



***Novel Coronavirus (COVID-19)
Antigen Test Kit (Colloidal Gold)
for self-testing***

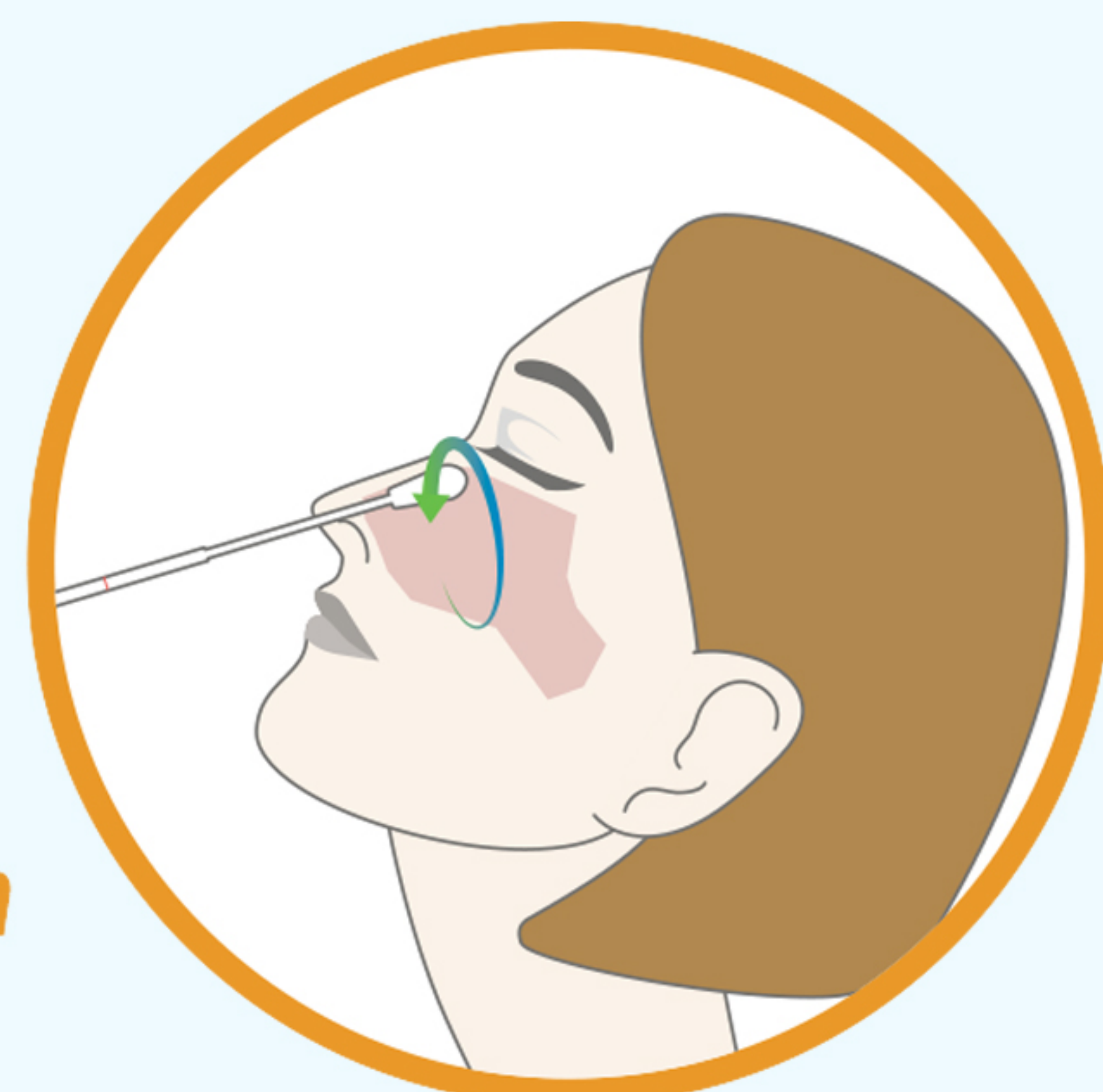
***SARS-Cov-2 Antigen Rapid Tests
for self-testing***

 **FAST**

 **CONVENIENT**

 **SENSITIVE**

15min



Registration No. HL 2069313-1



What is a coronavirus antigen test?

