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Analytical evaluation of a new point-of-care multiplex respiratory platform

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INTRODUCTION

Respiratory infections : 1st cause of Morbi-mortality worldwide [Elderly and children < 5 years old]

- Leading cause of antibiotics prescription
- Viral infections main causative agent or trigger of bacterien infections

During Outbreaks: Socio-economic impact

- Overkrowding primary health care and lengthening of waiting time

Democratisation of Syndromic panel for respiratory pathogens since last decades

Availability of PCR Multiplex POCT: gain time and efficious managemnt of healthcare in community

OBJECTIVES

- Evaluation of Sensitivity of the Flash Dx RP 1.1 compared to reference technologies (GeneXpert-Cepheid and/or Filmarray RP 2.1 plus-Biomérieux and/or RGene- Biomérieux)
- Evaluation of Overall/individual Specificity
- Correlation study of Threshold Cycles obtained by Flash Dx and Rgene
- Diagnostic performance Evaluation on Coinfected samples
- Evaluate simplicity and ease of use

METHODS

-  Miniaturised PCR Multiplex diagnostic tool (POCT)
-  Detection : 13 targeted Bacteria and Viruses
-  Cartridge with 42 Primers Target
-  Samples : Nasopharyngal swab, Broncho alveolar lavage



Screening and test:

- 61 Positive samples with GeneXpert : SARS-CoV2, VRS, Flu-A, Flu-B
- 64 Positive samples with Filmarray : hRV /EV, hPIV, ADV, hMPV, MP, BP
- 13 Negative samples
- 15 Positive samples for 2 or more pathogens

Controle Ct : Rgene (hRV /EV, hPIV, ADV, hMPV) and Altona (hMPV)

