

Evaluation of the performance of the Hologic Panther fusion 4 plex-assay

P0170

Robert Ehret, Medard Solecki, Dima Schmid, Martin Obermeier
Medical Center for Infectious Diseases (MIB), Berlin

Contact: ehret@mvz-mib.de

AIM

The objective of this study was to analyze the clinical sensitivity and specificity of the Panther fusion 4 plex-Assay (Panther-4plex) in positive and negative nasopharyngeal samples for the respiratory viruses SARS-CoV-2, influenza A and B (FluA, FluB) and RSV in direct comparison to other on-market assays (Abbott Alinity m Resp-4-plex (Alinity-4plex) and Seegene Allplex RV master (Allplex)).

RESULTS

All 100 negative pretested samples were confirmed negative with the Panther-4plex and the Allplex assays. For SARS-CoV-2 all samples with a retest Alinity-4plex result below 25 (n=36) were detected with all tests. Of 17 samples between Ct 25 and 30 Panther-4plex hit all, Allplex missed one. Of 35 samples Ct 30-35 Panther 4plex confirmed 31 and Allplex confirmed only 12 samples as positive. Above Ct 35 (n=14) Panther-4plex confirmed 8 and Allplex none. In the same categories we achieved recovery rates of 4/4; 38/38, 30/43 and 2/14 for FluA, 2/2; 13/13; 10/16 and 1/11 for FluB and 8/8; 24/24; 40/42 and 4/18 for RSV with the Panther-4plex. For the Allplex the results were 4/4; 24/38; 7/43 and 1/14 for FluA, 2/2; 5/13; 1/16 and 0/11 for FluB, and 8/8; 24/24; 17/42 and 1/18 for RSV (s. Tab.1). One FluB and one RSV positive sample were only recovered by Panther-4plex.

METHODS

Leftover samples after routine testing (Alinity-4plex, TOR) were stored for 5 to 10 months at -20°C. We compared re-tested results positive at least in one assay for 102 positive SARS-CoV-2 samples, 99 positive for FluA, 43 FluB and 93 RSV samples, respectively, and 100 samples negative for all 4 pathogens. The pretest Ct-values were between 15 and 35. The samples were thawed and diluted to achieve enough volume for three retests done in parallel without any extra freeze-thaw cycles.

Tab. 1: Detection rates for SARS-CoV-2, influenza A and B (FluA, FluB) and RSV for the Panther-4plex and the Allplex assays in the four Alinity-4plex driven Ct-categories <25, 25-30, 30-35 and >35

Alinity-4plex (Ct-category)	detected SARS-CoV-2		detected FluA		detected FluB		detected RSV	
	n	by Panther-4plex	n	by Panther-4plex	n	by Panther-4plex	n	by Panther-4plex
<25	36	100%	4	100%	2	100%	8	100%
25-30	17	100%	38	100%	13	100%	24	100%
30-35	35	89%	43	70%	16	63%	42	93%
>35	14	57%	14	14%	11	9%	18	22%
	102		99		42		92	

