

LYHER®

INFLUENZA A/B ANTIGEN TEST KIT

The LYHER® Influenza A/B Antigen Test Kit is an in vitro immunoassay. The assay is for the direct and qualitative detection of antigen of Influenza A/B from nasopharyngeal secretions and oropharyngeal secretions. The kit is for in vitro diagnostic use.

- ✓ CE Marked
- ✓ Results in 15mins
- ✓ Easy to read results
- ✓ Easy to collect specimen at just 2-3.5cm depth
- ✓ Room temperature storage



FAST

SENSITIVE

CONVENIENT

PLEASE SCAN THE QR CODE
FOR TEST PROCEDURE VIDEO



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MDA registration no: IVDC3489323-140142

CLINICAL DATA

TABLE 1: INFLUENZA A TEST VS. RT-PCR

TEST RESULTES OF LYHER KIT	CLINICAL DIAGNOSIS (PCR RESULTS)		
	POSITIVE (+)	NEGATIVE (-)	TOTAL
POSITIVE (+)	314	0	314
NEGATIVE (-)	11	547	558
TOTAL	105	655	872

SENSITIVITY: 96.60%

SPECIFICITY: 100.00%

TABLE 2: INFLUENZA B TEST VS. RT-PCR

TEST RESULTES OF LYHER KIT	CLINICAL DIAGNOSIS (PCR RESULTS)		
	POSITIVE (+)	NEGATIVE (-)	TOTAL
POSITIVE (+)	190	0	190
NEGATIVE (-)	8	498	506
TOTAL	198	498	696

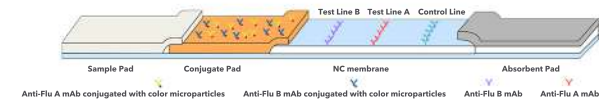
SENSITIVITY:94.40%

SPECIFICITY: 100.00%

INTERPRETATION OF RESULTS



TEST PRINCIPLE



The immune colloidal gold technique is used in the assay to detect antigens of Influenza A/B. There are one test strip for detecting influenza A/B in one device. The reagent binding pad is coated with anti-influenza A/B nucleoprotein monoclonal antibodies and mouse IgG which are both labeled with colloidal gold marker. A nitrocellulose membrane in test area of the strip is coated with recombinant anti- influenza A/B antibody. The quality control area within the nitrocellulose membrane is coated with goat anti-mouse IgG antibodies. When testing, the antibodies against Influenza A/B form immuno-complexes with the antigen protein of the corresponding virus in the specimen to be tested. As a result of chromatography, immuno-complexes move along the membrane and will be captured by anti-influenza A/B antibodies coated in the test area to form a visible line with red color (T line). The free colloidal gold marker or immune complexes continue to move forward and specifically bind to the goat anti-mouse antibody coated in the quality control area to form a visible line (C line). If the specimen does not contain the antigen of Influenza A/B, no test line will show, only quality control line (C line) will appear.

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.

