Clinical Evaluation of the 3M™ Rapid Detection Flu A+B Test

Pan American Society for Clinical Virology
Clinical Virology Symposium (CVS)
April, 2008

Authors:
C. C. Ginocchio, M. Lotlikar, L. Falk, M. Kowerska, S. Arora and M. Bornfreund
Virology Laboratory, Department of Laboratory Medicine, North Shore University Hospital, Manhasset, NY.
Clinical Evaluation of the 3M™ Rapid Detection Flu A+B Test

Background and Aims of Study

Background: Easy to use immunochromatographic methods for the detection of influenza A and influenza B can provide clinicians with rapid results. The specificity of the assays are generally good when used during influenza season, but the tests lack sufficient sensitivity. Therefore, continued improvement of these test methods are desirable. The new investigational 3M Rapid Detection Flu A+B Test (3M Medical Diagnostics, St Paul, MN) is a qualitative immunochromatographic cartridge assay. The assay utilizes fluorescent dried particles coated with anti-Influenza A and anti-Influenza B antibodies that react to influenza A or B antigens, respectively, if present in the sample. Detection is performed using the 3M Rapid Detection™ Reader.

The aims of this study were:

1) To evaluate the investigational 3M Rapid Detection Flu A+B Test for the direct detection of influenza A and influenza B in clinical respiratory samples.

2) To compare the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of the 3M assay to direct fluorescent antibody staining (DFA), rapid cell cultures (R-Mix) (Diagnostic Hybrids, Inc., OH), and to the BinaxNOW Influenza A+B test (Binax, Inc., ME).

Materials and Methods

Specimens: A total of 500 fresh respiratory specimens (nasopharyngeal (NP) aspirates, NP washings, NP swabs in viral transport media) were submitted for routine viral culture and DFA were included in this study. The samples were from both out-patients and in-patients and ages ranged from 2 weeks to 95 yr.

Methods:

1) Each specimen was then centrifuged to obtain NP cells to perform DFA for influenza A, B, RSV, adenovirus, parainfluenza 1, 2, 3, and Mycoplasma. (Note: 93 samples were rejected due to insufficient cellularity).

2) Replicates of serial dilutions of influenza A and influenza B clinical isolates were tested in parallel with the 3M and Binax assays. Results in red indicate last dilution with a positive result. * w = weak reaction, vw = very weak reaction.

3) The 3M test was significantly more sensitive than the Binax assay (p=0.008).

4) The automated reading of test results eliminated the potential for user reading or misinterpretation of test results.

5) Transfer the mixture of sample and fluorescent particles into the cartridge well.

6) Insert the cartridge into the reader.

Results: Comparison of 3M/Binax Assay Sensitivities

Results: Influenza A and Influenza B

<table>
<thead>
<tr>
<th>Assay</th>
<th>DFA</th>
<th>R-Mix</th>
<th>BinaxNOW</th>
<th>3M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sens</td>
<td>80.90</td>
<td>98.88</td>
<td>46.07</td>
<td>70.79</td>
</tr>
<tr>
<td>Spec</td>
<td>96.67</td>
<td>100</td>
<td>99.73</td>
<td>98.44</td>
</tr>
<tr>
<td>PPV</td>
<td>93.51</td>
<td>99.73</td>
<td>88.65</td>
<td>93.50</td>
</tr>
<tr>
<td>NPV</td>
<td>96.61</td>
<td>99.73</td>
<td>93.50</td>
<td>96.61</td>
</tr>
</tbody>
</table>

Influenza A Test Sensitivity (Sens), specificity (Spec), positive predictive value (PPV) and negative predictive value (NPV) for both influenza A and influenza B tests were based on 444 samples with valid results for all 4 tests.

Comparison of 3M results to individual assays. DFA results are presented in two ways: Top panel does not include samples with insufficient cells (QNS) indicated last dilution with a positive result. * w = weak reaction, vw = very weak reaction.

Summary and Conclusions

• The 3M assay demonstrated a superior analytical sensitivity (≥1 log) for the detection of both influenza A and B as compared to the Binax assay.

• The 3M assay demonstrated a superior specificity (p=0.001) for the detection of influenza A as compared to the Binax assay (70.79% vs 46.07%, respectively) and was less sensitive than DFA (60%).

• The 3M assay demonstrated a superior specificity for the detection of influenza B as compared to the Binax assay (p=0.001) and DFA (66.70% versus 37.4% and 73.06%, respectively).

• The 3M assay detected influenza A and B 4 samples that did not have sufficient cells for DFA. The reporting of a positive result for these samples would have been delayed by 24-48 hours, if dependent on the R-Mix cultures results.

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

• The automated reading of test results eliminated the potential for user reading or misinterpretation of test results.

Acknowledgement

This study was funded by a research grant from 3M.