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

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Authors:
D.A. Wilson, D. Warner, B. Yen-Lieberman
Cleveland Clinic, Cleveland, OH
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D.A. Wilson, D. Warner, B. Yen-Lieberman
Cleveland Clinic, Cleveland, OH

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 were used. This study was IRB approved. All samples were collected in M4 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. 3M and Binax FLU A & B test was performed well when compared to BinaxNOW. Our data showed that 3M™ Rapid Detection Flu A+B Test was more specific than BinaxNOW. However, neither test was comparable to PCR. The results of testing the samples in the study was not "immediately" performed, as in a point of care setting, which may account for the low 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.

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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D.A. Wilson
Cleveland Clinic
Dept of Microbiology L40
9500 Euclid Avenue
Cleveland, Ohio 44195
216-444-5944 (phone)
216-445-6984 (fax)
wilsond2@ccf.org
216-445-6984 (fax)
216-444-5944 (phone)
9500 Euclid Avenue
Cleveland Clinic
Dept of Microbiology L40
9500 Euclid Avenue
Cleveland, Ohio 44195
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