the labeling pad binds to the SARS-CoV-2 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-SARS-CoV-2 monoclonal antibody pre-coated by 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 SARS-CoV-2 antigen, a red color reaction line cannot be formed in the T zone. Regardless of whether the sample to be tested contains SARS-CoV-2 antigen, a red reaction line will always form in the quality control area (C).

REAGENTS

The test cassette contains anti-SARS-CoV-2 Nucleocapsid protein particles and anti-SARS-CoV-2 Nucleocapsid protein coated on the membrane.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

1.For professional in vitro diagnostic use only. Do not use after the expiration date.

2.The test should remain in the sealed pouch until ready to use.

3.All specimens should be considered potentially hazardous and handled in the same manner as an infection agent.

4.The used test should be discarded according to local regulations.

5.Avoid using bloody samples.

6.Wear gloves wen handing the samples, avoid touching the reagent membrane and sample well.

STORAGE AND STABILITY

1. Store the test as packaged between 2-30°C.
2. The Test stable until the expiration date printed on the outer packing, the product will be expired after 24 months.
3. Do not use beyond the expiration date.
4. Do not freeze any contents of the test
5. The test must remain in the sealed pouch until use.

KIT COMPONENTS

Materials provide

Test Midstream
Package Insert

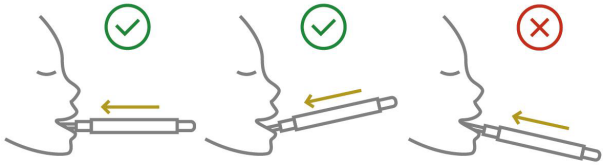
Materials required but not provide

Timer For timing use.

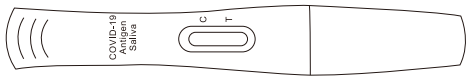
DIRECTIONS FOR USE

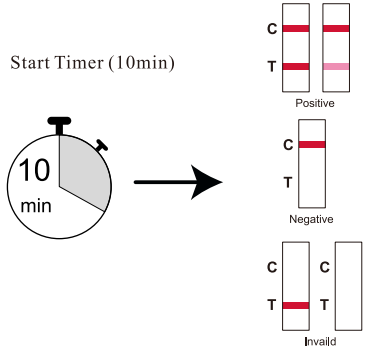
Before test, please read the instructions carefully.

1. Take the midstream to equilibrate to room temperature.
2. Open the aluminum foil bag, take out the midstream
3. Insert the absorbent tip into the mouth. Make sure midstream is horizontally placed.



4. Swab the absorbent tip in the mouth and tongue to collect oral fluid.
5. Take the absorbent tip out from the mouth when the purple color move across the result window in the center of the midstream.
6. Wait for 10 minutes and read the results.





NOTE:

****When sampling, gently hold it in mouth and let saliva naturally adsorb on the absorbent tip.***

****Do not eat, drink, or smoke prior to the test for at least 30 Minutes.***

****Any saliva specimen is appropriate for testing, but the saliva specimen collected in the morning, before mouth rinsed, eating, or drinking, is recommended.***

INTERPRETATION OF RESULTS

NEGATIVE RESULT:

One colored line appears in the control line region (C). No line appears in the test region (T). A negative result indicates that SARS-CoV-2 antigen is not present in the specimen or is present below the detectable level of the test.

POSITIVE RESULT:

Two lines appear.one colored line should be in the control region (C) and another apparent colored line should be in the test region (T). A positive result indicates that SARS-CoV-2 was detected in the specimen.

INVALID RESULT:

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

NOTE:

The intensity of the color in test line region (T) will vary depending on the concentration of SARS-CoV-2 Antigen present in the specimen. Therefore, any shade of color in the test line region(T) should be considered positive.

QUALITY CONTROL

The test contains a built-in internal control in the midstream. A color band appearing in the control region (C) is designed as an internal control. The appearance of the control line confirms that sufficient flow has occurred, and that the midstream is working normally. If the control line does not appear within 10 minutes, it is considered an error in the test result and it is recommended to test again with the same sample and a new device.

LIMITATIONS OF THE TEST

1. The result of the test should not be taken as a confirmed diagnosis, for clinical reference only. Judgement should be made along with RT-PCR results, clinical symptoms, epidemiological information, and further clinical data.
2. The Test 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 must be equilibrated to room temperature (18℃~26℃) 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. React less than 10 minutes may lead a false negative result; React more than 10 minutes may lead a false positive result.
7. Positive test results do not rule out co-infections with other pathogens.
8. Negative test results are not intended to rule in other viral or bacterial infections.
9. Negative results should be treated as presumptive and confirmed with a molecular assay.
10. Clinical performance was evaluated with fresh samples.
11. Users should test specimens as quickly as possible after specimen collection.

PERFORMANCE CHARACTERISTICS

Clinical Verification

The performance of Test was established with 232 sample collected from symptomatic patients, who with symptoms onset within 7 days.

