SWISSONEMED®
WIZBIOTECH

PROFESSIONAL USE

SARS-CoV-2 Antigen Rapid Test (SALIVA)

ANTIGEN RAPID TEST

Very reliable
Detect 2-3 days after contracted virus
No cross reactivity
Recognizes all known mutations
User friendly
BfArM registered
PEI registered & evaluated
Test result under 20 minutes

Respect Yourself - Protect Yourself - Test Yourself

swissonemed.ch/saliva-professional

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SARS-CoV-2 Antigen Rapid Test (SALIVA)
SPIT & SALIVA QUICK TEST

HOSPITALS, DOCTOR'S OFFICES, TEST STATIONS, SCHOOLS, UNIVERSITIES, COMPANIES, AUTHORITIES AND MORE

Packaging Quantities For Professional Use Nasal Swab

Article Number: 500.51
Packaging Unit: 1 Single TEST Kit

Article Number: 500.61
Packaging Unit: 5 Single TEST Kits

Article Number: 500.71
Packaging Unit: 10 Single TEST Kits

Article Number: 500.81
Packaging Unit: 25 Single TEST Kits

Article Number: 500.91
Packaging Unit: 500 Single TEST Kits

PRODUCT DESCRIPTION

1.) Product Name

SARS-CoV-2 Antigen Rapid Test (SALIVA)

2.) Intended Use

The production is intended for the qualitative detection of SARS-CoV-2 Antigen (Nucleocapsid protein) in Saliva sample from patients with suspected SARS-CoV-2 infection within the first 7 days after symptom onset in vitro. It is applicable to the home self-testing or professional testing occasions.

3.) Packing Specification

1, 5, 10, 25, 500 Single Test Kit Sets

4.) Reagent Storage And Stability

The kit is stored 2~30°C, dry and out of direct sunlight (freezing is forbidden). The shelf life of the kit is 24 months. The test device should be used within 60 minutes after opening the aluminum foil bag. For expiration date, please refer to the product label.

5.) Kit Components

1)	Specification
2)	Test device
3)	Single individual aluminum foil bag packing
4)	Extraction tube
5)	Filled with Treatment solution
6)	Disposable sampling rod
7)	Disposable sample container
8)	Instructions for Use
9)	Quick reference guide

6.) Principle

SARS-CoV-2 Antigen Rapid Test (Saliva) employs immuno-lateral chromatography technology for the qualitative detection of antigen. The colloidal gold particles labeled with the anti-SARS-CoV-2 antibody 1 and Rabbit IgG are fixed on the conjugation pad. The anti-SARS-CoV-2 antibody 2 is bound on the test line (T line) of nitrocellulose membrane. The Goat Anti-Rabbit IgG is bound on the control line (C line) of nitrocellulose membrane. When the concentration of SARS-CoV-2 in the specimen is higher than the minimum detection limit, which can conjugate with the anti-SARS-CoV-2 antibody 1 labeled with colloidal gold particles to form a complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by the anti-SARS-CoV-2 antibody 2 bound on the test line, forming „Au-Anti-SARS-CoV-2 antibody 1-(SARS-CoV-2) -Anti-SARS-CoV-2 antibody 2 complex. These complexes are deposited to display color as the determination of antigen positive, the Rabbit IgG labeled with colloidal gold particles conjugate with the Goat Anti-Rabbit IgG and deposit to display color as the determination of quality of the control line. When the concentration of SARS-CoV-2 in the specimen is lower than the minimum detection limit or the specimen have no SARS-CoV-2, the complexes only deposit and display color in the control line.

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Summary of the Performance of the SARS-CoV-2 Antigen Saliva Rapid Test Compared to RT-PCR

WIZ Results	Reference PCR Results		
	POS	NEG	TOTAL
POS	328	0	328
NEG	16	555	571
TOTAL	344	555	899

SENSITIVITY: 95.35%

This is used to determine whether the virus was detected in people who are sick. If the sensitivity is given as 98% in a test, this means that 98 out of 100 infected people were detected, but the disease was not detected in 2 people.