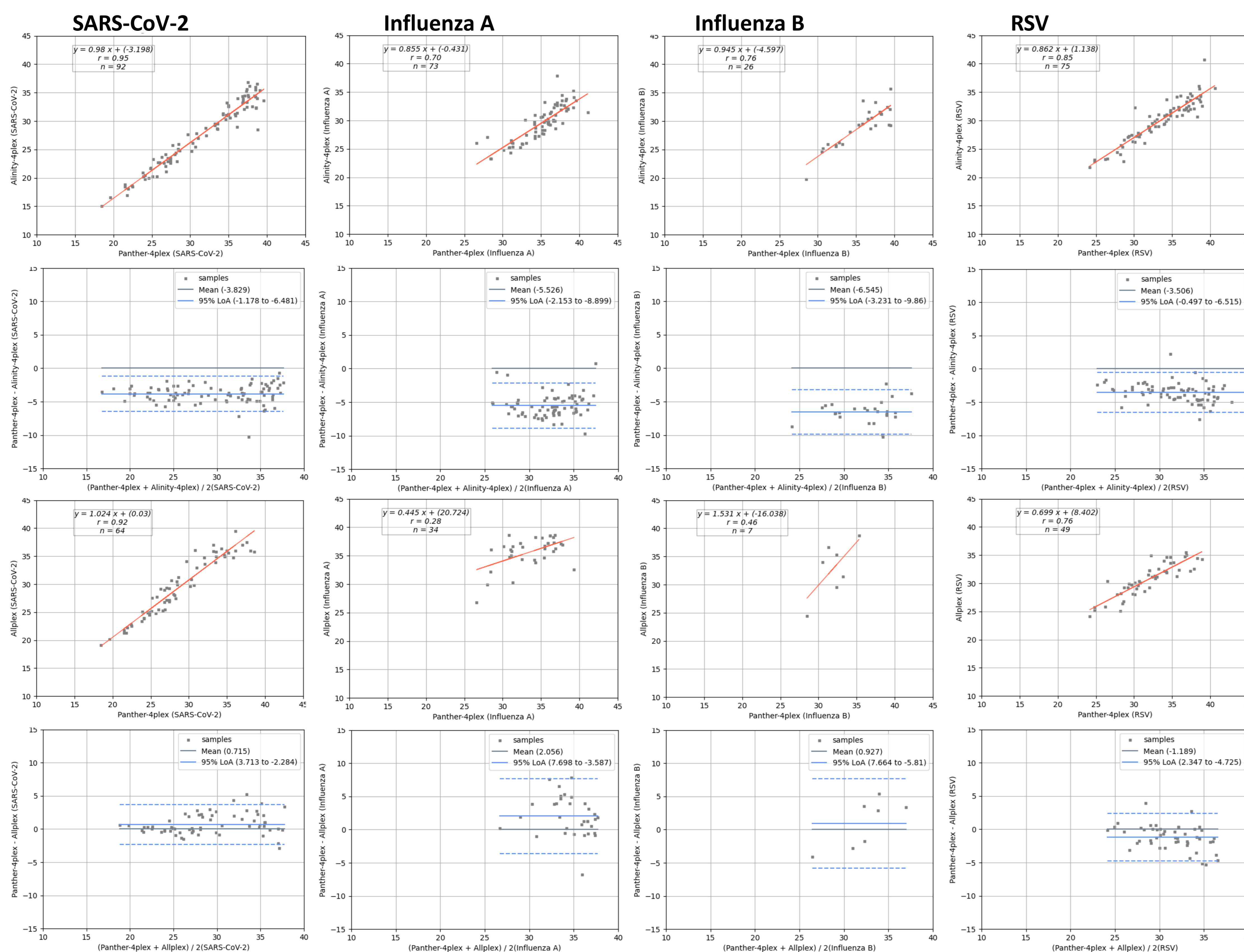


Fig. 1: Regression, and Bland-Altman plots for SARS-CoV-2, Influenza A, Influenza B and RSV comparing the Ct values of Panther-4plex with those of Alinity-4plex in the upper two rows and comparing the Ct values of Panther-4plex with those of Allplex in the lower two rows.

RESULTS continued

The Panther-4plex Ct-values showed a good correlation with the Alinity-4plex calculating coefficients of determination of $r=0.95$; 0.70 ; 0.76 and 0.85 for SARS-CoV-2, FluA, FluB and RSV, respectively. The Bland-Altman Plots resulted in a mean bias of 3.8; 5.5; 6.5 and 3.5 Ct units for the viruses with the lower Ct-values in the Alinity-4plex.

Correlations were weaker comparing the Ct-values of Panther-4plex with Allplex ($r=0.92$; 0.28 ; 0.46 and 0.76 ; and mean bias of 0.7; 2.1; 0.9 and 1.2 for SARS-CoV-2, FluA, FluB and RSV, respectively, here with less differences in the Ct-values highs. These Ct value differences are also reflected in the probit analysis for SARS-CoV-2, with the lowest 95% hit rate for the Alinity-4plex (s. Fig 2).

