PRE-MARKET EVALUATION OF THREE NOVEL REAL TIME PCR RESPIRATORY VIRUS ASSAYS COMPARED TO TWO FDA-CLEARED MOLECULAR PANELS

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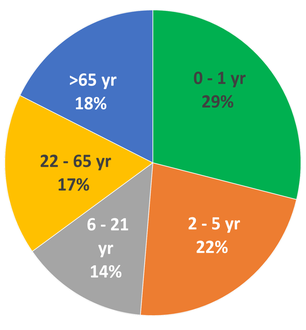
Background and Aims

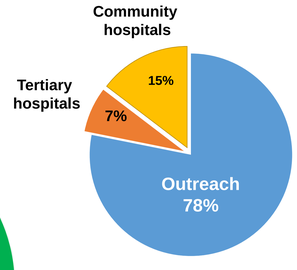
Rapid and accurate detection of pathogens associated with respiratory tract infections (RTI) continues to have a fundamental impact on decision making for optimal treatment and triaging. Existing FDA-cleared molecular respiratory assays consist of either small multiplex panels with 2-3 targets (i.e. Flu/RSV) or large syndromic testing panels with usually more than 11 targets (i.e. multiple bacteria and viruses), with no options in between. The Panther Fusion Respiratory (Fusion) assays offer a flexible option with three small panels consisting of Flu A/B/RSV, Paraflu 1-4, and AdV/hMPV/RV. This study compares the novel Fusion assays (Hologic, pre-market) with two FDA-approved syndromic panels, the BioFire Diagnostics FilmArray RP (BioFire) and Luminex NxTAG RPP (Luminex).

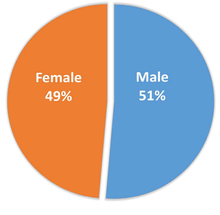
Methods and Materials

485 prospectively collected nasopharyngeal swab specimens were tested at Northwell Health Laboratories with all three platforms to determine performance characteristics for Influenza A and B (Flu A/B), Respiratory Syncytial Virus (RSV), Parainfluenza virus 1-4 (Paraflu), Adenovirus (AdV), Human Metapneumovirus (hMPV), and Rhinovirus (RV). Non-matching targets such as Human Bocavirus were disregarded. Discordant results for all targets were evaluated with laboratory-developed tests. A true positive was defined as being positive by all three of the tested panels or being positive by 3 out of 4 after resolution of discordant results. Hands-on-time, walkaway time, return visits to instrument, and total turn-around-time were recorded to evaluate workflow.

PATIENT DEMOGRAPHICS AGE, GENDER & LOCATION







RESULTS

The overall concordant positivity and negativity rate was 64% (310/485) and 18% (88/485), respectively, with a total of 359 matching targets between all 10 targets, including 47 double and 2 triple infections. The overall sensitivity and specificity values for each method were as follows: Fusion 97.2% and 100%, BioFire 97.8% and 100%, and Luminex 98.87% and 99.93% respectively. Sensitivities of each assay fluctuated by viral target.

Before discordant resolution, the greatest discrepancies were seen for detection of Flu A and RV: BioFire 87.3%, Luminex 94.8% and Fusion 100% for Flu A; BioFire 98.7%, Luminex 96.2% and Fusion 78.1% for Entero/Rhino. Tables represent performance after discordant resolution.

Flu A		Consensus +	Consensus -	Sensitivity	Specificity
Fusion	+	55	0	100.00%	100.00%
	-	0	430		
BioFire	+	47	0	85.45%	100.00%
	-	8	430		
Luminex	+	52	1	94.55%	99.77%
	-	3	429		

Flu B		Consensus +	Consensus -	Sensitivity	Specificity
Fusion	+	42	1	100.00%	99.77%
	-	0	442		
BioFire	+	42	0	100.00%	100.00%
	-	0	443		
Luminex	+	42	0	100.00%	100.00%
	-	0	443		

RSV		Consensus +	Consensus -	Sensitivity	Specificity
Fusion	+	53	2	100.00%	99.54%
	-	0	430		
BioFire	+	48	0	90.57%	100.00%
	-	5	432		
Luminex	+	48	1	90.57%	99.77%
	-	5	431		

