

3M™ Rapid Detection Flu A+B Test Demonstrates Superior Sensitivity against Leading Hospital Competitor in the Detection of Influenza, New Data Reveals

ST. PAUL, Minn.--([BUSINESS WIRE](#))--3M Health Care announced today that its 3M™ Rapid Detection Flu A+B Test demonstrated better clinical and analytical sensitivity when compared to the BinaxNOW® Influenza A & B Test for influenza A and B. The research was conducted by clinical virology researchers from the North Shore-Long Island Jewish (LIJ) Health System. The results were recently presented at the 24th Annual Clinical Virology Symposium in Daytona Beach, FL.

The study evaluated the Rapid Detection Flu Test for the direct detection of influenza A and B in clinical respiratory samples and compared the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of the 3M test to the BinaxNOW test. Both rapid tests provide results in less than 20 minutes. In addition, the study also evaluated the performance of the test as compared to two conventional methods of diagnosing influenza A and B, direct fluorescent antibody staining (DFA) (1.5 to 3 hours for results) and rapid cell culture (R-Mix) (24 to 48 hours to results).

“Clinicians battling infection during the height of the flu season have two great needs: tests that work rapidly and tests that can accurately pinpoint patients both with and without influenza,” said Christine Ginocchio, PhD., lead author and director of Microbiology, Virology and Molecular Diagnostics from the Department of Laboratory Medicine at the North Shore-LIJ Health System Laboratories. “The results demonstrated that the 3M Rapid Detection Flu A+B Test is more reliable and much more sensitive than the BinaxNOW test. This is positive news for clinicians as they prepare for this year’s flu season.”

Study results found that:

The 3M test demonstrated superior analytical sensitivity (>1 log) for the detection of both influenza A and B as compared to the BinaxNOW test.

The 3M test demonstrated superior clinical sensitivity ($P = 0.008$) for the detection of influenza A as compared to the BinaxNOW test (70.79 percent versus 46.07 percent, respectively) and was less sensitive than DFA (approximately 70.79 percent versus 80.90 percent).

The 3M test demonstrated superior clinical sensitivity for the detection of influenza B as compared to the BinaxNOW test ($P = <0.0001$) and DFA (86.79 percent versus 37.74 percent and 73.58 percent, respectively). The automated reading of test results eliminated the potential for user misreading or misinterpretation of test results.

The easy to use reader and printer provided documentation of instrument quality control and test results.

The study included a total of 500 prospective respiratory specimens – from out-patients and in-patients ages two weeks to 99 years – submitted for routine viral culture and DFA. The evaluation was based on 464 samples with valid results for all four tests.

“As a highly contagious disease, quick and accurate diagnosis is essential to limit influenza spread, and potentially reduces costs and improves patient outcomes in the health care setting,” said Jeff Hillins, Medical Diagnostics global business manager, 3M Health Care. “This study showed the 3M Rapid Detection Flu A+B Test is able to quickly and reliably detect the influenza virus, which will help hospital laboratories.”

ABOUT 3M™ RAPID DETECTION FLU A+B TEST

Expected to be available prior to the 2008-2009 flu season, the 3M Rapid Detection Flu A+B Test quickly delivers objective results through an easy-to-use self-timed reader. Requiring less than three minutes of prep

time, positive or negative results are detected, differentiated as influenza A or B and displayed by the automated 3M™ Rapid Detection Reader. The fluorescent reader helps eliminate user interpretation errors, which can lead to both false negative or false positive results.

The Rapid Detection Flu Test is the first 3M diagnostic test to be launched following a 2006 agreement between 3M and Response Biomedical Corporation to develop and commercialize diagnostic products targeting hospital and community acquired infectious diseases using Response Biomedical's technology.

ABOUT 3M HEALTH CARE

Since inventing Ioban™ antimicrobial incise surgical drapes more than 30 years ago, 3M has been a worldwide leader in developing health care products and services that address infection control. 3M Health Care, one of 3M's six major business segments, is dedicated to improving the practice, delivery and outcome of patient care and is a leading provider of solutions for medical, oral care, drug delivery and health information markets.

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BinaxNOW is a trademark of Binax, Inc.

3M Stephanie Sanderson, 651-733-8588 sjsanderson@mmm.com or WeissComm Partners Molly Rabinovitz, 312-284-4709 mrabinovitz@wcpglobal.com

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