Clinical Evaluation of the 3M™ Rapid Detection RSV Test in Nasopharyngeal Aspirate Specimens

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Authors:
Ella M. Swierkosz and Timothy J. Bonnot
Department of Pathology, Saint Louis University and Cardinal Glennon Children’s Medical Center,
St. Louis, MO
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Department of Pathology, Saint Louis University and Cardinal Glennon Children’s Medical Center, St. Louis, MO

ABSTRACT

The 3M™ Rapid Detection RSV Test (3M Health Care, Saint Paul, MN) is a rapid immunochromatographic test that utilizes the 3M™ Rapid Detection Reader to detect 3M™ RSV antibodies. This test was compared to other rapid tests, culture and DFA in infants at low prevalence of RSV. 165 nasopharyngeal aspirates were collected from infants aged ≤ 2 years. The 3M™ RSV test was found to be 98% sensitive, 100% specific, and 98% negative predictive value (NPV) and 100% positive predictive value (PPV), while DFA and culture were significantly more sensitive. Specimens that were negative on DFA but positive on the 3M™ RSV test were confirmed by culture or DFA. The 3M™ RSV test was found to be highly accurate and specific for the detection of RSV and should be considered as a rapid point of care test for the diagnosis of RSV in young children.

METHODS

This was an RSV-approved, randomized, prospective clinical trial involving infant specimens. The 3M™ Rapid Detection RSV Test (3M Health Care, Saint Paul, MN) was compared to nasopharyngeal aspirates and nasopharyngeal swabs by DFA using the 3M™ Rapid Detection Reader. DFA was performed using the 3M™ RSV DFA reagent (DHI) on a microscope slide by cytocentrifugation. All samples were stained with the 3M™ RSV DFA reagent and examined with a fluorescence microscope for granular cytoplasmic fluorescence.

RESULTS

The sensitivity of the 3M™ RSV test was found to be 98% (95/97) and the specificity was 100% (46/46). The negative predictive value (NPV) was 98% (95/96) and the positive predictive value (PPV) was 100% (95/95). The 3M™ RSV test was found to be highly accurate and specific for the detection of RSV and should be considered as a rapid point of care test for the diagnosis of RSV in young children.

DISCUSSION

The 3M™ Rapid Detection RSV Test was found to be highly sensitive and specific for the detection of RSV in young children. The test was found to be highly accurate and specific for the detection of RSV and should be considered as a rapid point of care test for the diagnosis of RSV in young children. The test was found to be highly accurate and specific for the detection of RSV and should be considered as a rapid point of care test for the diagnosis of RSV in young children.

ACKNOWLEDGMENTS

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3M™ RSV Test: 3M Health Care, Saint Paul, MN

RESULTS & DISCUSSION

1. DFA was the most sensitive test using the 3M test methodology.

2. The 3M™ Rapid Detection RSV Test was more sensitive than Xpect® RSV and BinaxNOW® RSV.

3. Xpect® RSV had the lowest sensitivity among rapid immunochromatographic methods for the highest PPV (100%).

4. Additive cut-off points may not occur for all rapid tests with similar specificity.

5. NPV must be used to determine low prevalence of RSV.

TABLE 1: TEST PERFORMANCE

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
<th>NPV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3M™ RSV</td>
<td>98</td>
<td>100</td>
<td>100</td>
<td>98</td>
</tr>
<tr>
<td>DFA</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>98</td>
</tr>
</tbody>
</table>

*including only specimens for which both DFA and culture results were available and excluding indeterminates

FIGURE 1: 3M RAPID DETECTION RSV TEST STAGE

FIGURE 2: PRINCIPLES OF THE TEST

FIGURE 3: CARDS/REACTIO FOR 3M RAPID DETECTION RSV TEST

FIGURE 4: 3M RAPID DETECTION RSV TEST DETAIL
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