

Clinical Evaluation of the 3M™ Rapid Detection RSV Test

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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% (43/44), Sensitivity 88% (22/25), PPV 96% (22/23), NPV 93% (43/46). Testing by 4 methods (PCR, DSFA, 3M, Binax) was done on 75 samples; 64/75 were in total agreement. For the discrepant: 11/11 PCR (+), 7/11 DSFA (+), 5/11 3M (+), 0/11 Binax (+).

Conclusion: Our data showed that 3M™ Rapid Detection RSV Test performed well particularly when compared to BinaxNOW RSV. Neither test was as sensitive as PCR; however PCR requires more expansive equipment and training. The 3M automated reader documents the results in real time which makes this an excellent choice as a point of care test in ED and ICU sites.

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.

STUDY SAMPLES

Nasopharyngeal Swab	78
Throat Swab*	2
DFA/Culture > 24 hrs*	3
Total	83

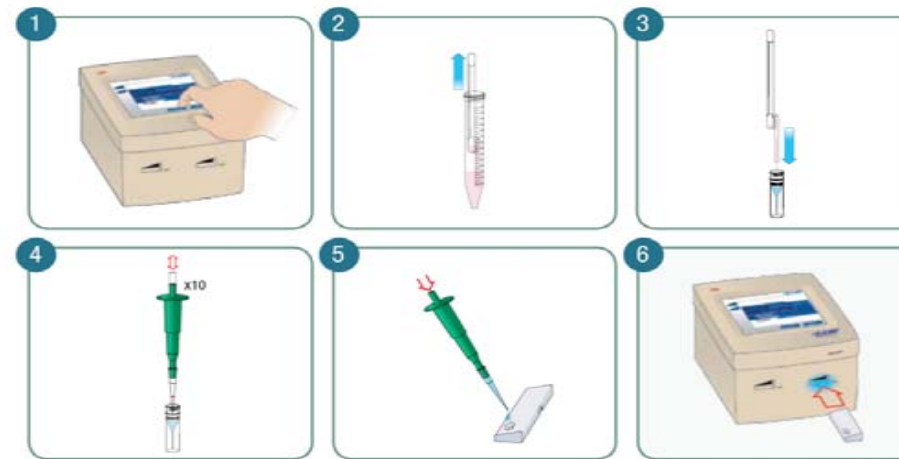
* Data excluded

RESULTS SUMMARY

N=78	DSFA	Culture	PCR	3M	Binax
RSV (+)	25	18	28	23	18
RSV (-)	53	60	47	55	60
	78	78	75*	78	78

* 3 samples not tested by PCR

3M RSV Test Procedure:



A printer connected to the Rapid Detection Reader provided a documented record of the test results.



RESULTS: Comparison of 3M Test vs DSFA/Culture

All samples positive for RSV were from patients < 6 years old

< 6 yrs (N=60)	Sens.	Spec.	PPV	NPV
	88.0 % (22/25)	97.7 % (43/44)	95.6% (22/23)	93.4% (43/46)

All Ages (N=78)	Sens.	Spec.
	88.0 % (22/25)	98.1 % (52/53)

All Ages	DSFA and/or Culture			
	+	-	Total	
3M	+	22	1 ^b	23
	-	3 ^a	52	55
	Total	25	53	78

^a Binax (-), PCR (+) crossing points: 27.04, 22.01, 25.25
^b Binax (-), PCR (+) crossing point: 18.85

RESULTS: Comparison of 3M Test vs PCR

All Ages (N=75)	Sens.	Spec.
	78.6% (22/28)	100% (47/47)

All Ages	PCR			
	+	-	Total	
3M	+	22	0	22
	-	6 ^c	47	53
	Total	28	47	75

^c 3 samples = DSFA (-), 3M (-), Binax (-) PCR crossing points: 32.82, 31.23, 31.70
3 samples = DSFA (+), 3M (-), Binax (-) PCR crossing points: 27.04, 22.01, 25.24

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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