

Evaluation of the performance of the high-throughput multiplex Alinity m Resp-4-Plex assay

PP-146

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BACKGROUND

The objective of this study was to evaluate the accuracy of the Abbott Alinity m Resp-4-Plex assay with regard to detection and differentiation of the respiratory viruses SARS-CoV-2, Flu A, Flu B and RSV in comparison to another on-market assay (Seegene Allplex SARS-CoV-2/Flu-A/Flu-B/RSV assay). Additionally, the detection rates of the Alinity m Resp-4-Plex, Alinity m SARS-CoV-2, RealTime SARS-CoV-2 assays (Abbott GmbH), and the Allplex SARS-CoV-2/Flu-A/Flu-B/RSV assay (Seegene) were determined.

METHODS

Leftover, de-identified patient samples after routine testing with the Alinity m Resp-4-Plex assay or with Allplex SARS-CoV-2/Flu-A/Flu-B/RSV were retested with the other assay: 300 samples negative for all 4 pathogens, and 196, 40, 6 and 119 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. Evaluation of the detection rates for SARS-CoV-2 of the Alinity m Resp-4-Plex, Alinity m SARS-CoV-2, and RealTime SARS-CoV-2 assays was performed. To determine the lower limits of detection by probit analysis, a dilution series of the first WHO International Standard for SARS-CoV-2 to target concentration of 200/100/50/25/10/5 IU/mL was tested head-to-head in replicates of 20 for 25 and 50 IU/mL and otherwise in replicates of 10, respectively.

RESULTS

In the Alinity m Ct categories <25; 25-30; 30-35; and >35, Allplex detected SARS-CoV-2 in 45/45; 46/46; 24/54 and 2/51 samples, respectively, however, showing higher Ct-values and partially only positive for one of three genes. The last winter season did not yield many positive samples for the other viruses in our submission collective. Thus, specimen numbers are lower, especially for influenza B. Based on the Alinity m Ct categories above, for RSV, the recovery rates were 6/6; 16/16; 12/31 and 1/66; for influenza A 15/16; 3/3; 8/13 and 1/8 and for influenza B 1/1; 0/0; 1/1 and 0/4, respectively.

Samples with a difference of more than 10 Ct values had been repeated in parallel by both assays (partly diluted), if sufficient volume was available.

The regression analysis for the SARS-CoV-2 results achieved an R² value of 0.91 with a shift of four Ct values indicating a higher sensitivity of the Alinity m Resp-4-Plex assay. Due to the small number of samples, comparing the detection rates for the other viruses was less conclusive, but showed a tendency towards a higher sensitivity of the Alinity m Resp-4-Plex assay as well.

The determination of the detection limits for SARS-CoV-2 using the 1st WHO standard for Alinity m Resp-4-Plex, Alinity m SARS-CoV-2, RealTime SARS-CoV-2, and AllplexTM SARS-CoV-2/Flu-A/Flu-B/RSV led to 95% hit rates at 88.4 IU/mL, 97.1 IU/mL, 706.6 IU/mL, and 1042 IU/mL, respectively.

