

High detection rates of SARS-CoV-2, Influenza A, Influenza B, and RSV with the multiplex Alinity m Resp-4-Plex assay

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Background

In a joint statement, WHO and ECDC emphasized the importance of monitoring SARS-CoV-2, influenza and RSV to better understand the impact of co-circulation of respiratory viruses and to strengthen prevention and control measures. Thus, the objective of this study was to evaluate the accuracy of the Alinity m Resp-4-Plex assay regarding detection and differentiation of the respiratory viruses SARS-CoV-2, influenza A, influenza B and RSV in comparison to another on-market assay (Allplex SARS-CoV-2/Flu-A/Flu-B/RSV).

METHODS

Following initial testing with Alinity m Resp-4-Plex (Abbott Molecular Inc., USA) or with Allplex SARS-CoV-2/Flu-A/Flu-B/RSV (Seegene, Korea), leftover de-identified patient samples were retested with the other assay as follows: 300 samples negative for all 4 pathogens, 201, 198, 73, and 188 samples positive for SARS-CoV-2, influenza A, influenza B, and RSV, respectively. Samples were categorized according to their Alinity m Ct values: <25; 25-30; 30-35; >35. The detection rates by the Allplex assay in comparison to the Alinity assay were determined. The correlation of the Ct values was investigated in regression analyses and Bland-Altman plots.

RESULTS

In the Alinity m Ct-categories <25; 25-30; 30-35 and >35, Allplex detected SARS-CoV-2 in 47/47; 46/49; 24/54 and 2/51 samples, respectively, with higher Ct-values and partially only positive for one of three genes. For influenza A, the recovery rates were 83/84; 43/49; 25/39 and 3/26; for influenza B 35/37; 5/19; 2/9 and 0/8; and for RSV 21/21; 33/33; 32/56 and 5/78, respectively. Overall detection rates were 59%, 78%, 58%, and 48% for the four respiratory viruses, respectively. Two influenza A samples pretested positive with Allplex could not be confirmed by Alinity m Resp-4-Plex. However, retesting of the samples with the two methods provided negative results for both assays. All 300 negative samples by Alinity m Resp-4-Plex were also tested negative by Allplex. Ct values between the two methods correlated well for SARS-CoV-2 and RSV (Pearson's correlation coefficient $r > 0.92$) while correlation was weaker for the Ct values of influenza A and B ($r = 0.564$ and 0.403 , respectively).

Alinity m Resp-4-Plex (Ct-category)	n	SARS-CoV-2 detected by Allplex		Flu A detected by Allplex		Flu B detected by Allplex		RSV detected by Allplex				
<25	47	47	100%	84	83	99%	37	35	95%	21	21	100%
25-30	49	46	94%	49	43	84%	19	5	26%	33	33	100%
30-35	54	24	44%	39	25	68%	9	2	22%	56	32	57%
>35	51	2	4%	26	3	12%	8	0	0%	78	5	6%
Total:	201	119	59%	198	154	78%	73	42	58%	188	91	48%

RESULTS

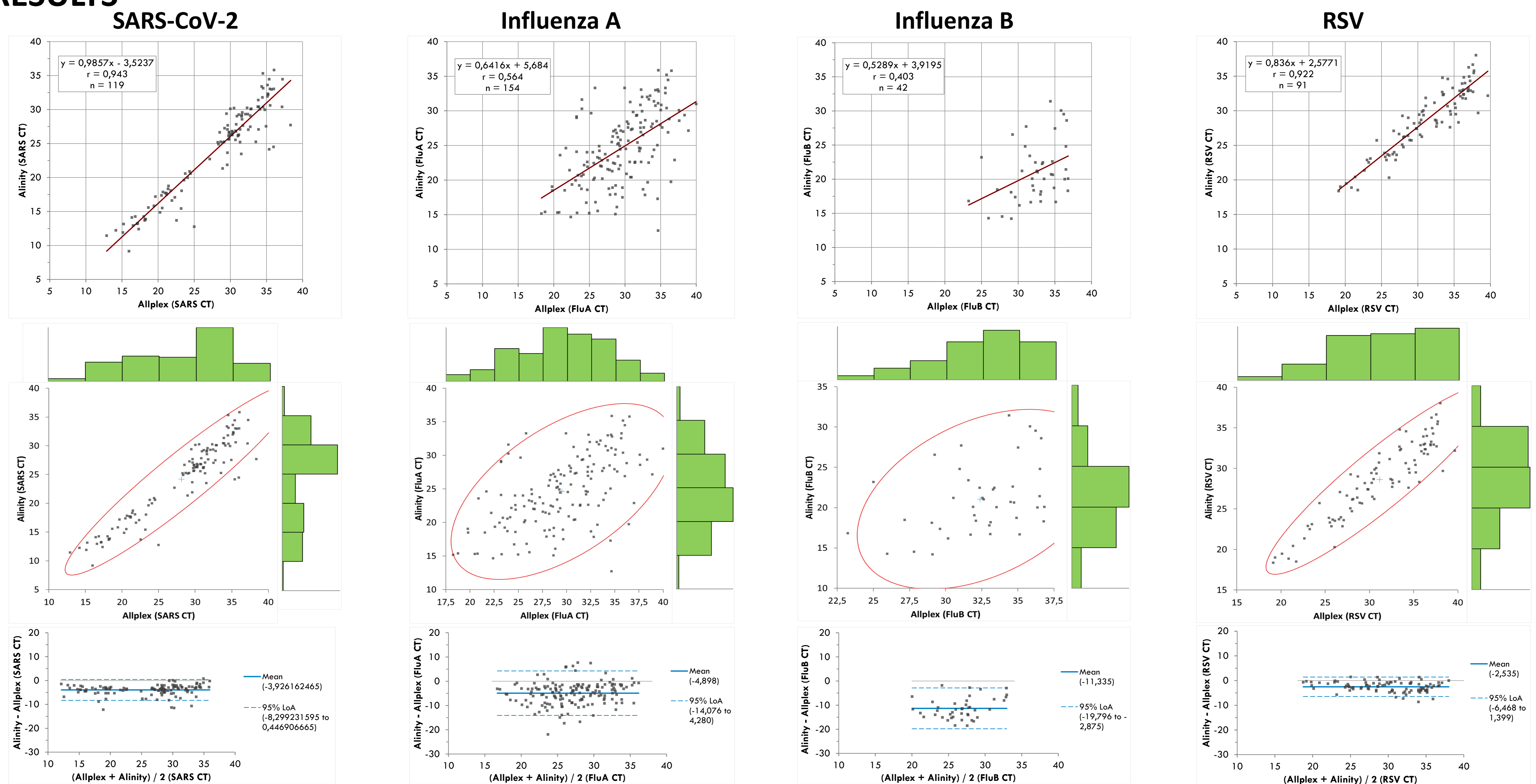


Fig. 1: Regression, density ellipse with histograms and Bland-Altman plots for SARS-CoV-2, Influenza A, Influenza B and RSV comparing the Ct values of Alinity m Resp-4-Plex with those of Allplex

CONCLUSIONS

In this comparative evaluation of Alinity m and Allplex using a large number of clinical samples positive for either one of the four respiratory viruses and falling into different Ct categories ($n=660$), Alinity m Resp-4-plex showed considerably higher detection rates compared to Allplex SARS-CoV-2/Flu-A/Flu-B/RSV and a specificity of 100%. Discordant results between the two methodologies could be due to additional freeze/thaw cycles of specimens prior to testing. Nevertheless, the higher sensitivity of the Alinity m Resp-4-Plex assay remains obvious.

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