

COVID-19 And Influenza A/B Antigen Test Kit



 **FAST**

 **SENSITIVE**

 **CONVENIENT**

LYHER[®]



The LYHER® COVID-19 and Influenza A/B Antigen Test Kit 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 nasopharyngeal secretions and oropharyngeal secretions. The kit is for in vitro diagnostic use.



Test device

Extraction buffer

Package insert



Swab



CE Marked



Results in 15mins



Easy to read results

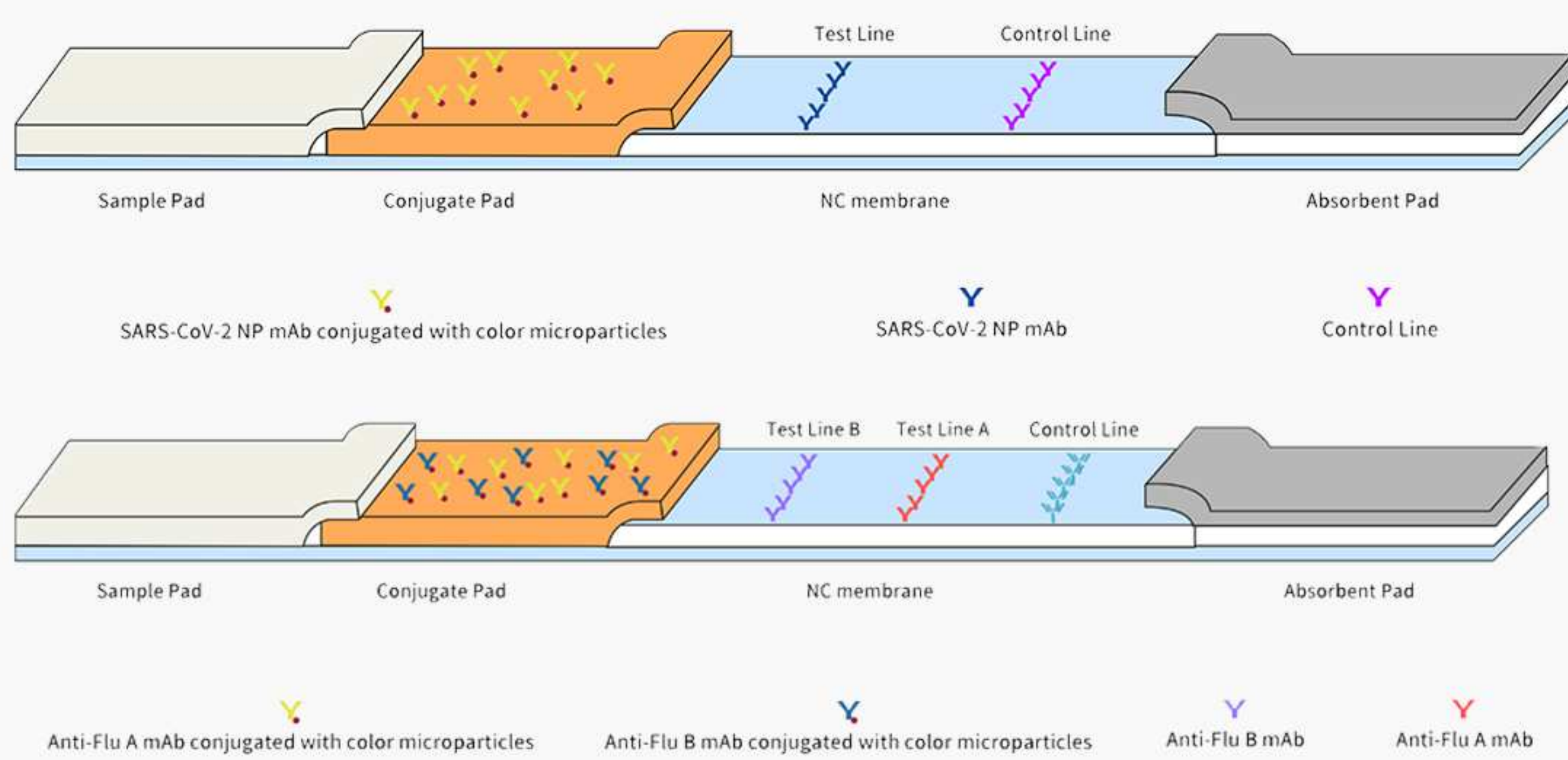


Easy to collect specimen at just 2-3.5cm depth



Room temperature storage

Test Principle



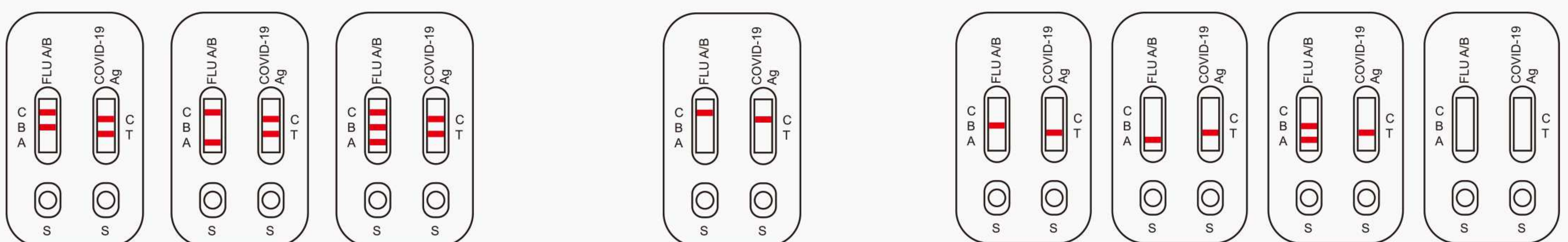
The immune colloidal gold technique is used in the assay to detect antigens of SARS-CoV-2 and Influenza A/B. The sample pad is coated with colloidal gold bound antibodies. The quality control area is coated with goat anti-mouse IgG, and test area with anti-SARS-CoV-2 or Influenza A/B antibodies. When 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

1. This product can be used for nasopharyngeal or oropharyngeal swab samples. Nasopharyngeal swab specimens are recommended strongly.
2. Protective measures shall be taken when collecting specimens and the specimens shall be collected in accordance with the licensed collection techniques.
3. Before collecting specimen, ensure that the specimen tube is sealed and the extraction buffer does not leak out. Then tear the seal off the tube pre-filled with buffer and gently place it on the tube stand.
4. Collection of Specimens:
 - **Oropharyngeal specimen:** With the patient's head slightly lifted up, and the mouth wide open, the patient's tonsils are exposed. With a clean swab, the patient's tonsils are gently rubbed back and forth at least 3 times, and then the patient's posterior pharyngeal wall are rubbed back and forth at least 3 times.
