Performance of Abbott Alinity m and RealTime SARS-CoV-2 assays in clinical practice

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Background

The Alinity m SARS-CoV-2 assay (AlinSARS) is a recently launched realtime PCR test for the Alinity m system, a fully automated, continuous and random access analyzer with a processing capacity of 300 samples in an approximately 8-hour shift. The RealTime SARS-CoV-2 assay (RT-SARS) is a realtime PCR test for the m2000 batch analyzer system. Both assays target the RdRp- and N-genes of SARS-CoV-2 and were evaluated for the usability in clinical routine testing.

Methods

To assess the clinical performance of AlinSARS and RT-SARS, frozen leftover patient samples were retested either with RT-SARS only or with both assays. Overall, 78 negative and 79 positive samples were pre-selected based on an inhouse method utilizing E-gene and RdRp-gene amplification or Seegene Allplex™ 2019-nCoV. Cross-reactivity was evaluated by retesting 40 SARS-CoV-2 negative samples that were positive for other respiratory pathogens (26 Influenza A, 6 Influenza B, 2 RSV A, 1 RSV B, 3 M. pneumoniae, 1 B. parapertussis, 1 H. influenzae). Samples were pretested with Seegene Allplex™ Respiratory Panels 1 and 4. To assess the lower limit of detection (LOD), positive assay controls (1000 cps/mL) were diluted with 0.9% NaCl to target concentrations between 1000 and 2.5 cps/mL. Between 9 and 20 replicates per concentration were tested with Alinity-SARS or RT-SARS.

Tab. 1: Preselected positive and negative samples

pretest		pos (n)	neg (n)	agreement (%)
RT-SARS	pos (n)	79	0	100
	neg (n)	0	78	100
AlinSARS	pos (n)	79	0	100
	neg (n)	0	78	100

Tab. 2: Cross-reactivity RT-SARS and AlinSARS

Sample #	Respiratory pathogen in sample	Results RT-SARS	Sample #	Respiratory pathogen in sample	Results AlinSARS
1	Influenza A (H3)	nd	1	Influenza A	nd
2	Influenza A (H3)	nd	2	Influenza A	nd
3	Influenza A (H3)	nd	3	Influenza A (H3)	nd
4	Influenza A (H3)	nd	4	Influenza A (H3)	nd
5	Influenza A (H3)	nd	5	Influenza A (H3)	nd
6	Influenza A (H3)	nd	6	Influenza A (H3)	nd
7	Influenza A (H1pdm09)	nd	7	Influenza A (H3)	nd
8	Influenza A (H1pdm09)	nd	8	Influenza A (H3)	nd
9	Influenza A (H1pdm09)	nd	9	Influenza A (H3)	nd
10	Influenza A (H1pdm09)	nd	10	Influenza A (H3)	nd
11	Influenza A (H1pdm09)	nd	11	Influenza A (H1pdm09)	nd
12	Influenza B	nd	12	Influenza A (H1pdm09)	nd
13	Influenza B	nd	13	Influenza A (H1pdm09)	nd
14	Influenza B	nd	14	Influenza A (H1pdm09)	nd
15	Influenza B	nd	15	Influenza A (H1pdm09)	nd
16	Influenza B	nd	16	M. pneumoniae	nd
17	Influenza B	nd	17	M. pneumoniae	nd
18	RSV A	nd	18	M. pneumoniae	nd
19	RSV A	nd	19	B. parapertussis	nd
20	RSV B	nd	20	H. influenzae	nd

Results

100% concordance was observed between the Abbott assays and the comparator assays (s. Tab. 1) as well as between the Abbott assays RT-SARS and AlinSARS, even in weak positive samples (ct>35).
No cross-reactivity with other common respiratory pathogens (Influenza A/B, RSV A/B, M. pneumoniae, B. pertussis, H. influenza) was observed for both Abbott assays (Tab. 2).
The Abbott assays showed 100% detection rates at 50 cps/mL and we calculated LODs of 24 cps/mL (AlinSARS, Tab. 3 A) and 38 cps/mL (RT-SARS, Tab. 3 B) by Probit analysis.
The capability of Alinity-SARS to detect the SARS-CoV-2 variants of concern B.1.1.7 and B.1.351 was demonstrated in clinical routine testing.

Conclusions

Alinity-SARS and RT-SARS showed excellent concordance with our laboratory test methods as well as among each other. No cross-reactivity with other respiratory pathogens was observed. With LODs of 24 cps/mL and 38 cps/mL, respectively, both assays were more sensitive than stated by the manufacturer (100 cps/mL. Both assays are reliable and sensitive tools in routine diagnostics.

Tab. 3: Limited dilutions AlinSARS (A) and RT-SARS (B)

A: Target concentr. (cps/mL)	Replicates tested (n)	Replicates detected (n)	Replicates detected (%)	B: Target concentr. (cps/mL)	Replicates tested (n)	Replicates detected (n)	Replicates detected (%)
400	10	10	100%	1000	10	10	100%
300	10	10	100%	500	10	10	100%
200	10	10	100%	250	10	10	100%
100	19	19	100%	100	20	20	100%
50	10	10	100%	50	10	10	100%
25	10	9	90%	10	10	5	50%
10	9	8	89%	5	10	3	30%
5	9	3	33%	2.5	10	2	20%