

OSOM[®] Influenza A&B Test Package Insert Update

Added H1N1 strain (Mexico/4108/2009) to the Analytical Reactivity section

The OSOM Influenza A&B Test has been shown to detect the Mexico/4108/2009 virus in culture isolates. The estimated detectable level for this strain was 8×10^6 EID₅₀/mL.

Although this test has been shown to detect the 2009 H1N1 virus cultured from a positive human respiratory specimen, the performance characteristics of this device with clinical specimens that are positive for the 2009 H1N1 influenza virus have not been established.

The OSOM Influenza A&B test can distinguish between influenza A and B viruses, but it cannot differentiate influenza subtypes.

For additional information and updates, please refer to the CDC Website:
http://www.cdc.gov/h1n1flu/guidance/rapid_testing.htm

NOTE: As stated in the Limitations section:

- Additional testing is required to differentiate any specific influenza A subtypes or strains, in consultation with state or local public health departments.
- For the most current version of the package insert, go to www.genzymediagnostics.com