SaliCOV

Saliva COVID-19 Rapid Test KIT

• For saliva use only • For in vitro Diagnostic Use Only • Prescription use Only

INTENDED USE

The Salignostics SaliCOV Saliva-based COVID-19 Test Kit is an in-vitro diagnostic medical device for a one-step rapid and direct qualitative detection of SARS-CoV-2 virus Nucleocapsid Protein (NP) in saliva. Antigen may be detectable in saliva specimens during the acute phase of infection, therefore positive results indicate the presence of COVID-19 viral antigens.
The SaliCOV Test Kit is intended to be used by minimally trained healthcare professional at the Point Of Care (POC), i.e., in near patient settings.
The SaliCOV Test is designed to detect antigen from the SARS-CoV-2 in Saliva from patients who are suspected of COVID-19 by their healthcare provider within the first 5 days of symptom onset or 7 days within close contact with a positive COVID-19 case.

SUMMARY AND EXPLANATION OF THE TEST

Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARS-CoV-2 is an enveloped, single-stranded RNA virus of the β genus. The virus can cause mild to severe respiratory illness and has spread globally. The SARS-CoV-2 virion is crown-shaped with a diameter of ~50–200 nm, having four structural proteins: spike (S), envelope (E), membrane (M), and nucleocapsid (NP). The S, E, and M proteins are responsible for viral envelope generation and the N protein carries the RNA genome (~30 kb).

Salignostics SaliCOV Test Kit is a rapid lateral flow immunoassay which enables a one-step rapid and direct qualitative detection of SARS-CoV-2 virus Nucleocapsid Protein (NP) in saliva. Antigen may be detectable in saliva swab specimens during the acute phase of infection, therefore positive results indicate the presence of COVID-19 antigens. However, clinical correlation with patient history and other diagnostic information is necessary to determine infection status. 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 COVID-19, and confirmed with a molecular assay, if necessary, for patient management

PRINCIPLES OF THE PROCEDURE

The SaliCOV Test consists of an Analytical unit and a Saliva collection handle.

The Saliva collection handle is a non-sterile plastic applicator with an absorbent sponge tip intended for the absorbance and direct collection of saliva from the patient's mouth.

The SaliCOV Analytical unit is composed of a saliva processing unit and a Lateral Flow Immunoassay (LFIA) strip, enclosed in a plastic housing.

The LFIA strip contains SARS-CoV-2 specific antibodies and secondary antibodies immobilized on the membrane. If SARS-CoV-2 antigen is present in the saliva, a complex formed between the anti-SARS-CoV-2 conjugate and the virus will be captured by the specific anti-SARS-CoV-2 monoclonal antibodies coated on the test line zone (T). Absence of the T line suggests a negative result. The Control (C) line includes non-specific antibodies and indicates that the test is working properly.

Saliva collection and device assembly are performed by the patient under the supervision of the POC operator, which then reads and interprets the results. The patient immerses the absorbent foam of the Collection handle in the mouth, for a sufficient amount of time, to absorb saliva, and then connects the Collection handle to the Analytical unit. Children can be assisted by their parents.

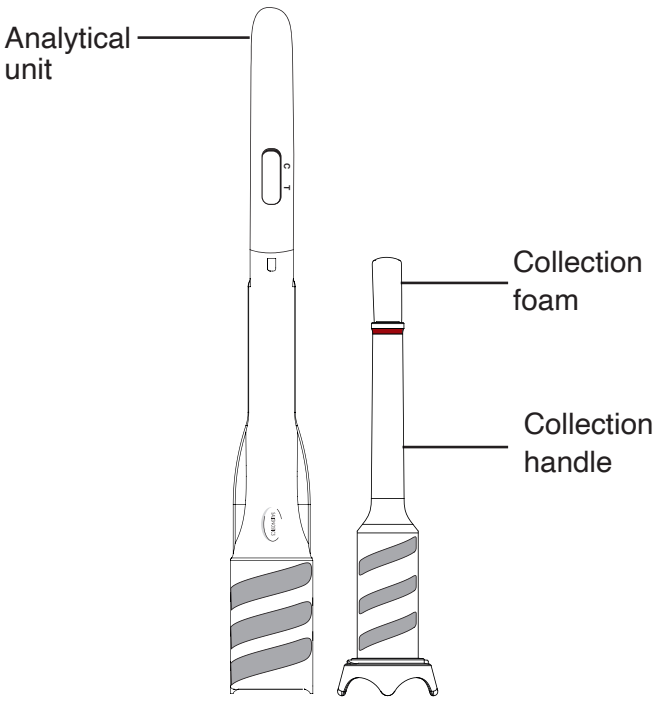
The device is then handed to the POC operator. The results are presented in a window located in the plastic housing of the Analytical unit and are interpreted by the POC operator according to the device instructions for use.

REAGENTS AND MATERIALS

No special instruments are needed for test performance.