RESULTS

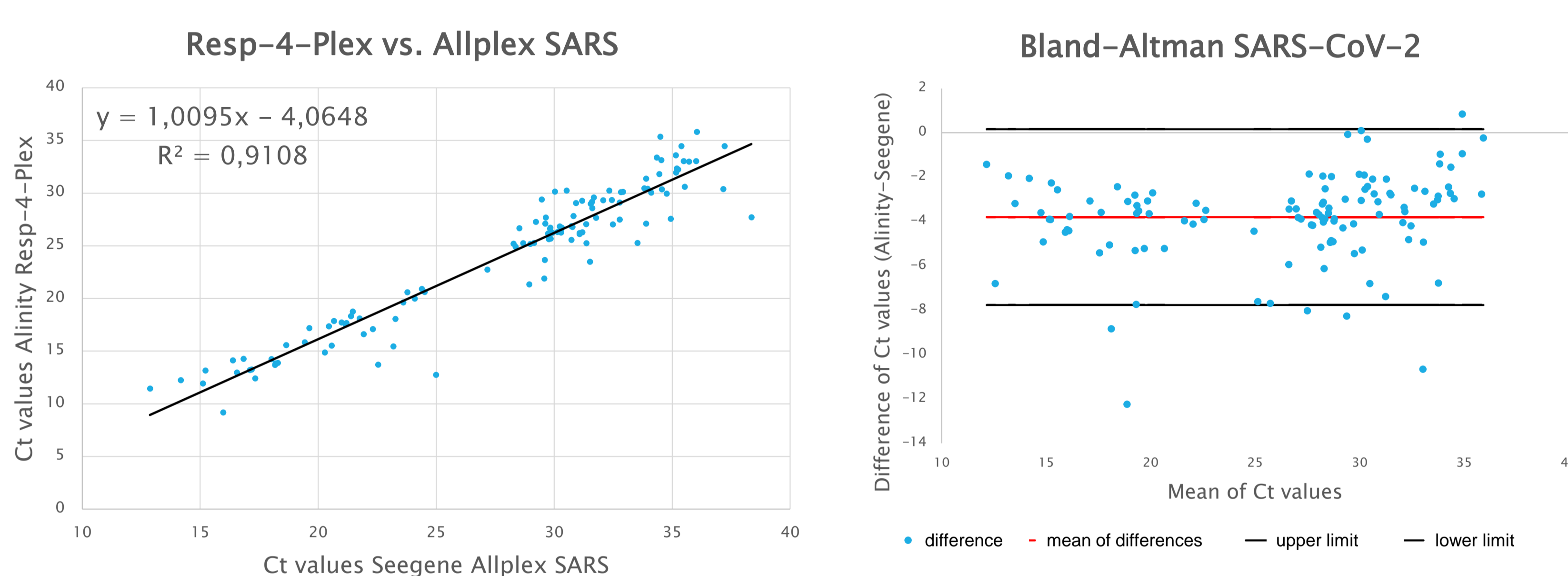


Fig. 1: Regression and Bland Altman Plot SARS-CoV-2 Alinity m Resp-4-Plex vs. Allplex

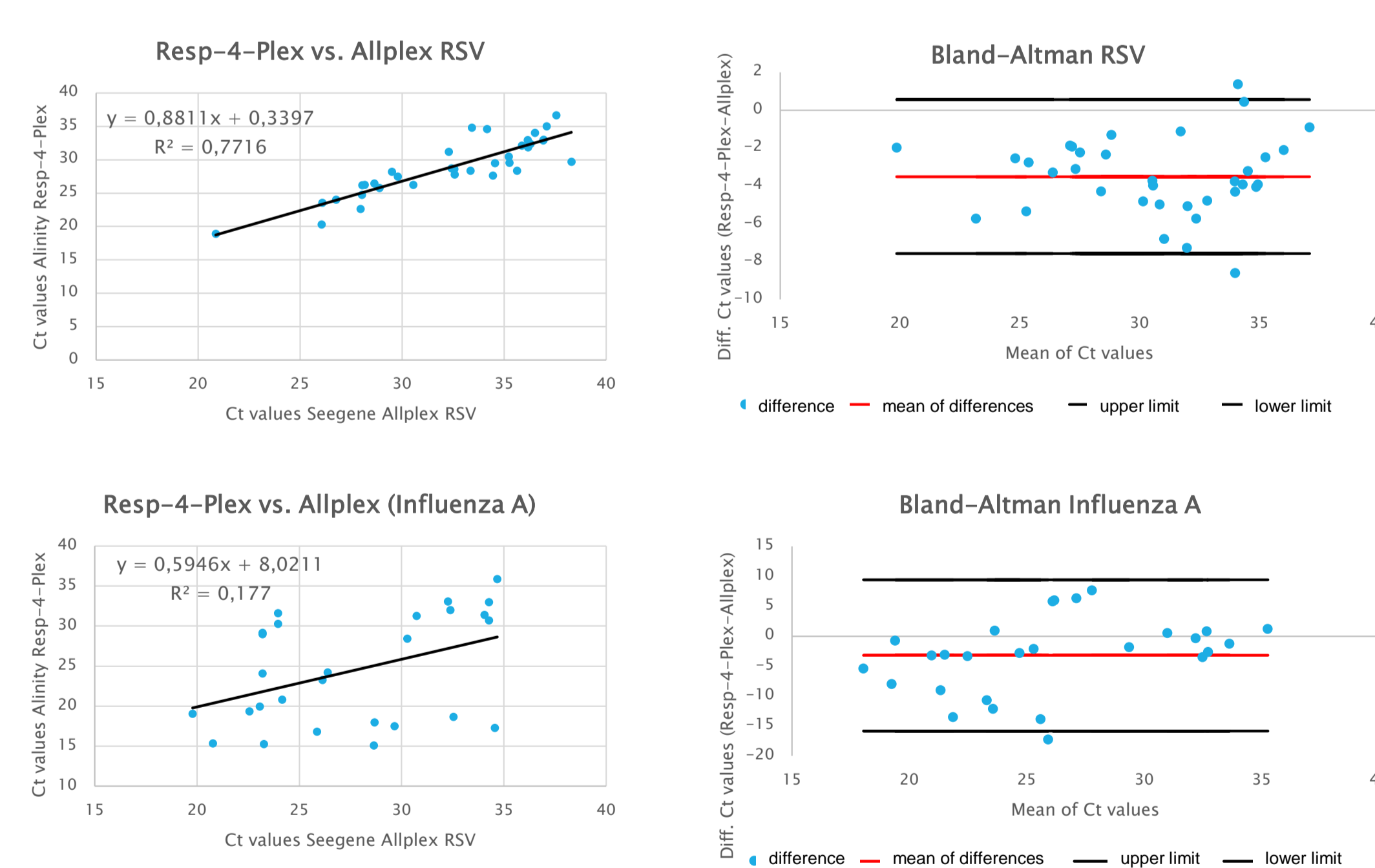


Fig. 2: Regression and Bland-Altman Plot RSV and Influenza A Alinity m Resp-4-Plex vs. Allplex