An antigen test is a diagnostic test that checks to see if you're infected with the coronavirus. The test looks for proteins (antigens) in a sample taken from your nose or throat. Antigen tests are **faster** than PCR tests.

LYHER®

LYHER® SARS-Cov-2 Antigen Rapid Tests for self-testing(Colloidal Gold) is an in vitro immunoassay. The assay is for the direct and qualitative detection of antigen of SARS-CoV-2 Protein N from nasopharyngeal, oropharyngeal, Nasal, Saliva and sputum secretions specimens. The kit is for in vitro diagnostic use, and for measuring SARS-CoV-2 antigen from a nasal swab.

Product Features



1 test/kit



5 tests/kit



25 tests/kit



CE Marked



Results in 15mins



Easy to collect sample



No equipment needed



Room temperature storage

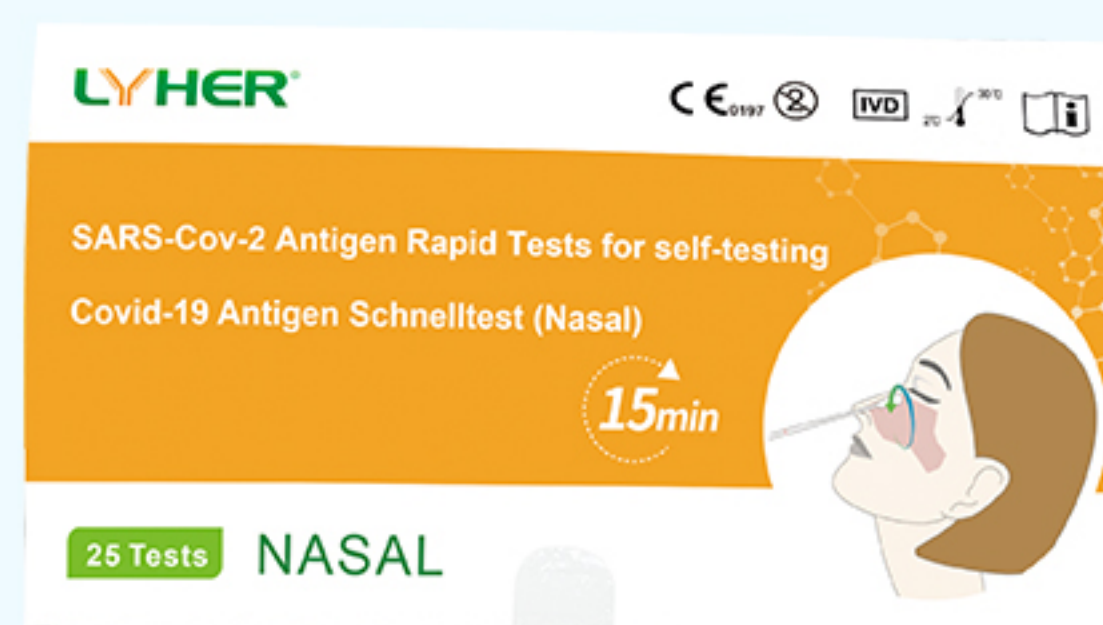


Easy to read results

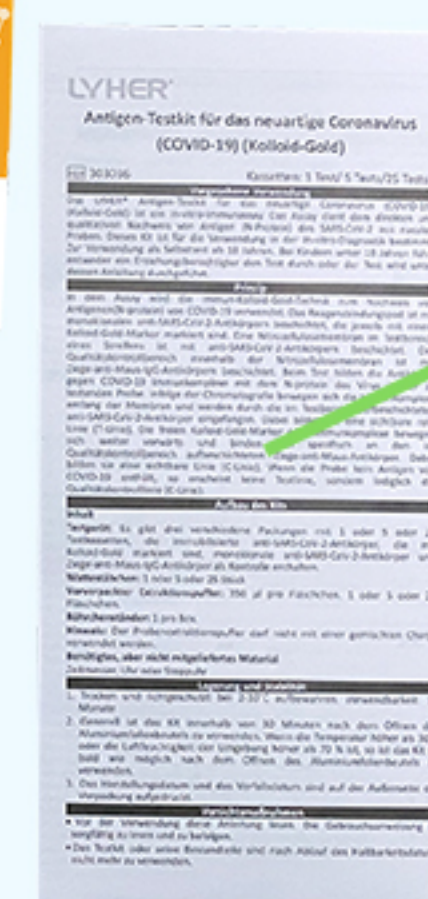
Tube Stand

Swab

Test device

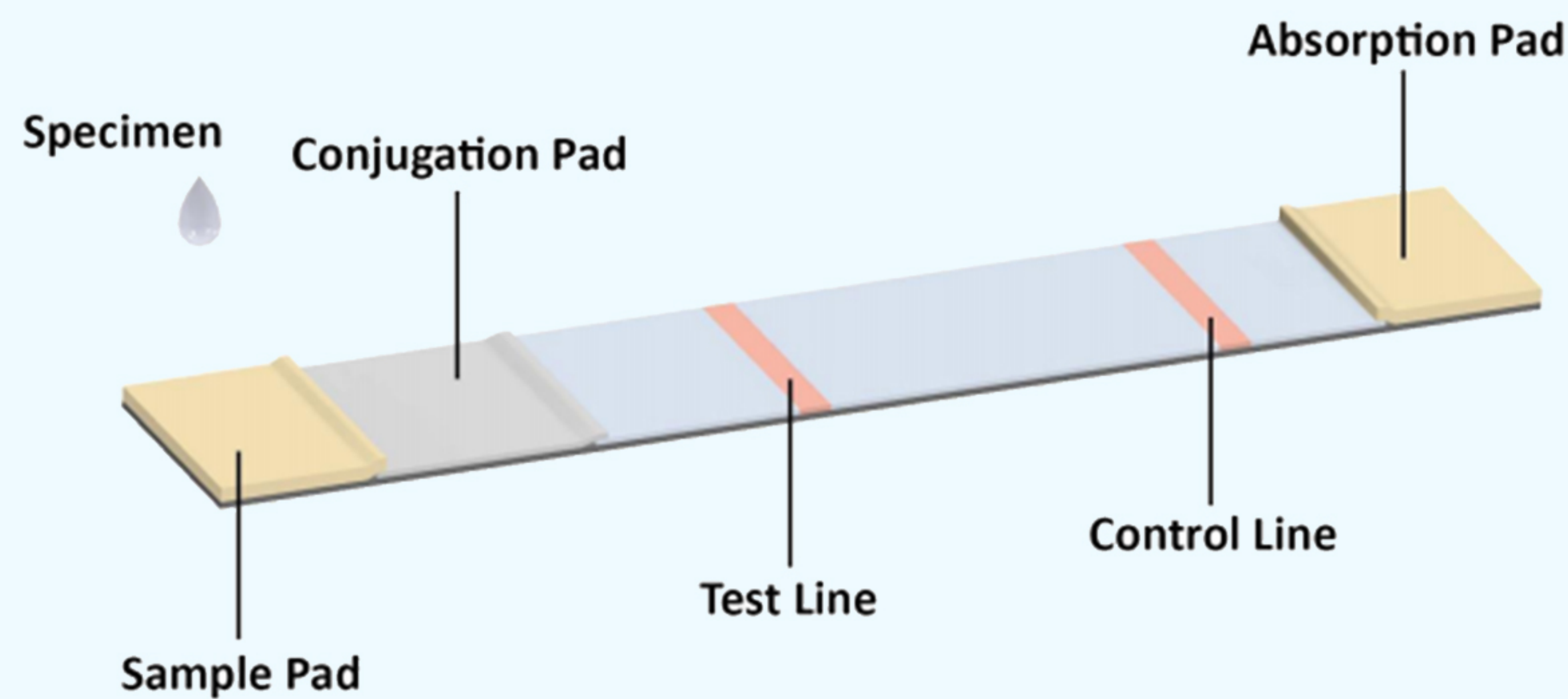


Package insert



Prepackaged extraction buffer

Test Principle



The test line is coated with anti-SARS-CoV-2 antibodies .

The Control line is coated with goat anti-mouse IgG antibodies .

