The PathFlow™ Flu A/B Combi is a rapid chromatographic immunoassay for the qualitative detection of influenza A and B antigens in nasopharyngeal swab, throat swab or nasal aspirate specimens.

What is the Test?
- The PathFlow” Flu A/B Combi is a qualitative, lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in nasopharyngeal swab, throat swab or nasal aspirate specimens; including (but not exclusive to) subtypes A/H1N1, A/H3N2 and A/H5N1.

What is the Disease?
- Influenza (commonly known as ‘flu’) is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus.
- Seasonal influenza outbreaks occur each year during the autumn and winter months. Type A viruses are typically more prevalent then type B and are associated with the most serious epidemics; whilst type B infections are usually milder – type C is also only usually associated with mild symptoms or asymptomatic carriage.

Symptoms
- Symptoms can include; sudden fever, rhinitis, headache, fatigue, sore throat, cough and myalgia. Usually resolving within 2 to 7 days, though a cough may persist for several weeks.

Mortality/Morbidity – Clinical Implications
- The risk of serious illness from influenza is higher amongst young children, elderly and those whom suffer from underlying health conditions or immunosuppression.
- Although usually self-limiting, Influenza can exacerbate underlying medical conditions and sometimes present life-threatening complications, such as; bronchitis, primary viral pneumonia/secondary bacterial pneumonia, or in children – otitis media (middle ear infection).

■ Complete system, no additional reagents required.
■ Simple and easy to use.
■ Rapid result offered. Available after 15 minutes or within 15-20 minutes.
■ Can be used for nasopharyngeal swab samples, throat swab samples and nasal aspirate.
■ In-built procedural control.
■ Early diagnosis of influenza A/B is paramount in a clinical environment; enabling for the ability to provide greater levels of patient care and management.
Why use PathFlow™

- The gold standard of laboratory diagnosis is 14-day cell culture; however, results are often obtained too late in the clinical course for effective patient intervention.
- The PathFlow™ Flu A/B Combi qualitatively detects presence of Influenza A and/or Influenza B antigen in nasopharyngeal/throat swab or nasal aspirate specimens.

### Performance – Tested vs. RT-PCR

#### Nasopharyngeal Swab Specimen

<table>
<thead>
<tr>
<th>Type</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type A</td>
<td>99.0%</td>
<td>98.9%</td>
<td>98.5%</td>
</tr>
<tr>
<td>Type B</td>
<td>97.7%</td>
<td>99.0%</td>
<td>98.6%</td>
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</table>

#### Throat Swab Specimen

<table>
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<th>Type</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type A</td>
<td>95.1%</td>
<td>99.3%</td>
<td>98.1%</td>
</tr>
<tr>
<td>Type B</td>
<td>94.2%</td>
<td>99.4%</td>
<td>97.8%</td>
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</table>

#### Nasal Aspirate Specimen

<table>
<thead>
<tr>
<th>Type</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type A</td>
<td>100%</td>
<td>99.2%</td>
<td>99.3%</td>
</tr>
<tr>
<td>Type B</td>
<td>97.9%</td>
<td>99.4%</td>
<td>98.8%</td>
</tr>
</tbody>
</table>

### Ordering Information

- Code – M591CE
- Description – PathFlow™ Influenza A/B Combi
- Size – 25 Test Kits
- Storage – 2°C-30°C

### Procedure

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Place the extraction tube in the workstation – hold the reagent bottle upside down and squeeze the bottle to let the solution drop into the extraction tube, adding 10 drops.
2. Place the swab specimen in the extraction tube, rotate the swab for approximately 10 seconds.
3. Remove the swab while squeezing the swab head against the inside of the extraction tube.
4. Fit the dropper tip on top of the extraction tube.
5. Add three drops of the solution to the sample well and start the timer. Read the result at 15 minutes and do not interpret after 20 minutes.

### Interpretation of Results

- **POSSITIVE** Influenza A: Two distinct coloured lines appear
- **POSSITIVE** Influenza B: Two distinct coloured lines appear
- **POSSITIVE** Influenza A and Influenza B: Three distinct coloured lines appear
- **NEGATIVE**: One coloured line appear
- **INVALID**: Control line fails to appear. Insufficient specimen volume

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