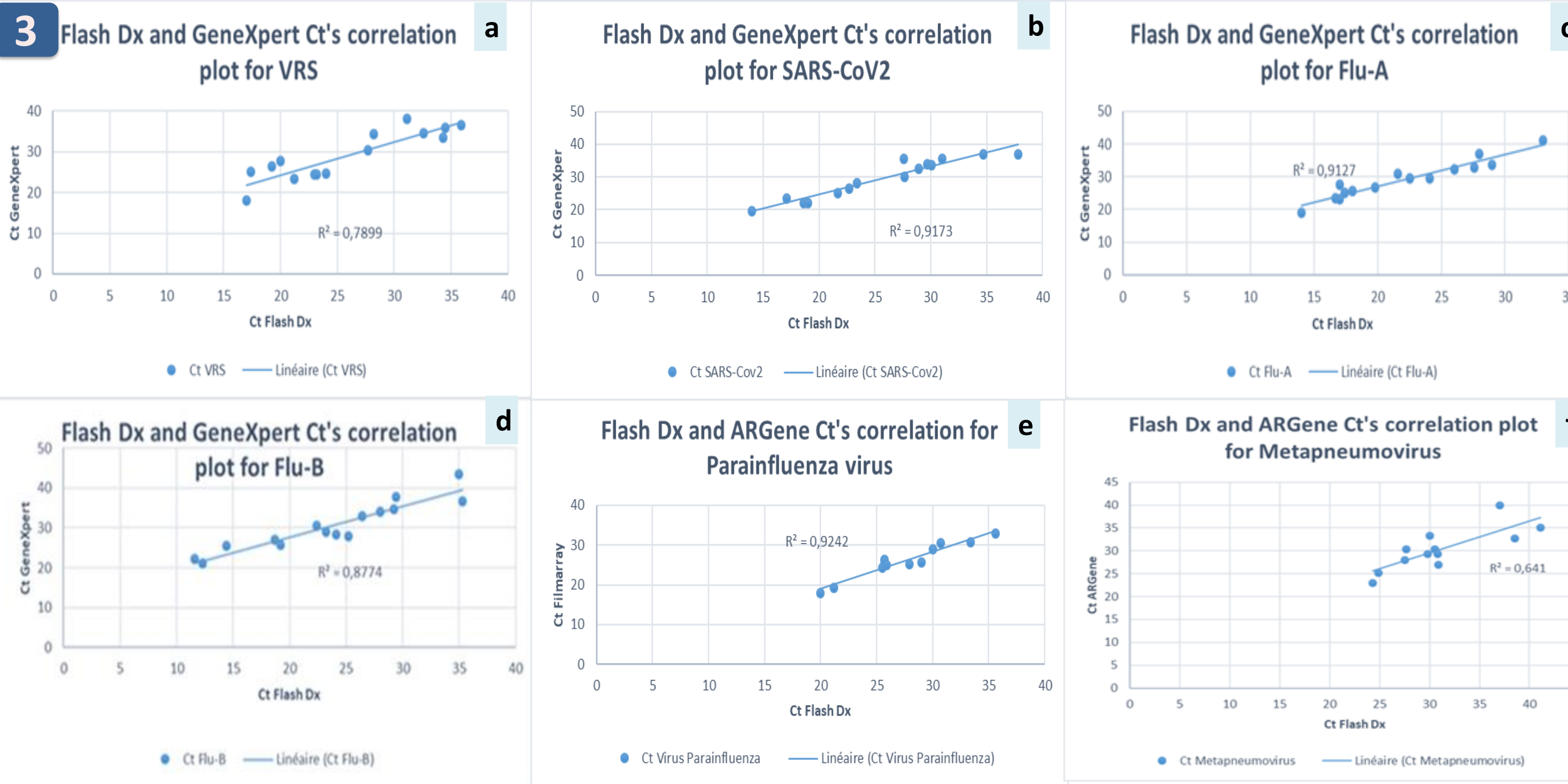
RESULTS

1	Pathogens (n total tested)	Methods	Reference Ct range	False negatives	Flash Dx Sensitivity (95% CI) in single infection	Flash Dx Sensivity (95% CI) with coinfection	Specificity
	SARS-CoV2 (n=18)	GeneXpert®, Cepheid	14 to 38	2	100%; *(n=15)	88,9% (74,4%-100%); *(n=15), **(n=3)	100%
	RSV-A, RSV-B (n=16)	GeneXpert®, Cepheid	17 to 36	0	100%; *(n=15)	100%; *(n=15), **(n=1)	100%
	Influenza A (n=17)	GeneXpert®, Cepheid	14 to 37	1	93,75% (97,45%-100%); *(n=16)	94,18% (80,34%-100%); *(n=16), **(n=1)	100%
	Influenza B (n=15)	GeneXpert®, Cepheid	12 to 35	0	100%; *(n=15)	100%; *(n=15), **(n=0)	100%
	Human Adenovirus (hADV) (n=15)	Filmarray, Biomérieux ®	9 to 37	6	62,5% (38%-84,79%); *(n=8)	60% (35,2%-100%); *(n=8), *(n=7)	100%
	Human Parainfluenzavirus (hPIV-1, hPIV-2,hPIV-3)(n=18)	Filmarray, Biomérieux ®	19 to 31	0	100%; *(n=14)	100%; *(n=14), **(n=4)	100%
	Human Metapneumovirus (n=20)	Filmarray, Biomérieux ®	21 to 41	3	93,75% (83,14%- 100%); *(n=16)	85% (69,4%-100%); *(n=16), **(n=4)	100%
	Human Rhino/Enterovirus (n=18)	Filmarray, Biomérieux ®	24,6 to 34,8	3	91,67% (78,90%- 100%); *(n=12)	83,3% (66,1%-100%); *(n=12), **(n=6)	100%
	<i>Mycoplasma pneumoniae</i> (n=12)	Filmarray, Biomérieux ®	10 to 23	1	90% (73,03%- 100%); *(n=10)	91,66% (76%-100%); *(n=10), **(n=2)	100%
	<i>Bordetella pertusis</i> (n=4)	Filmarray, Biomérieux ®	6 to 23	0	*(n=0)	100%; *(n=0), **(n=4)	100%
	Negative samples (n=13)	Filmarray, Biomérieux ®	/	/	/	/	100%

Table 1: Target tested, discrepancies found with Flash-Dx, Individual sensitivity and specificity with single infected and coinfectcd samples

2	Co-infection (Filmarray)	Number of samples	Flash Dx	Reference technique
	hAdV + hRV/hEV (+/+)	3	(+ /+), (+ /- ^a), (- ^b /+) a : Ct = NA, b : Ct=29	(+ /+), (+ /-), (+ /+)
	hAdV + hMPV (+/+)	1	(+ /+)	(+ /-)
	hAdV + <i>B. pertussis</i> (+/+)	1	(+ /+)	(+ /+)
	hAdV + FluA (+/+)	1	(- ^a /+) a : Ct=37	(+ /+)
	hRV/hEV + <i>M. pneumoniae</i> (+/+)	1	(+ /+)	(+ /+)
	hMPV + SARS-CoV2 (+/+)	1	(- ^a /+) a : Ct=30	(+ /+)
	hMPV + VRS (+/+)	1	(+ /+)	(+ /+)
	hPIV + hRV/ hEV (+/+)	2	(+ /+), (+ /- ^a) a : Ct=27	(+ /+), (+ /+)
	hPIV + SARS-CoV2 (+/+)	1	(+ /- ^a) a : Ct=20,9	(+ /+)
	SARS-CoV2 + <i>B. pertussis</i> (+/+)	1	(- ^a /+) a : Ct=17,1	(+ /+)
	<i>B. pertussis</i> + SARS-CoV2+hAdV+hMPV (+/ + /+)	1	(+ /- ^a /- ^b /- ^c) a : Ct=22, b : Ct=22, c : Ct= NA	(+ /+ /+ /-)
	hRV/hEV + hPIV + <i>M. pneumoniae</i> (+/ + /+)	1	(+ /+ /+)	(+ /+ /+)

Table 2: List of coinfectcd samples and discrepancies results found, a, b, c: Ct values



Figures a, b, c, d, e, f: Ct values correlation graphs for VRS, SARS-CoV-2, Flu-A, Flu-B, hPIV and hMPV

CONCLUSION

- Turnaroud time= 1hour
- Validity rate: 94,90% (149/157)
- Overall sensitivity: 89.54% (95%IC; 84.40%-95%)
- Individual sensitivity varying between 83% and 100%
- Overall and individual specificity: 100% (95%IC; 100%)
- Very good Ct correlation with reference techniques
- Compact tool, easy to use, short response time
- Reliable for bedside use in community
- Fast and earliest management of respiratory infections
- Appropriate treatment/ Reduce overuse of Antibiotics
- Perspective: improvement of hADV detection
- Expand the panel with other bacterial targets

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