



Proof Source: S Raj et al 2018 - ID NOW™ Influenza A & B 2 Performance Comparison Study

Comparison of the ID NOW™ Influenza A & B 2, Cobas® Liat Influenza A/B, and Xpert® Xpress Flu Point-of-Care Nucleic Acid Amplification Tests for Influenza A/B Detection in Children

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Summary

The study aim was to compare the performance of three commercially available Clinical Laboratory Improvement Amendments (CLIA) waived Flu assays; ID NOW (Abbott), Liat (Roche) and GenXpert (Cepheid). 201 children <18 years old were prospectively enrolled from January to April 2018 and collected nasopharyngeal swab specimens in viral media. Aliquots were frozen for testing on different diagnostic platforms per manufacturer's instructions.

Overall performance was considered comparable between all three molecular assays, with ID NOW showing slightly higher performance in Flu B and slightly lower performance in Flu A (Table 1). Note, false-negative samples for ID-NOW™ had a high median CT value of 33.81. ID NOW™ Influenza A & B 2 generated the lowest invalid rates (0.5%) versus Liat (5.5%) and GenXpert (3.0%).

Time to results were favourable with ID NOW™ in early call out mode (5 min for positive specimen) or full call out mode (13 mins) when compared with Liat (20 mins) and GenXpert (30 mins). The performance of ID NOW™ Influenza A & B 2 was comparable in both full- and early call out mode.

Table 1 lists performance of ID-NOW™ Influenza A&B 2, Cobas® Influenza A/B nucleic acid (LIAT), Cepheid Xpert® Xpress Flu, and BD™ Veritor Flu A/B assay vs. a CDC Flu A/B PCR

Assay	Target	TP	FP	TN	FN	% Sensitivity (95% CI)	% Specificity (95% CI)
ID NOW™ Influenza A & B 2	Flu A	68	1	127	5	93.2 (84.1-97.5)	99.2 (95.1-100.0)
	FLU B	35	2	163	1	97.2 (83.8-99.9)	98.8 (95.2-99.8)
Cobas® Liat Influenza A/B	Flu A	73	1	127	0	100 (93.8-100)	99.2 (95.1-100.0)
	FLU B	34	4	161	2	94.4 (80.0-99.0)	97.6 (93.5-99.2)
Cepheid Xpert® Xpress Flu	Flu A	73	3	125	0	100 (93.8-100)	97.7 (92.8-99.4)
	FLU B	33	3	162	3	91.7 (76.4-97.8)	98.2 (94.4-99.5)
BD™ Veritor FLU A/B*	Flu A	58	1	126	15	79.5 (68.1-87.7)	99.2 (95.0-99.9)
	FLU B	24	1	163	12	66.7 (48.9-80.9)	99.4 (96.1-99.9)

TP: True Positive, FP: False Positive, TN: True Negative, FN: False Negative; Dual Flu A and B positive results: CDC Flu A/B PCR (2); ID NOW (4), LIAT (0), Xpert (0), BD (0); *BD results were available for 200 subjects. Standard-of-care testing for one subject was PCR based

Authors Conclusion

“Early flu diagnosis is critical for patient management and reduction of morbidity and mortality during seasonal epidemics. Overall, performance of all three molecular assays was found to be comparable. ID NOW™ Influenza A & B 2 is a CLIA-waived, simple-to-use molecular assay in which positive results can be obtained within 5 minutes. This advantage makes the assay suitable for point-of-care testing in an outpatient setting.

Other Key Points

- The study noted improvements compared with prior study results using first generation Alere i Influenza A&B assay, stating significant changes to both the amplification reaction and the analytical software were realized.
- All molecular assays had higher sensitivity than BD Veritor™ antigen test (Flu A: 79.5%; Flu B: 66.7%)