What is the Test?
- The PathFlow® Adenovirus antigen Rapid Test Cassette is a qualitative membrane-based immunoassay for the detection of adenovirus antigen in eye conjunctive swabs, throat swabs and nasal swabs.

What is the Disease?
- Although there are a variety of viruses that can cause infections in the lower respiratory tract (for example, Influenza & RSV) adenovirus are often the most common.
- Alongside respiratory tract infection, adenovirus have also been implicated in diseases affecting the ocular and gastrointestinal systems.
- Human adenoviruses are so far classified into 7 species: HAdV-A to G including a wide range of serovars.

Symptoms
- Adenoviruses can cause mild to severe illness; the latter is less common – usually isolated to individuals with weakened immune systems or existing respiratory/cardiac disease.
- Varying adenovirus serotypes are causative of different symptoms, including conjunctivitis, bronchitis, pneumonia, diarrhoea and others.
- Serotypes 8, 14, 16 and 17 have been shown to cause conjunctivitis, serotypes 7, 14, 21 cause respiratory symptoms and serotypes 40 and 41 can cause gastroenteritis.

Mortality/Morbidity – Clinical Implications
- Adenoviruses are known to cause respiratory illness, gastroenteritis and conjunctivitis with worldwide prevalence; being ubiquitous throughout the year.
- Adenoviruses are very stable in the environment and can persist from 7 days, up to 3 months; high survivability combined with low infectious dose (as few as 5 viral particles in susceptible individuals) is cause for major concern within healthcare environments.
- Although most adenovirus infections are mild and do not usually require any specific medical care, accurate diagnosis and clinical care is of particular importance for at-risk individuals – who may suffer from serious complications.

- Simple and easy to use system.
- Differential detection of adenovirus from other diseases preventing similar symptoms.
- Rapid results offered; positive results may be visible from as little as 3 minutes.
- Can be used with multiple sample types, including eye conjunctive swabs and throat/nasopharyngeal swabs.
Why use PathFlow®

- The differential diagnosis of various forms of conjunctivitis (viral, bacterial, allergic) is often difficult as they manifest similar symptoms.
- Cell culture in combination with immunofluorescence is the historical “gold standard” for identifying adenovirus in conjunctival specimens.
- Virus isolation requires an intensive process, technical expertise and may take up to 3 weeks to complete.
- PathFlow® Adenovirus allows for a rapid method of accurate diagnosis to allow for more appropriate patient management and to control the risk of spreading infections within healthcare institutions.

Performance – Tested vs. PCR

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>98.6%</td>
</tr>
<tr>
<td>Specificity</td>
<td>98.1%</td>
</tr>
<tr>
<td>Accuracy</td>
<td>98.2%</td>
</tr>
</tbody>
</table>

Ordering Information

- Code: M592CE
- Description – PathFlow® Adenovirus antigen
- Size: 20 Test Kits
- Storage: 2°C-30°C

Procedure

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it within one hour. Place the extraction tube in the workstation. Hold the extraction reagent bottle upside down. Squeeze the bottle and let the solution drop into the extraction tube freely without touching the edge of the tube. Add 10 drops of solution to the extraction tube.

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 as you remove it to expel as much liquid as possible from the swab, then fit the dropper tip on top of the extraction tube.

4. Add three drops of the solution to the sample well and then start the timer. A positive result may be visible at 3 minutes; however, the complete reaction time of 15 minutes is required to confirm a negative result.

Step 1. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it within one hour. Place the extraction tube in the workstation. Hold the extraction reagent bottle upside down. Squeeze the bottle and let the solution drop into the extraction tube freely without touching the edge of the tube. Add 10 drops of solution to the extraction tube.

Step 2. Place the swab specimen in the Extraction Tube. Rotate the swab for approximately 10 seconds.

Step 3. Remove the swab while squeezing the swab head against the inside of the extraction tube as you remove it to expel as much liquid as possible from the swab, then fit the dropper tip on top of the extraction tube.

Step 4. Add three drops of the solution to the sample well and then start the timer. A positive result may be visible at 3 minutes; however, the complete reaction time of 15 minutes is required to confirm a negative result.

Distributed by:

PathFlow® - Leading The Way to a Better Diagnosis

GMM147, Revision-2