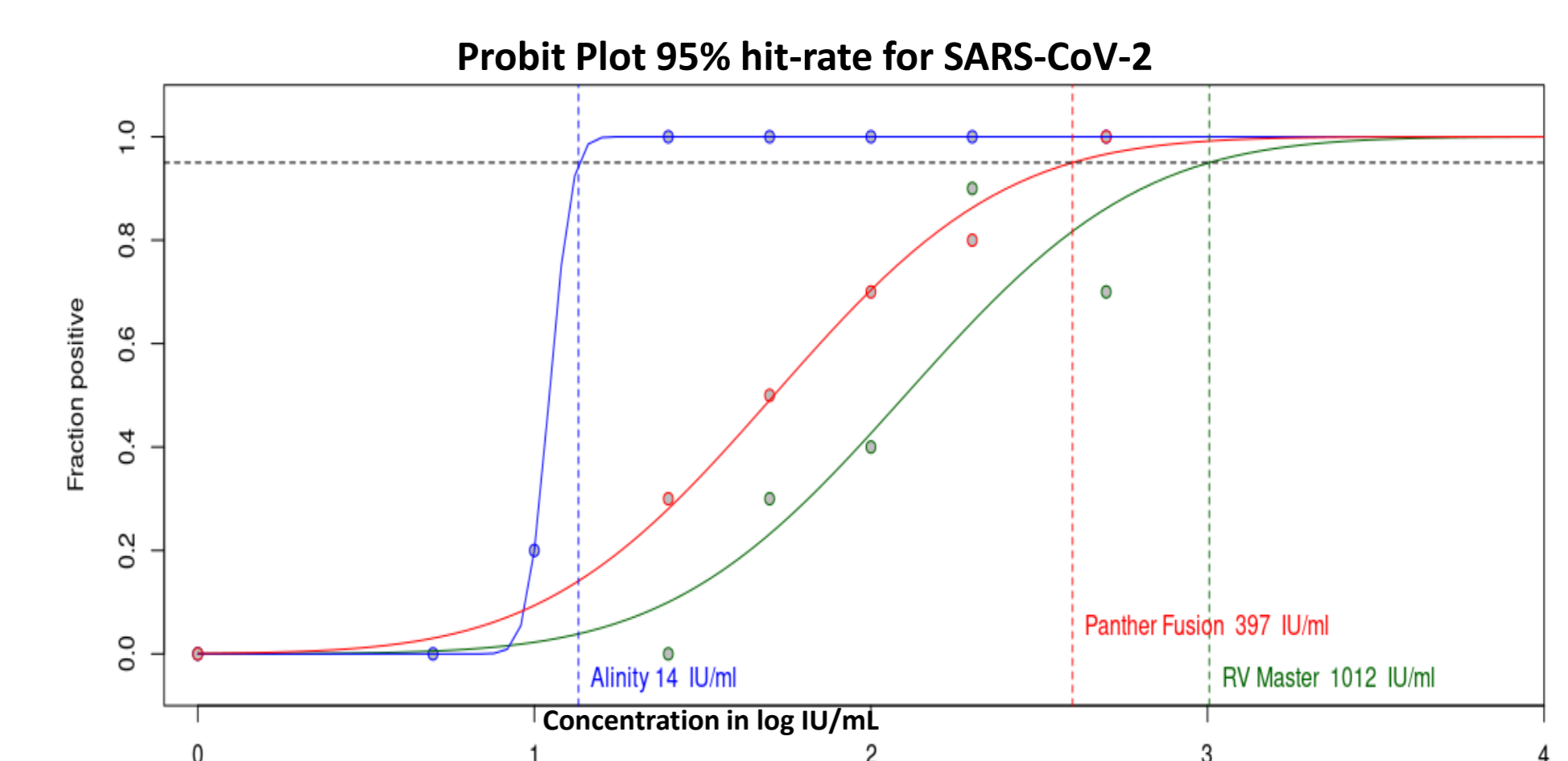


Fig. 2: Probit Plot 95% hit-rate for SARS-CoV-2 with the Alinity-4plex, Panther-4plex and Allplex (RV Master) assays

CONCLUSIONS

Testing 437 negative and positive clinical samples with different Ct-values, the Panther-4plex running on the Panther fusion showed a specificity of 100% and a higher sensitivity for SARS-CoV-2, FluA, FluB and RSV compared to the Allplex. In comparison with Alinity-4plex the sensitivity was lower. The Panther-4plex showed a very good performance with a high sensitivity in the clinical relevant range for all viruses. The Panther-4plex performs very well in the laboratory routine and is an asset to the portfolio there.

Acknowledgements

The study was funded by Hologic.