

Prospective Head-to-Head Comparison of Three Rapid Immunoassays for Influenza A & B

Aleta B. Bonner DVM, MD, MSPH
 Dell Children's Medical Center of Central Texas
 Austin, Texas (USA)

Objective

To conduct a prospective head-to-head comparison of the clinical performance of the Quidel QuickVue® A+B, Binax NOW® A&B, and BD Directigen™ EZ A+B Influenza tests versus viral culture using fresh aliquots of the same patient specimens. Viral culture will be used as the "gold standard" and the test performance characteristics of each rapid immunoassay will be determined by specimen type. Direct comparison of the three tests will be based on test performance characteristics for each specimen type.

Background and Significance

The determination of the sensitivities and specificities of rapid diagnostic devices for the detection of influenza A and B are based on comparisons of the various test devices to laboratory "gold standards" such as viral culture. Unfortunately, the accuracy of rapid diagnostic tests for the detection of influenza A and B depends not only on the quality of the test device, but also on multiple factors that are not easily controlled for in either the clinical or laboratory setting. These include proper procurement of an adequate sample, proper specimen handling, transport and testing. The interplay of these factors can easily vary based on the skill level of the personnel obtaining and testing the specimen, as well as specimen handling and timing between collection and testing. The accuracy of the determination of the test performance characteristics that is attributable directly to the device is dependent on the optimization of all of these factors in order to maximize test performance.

A head-to-head comparison of rapid immunoassays conducted in real-time, using aliquots of the same patient specimens would serve as a basis to eliminate variability due to factors not related directly to the tests themselves.

Methods

- A prospective study of 805 patients ages 1 month to 61 years of age presenting with ILI to the Emergency Departments of the Brackenridge and Dell Children's Hospitals during the winters of 2006-07 and 2007-08
- Informed consent obtained from the subject or the parent/legal guardian
- Specimens were collected by NP aspirate/wash and nasal swab
- Nasal swabs were immediately suspended in 1ml sterile saline
- Each specimen was used to run the three rapid influenza tests according to the manufacturer's instructions
- The remainder of each specimen was placed in 1 ml VTM and immediately frozen to -70°C. Viral culture was performed on each specimen.

	Nasopharyngeal Wash / Aspirate N=379	Nasal Swab N=426
Age Range (Yrs)	0.08 – 51	0.17 – 61
Mean Age (Yrs)	1.65	7.26
Gender M/F	228 / 198	205 / 174

Table 1. Subject Demographics Based on Sample Type

		NP Aspirate / Wash		Nasal Swab	
		Sensitivity	Specificity	Sensitivity	Specificity
Influenza A	QuickVue	96	91	88	87
	Directigen EZ	88	92	84	86
	BinaxNOW	92	91	77	90
Influenza B	QuickVue	85	93	81	95
	Directigen EZ	83	94	64	96
	BinaxNOW	83	98	63	98

Table 2. Sensitivity and Specificity for the Rapid Influenza Tests versus Viral Culture

Conclusions

- NP aspirate/washes and nasal swabs provided the most consistent performance characteristics between the three tests; demonstrating greater sensitivity for influenza A.
- This large, prospective, head-to-head comparison of rapid influenza tests emphasizes the importance of selecting the optimal test and specimen collection method for POC diagnosis.

Funding and Support

Quidel provided research funding and QuickVue Influenza A+B test kits.

This study included an analysis of throat swab specimens that are not cleared for use with QuickVue. Customers who wish to inquire about these results should contact Quidel's Regulatory Affairs department directly.