Clinical Evaluation of the 3M™ Rapid Detection RSV Test

25th Clinical Virology Symposium
April, 2009

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ABSTRACT

Background: Respiratory Syncytial Virus (RSV) is associated with seasonal respiratory infections particularly in pediatric and elderly populations. We evaluated the performance characteristics of 3M™ Rapid Detection RSV Test.

Materials and Methods: The 3M™ Rapid Detection RSV Test is an immunochromatographic assay that utilizes an automated reader. Eighty-one nasopharyngeal swabs (NPS), collected in M4 Viral Transport Media (Remel), were de-identified then tested with 3M Test and BinaxNOW RSV Test (Inverness). Viral culture and direct fluorescent antibody testing (DSFA) were performed as the reference methods. Results from RT-PCR for RSV (ProFLU Plus: Prodesse, Inc) were included for comparison.

Results: Seventy-eight (78) samples were included in the analysis. DSFA was positive (+) in 25/78 samples; 22 of the 25 samples were positive (+) by 3M RSV Test. The 3 discrepancies were confirmed positive (+) by PCR and were negative (-) with Binax Test. DSFA was negative (-) in 53/78 samples; 52 of the 53 samples were negative (-) by 3M. One sample which was 3M (+), DSFA (-) and Binax (-) was confirmed as PCR (+). For all samples tested, comparison of 3M Test vs. DSFA: Specificity 98% (52/53), Sensitivity 88% (22/25), PPV 96% (22/23) and NPV 95% (52/55). For patients < 6 y/o (N=69), comparison of 3M Test vs. DSFA: Specificity 98% (52/53), Sensitivity 88% (22/25), PPV 96% (22/23) and NPV 95% (52/55). For patients < 6 y/o (N=69), comparison of 3M Test vs. DSFA: Specificity 98% (43/44), Sensitivity 91% (18/23), PPV 95% (18/23) and NPV 97% (43/43).

Conclusion: Our data showed that 3M™ Rapid Detection RSV Test performed well particularly in pediatric and elderly populations. We evaluated the performance characteristics of 3M™ Rapid Detection RSV Test. The results obtained were compared to DSFA/Culture, RT-PCR, and the BinaxNOW RSV Test (Inverness).

INTRODUCTION

We evaluated the performance characteristics of the 3M™ Rapid Detection RSV Test. The results obtained were compared to DSFA/Culture, RT-PCR, and the BinaxNOW RSV Test (Inverness).

MATERIALS AND METHODS

1. Left-over & de-identified samples received for detection of respiratory viruses were used in this study.
2. Samples were collected in M4 viral transport media (Remel).
3. The 3M™ Rapid Detection RSV Test and BinaxNOW® RSV test were performed after the sample was tested by the routine ProFLU+™ Assay (Prodesse, Inc).
4. Tests were performed according to manufacturer’s instructions.
5. Direct Fluorescent Antibody testing and cell cultures for RSV were performed.

RESULTS

RESULTS SUMMARY

<table>
<thead>
<tr>
<th></th>
<th>DSFA</th>
<th>Culture</th>
<th>PCR</th>
<th>3M</th>
<th>Binax</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSV (+)</td>
<td>25</td>
<td>18</td>
<td>28</td>
<td>23</td>
<td>18</td>
</tr>
<tr>
<td>RSV (-)</td>
<td>53</td>
<td>60</td>
<td>47</td>
<td>55</td>
<td>60</td>
</tr>
</tbody>
</table>

3M RSV Test Procedure:

1. A printer connected to the Rapid Detection Reader provided a documented record of the test results.
2. For patients < 6 years old (N=75), comparison of 3M Test vs. DSFA: Specificity 98% (47/47), Sensitivity 78.6% (22/28), PPV 100% (22/22) and NPV 93.4% (47/47).

CONCLUSIONS

The 3M™ Rapid Detection RSV Test performed well when compared to BinaxNow. With an automated reader, the 3M™ Rapid Detection RSV Test reduces the ambiguity of manually read Binax cards.

The automated printer lends itself to real time documentation of results and Quality Control, particularly in an ED or ICU setting.

The 3M™ Rapid Detection RSV Test could be implemented easily in a busy ICU and ED.
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