

Clinical Evaluation of a Rapid Test for the Detection of Influenza A and B

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ABSTRACT

Background: Influenza is a contagious viral infection of the respiratory tract. Detection of Influenza A and Influenza B as a point of care test may improve isolation protocols and rapid treatment. We evaluated the 3M™ Rapid Detection Flu A + B Test.

Materials and Methods: Samples received in the clinical lab for routine testing of Flu A, Flu B and RSV by PCR was used. This study was IRB approved. All samples were collected in M4 Viral Transport Media (Remel) and tested with 3M™ Rapid Detection Flu A+B Test and the BinaxNOW Influenza A & B test. Binax requires samples be tested within 24 hours of collection and 3M within 72 hours of collection. Both 3M and Binax are immunochromatographic assays. 3M utilizes an automated Reader which measures the amount of fluorescence and Binax is read manually for the presence of pink-band on a disposable card. 3M and Binax were performed ≤ 24 hours after collection; results were compared. Results from ProFLU Plus (Prodesse, Inc) a FDA cleared one-step RT-PCR test were also included.

Results: One hundred and two (102) nasal and nasopharyngeal samples were tested. 3M detected **FLU A** in 12 samples; Binax detected **FLU A** in 9 of the 12 samples. One sample was **FLU A (+)** by 3M and **FLU A (-)** by both PCR and Binax. 3M detected **FLU B** in 19 samples. Binax detected **FLU B** in 12/19 samples; for two of the 7 negative samples, a weak **FLU B** band was seen after 30 minutes. Two (2) samples were detected by 3M as dual positive for **FLU A** and **FLU B**. Both samples were negative by Binax; (1) **FLU A (+)** by PCR and the other **FLU B (+)** by PCR. For the 102 samples tested by PCR: 32 **FLU A (+)**, 36 **FLU B (+)**, and 34 **FLU A& B (-)**; while 3M detected: 12 **FLU A** and 19 **FLU B** and Binax detected: 9 **FLU A** and 12 **FLU B**.

Conclusion: Our data showed that 3M™ Rapid Detection Flu A+B Test was more sensitive than BinaxNOW. However, neither test was comparable to PCR. The testing of samples in the study was not “immediately” performed, as in a point of care setting, which may account for the lower detection rate. The 3M test utilizes automated reading and documents the results in real time which makes this an excellent choice as a point of care test in ED and ICU sites.

BACKGROUND

Rapid diagnosis of influenza during the respiratory season has a significant impact on patient care. 3M™ Rapid Detection Flu A+B Test is an immunochromatographic assay that utilizes an automated Reader. We evaluated the 3M™ Rapid Detection Flu A+B Test and compared to BinaxNOW® Influenza A&B Rapid Test.

MATERIALS and METHODS

- Left-over & de-identified samples received for detection of respiratory viruses were used in this study.
- Samples were collected in M4 media (Remel).
- The 3M™ Rapid Detection Flu A+B Test and BinaxNOW® Influenza A&B Test were performed after the sample was tested by the routine ProFLU+™ Assay (Prodesse, Inc).
- Tests were performed according to manufacturer's instructions.

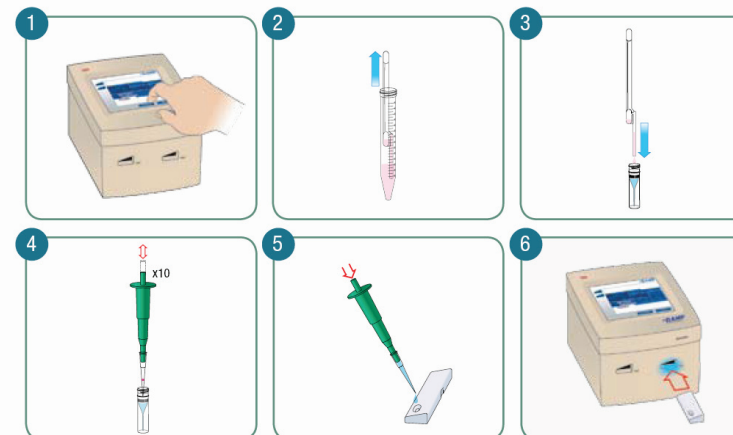
SPECIMEN TYPES

Mouth	1
Nasal	52
Nose	13
Nasopharyngeal Swab (NPS)	35
Throat	1
Total	102

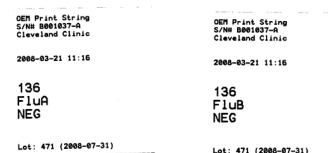
RESULTS SUMMARY

N=102	3M Test	Binax
Flu A (+)	12	9
Flu B (+)	19	12
Flu Neg (-)	69	81
Flu A (+) & Flu B (+)	2	0
	102	102

3M Influenza A + B Test Procedure:



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



RESULTS: Comparison of 3M Test and Binax

Influenza A	Binax			Total
	+	-		
3M Test	+	9	3 ^a	12
	-	0	88	88
	A&B +	0	2	2
	Total	9	93	102

^a 3M test detected 3 additional Positives which were missed in Binax test.
2/3 samples were **FLU A (+)** by PCR, 1/3 samples was **FLU A (-)** by PCR

Influenza B	Binax			Total
	+	-		
3M Test	+	12	7 ^b	19
	-	0	81	81
	A&B +	0	2	2
	Total	12	90	102

^b 3M test detected 5 additional Positives which were missed by Binax test.
The 5 additional tests were also **FLU B** positive by PCR

Influenza A and B	Binax			Total
	+	-		
	+	0	2 ^c	2
3M Test	-	0	100	100
	Total	0	102	102

^c (1) sample = 3M Flu A(+) and Flu B(+), Binax Flu A(-) and B(-), PCR Flu A (+)
(1) sample = 3M Flu A(+) and Flu B(+), Binax Flu A (-) and B(-), PCR Flu B(+)

CONCLUSIONS

The 3M™ Rapid Detection Flu A+B Test performed well when compared to BinaxNow.

Results of our study showed that 3M test out-performed Binax test on both Flu A and Flu B when using the Real-time PCR as the gold standard.

The 3M Test with the automated reader reduces the ambiguity of manually reading Binax cards.

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

3M Rapid Detection Flu A+B Test is a better choice in the busy ICU and ED environment.

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