Evaluation of the 3M™ Rapid Detection RSV Test and The Binax Now® RSV Test for Detection of Respiratory Syncytial Virus in Pediatric Patients

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EVALUATION OF THE 3M™ RAPID DETECTION RSV TEST AND THE BINAX NOW® RSV TEST FOR DETECTION OF RESPIRATORY SYNCYTIAL VIRUS IN PEDIATRIC PATIENTS

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Background:

Detection of respiratory syncytial virus (RSV) infection in children affects patient management and infection control measures. Viral culture, nucleic acid amplification tests, and direct immunofluorescent antibody (DFA) tests for RSV are accurate, but they require technical expertise and can have long turn-around times. Rapid immunoassays for RSV are simple and have short turn-around times. If rapid immunoassays for RSV are accurate, they can be a useful addition to the available diagnostic tests for RSV tests.

Objective:

We evaluated the performance of the investigational 3M™ Rapid Detection RSV test and the Binax NOW® RSV test for detection of RSV in respiratory specimens from children younger than six years old in comparison to respiratory shell vial cultures and DFA. The 3M™ Rapid Detection RSV test and the Binax NOW® RSV test are both qualitative immunochromatographic assays. The 3M™ Rapid Detection RSV test utilizes the 3M Rapid Detection reader to objectively detect RSV in respiratory specimens while the Binax NOW® RSV test is visually interpreted. Two specimen types were used: nasopharyngeal (NP) aspirates and nasal washes/ aspirates submitted for RSV testing with a minimum volume of 2ml. All testing was performed within 24 hours of specimen collection.

Methods:

Samples A total of 134 specimens were collected: 128 nasopharyngeal aspirates and 6 nasal wash/aspirates. One nasopharyngeal aspirate specimen was excluded from the Binax NOW® RSV data due to a technical error unrelated to the Binax NOW® RSV test performance.

Viral culture Respiratory viral culture was performed with R-Mix shell vials (Diagnostic Hybrids Inc.) stained with the SimulFluor Respiratory Screen (Millipore) at both 24 and 48 hours.

DFA testing DFA testing was performed using cytospun slides stained with the SimulFluor Respiratory Screen.

Immunochromatographic Assays Both the Binax NOW® RSV (Inverness Medical) and the 3M™ Rapid Detection RSV (3M Health Care) tests were performed according to the manufacturers' instructions. No specimen preparation was normally required for either test. If an invalid result was obtained from direct testing on the Binax NOW® RSV and 3M™ Rapid Detection RSV tests the specimen was diluted with sterile saline and retested.

True Positive/Negative Definition If either or both viral culture or DFA was positive then the specimen was considered a true positive, and if both viral culture and DFA were negative then the specimen was considered a true negative.

IRB Approval This study was approved by the Committee on Clinical Investigation at Children's Hospital Boston.

Support Materials were supplied by 3M Health Care and Response Biomedical Corporation.

Results:

Table 1. Prevalence of RSV by Specimen Type

	Reference Result		
Sample Type	Negative	Positive	Total
Nasal Wash/ Aspirate	1	5	6
NP Aspirate	81	47	128
Total	82	52	134

Prevalence for nasal wash was 83% and NP Aspirate was 37%.

Table 2. 3M™ Rapid Detection RSV vs. Reference Methods: NP Aspirate

Reference Result	3M™ Rapid Detection RSV Result		
Frequency	Negative	Positive	Total
Negative	77	4	81
Positive	11	36	47
Total	88	40	128

Table 3. 3M™ Rapid Detection RSV vs. Reference Methods: Nasal wash/aspirate

Reference Result	3M™ Rapid Detection RSV Result		
Frequency	Negative	Positive	Total
Negative	1	0	1
Positive	0	5	5
Total	1	5	6

Table 4. Binax NOW® RSV vs. Reference Methods: NP Aspirate

Reference Result	Binax NOW® RSV Result		
Frequency	Negative	Positive	Total
Negative	79	2	81
Positive	15	31	46
Total	94	33	127

Table 5. Binax NOW® RSV vs. Reference Methods: Nasal wash/aspirate

Reference Result	Binax NOW® RSV		
Frequency	Negative	Positive	Total
Negative	1	0	1
Positive	0	5	5
Total	1	5	6

Table 6. Sensitivity/Specificity by Test Method

Test	Specimen Type	N	Sensitivity	Specificity
3M™ Rapid Detection RSV	NP Aspirate	128	77%	95%
Binax NOW® RSV	NP Aspirate	127	67%	98%
3M™ Rapid Detection RSV	Nasal wash/ aspirate	6	100%	100%
Binax NOW® RSV	Nasal wash/ aspirate	6	100%	100%

Table 7. Result Agreement Between 3M™ Rapid Detection RSV and Binax NOW® RSV: Nasal wash/aspirate

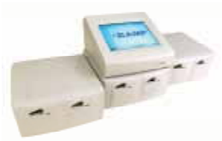
3M™ Rapid Detection RSV Result	Binax NOW® RSV		
Frequency	Negative	Positive	Total
Negative	1	0	1
Positive	0	5	5
Total	1	5	6

Table 8. Result Agreement Between 3M™ Rapid Detection RSV and Binax NOW® RSV: NP Aspirate

3M™ Rapid Detection RSV Result	Binax NOW® RSV		
Frequency	Negative	Positive	Total
Negative	88	0	88
Positive	6	33	39
Total	94	33	127

Two of the six discordant results were negative by the reference method; Binax NOW® RSV results were negative and 3M™ Rapid Detection RSV results were positive. The other four discordant results were positive by the reference method; 3M™ Rapid Detection RSV results were positive and Binax NOW® RSV results were negative.

Illustration 1. 3M Rapid Detection Reader



The 3M Rapid Detection reader is an automated system that is capable of testing and interpreting up to six different assays at the same time. Upon test completion, the reader displays the results, which can then be printed out or downloaded to a computer system.

Conclusions:

- Both the 3M™ Rapid Detection RSV test and Binax NOW® RSV were simple to perform
- There was no statistically significant difference in sensitivity or specificity between the 3M™ Rapid Detection RSV test and Binax NOW® RSV because neither sample size was sufficient to provide power to detect a difference.
- There was a trend toward greater sensitivity with the 3M™ Rapid Detection RSV test.

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