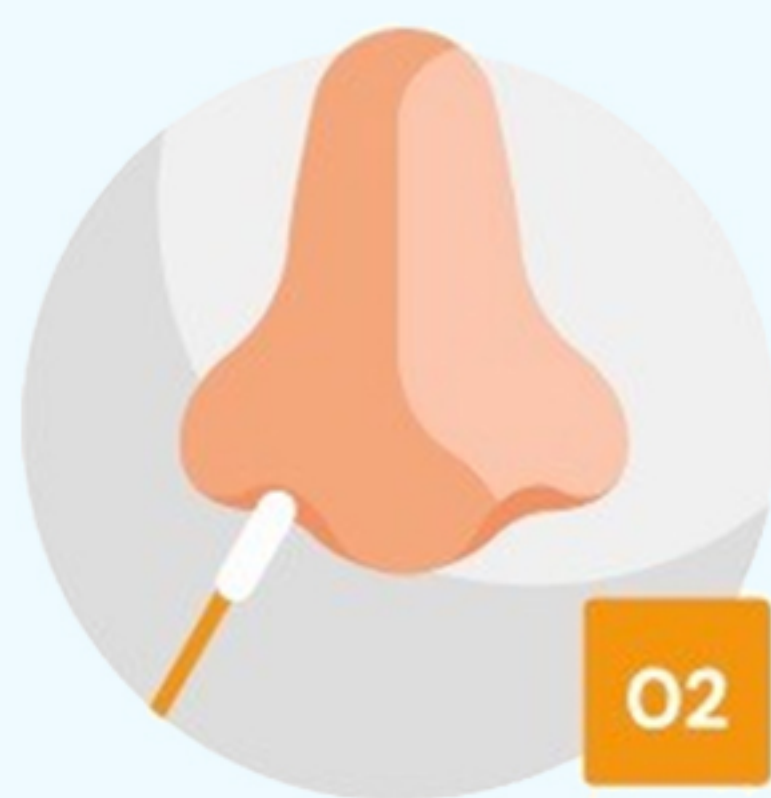
The conjugation pad is coated with anti-SARS-CoV-2 monoclonal antibodies .

If the specimen contains the antigen of SARS-CoV-2, a colored test line(T line) will be visible in the result window. If the specimen does not contain the antigen of SARS-CoV-2, no test line will show, only quality control line(C line) will appear.

Test Procedure



01. Insert the cotton swab into a nostril gently. Insert the tip of the cotton swab 2-4 cm (for children is 1-2 cm) until resistance is felt.



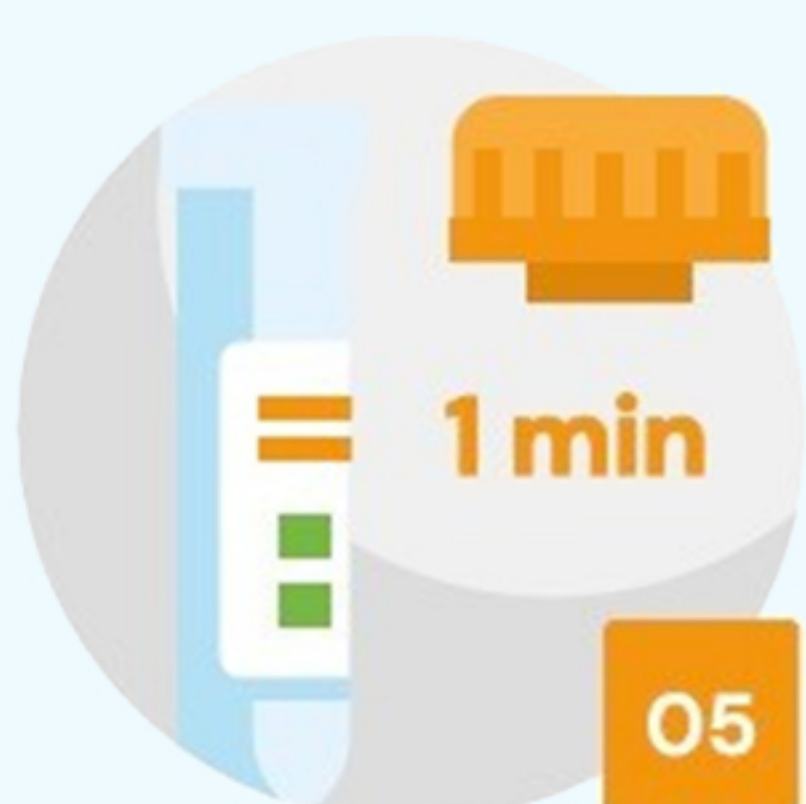
02. Swirl the cotton swab along the nasal mucosa 5 times within 7-10 seconds to ensure that both mucus and cells are absorbed.



