SWISSONEMED®
WIZBIOTECH

SELF-TEST/LAY USE

SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)
NASAL SWAB

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/nasal-self-test

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SELF-TESTS, ON THE ROAD, HOME USE & MORE

Packaging Quantities For Professional Use Nasal Swab

Article Number: 500.10 Packaging Unit: 1 Single TEST Kit	**Article Number: 500.20 Packaging Unit: 5 Single TEST Kits**	**Article Number: 500.30 Packaging Unit: 10 Single TEST Kits**
Article Number: 500.40 Packaging Unit: 20 Single TEST Kits	**Article Number: 500.41 Packaging Unit: 500 Single TEST Kits**	

PRODUCT DESCRIPTION

Product Name

SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) NASAL SWAB

Intended Use

This SARS-CoV-2 Antigen Rapid Test is a nasal swab, in which a painless and uncomplicated swab is carried out in the anterior nasal cavity. The process of using the nasal swab is simple and easy to use giving you accurate results in less than 20 minutes. SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) is intended for the qualitative detection of SARS-CoV-2 Antigen (Nucleocapsid protein) in nasal sample from patients with suspected SARS-CoV-2 infection within the first 2-3 days after symtom onset in vitro.

Packing Specification

1, 5, 10, 20, 500 Single Test Kit Sets

Reagent Storage And Stability

Store the kit at 2-30°C/ 36-86°F, out of direct sunlight, valid for 24 months. Do not freeze the kit. The test device should be used within 60 minutes after opening the foil pouch. For production date and expiration date, please refer to the product label.

Kit Components

1) Test device: Mouse anti- SARS-CoV-2 monoclonal antibody, Goat Anti-Mouse IgG polyclona antibody, Nitrocellulose membrane
2) Extraction solution: Phosphate Buffer solution (0.01M, pH7.4±0.2)
3) Disposable swabs
4) Package insert

Principle

SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) employs immuno-lateral chromatography technology for the qualitative detection of antigens [3, 4]. The colloidal gold particles labeled with the anti-SARS-CoV-2 antibody 1 are fixed on the conjugation pad. The anti-SARS-CoV-2 antibody 2 is bound on the "T" test line of nitrocellulose membrane. The Goat Anti-Mouse IgG is bound on the "C" control 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-SARSCoV-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 rest of anti-SARS-CoV-2 antibody 1 labeled with colloidal gold particles conjugate with the Goat Anti-Mouse IgG and deposit to display color as the determination of quality of the "C" control line. When the concentration of SARS-CoV-2 in the specimen is lower than the minimum detection limit or no SARS-CoV-2, the complexes only deposit and display color in the "C" control line.

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Summary of the Performance of the SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) Compared to RT-PCR

WIZ Results	Reference PCR Results		
	POS	NEG	TOTAL
POS	328	0	328
NEG	14	517	531
TOTAL	342	517	859

SENSITIVITY: 95.91%

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: 98.37%

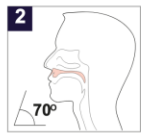
The precision of a test is determined by totaling the number of true positives and true negatives and dividing by the total number of samples. This shows how accurate a test is.

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

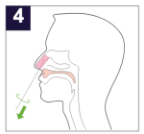
QUICK GUIDE

No food, drinks, or smoking for 30 minutes before swab test.

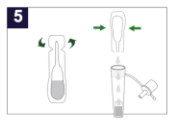


Tilt your head back 70 degrees.

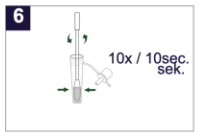
Insert swab into one nostril and go about 2cm deep.



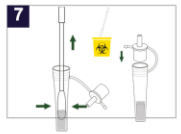
Rotate the swab 5 times and then remove it, then insert it into the other nostril and repeat the steps again.



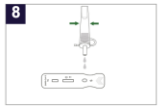
Remove the cap off of the extraction solution and squeeze the liquid into the extraction tube.



Insert the tip of the swab into the extraction tube and solution, press it on the side of the tube, and rotate it for 10 seconds (or around 10 rotations).



While the swab is in the extraction tube, squeeze the sides of it to release any liquid still held in the swab. Discard the swab, and tighten the lid of the tube.



While holding the extraction tube vertically, carefully dispense two (2) drops into the sample well of the device.

View your result within 15-20 minutes.