



## Technical Bulletin

### FluMist® Live Attenuated Intranasal Vaccine and Viral Shedding

According to the FDA Guidance on In Vitro Diagnostic Devices to Detect Influenza A Viruses, issued on May 1, 2007, it states that “individuals who received nasally administered influenza A vaccine may have positive test results for up to three days after vaccination.”<sup>1</sup> This is the current guidance in our QuickVue® Influenza, QuickVue Influenza A+B, and Sofia® Influenza A+B Package Inserts.

On October 8, 2009, the H1N1 Clinicians Questions and Answers from the CDC website have stated that the live attenuated influenza vaccine viruses in LAIV (seasonal vaccine and 2009 H1N1 monovalent vaccine) can cause a positive result on a rapid influenza diagnostic test. The tests are designed to detect influenza viruses and cannot differentiate between live attenuated and wild-type influenza viruses. A positive test in a person who recently (in previous 7 days) received LAIV (Live Attenuated Intranasal Vaccine) and who also has an influenza-like illness could be caused by either LAIV or wild-type influenza virus.<sup>2</sup>

Also, the MedImmune Package Insert for the FluMist Live Influenza Intranasal Vaccine (June 2009) has stated that virus shedding was evaluated for 21 days by culture of nasal swab specimens (for patients who received one dose of FluMist). Wild-type A (H3N2) influenza virus was documented to have circulated in the community and in the study population during the trial, whereas Type A (H1N1) and Type B strains did not. At least one vaccine strain was isolated from 80% of FluMist recipients; strains were recovered from 1-21 days post vaccination (mean duration of 7.6 days  $\pm$  3.4 days).<sup>3</sup>

Please contact Quidel Technical Support at 800.874.1517 (in the U.S.), 858.552.1100 (outside the U.S.) or [technicalsupport@quidel.com](mailto:technicalsupport@quidel.com) if you have any questions regarding the QuickVue and/or Sofia Influenza A+B FIA, or any Quidel product. Our hours of operation are Monday through Friday, 7:00 a.m. to 5:00 p.m. Pacific Time.

You may also visit our website at [quidel.com](http://quidel.com) for information on Quidel’s line of Rapid Diagnostics, Molecular Diagnostics, Cell Culture and Specialty Diagnostics (Bone Health and Autoimmune & Complement). Other product information available on our website includes: CPT codes, CLSI procedure guides, MSDS, and Package Inserts.

<sup>1</sup>Guidance for Industry and FDA Staff: In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path. May 1, 2007 (page 10).

<sup>2</sup>[http://www.cdc.gov/h1n1flu/vaccination/clinicians\\_qa.htm](http://www.cdc.gov/h1n1flu/vaccination/clinicians_qa.htm).

<sup>3</sup>MedImmune: FluMist® Influenza Vaccine Live, Intranasal, Intranasal Spray, 2009-2010 Formula. Section 14.5: Transmission Study, June 2009.