

RSV Test Cassette (Nasopharyngeal Swab/Nasal Aspirate)

The RSV Test Cassette (Nasopharyngeal Swab/Nasal Aspirate) is intended for in vitro detection of Respiratory Syncytial Virus antigens in nasopharyngeal swab or nasal aspirate specimens. It is intended to aid in the rapid differential diagnosis of Respiratory Syncytial Virus viral infections.

The RSV Test Cassette (Nasopharyngeal Swab/Nasal Aspirate) detects Respiratory Syncytial Virus nucleoproteins based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains Respiratory Syncytial Virus nucleoproteins, it attaches to the fluorescent microspheres-conjugated anti-Respiratory Syncytial Virus antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of Respiratory Syncytial Virus in the sample correlates with the fluorescence signal intensity captured on the T line, which Fluorescence Immunoassay Analyzer can scan. The Respiratory Syncytial Virus testing result will be displayed on the Fluorescence Immunoassay Analyzer screen.

The test result of each specimen is given as Pos (+) or Neg (-) with a Reference Value. This Value is calculated so that a measured signal is divided by an appropriate cutoff value.

- Test results of a Value ≥ 1.00 are considered positive.
 - Test results of a Value < 1.00 are considered negative.
- Sensitivity $\geq 92\%$, specificity $\geq 92\%$

