

Famwell™ Flu A/B Antigen Rapid Test

Combo Testing

Detects Influenza A and B viruses in a single test

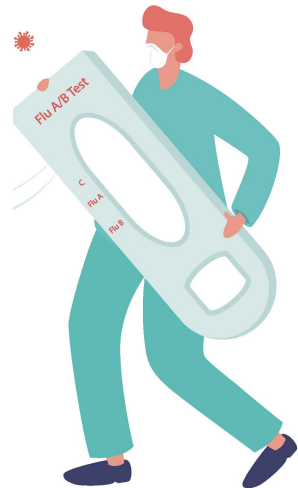
Rapid & Precise

Delivers reliable results in just 10 minutes

Internationally Certified

Cleared by the **US FDA**

CLIA Waived



THE FIRST CHOICE RAPID TEST IN EARLY DIAGNOSIS

Influenza (flu) is a contagious respiratory illness caused by influenza viruses that infect the nose, throat, and lungs. Some people, such as older people, young children, and people with certain health conditions, are at higher risk of serious flu complications. There are two main types of influenza (flu) viruses: Types A and B. The influenza A and B viruses that routinely spread in people (human influenza viruses) are responsible for seasonal flu epidemics each year.

5%-20%

get the flu on average
each year

In the U.S.

140,000-710,000
are **hospitalized**
due to flu each year

12,000-52,000
of flu **deaths**
each season

* Source: Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases (NCIRD)

Intended Use



The Famwell™ Flu A/B Antigen Rapid Test is a rapid chromatographic immunoassay intended for the qualitative detection and differentiation of influenza A and B viral nucleoprotein antigens directly from nasopharyngeal swabs from patients with signs and symptoms of respiratory infection.

The test is intended for use as an aid in the differential diagnosis of acute influenza A and B viral infections. The test is not intended to detect influenza C antigens.

Negative test results are presumptive and should be confirmed by viral culture or an FDA cleared influenza A and B molecular assay. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions.

Specifications:

Sample Types: Nasopharyngeal Swab

Type of Use: POC (Prescription) Use

Packing Size: 25 tests/box

Test Format: Cassette

Result Time: 10 minutes

Packaging: 25 tests/box

Storage Condition: 4°C–30°C

Shelf Life: 18 months

Qualification: FDA Approval & CLIA Waived

Sensitivity / Specificity:

Influenza A

PPA

85.7%

NPA

99.5%

Influenza B

PPA

85.7%

NPA

100%

* PPA: Positive Percent Agreement

NPA: Negative Percent Agreement

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