03. Dip the head of the cotton swab into the diluent after taking the sample from the nose.



04. Squeeze the sample tube with a cotton swab **10-15 times** to mix evenly so that the wall of the sample tube touches the cotton swab.



05. Keep it upright for **1 minute** to keep as much sample material as possible in the diluent. Discard the cotton swab. Place the dropper on the test tube.



06. Add the sample as follows. Place a clean dropper on the sample tube. Invert the sample tube so that it is perpendicular to the sample hole (S). Add **3 DROPS** of the sample.

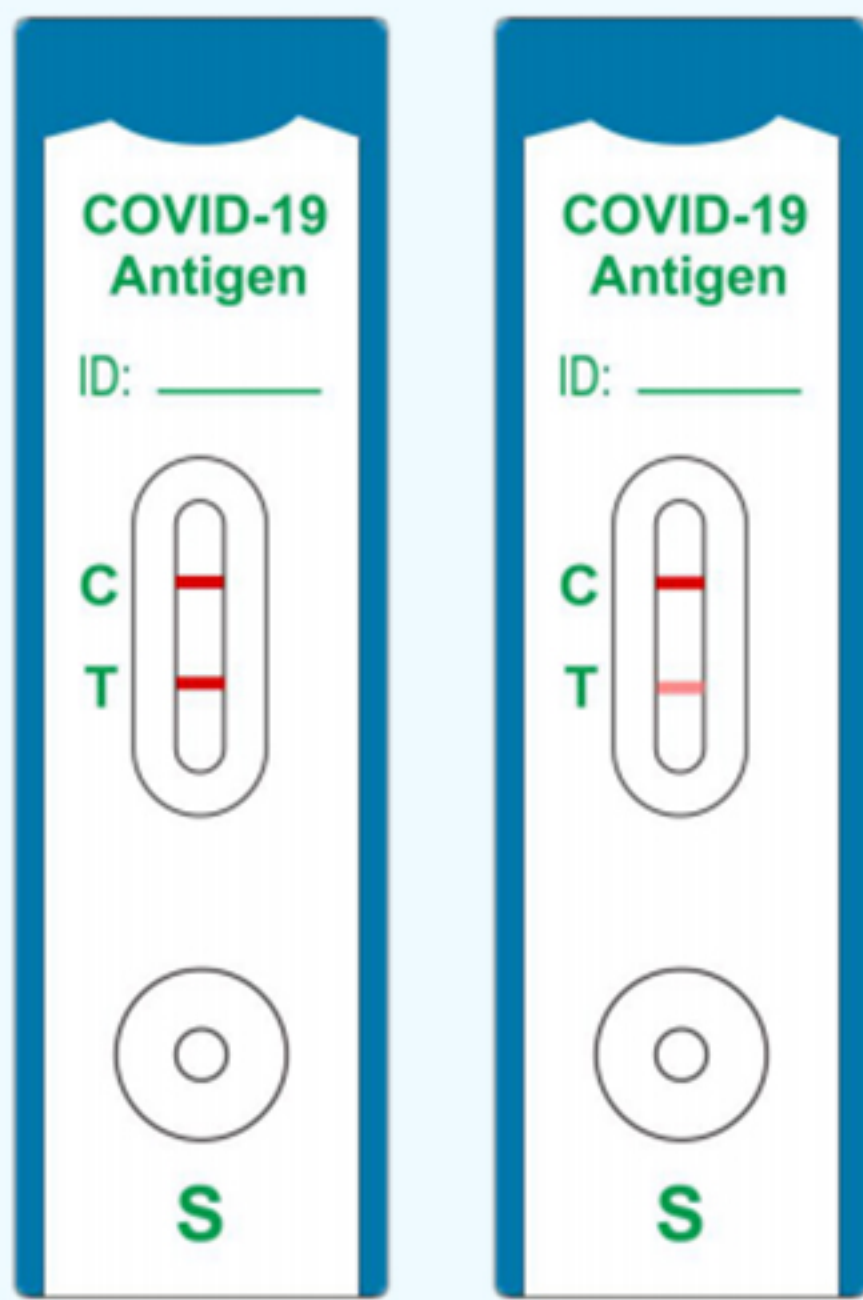


07. Set the timer for **15 MINUTES**.



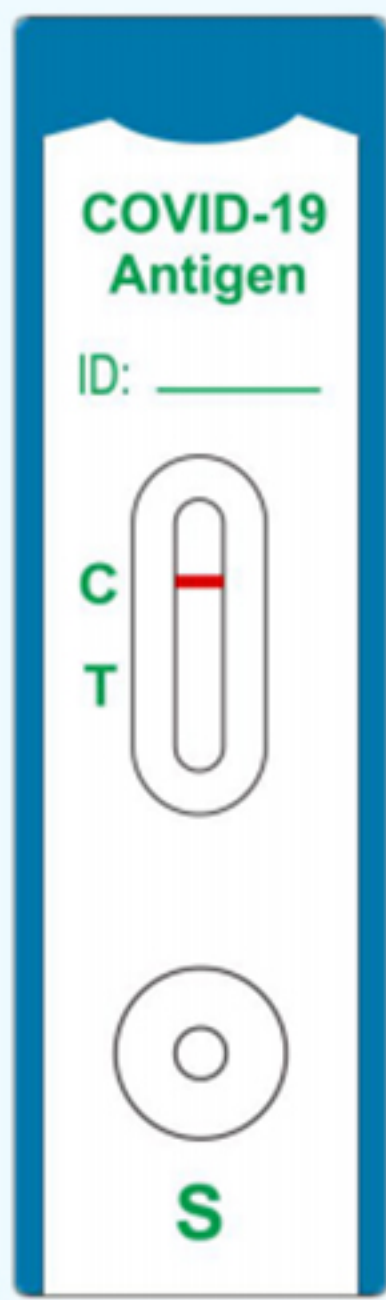
08. Read the result after **15 MINUTES**.

