The Analytical Sensitivity of the 3M™ Rapid Detection Flu A+B Assay

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Introduction and Purpose

Currently available tests for the rapid diagnosis of influenza lack sensitivity compared to viral culture, generally require subjective interpretation and lack automation. The investigational 3M™ Rapid Detection Flu A+B Test is a lateral flow immunochromatographic assay that detects and differentiates influenza A&B from nasal and nasopharyngeal swabs and aspirates. The results generated in this assay are read and interpreted by the automated 3M™ Rapid Detection Reader.

The purpose of this study was to compare the analytical sensitivity of the 3M Rapid Detection Flu A+B Test with three other commercially-available rapid influenza antigen detection assays. The assays used as comparators included the BD Directigen™ EZ Flu A+B, Inverness BinaxNOW® Influenza A&B and the Quidel QuickVue® Influenza A+B tests.

The 3M Rapid Detection Flu A+B Test detects and differentiates between Influenza A&B. It's an objective lateral flow immunochromatographic (IC) assay able to detect nucleoprotein antigen using nasal washes, NP swabs and aspirates. An automated Reader allows connectivity to laboratory information systems.

Study Design

Five different influenza A (2 H1N1 and 3 H3N2) and five different influenza B viruses were prepared in primary rhesus monkey kidney cells. The $TCID_{50}$ of each virus was calculated using the Reed-Muench method. The virus titers ranged from 32,768 to 121,072 $TCID_{50}$ for the Influenza A strains and 44,728 to 98,304 $TCID_{50}$ for the Influenza B strains. Each virus was diluted in serial two-fold dilutions into normal saline. For kit testing, the lowest starting dilution was 1/32 and the highest ending dilution was 1/2048. For all experiments, this proved to be a suitable range to achieve positive and negative results with the majority of the assays tested. Each dilution was tested in duplicate for each assay according to the manufacturer's instructions. The following tests were used: Directigen™ EZ Flu A+B, BinaxNOW® Influenza A&B, QuickVue® Influenza A+B and 3M Rapid Detection Flu A+B Test. Results reported are the highest dilution for which any replicate of the assay was positive.

- 1 min extraction step
- 10 min incubation
- generally easy to read
- CLIA waived

Quidel QuickVue® Influenza A+B

- no extraction step for nasal wash
- 15 min incubation
- generally easy to read
- CLIA waived

Inverness Binax NOW® Influenza A&B

- investigational product
- 15 min incubation
- automatic results
- non-waived

3M™ Rapid Detection Flu A+B Test

- one reagent
- 15 minute incubation
- generally easy to read
- non-waived

BD Directigen™ EZ Flu A&B

Results

The analytical sensitivity of each rapid influenza assay with each virus tested. Values in the table indicate the last dilution for which the test was deemed positive.

Influenza	Titer	3M™	BD™ EZ	Quidel®	BinaxNow®
A/New Caredonia/20/99 (H1N1)	32,762	2,048	1,024	2,048	512
A/Korea/770/2002 (H3N2)	131,072	1,024	1,024	1,024	128
A/Panama/2007/99 (H3N2)	49,152	2,048	512	1,024	256
A/H1N1/Taiwan/87 (H1N1)	49,152	512	256	512	128
A/H3N2/Phillipines/86 (H3N2)	32,768	1,024	256	1,024	256
B/Shizuoka/15/2001	98,304	2,048	256	1,024	512
B/Sichuan/379/99	98,304	2,048	256	1,024	256
B/HongKong/330/2001	98,304	1,024	128	512	256
B/Shanghai/361/2002	44,728	2,048	128	512	256
B/USSR/86	49,152	2,048	256	1,024	512

Summary comparison of the analytical sensitivity for each assay.

	Comparator Assay	3M™ Best	3M™ Equal	3M™ Worst
Influenza A Sensitivity	QuickVue®	1	4	0
	Directigen™ EZ	4	1	0
	BinaxNOW®	5	0	0
Influenza B Sensitivity	QuickVue®	5	0	0
	Directigen™ EZ	5	0	0
	BinaxNOW®	5	0	0

Results (cont.)

Archived samples (60) were tested using the 3M™ Rapid Detection Flu A+B Assay

- 30 were previously positive by culture and antigen detection (QuickVue or Directigen EZ)
- 30 were negative by both culture and antigen

In this population, the 3M™ Rapid Detection Flu A+B Assay showed:

- 100% sensitivity
- 100% specificity

Substantiates, at a minimum, equivalence to other available rapid influenza antigen detection assays

Summary and Conclusions

Influenza A

The 3M™ Rapid Detection Flu A+B Assay is analytically:

- *More sensitive* than the BinaxNOW and Directigen EZ Influenza tests
- *Equally sensitive* to the QuickVue Influenza test

Influenza B

The 3M™ Rapid Detection Flu A+B Assay is analytically:

- *More sensitive* than the BinaxNOW, Directigen EZ and QuickVue influenza tests

Reference

Suzanne E. Dale, PhD., Christine Mayer BS., Marie C. Mayer BS., and Marilyn A. Menegus PhD., "The Clinical and Analytical Sensitivity of the 3M Rapid Detection Flu A+B Assay." Presented at Infectious Diseases Society of America, October, 2007

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