SARS-CoV-2 Antigen Saliva Lolly Test	Comparative RT-PCR Test Result		
	Positive (+)	Negative (-)	Total
Detected Positive	108	1	109
Detected Negative	7	116	123
Total	115	117	232
Sensitivity	93.91%, 95% CI (87.97,97.02)		
Specificity	99.15%, 95% CI (95.32, 99.85)		
Accuracy	96.55%, 95% CI (93.34, 98.24)		

Positive results broken down by days since symptom onset:

Days since symptom onset	RT-PCR Positive (+)	SARS-CoV-2 Antigen Saliva Lolly Test	PPA
1	13	13	100%
2	32	32	100%
3	52	51	98.08%
4	69	67	97.10%
5	86	83	96.51%
6	102	97	96.00%
7	115	108	93.91%

Positive results broken down by CT value:

SARS-CoV-2 Antigen Saliva Lolly Test	Comparative RT-PCR Method (Positive by Ct Value)	
	Positive (Ct<=25)	Positive (25<Ct)
Detected Positive	69	39
Total	70	45
Positive agreement	98.57%	86.67%

Detection Limit

When the virus content is greater than 400$TCID_{50}$/ml, the positive detection rate is greater than 95%. When the virus content is less than 200$TCID_{50}$/ml, the positive detection rate is less than 95%, so the minimum detection limit of this product is 400$TCID_{50}$ /ml.

Precision

Three consecutive batches of reagents were tested for precision. Different batches of reagents were used to test the same negative sample 10 times in succession, and the results were all negative. Different batches of reagents were used to test the same positive sample 10 times in succession, and the results were all positive.

HOOK effect

When the virus content in the sample to be tested reaches 4.0*$10^5$$TCID_{50}$/ml, the test result still does not show the HOOK effect.

Cross-Reactivity

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

Name	Concentration
HCOV-HKU1	10^5TCID_{50} /ml
Staphylococcus aureus	10^6TCID_{50} /ml
Group A streptococci	10^6TCID_{50} /ml
Measles virus	10^5TCID_{50} /ml
Mumps virus	10^5TCID_{50} /ml
Adenovirus type 3	10^5TCID_{50} /ml
Mycoplasma pneumonia	10^6TCID_{50} /ml
Paraimfluenzavirus, type2	10^5TCID_{50} /ml
Human metapneumovirus	10^5TCID_{50} /ml
Human coronavirus OC43	10^5TCID_{50} /ml
Human coronavirus 229E	10^5TCID_{50} /ml
Bordetella parakeratosis	10^6TCID_{50} /ml
Influenza B Victoria STRAIN	10^5TCID_{50} /ml
Influenza B YSTRAIN	10^5TCID_{50} /ml
Influenza A H1N1 2009	10^5TCID_{50} /ml
Influenza A H3N2	10^5TCID_{50} /ml
H7N9	10^5TCID_{50} /ml
H5N1	10^5TCID_{50} /ml
Epstein-Barr virus	10^5TCID_{50} /ml
Enterovirus CA16	10^5TCID_{50} /ml
Rhinovirus	10^5TCID_{50} /ml
Respiratory syncytial virus	10^5TCID_{50} /ml
Streptococcus pneumonia-ae	10^6TCID_{50} /ml
Candida albicans	10^6TCID_{50} /ml
Chlamydia pneumoniae	10^6TCID_{50} /ml
Bordetella pertussis	10^6TCID_{50} /ml
Pneumocystis jiroveci	10^6TCID_{50} /ml
Mycobacterium tubercu- losis	10^6TCID_{50} /ml
Legionella pneumophila	10^6TCID_{50} /ml
Human coronavirus NL63	10^5TCID_{50} /ml
MERS coronavirus	10^5TCID_{50} /ml

Interfering Substances

The test results do not be interfered with the substance at the following concentration:

Interfering substance	Conc.	Interfering substance	Conc.
Whole Blood	4%	Compound Benzoin Gel	1.5mg/ml
Ibuprofen	1mg/ml	Cromolyn glycate	15%
tetracycline	3ug/ml	chloramphenicol	3ug/ml
Mucin	0.5%	Mupirocin	10mg/ml
Erythromycin	3ug/ml	Oseltamivir	5mg/ml
Tobramycin	5%	Naphazoline Hydrochlo-ride Nasal Drops	15%
menthol	15%	Fluticasone propionate spray	15%
Afrin	15%	Deoxyepinephrine hydro-chloride	15%

BIBLIOGRAPHY

1.Weiss SR, Leibowitz JZ. Coronavirus pathogenesis. Adv Virus Res 2011; 81:85-164

2.Cui J,Li F,Shi ZL.Origin and evolution of pathogenic coronaviruses.Nat Rev Microbiol 2019;17:181-192.

3.Su S,Wong G,Shi W,et al.Epidemiology,genetic recombination,and pathogenesis of coronaviruses. Trends Microbiol 2016; 24:490-502.

Index of Symbols

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	Catalogue numb

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Area C, Building 2, No.365, Wuzhou Road,Yuhang Economi Development Zone,Hangzhou City 311100 Zhejiang China
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EC REP **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestrasse 80, 20537 Hamburg, Germany

CE