

**Q: What is this test's principle ?**

A: The Influenza A/B Rapid Test is a membrane method based chromatographic immunoassay for the qualitative and differential detection of the Influenza virus type A and type B antigens extracted from Nasal / Throat / Nasopharyngeal swab specimens.

**Q: Is this test for symptomatic patients only?**

A: Yes, this test is for individuals who have onset of symptoms, such as a sudden fever, cough (usually dry), headache, muscle and joint pains and so on.

**Q: How does the test work ?**

A: When Influenza A or B antigens are present in the specimens, the Influenza A or B antigen will first binds with the anti-Influenza A or B antibody conjugated to form an antigen-antibody conjugate complexes, then the conjugated complexes migrate across the test strip to the reaction area and are captured by the A-antibody line or the B-antibody line, precoated on the membrane, if present there will be a visible A line or a B line, or both line A and B will be visible.

**Q: Is this test for Professional Use only ?**

A: Yes, this test is intended to be used by professionals as a screening test and provides an aid in the diagnosis of acute influenza type A and B viral infections.

**Q: What types of specimens can be used to run the test?**

A: Nasal, Throat and Nasopharyngeal swab specimens.

**Q: What is the sensitivity, specificity and accuracy for this test?**

A: The results for **Influenza A** are: Relative Sensitivity: 100.00% (93.60%-100.00%)\*, Relative Specificity: 99.22% (97.01%-99.97%)\* and Accuracy: 99.38% (97.63%-99.98%)\*

The results for **Influenza B** are: Relative Sensitivity: 100.00% (90.62%-100.00%)\*, Relative Specificity: 99.61% (97.59%-99.99%)\* and Accuracy: 99.67% (97.95%-99.99%)\*

\*95% Confidence Intervals

**Q: What is the precision ?**

**Intra-Assay :** Within-run precision has been determined by using 10 replicates of specimens: negative control and Influenza A and Influenza B antigen positive controls. The specimens were correctly identified >99% of the time.

**Inter-Assay :** Between-run precision has been determined by 10 independent assays on the same specimen: negative specimen and Influenza A and Influenza B antigen positive specimen. Three different lots of the Influenza A/B Rapid Test have been tested using these specimens. The specimens were correctly identified >99% of the time.

**Q: How do I know that the test was run properly?**

A: The appearance of a colored line at the Control Line region tells you that you followed the test procedure properly and the proper amount of sample was used.