

Evaluation of the new Alinity m Resp-4-Plex assay

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BACKGROUND

Respiratory infections like SARS-CoV-2 or influenza often lead to unspecific symptoms. In the past winter 2020/2021, probably due to Corona protection measures, no or a very low wave of influenza infections was perceived. However a solitary testing for SARS-CoV-2 could lead to an underestimation of other respiratory infections (e.g. influenza). The new Alinity m Resp-4-Plex assay (A4PLEX) is a multiplex assay for SARS-CoV-2, influenza A/B and RSV. We evaluated the performance using clinical samples.

METHODS

20 fresh samples tested SARS-CoV-2 positive with the Alinity m SARS-CoV-2 assay (ASC2) and/or the Seegene Allplex™ SARS-CoV-2/FluA/FluB/RSV Assay (SC2FABR) and tested negative for influenza A/B and RSV (SC2FABR) were retested on the A4PLEX. If there was not enough residual material available, the swab was shaken out again or the extract was slightly diluted. Additional 19 samples tested positive for other respiratory viruses (11 influenza A, 5 influenza B and 3 RSV with the Allplex™ Respiratory Panel 1 = ARP1) in the season 2019/2020 that were archived at -20°C were also tested with the A4PLEX.

RESULTS

Table 1: Samples tested positive for respiratory viruses (Influenza A/B, RSV A/B) with the Allplex™ Respiratory Panel 1

†Sample with a low viral load that had been stored for >1 year prior to retesting with A4PLEX.

Sample no.	Alinity m Resp-4-Plex Assay		Seegene Allplex™ SARS-CoV-2/FluA/B/RSV Assay	
	respiratory virus	Ct-value	respiratory virus	Ct-value
1	Influenza B	31.4	Influenza B	29.4
2	RSV	24.0	RSV A/B	24.4
3	Influenza B	32.8	Influenza B	30.5
4	Influenza A	23.5	Influenza A	29.1
5	Influenza A	26.5	Influenza A	23.9
6	Influenza A	37.1	Influenza A	36.6
7	Influenza B	28.0	Influenza B	26.4
8	Influenza A	26.9	Influenza A	27.7
9	Influenza A	30.6	Influenza A	35.1
10	Influenza B	24.8	Influenza B	26.6
11	not detected†	-	Influenza B	40.9
12	Influenza A	29.4	Influenza A	33.2
13	Influenza A	31.3	Influenza A	30.7
14	RSV	33.4	RSV A/B	33.1
15	RSV	22.2	RSV A/B	22.5
16	Influenza A	26.5	Influenza A	24.7
17	Influenza A	27.7	Influenza A	27.8
18	Influenza A	30.7	Influenza A	24.6
19	Influenza A	33.7	Influenza A	35.0

Table 2: Samples tested SARS-CoV-2 positive with the Alinity m SARS-CoV-2 assay (ASC2) and/or the Seegene Allplex™ SARS-CoV-2/FluA/FluB/RSV Assay (SC2FABR)

n.t.= not tested; *The lowest Ct-values of the three genes tested in the SC2FABR assay is noted

Sample no.	Alinity m Resp-4-Plex Assay		ASC2 / SC2FABR Assay	
	SARS-CoV-2	Ct-value	SARS-CoV-2	Ct-value*
1	positive	28.4	positive	33.8 / 28.8
2	positive	29.9	positive	n.t. / 30.4
3	positive	19.1	positive	23.3 / 19.6
4	positive	24.1	positive	30.0 / 24.6
5	positive	14.3	positive	19.5 / 14.6
6	positive	18.4	positive	23.5 / 19.0
7	positive	15.2	positive	n.t. / 16.4
8	positive	14.2	positive	17.6 / 14.6
9	positive	28.7	positive	31.5 / 27.7
10	positive	24.0	positive	29.0 / 23.6
11	positive	15.4	positive	20.4 / 16.0
12	positive	19.6	positive	23.8 / 20.5
13	positive	32.2	positive	36.6 / 34.3
14	positive	17.2	positive	n.t. / 17.9
15	positive	34.1	positive	n.t. / 33.9
16	positive	20.4	positive	n.t. / 21.5
17	positive	16.0	positive	n.t. / 17.3
18	positive	22.5	positive	n.t. / 23.1
19	positive	32.2	positive	n.t. / 35.9
20	positive	12.8	positive	n.t. / 11.9

RESULTS

All SARS-CoV-2 positive samples were positively tested with the A4PLEX with a good correlation compared to the Ct-Values of SC2FABR. Ct-values ranged from 11.9 to 35.9 with SC2FABR and from 12.8 to 34.1 with A4PLEX. All 11 samples tested positive for influenza A and 4 positive for influenza B were detected with the A4PLEX. 1 positive influenza B sample was not detected with the A4PLEX. This sample was stored for more than a year at -20°C and had an initial Ct-value of 40.9 in the ARP1. Finally, all 3 samples tested positive for RSV were also correctly identified with A4PLEX. For all tested samples, no cross-reactivity with other pathogens was observed with A4PLEX.

CONCLUSIONS

In this small evaluation the new Alinity m Resp-4-Plex assay showed excellent performance. SARS-CoV-2, influenza A and B as well as RSV could reliably be identified. The Alinity m as a random-access molecular analyzer allows rapid diagnostics of high quality for viral respiratory infections.

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