Interpretation of Results



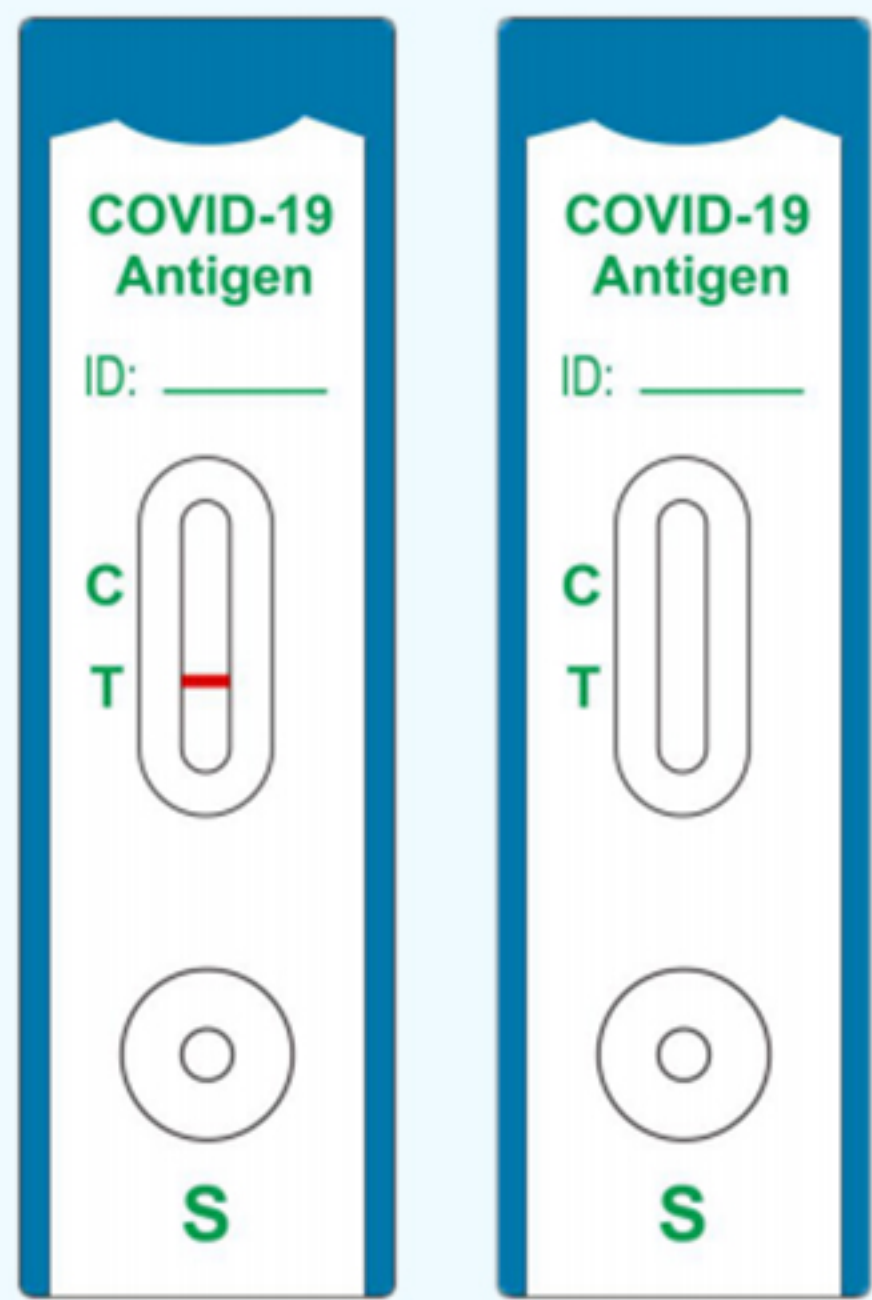
POSITIVE

Two colored lines appear on the membrane. One colored line appears in the control region (C) and the other line appears in the test region (T).



NEGATIVE

Only a single colored line appears in the control region (C). No visible colored line appears in the test region (T).



INVALID

The control line does not appear. The tests results which do not show a control line after the specified reading time should be discarded. The sample collection should be checked and repeated with a new test. Stop using the test kit immediately and contact your local dealer if the problem persists.

Clinical Data

The LYHER® SARS-Cov-2 Antigen Rapid Tests for self-testing was examined with nasal mucus samples from individuals either infected or uninfected with SARS-CoV-2 and compared with a molecular test (RTPCR test), in order to determine sensitivity and specificity. The study was done with 411 samples.

COVID-19 Antigen Self-Test Compared to RT-PCR			
Test results from the Lyher kit	Clinical Diagnosis (PCR results)		
	Positive (+)	Negative (-)	Total
Positive (+)	152	1	153
Negative (-)	8	250	258
Total	160	251	411

Sensitivity: 95.0%

Specificity: 99.6%

