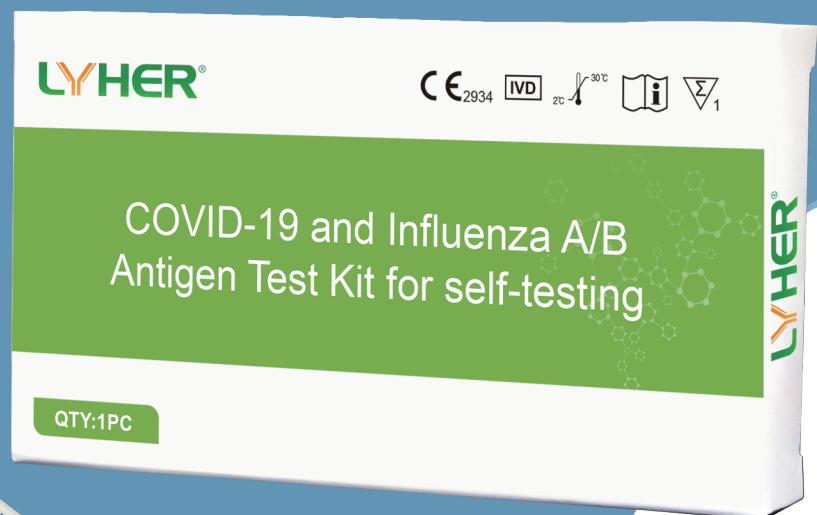


COVID-19 And Influenza A/B

Antigen Test Kit (for Self Testing)



 **FAST**

 **SENSITIVE**

 **CONVENIENT**

LYHER®

The LYHER® **COVID-19 and Influenza A/B Antigen Test Kit for self-testing** is an in vitro immunoassay. The assay is for the direct and qualitative detection of antigen of SARS-CoV-2 and Influenza A/B from nasal swab. The kit is for in vitro diagnostic use by non-professionals only. This test is authorized for non-prescription home use with self-collected nasal swab specimens directly from individuals aged 14-70 years. For individuals who are aged 2-13 years and older than 70 years, the test shall be carried out by an adult or under the help of an adult.



CE Marked



Results in 15mins



Easy to read results

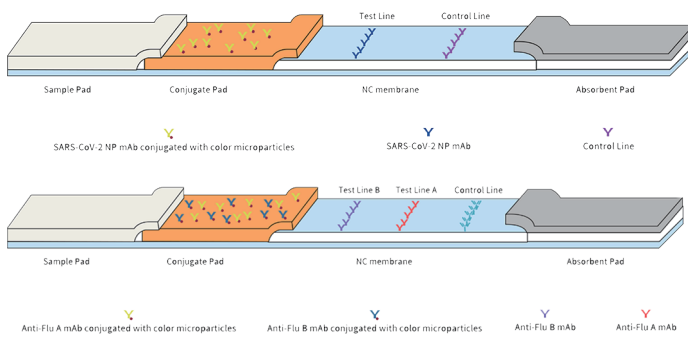


**Easy to collect
specimen at just
2-3.5cm depth**



**Room temperature
storage**

Test Principle



The immune colloidal gold technique is used in the assay to detect antigens of SARS-CoV-2 and Influenza A/B. The sample pad is coated with colloidal gold bound antibodies. The quality control area is coated with goat anti-mouse IgG, and test area with anti-SARS-CoV-2 or Influenza A/B antibodies. When testing, if there are any SARS-CoV-2 or Influenza A/B antigen, the T line will become visible red. The C line should be red after add sample.

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.



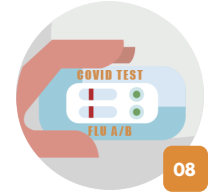
05. Keep it upright for **1 minute** to keep as much sample material as possible in the diluent. Discard the cotton swab. Place the dropper on the test tube.



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 into each sample hole.

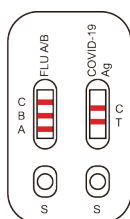
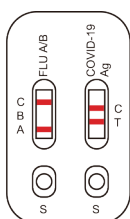
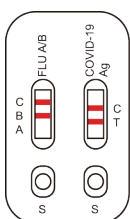


07. Set the timer for **15 MINUTES**.

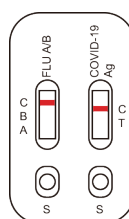


08. Read the result after **15 MINUTES**.

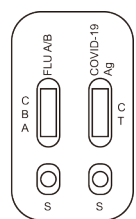
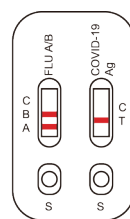
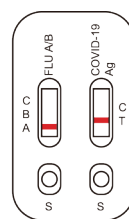
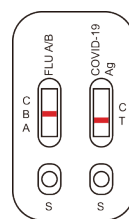
Interpretation of Results



POSITIVE



NEGATIVE



INVALID

Clinical Data

Table 1: COVID-19 Rapid Test vs. RT-PCR

Test Results of Lyher Kit	Clinical diagnosis(PCR results)		
	Positive(+)	Negative(-)	Total
Positive(+)	103	0	103
Negative(-)	7	460	467
Total	110	460	570

Sensitivity: 93.67%

Specificity: more than 99%

Table 2: Influenza A Test vs. RT-PCR

Test Results of Lyher Kit	Clinical diagnosis(PCR results)		
	Positive(+)	Negative(-)	Total
Positive(+)	72	0	72
Negative(-)	1	280	281
Total	73	280	353

Sensitivity: 98.63%

Specificity: more than 99%

Table 3: Influenza B Test vs. RT-PCR

Test Results of Lyher Kit	Clinical diagnosis(PCR results)		
	Positive(+)	Negative(-)	Total
Positive(+)	30	0	30
Negative(-)	0	323	323
Total	30	323	353

Sensitivity: more than 99%

Specificity: more than 99%