 - **Nasopharyngeal specimen:** Let the patient's head relax naturally. Turn the swab against the wall of the nostril slowly into the nostril, to the nasal palate, and then rotate while wiping and remove slowly.

Treatment of Specimen: Insert the swab head into the extraction buffer after specimen collection, mix well, squeeze the swab 10-15 times by compressing the walls of the tube against the swab, and let it stand for 1 minute to keep as many samples as possible in the specimen extraction buffer. Discard the swab.
5. Swab specimens should be tested as soon as possible after collection. Use freshly collected specimens for best test performance.
6. If not tested immediately, the swab specimens can be stored between 2-8°C for 4 hours after collection or be stored at room temperature for 1 hour. If long-term storage is required, it should be kept at -70°C to avoid repeated freeze-thaw cycles.
7. Do not use specimens that are obviously contaminate with blood, as it may interfere with the flow of sample with the interpretation of test results.

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 (+)	51	0	51
Negative (-)	2	140	142
Total	53	140	193

Sensitivity: 96.23%

Specificity: 100.00%

Table 2: Influenza A Test vs. RT-PCR

Test Results of Lyher Kit	Clinical diagnosis (PCR results)		
	Positive (+)	Negative (-)	Total
Positive (+)	32	0	32
Negative (-)	0	161	161
Total	32	161	193

Sensitivity: 100.00%

Specificity: 100.00%

Table 3: Influenza B Test vs. RT-PCR

Test Results of Lyher Kit	Clinical diagnosis (PCR results)		
	Positive (+)	Negative (-)	Total
Positive (+)	17	0	17
Negative (-)	1	175	176
Total	18	175	193

Sensitivity: 94.44%

Specificity: 100.00%

TEL: +86-571-87653090

WEB: www.lyherbio.com

FAX: +86-571-8665800

EMAIL: office@lyher.com