SPECIFICITY: 100%

The accuracy of a test. if a test has 97% specificity, it means that 97 out of 100 people got a true negative test result. However, three people got a positive result even though they are not infected. It is also known as a false positive.

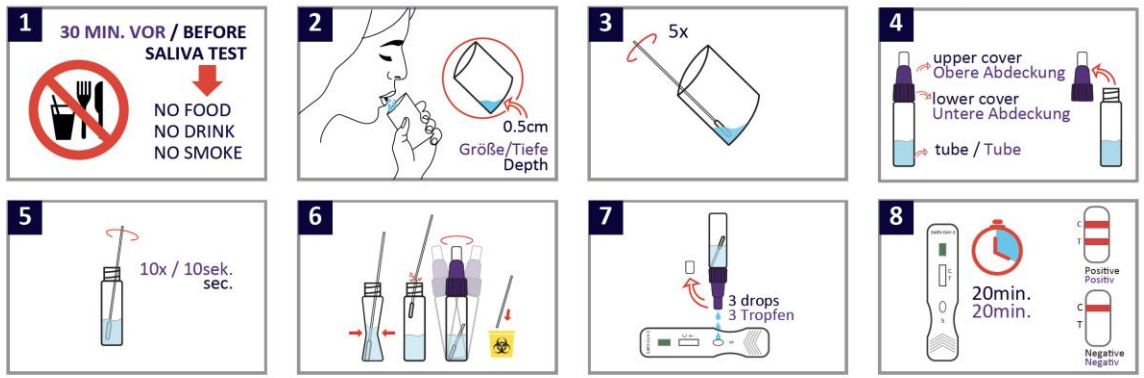
Precision: 98.22%

The precision of a test is determined by totaling the number of true positives and true negatives and dividing by the total number of samples. This shows how accurate a test is.

EXPLANATION OF TERMS:

C.I.: Confidence Interval
PPA: Positive Percent Agreement= True Positives / (True Positives + False Negatives)
NPA: Negative Percent Agreement= True Negatives / (True Negatives + False Positive)
OPA: Overall Percent Agreement= True Positives + True Negatives) / Total Samples

Gebrauchsanweisung / Instructions for use ⚠



1.30 Minuten vor dem Speicheltest nicht essen, nicht trinken, nicht rauchen. 2. Spucken Sie bis zu einer Tiefe von 0,5 cm in den Einweg-Probenbehälter. 3. Rühren Sie den Speichel mit dem Stäbchen 5x um. 4. Lösen Sie die untere Abdeckung des Extraktionsrohrs. 5. Verrühren Sie den Speichel etwa 10 Sekunden lang gründlich mit dem Stäbchen. 6. Drücken Sie die Spitze des Stäbchens durch das Extraktionsrohr und brechen. Sie dieses an der Einkerbung am unteren Ende durch. Den unteren Teil des Stäbchens lassen Sie im Extrationsrohr und verschließen dieses fest.. 7. Geben Sie nun 3 Tropfen auf die Probenvertiefung des Testgeräts und halten Sie das Rohr dabei senkrecht. 8. Nach 20 Minuten wird das Testergebnis angezeigt. Interpretation der Test Ergebnisse, siehe bitte Gebrauchsanweisung

1. No food, no drink, no smoke, 30 minutes before saliva test. 2. Spit saliva into the disposable sample container for 0.5cm in depth 3. Use the rod head to stir the saliva counter clockwise for 5 circles. 4. Loosen the lower cover of extraction tube. 5. Rotate the rod close to the extraciton tube wall for about 10 seconds or 10 times. 6. Squeeze the tip of the rod through extraction tube and break the disposable sampling rod to leave the rod head in the extraction tube. 7. Add 3 drops vertically into the sample well of the test device. 8. View the result within 20 minutes.