A feasibility study showed that 100% of participants understood how the results should be interpreted. Of the participants, 70% found the instructions for use very clear and 30% clear. Of the participants, 76% found the reading of the test result very clear and 23% clear. Of the participants, 67% found the test very easy and 33% easy. 97.81% of different test results were interpreted accurately. 84.67% of participants completed the test without help.

Caution

1. The color intensity in the test region (T) may vary depending on the concentration of virus proteins present in the nasal mucus sample. Therefore, any color in the test region should be considered positive. It should be noted that this is only a qualitative test and cannot determine the concentration of viral proteins in the nasal mucus sample.
2. Insufficient sample volume, improper procedure or expired tests are the most likely reasons why the control line does not appear.

Ordering information

SARS-Cov-2 Antigen Rapid Tests for self-testing			
Code	Specimen	Specification	Carton size L*W*H
303036	Nasal	1test/kit;1000Tests/CTN	705*650*530mm
		5tests/kit;1000Tests/CTN	810*410*400mm
		25tests/kit;1000Tests/CTN	620*455*342mm

LYHER® SARS-Cov-2 Antigen Rapid Tests for self-testing(Colloidal Gold) produced by LAIHE BIOTECH CO., LTD.
LYHER® is one of the top three Chinese suppliers and brands that has been the first batch to be shortlisted in the self-test list of German BfArM