AdV		Consensus +	Consensus -	Sensitivity	Specificity
Fusion	+	50	1	92.59%	99.77%
	-	4	430		
BioFire	+	47	1	87.04%	99.77%
	-	7	430		
Luminex	+	50	1	92.59%	99.77%
	-	4	430		

hMPV		Consensus +	Consensus -	Sensitivity	Specificity
Fusion	+	47	1	100.00%	99.77%
	-	0	437		
BioFire	+	43	0	91.49%	100.00%
	-	4	438		
Luminex	+	44	1	93.62%	99.77%
	-	3	437		

RV		Consensus +	Consensus -	Sensitivity	Specificity
Fusion	+	61	2	84.72%	99.52%
	-	11	411		
BioFire	+	61	10	84.72%	97.58%
	-	11	403		
Luminex	+	65	14	90.28%	96.61%
	-	7	399		

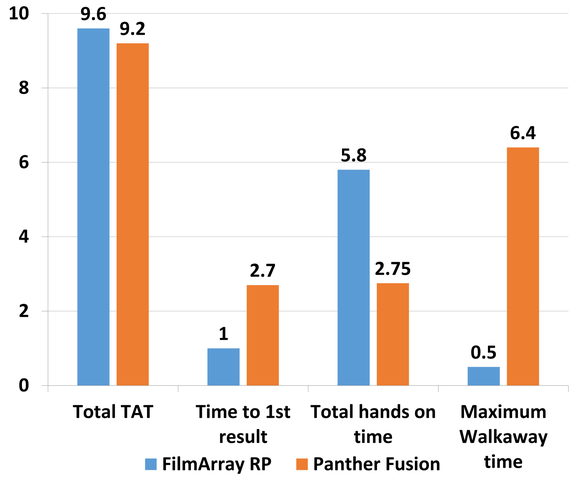
Para 1		Consensus +	Consensus -	Sensitivity	Specificity
Fusion	+	42	0	100.00%	100.00%
	-	0	443		
BioFire	+	42	0	100.00%	100.00%
	-	0	443		
Luminex	+	42	0	100.00%	100.00%
	-	0	443		

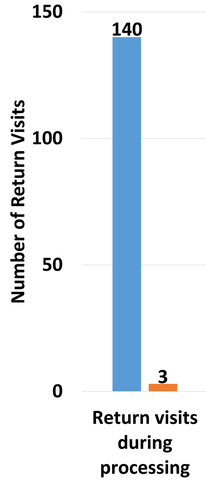
Para 2		Consensus +	Consensus -	Sensitivity	Specificity
Fusion	+	39	1	88.64%	99.77%
	-	5	440		
BioFire	+	41	0	93.18%	100.00%
	-	3	441		
Luminex	+	44	0	100.00%	100.00%
	-	0	441		

Para 3		Consensus +	Consensus -	Sensitivity	Specificity
Fusion	+	40	0	95.24%	100.00%
	-	2	443		
BioFire	+	41	0	97.62%	100.00%
	-	1	443		
Luminex	+	40	0	95.24%	100.00%
	-	2	443		

Para 4		Consensus +	Consensus -	Sensitivity	Specificity
Fusion	+	38	1	95.00%	99.78%
	-	2	444		
BioFire	+	37	2	92.50%	99.55%
	-	3	443		
Luminex	+	33	1	82.50%	99.78%
	-	7	444		

Lower sensitivity of the Fusion RV assay may partially be explained by the assay design for detection of Rhinovirus only. In contrast to Luminex and BioFire, the Fusion RV assay does not appear to cross react with Enterovirus.





Workflow evaluation for 140 samples: Panther Fusion Respiratory Panels compared to BioFire Film Array RP

Although the time to first result is faster for Luminex and BioFire, the Panther Fusion System requires significantly less return visits and hands-on time, enabling the best walkaway option with a comparable total turn-around-time.

CONCLUSIONS

- The Panther Fusion Respiratory (Fusion) assays performance is similar or better compared to Luminex and BioFire.
- The individual panels consist of Flu A/B/RSV, Paraflu 1-4, and AdV/hMPV/RV that can be adaptably performed, individually or combined, providing results for as little as three or as many as ten targets.
- This flexibility provides a viable option for directed ordering and individual pricing.

Panther

TMA

TMA plus real-time TMA

The Panther Fusion™

TMA plus real-time TMA plus PCR