

Evaluation of BioFire FilmArray Respiratory Panel for Detection of Viruses

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Background

- Acute respiratory infection (ARI) causes significant morbidity & mortality in young children & the elderly.
- Majority of ARI is of viral etiology.
- Timely diagnosis can avoid unnecessary use of antimicrobials, reduce the length of stay and allow better infection control.
- FilmArray v1.7 Respiratory Panel (FilmArray RP) (BioFire Diagnostics, Salt Lake City, UT) is a multiplexed nucleic acid test for 17 viruses & 3 bacterial pathogens.
- Reported overall sensitivity & specificity were over 80% but most data were from paediatric patients and local data are lacking.
- We review the performance of FilmArray RP done in 2019.

Method

- Respiratory specimens obtained during the clinical routine with FilmArray RP done in 2019 in Queen Elizabeth Hospital were investigated.
- Sensitivity & specificity of FilmArray RP for Adenovirus (Adeno), Human metapneumovirus (hMPV), Human Rhinovirus/Enterovirus (Rhino/EV), Influenza A/H1 (Flu A H1), Influenza A/H3 (Flu A H3), Influenza B (Flu B), Parainfluenza virus 1-4 (PIV-1-4), Respiratory syncytial virus (RSV) were evaluated.
- Results of the paired samples sent to Public Health Laboratory Services Branch (PHLSB) for respiratory multiplex PCR were matched and regarded as the gold standard for comparison.

Table 1. Age distribution of samples collected.

Age (years)	No. of specimens (% of total)
0-18	86 (26%)
19-64	165 (50%)
≥65	78 (24%)

Sample type/result	No. of samples	% of total
Negative samples	191	58.1%
Positive samples	138	41.9%
Single detections	121	36.8%
Co-detections	17	5.17%

Table 2. Positivity rate for FilmArray RP for all samples.

Age group	No. of positive samples	% positive
≤5 yrs (n = 67)	54	80.6%
6-18 yrs (n = 19)	11	57.9%
19-64 yrs (n =165)	53	32.1%
≥65 yrs (n = 78)	20	25.6%

Table 3. Positivity rate for FilmArray RP by age groups.

Table 4. No. of target detected by FilmArray RP in the same specimen.

Age group	No. of targets positive			
	0	1	2	3
≤5 yrs (n = 67)	13 (19.4%)	40 (59.7%)	13 (19.4%)	1 (1.49%)
6-18 yrs (n = 19)	8 (42.1%)	10 (52.6%)	1 (5.26%)	0 (0%)
19-64 yrs (n =165)	112 (67.9%)	52 (31.5%)	1 (0.61%)	0 (0%)
≥65 yrs (n = 78)	58 (74.4%)	19 (24.4%)	1 (1.28%)	0 (0%)

Table 5. Performance summary & characteristics of FilmArray RP.

Analyte	Sensitivity			Specificity			Kappa
	TP/(TP+FN)	%	95% C.I.	TN/(TN+FP)	%	95% C.I.	
Flu A all	71/74	95.9	88.6-99.1	252/255	98.8	96.6-99.8	0.95
Flu A H1	60/62	96.8	88.8-99.6	264/268	98.9	96.8-99.8	0.95
Flu A H3	10/12	83.3	51.6-97.7	317/317	100	98.8-100	0.91
Flu B	0/0	N/A	N/A	329/329	100	98.9-100	N/A
RSV	10/11	90.9	58.7-99.7	317/318	99.7	98.3-100	0.91
Rhino/EV	17/18	94.4	72.7-99.9	294/311	94.5	91.4-96.8	0.63
hMPV	6/6	100	54.1-100	323/323	100	98.9-100	1
PIV-1	2/2	100	15.8-100	327/327	100	98.9-100	1
PIV-2	3/3	100	29.2-100	326/326	100	98.9-100	1
PIV-3	3/3	100	29.2-100	325/326	99.7	98.3-100	0.86
PIV-4	3/4	75	19.4-99.2	324/325	99.7	98.3-100	0.75
Adeno	5/5	100	47.8-100	324/324	100	98.9-100	1

Results

- 329 paired specimens from 318 patients were analysed.
- Overall positivity rate of FilmArray RP was 41.9%.
- Detection rate was highest, 80.6%, in young children (≤5 years of age), also as the codetection rate.
- Sensitivity ≥90.9% for detection of all except 2 analytes: Flu A H3 (83.3%) & PIV-4 (75%).
- FluA H3, Flu B, hMPV, PIV-1, PIV-2 & Adeno had a specificity of 100%.
- Flu A, Flu A H1, RSV, Rhino/EV, PIV-3 & PIV-4 had a specificity of ≥94.5%.
- Overall sensitivity of FilmArray RP is 94.8% and specificity is 99.3%.
- Kappa score >0.7 for all positive viruses except Rhino/EV.
- Multiple infections were more commonly detected by FilmArray RP (5.17%) than PHLSB (0.61%).
- 76.5% of multi-analyte-positive samples had combinations with Rhino/EV.
- All of the positive Rhino/EV in multi-analyte-positive samples were not detected by PHLSB.

Conclusion

- Overall sensitivity of FilmArray RP is 94.8% and specificity is 99.3%.
- Sensitivity ≥90.9% for detection of all except 2 analytes.
- Specificity ≥94.5% for all analytes.
- Good agreement with Respiratory Multiplex PCR at PHLSB except Rhino/EV.
- Multiple infections were more commonly detected by FilmArray RP than PHLSB.
- Majority of multi-analyte-positive samples had combinations with Rhino/EV, all of these positive Rhino/EV were not detected by PHLSB.
- A third independent assay would be required to investigate the discrepant results.