The PathFlow™ RSV is a rapid chromatographic immunoassay for the qualitative detection of Respiratory **Syncytial Virus antigen in nasopharyngeal** swab or nasal aspirate specimens. It is intended to aid in the rapid differential diagnosis of respiratory syncytial virus viral infections.



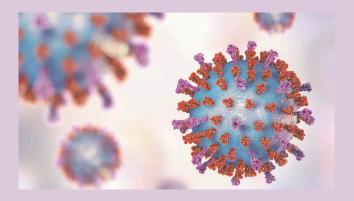
 The PathFlow[™] RSV is a qualitative, lateral flow immunoassay for the detection of Respiratory Syncytial Virus nucleoproteins in nasopharyngeal swab or nasal aspirate specimens.

What is the Disease?

- Respiratory Syncytial Virus (RSV), is a common cause of respiratory tract infection and a major cause of respiratory illness in infants and young children (such as bronchiolitis and pneumonia).
- · Almost all children are infected with RSV at least once by the time they are 2-3 years old.

Symptoms

- In adults, it may only produce symptoms of a common cold, such as congestion, sore throat, mild headache, cough, fever, and a general feeling of being ill.
- · But in premature babies and children with pre-existing conditions affecting the lungs, heart, or immune system, RSV infections can lead to other more serious illnesses.



Mortality/Morbidity – Clinical Implications

- · RSV is highly contagious and can be spread through coughing/sneezing of aerosolized droplets containing live virus. Due to a combination of high infectivity rates, lengthy shedding period and environmental survivability; RSV has emerged as a serious cause of hospitalacquired infection.
- The rapid identification and diagnosis have become increasingly important due to the availability of effective antimicrobial treatments. Swift identification/diagnosis can lead to a reduction in the use of antimicrobial therapy, reduced hospital stays, and a total reduction in costs associated with effective and efficient patient care.
 - Complete system, no additional reagents
 - Simple and easy to use.

 - Can be used with both nasopharyngeal

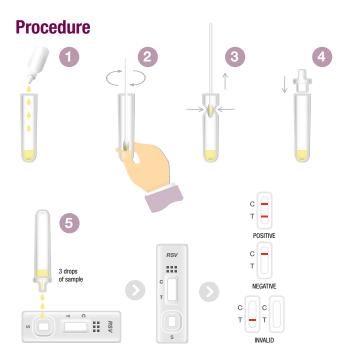
Why use PathFlow™

- RSV can be detected in human respiratory samples by a variety of methods, including; virus culture testing and cell culture confirmation, enzyme immunoassay (EIA) and immunofluorescent assay. Although tissue culture remains the diagnostic test standard, it requires culture facilities and can take a considerable amount of time to complete; potentially reducing the ability to make appropriate patient care decisions.
- The RSV Rapid Test Cassette qualitatively detects the presence of Respiratory Syncytial Virus antigen in nasopharyngeal swab or nasal aspirate specimens, providing results after 15 minutes, allowing for decision making to be conducted much sooner than alternative methods.

Performance – Tested vs. RT-PCR Nasopharyngeal Swab Specimen Sensitivity – 92.7% Specificity – 98.0% Accuracy – 95.6% Nasal Aspirate Specimen Sensitivity – 92.6% Specificity – 98.5% Accuracy – 96.0%

Ordering Information Code – M590CE Description – PathFlow™ RSV Size – 25 Test Kits

Storage - 2°C-30°C



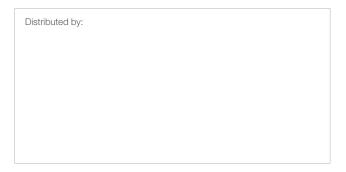
Step 1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Place the extraction tube in the workstation – hold the reagent bottle upside down and squeeze the bottle to let the solution drop into the extraction tube, adding 10 drops.

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.

Step 4. Fit the dropper tip on top of the extraction tube.

Step 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.









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GMM137, Revision -1

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