KIT CONTENTS

A sealed pouch with a Collection handle, Analytical unit and a preservative silica bag (to be tossed away).
Do not use the kit if the parts are broken or damaged.



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PRECAUTIONS

1. For professional in vitro diagnostic use only.
2. This test is only for the detection of SARS-CoV-2 antigen, not for any other viruses or pathogens.
3. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
4. Proper sample collection is essential for correct results. Inadequate or inappropriate sample collection may yield false test results.
5. Leave test sealed in its foil pouch until just before use.
6. Do not use kit past its expiration date.
7. Do not use if the foil pouch is damaged or opened. The test should be performed immediately after opening the pouch.
8. Do not reuse the used test.
9. Do not store specimens in viral transport media for specimen storage.
10. All components of this kit should be discarded as Biohazard waste according to local regulatory requirements. Patient samples and test devices should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
11. Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19.
12. INVALID RESULTS can occur when an insufficient volume of saliva is used. Visibility of the blue saturation indicator in the Collection sponge indicates that the patient has absorbed adequate saliva volume.
13. Saliva collection unit in the kit is for use with SaliCOV Test Kit. Do not use other saliva collection method with this kit.

STORAGE AND STABILITY

Store kit and perform the test at 10-30°C. Do not freeze.

Test devices that have been outside of the sealed pouch for more than 1 hour should be discarded.

Do not use the SaliCOV Test Kit after expiration date.

QUALITY CONTROL

Salignostics SaliCOV Test Kit has a built-in procedural control: the control line.

The control line determines:
• if an adequate amount of saliva was used.
•if chemicals are working properly.

SPECIMEN COLLECTION AND HANDLING

The test should be performed at least 30 minutes after eating, drinking or smoking

Test saliva= immediately after collection for optimal test performance. Inadequate saliva collection or improper sample handling may yield erroneous results.

Saliva Only: the SaliCOV Collection handle provided in the kit is to be used for saliva collection.

Saliva is collected by the patient under the supervision of the POC operator.

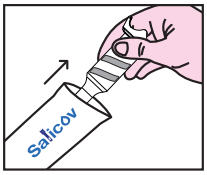
TEST PROCEDURE

Self-collection of saliva by the patient:
Ask the patient to review the Patient Quick Reference Instructions (QRI) and ask if the procedure is clear.

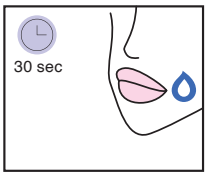
The test should be performed at least 30 minutes after eating, drinking or smoking.

The test should be performed immediately after opening the pouch. The collection sponge should not come into contact with the hands or the surface.

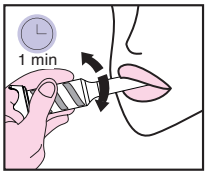
To collect saliva using the Collection handle, the patient is instructed to:



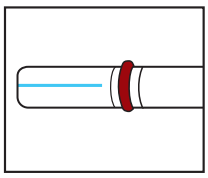
1. Take the device out of the pouch



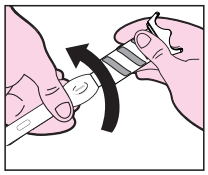
2. Allow saliva to pool in mouth (for at least 30 seconds).



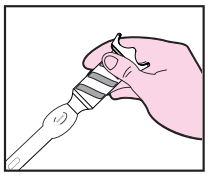
3. Place the Collection foam in the mouth for at least 1 minute. While collecting saliva, roll the foam in the mouth from side to side a few times to increase saliva absorbance.



A blue line should be clearly visible throughout the Collection foam.
If the blue line is not clearly visible, the patient should continue to collect saliva for 1 additional minute.



4. Screw the Collection handle clockwise into the Analytical unit, until it is secured. Afterword's, the test is not to be reopened.



5. The test is then handed to the POC operator.

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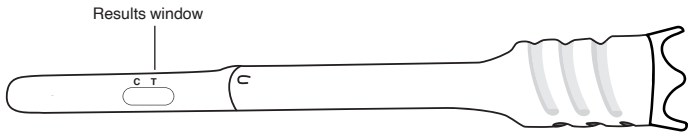
Steps to be performed by the POC operator:

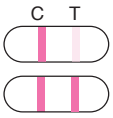
15-minutes Incubation:



1. Lay the SaliCOV device on a flat clean surface with the Result Window facing up. You may see a pink color moving across the Result Window, within 1-4 minutes.
This indicates that the test is working.
2. Read the result within 15 minutes from connecting the Collection handle to the Analytical unit. The test result should not be read and interpreted after 20 minutes. Disregard any changes to the result after this time.

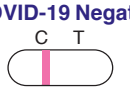
INTERPRETATION OF RESULTS

COVID-19 Positive:



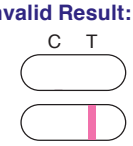
TWO PINK LINES in the Result Window.
One line may be lighter than the other.
Appearance of the results may vary.
Please Note: The Test line can be very faint, however any pink visible at the test line area indicates a positive result.