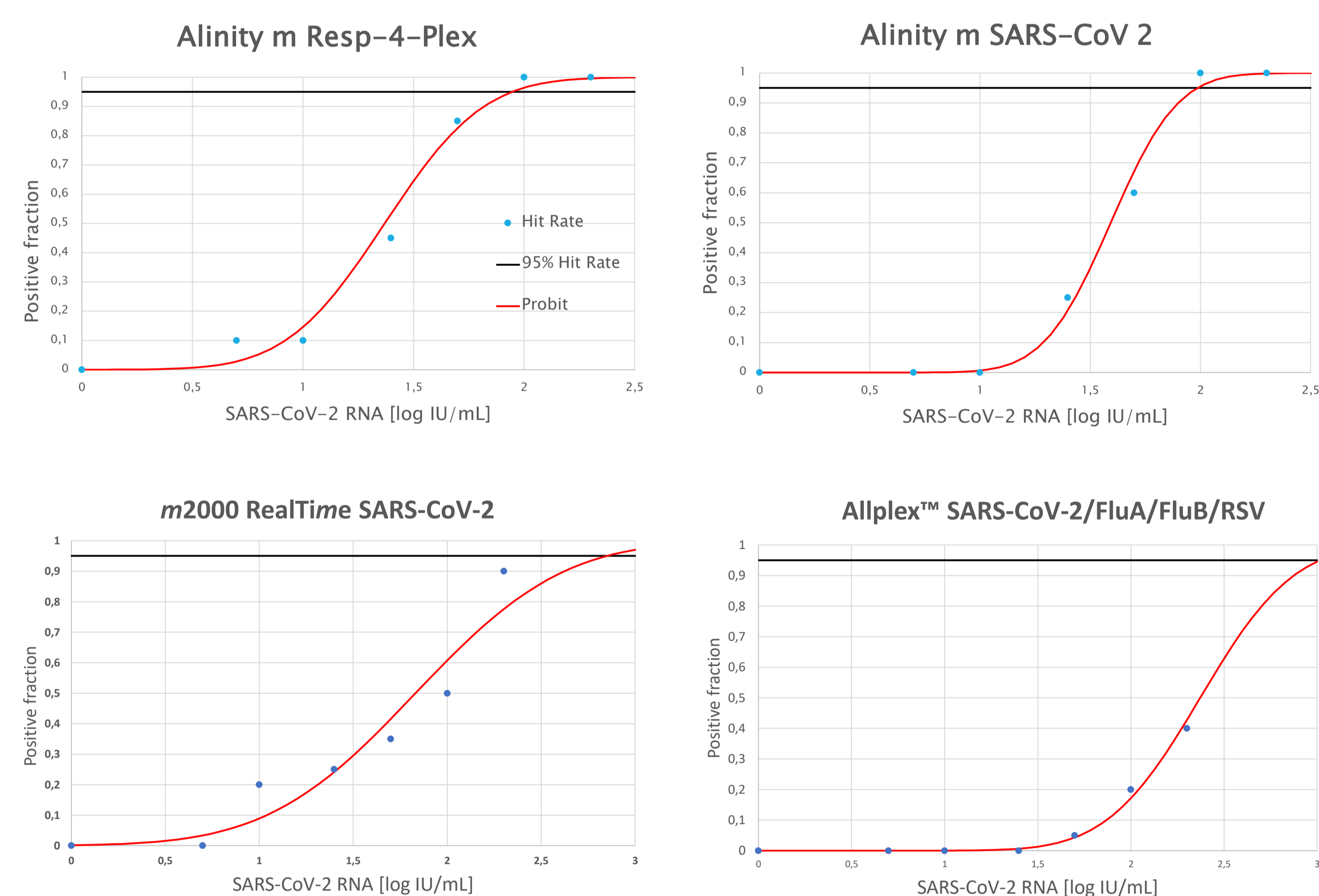


Fig. 3 and Tab.1: Probit analysis 95% hit rate SARS-CoV-2 RNA; 1st WHO standard [IU/mL]

Assay	95% hit rate (log10 IU/mL)	95% hit rate (IU/ml)
Alinity m Resp-4-Plex	1.9464	88.4
Alinity m SARS-CoV-2	1.9871	97.1
m 2000 RealTime SARS-CoV-2	2.8492	706.6
Allplex TM SARS-CoV-2/FluA/FluB/RSV	3.0179	1042

CONCLUSIONS

Testing a large number of samples of different Ct categories, the Alinity m Resp-4-Plex showed considerably higher sensitivity for SARS-CoV-2 compared to the Allplex SARS-CoV-2/Flu-A/Flu-B/RSV and a specificity of 100%. A similar trend to higher sensitivity of the Alinity m Resp-4-Plex was also observed for RSV, influenza A and influenza B. The higher sensitivity of especially Alinity m assays was confirmed by testing dilutions of the new 1st WHO standard for SARS-CoV-2.

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