COVID-19 Negative:



ONE control PINK LINE in the Result Window

Invalid Result:



No control line or inhomogeneous flow over the LFIA strip.
The patient results cannot be interpreted

LIMITATIONS

- For saliva use only
- This test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. 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.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- The performance of the Salignostics SaliCOV Test Kit was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- False negative results may occur if a specimen is improperly collected or handled.
- False results may occur if test is read before the elapse of 15 minutes or after 30 minutes. Saliva should be testes immediately after collection.

PERFORMANCE CHARACTERISTICS

CLINICAL PERFORMANCE

In this study, saliva samples were collected from volunteers who attended COVID-19 testing centers, withing five (5) days since onset of symptoms. Overall, all negative samples and positive samples with RT-PCR Ct<30 were tested using the SaliCOV Test Kit. .

From the pre-collected saliva samples, 88 positive samples (with Ct<30) and 300 negative samples (as determined by swab RT-PCR) were each tested using FDA EUA saliva PCR test. Results are presented below.

SaliCOV Test Kit	Saliva RT-PCR (Comparator)		
	Positives	Negatives	Total
Positive	72	0	72
Negative	16	300	316
Total	88	300	388
PPA: 72/88 = 82% (95% CI: 72.2% - 89.2%)			
NPA: 300/300 = 100% (95% CI: 98.8%-100%)			

PPA - Positive Percent Agreement (Sensitivity)
NPA - Negative Percent Agreement (Specificity)

ANALYTICAL PERFORMANCE

Limit of Detection - LOD (Analytical Sensitivity):
Limit of Detection (LoD) studies determined the lowest detectable concentration of SARS-CoV-2 at which 100% of all (true positive) replicates test positive. Following calibration studies, a study was performed to confirm the analytical sensitivity / limit of detection (LoD) of the SaliCOV test, by spiking pooled negative saliva with γ-irradiated SARS-CoV-2 at a concentration of 20 TCID50/ml. All 20 samples spiked with SARS-CoV-2 at 20 $TCID_{50}$/ml provided positive result, therefore 20 $TCID_{50}$/ml SARS-CoV-2 was determined as the LoD for the Test.

Cross Reactivity (Analytical Specificity) and Microbial Interference
Cross reactivity and potential interference of SaliCOV Test was evaluated by testing commensal and pathogenic microorganisms that may be present in saliva. Each of the organism and viruses were tested in triplicate in the presence of 60 $TCID_{50}$/ml γ-irradiated SARS-CoV-2 (for interference) or 5-replicates in the absence of γ-irradiated SARS-CoV-2 (for cross-reactivity). No cross-reactivity or interference was seen with the with Human coronavirus 229E, Human respiratory syncitial virus (RSV) A, Human parainfluenzavirus 2, Human adenovirus 1, Betacoronovirus 1, Influenza B virus, Enterovirus D68, Betacoronovirus 1, Strep Mutans, Psuedomons Aerogenosa and Streptococcus Sanguis. In addition, the following are not expected to cause cross-reactivity or interference: human coronavirus (OC43, NL63 & HKU1), influenza A virus, RSV B, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila and Parainfluenza (1, 3, 4), based on data by the manufacturer of the LFIA strip.

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Endogenous Interference Studies
The following substances, naturally present in saliva or that may be artificially introduced into saliva, did not cause interfere with the ability of the SaliCOV to detect SARS-CoV2 positive sample: Crest/ Listerine Mouthwash, Naso GEL (NeilMed), Fluticasone Propionate, CVS Nasal Drops (Phenylephrine), Mupirocin, Tamiflu (Oseltamivir Phosphate), CVS Nasal Spray (Cromolyn), Alcohol (Ethanol), Nicotine, Vaseline, Zinc, Resyl Syrup, Biotin Toothpaste, as well as pH=5 and pH=8. In addition, the following are not expected to cause interference: human blood (with EDTA anticoagulant), Mucin, Antiviral Drugs (Ribavirin), Antibiotics (Levofloxacin, Azithromycin, Meropenem, Tobramycin), nasal corticosteroids (Beclomethasone, Hexadecadrol, Flunisolide, Triamcinolone, Budesonide, Mometasone, Fluticasone, Fluticasone propionate), based on data by the manufacturer of the LFIA strip.

High Dose Hook Effect
High Dose Hook Effect studies determine the level at which false negative results can be seen when very high levels of target are present in a tested sample. No high dose hook effect was observed when tested with up to a concentration of up to 1000-times the Limit of Detection (LoD) of the SaliCOV Test (i.e. $2*10^4$ $TCID_{50}$/mL of γ-irradiated SARS-CoV-2).

	Manufacturer
REF	Catalog Number
IVD	In vitro diagnostic medical device
	Consult instruction for use
	Do not reuse
	Do not use if package is damaged
	Storge temperature
	Keep dry
	Use by
EC REP	Authorized European Representative
	Disposal
LOT	Lot number
QTY	Units in box

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