Performance comparison of the Hologic Aptima SARS-CoV-2 assay with the Abbott RealTime, the Abbott Alinity m and an inhouse SARS-CoV-2 assay

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Background

The Hologic Aptima SARS-CoV-2 assay utilizes TMA® technology on the Panther® system, a fully automated random access analyzer. The assay is intended for the qualitative detection of SARS-CoV-2 RNA from nasopharyngeal and oropharyngeal swab specimens, nasopharyngeal wash/aspirate or nasal wash. Specificity and sensitivity is crucial in screening for SARS-CoV-2 during the pandemics. We compare its performance with the Abbott RealTime and Alinity m and an inhouse SARS-CoV-2 assay.

Methods

In September 2020 an amount of 100 samples were tested prospectively without any preselection with the four assays (Hologic Aptima SARS-CoV-2; Abbott RealTime and Alinity m SARS-CoV-2 assays and an inhouse SARS-CoV-2 assay (multiplex rtPCR with TIBmolbiol primer/probes for E-gene and RdRP-gene, extraction and cell-control) .
100 samples were tested according to the following algorithm. Samples were first tested with RealTime or inhouse assay. Residual volumes of samples were selected, stored at -20°C and if necessary diluted to sufficient volume prior to re-testing with all four assays according to the following criteria:

Group 1: 25 samples with a negative diagnostic result,
Group 2: 25 samples with a positive diagnostic result, Ct-values < 25
Group 3: 25 samples with Ct-values between 25 and 35
Group 4: 25 samples with a positive diagnostic result, Ct-values >35.

Ct values of RealTime pretested samples were corrected by adding ten cycles due to uncounted precycles in the RealTime protocol.

Tab. 1: Performance comparison of the Hologic Aptima SARS-CoV-2 assay with the Abbott RealTime, the Abbott Alinity m and an inhouse SARS-CoV-2 assay

SARS-CoV-2 Ct-group (pretest)	No.	Hologic Aptima (TMA total RLU)	Hologic Aptima pos/neg	Abbott RealTime Ct-value *)	Abbott Alinity M Ct-value	inhouse E-gene Ct-value	inhouse RdRP-g. Ct-value
negative samples	1	281	neg	nd	nd	na	na
	2	281	neg	nd	nd	na	na
	3	282	neg	nd	nd	na	na
	4	273	neg	nd	nd	na	na
	5	286	neg	nd	nd	na	na
	6	284	neg	nd	nd	na	na
	7	286	neg	nd	nd	na	na
	8	278	neg	nd	nd	na	na
	9	281	neg	nd	nd	na	na
	10	287	neg	nd	nd	na	na
	11	284	neg	nd	nd	na	na
	12	284	neg	nd	nd	na	na
	13	285	neg	nd	nd	na	na
	14	289	neg	nd	nd	na	na
	15	265	neg	nd	nd	43,22	na
	16	289	neg	nd	nd	na	na
	17	287	neg	nd	nd	na	na
	18	276	neg	nd	nd	na	na
	19	281	neg	nd	nd	na	na
	20	293	neg	nd	nd	na	na
	21	279	neg	nd	nd	na	na
	22	285	neg	nd	nd	na	na
	23	287	neg	nd	nd	na	na
	24	285	neg	nd	nd	na	na
	25	271	neg	nd	nd	na	na
Ct-value < 25	1	1214	pos	12,66	25,39	24,52	28,09
	2	1189	pos	7,44	20,07	19,58	23,72
	3	1199	pos	14,28	27,31	26,85	30,29
	**) 4	264	neg	nd	nd	na	na
	5	1225	pos	13,01	26,17	25,11	28,63
	6	1210	pos	7,61	20,26	20	24,01
	7	1183	pos	9,62	22,61	22,06	25,57
	8	1231	pos	9,95	22,29	22,25	26,1
	9	1173	pos	11,18	24,41	23,17	26,96
	10	1182	pos	9,49	21,57	21,81	25,6
	11	1218	pos	12,75	25,53	25,09	28,62
	12	1157	pos	4,87	16,72	16,75	20,7
	13	1148	pos	13,56	26,29	25,24	28,97
	14	1219	pos	8,97	23,63	21,16	24,97
	15	1210	pos	11,45	24,19	23,78	27,35
	16	1208	pos	12,45	24,94	24,7	28
	17	1214	pos	12,2	24,58	23,28	28,03
	18	1193	pos	9,36	22,29	21,49	25,03
	19	1227	pos	10,9	23,86	22,28	26,59
	20	1189	pos	10,62	24,04	22,96	26,63
	21	1185	pos	11,47	29,25	23,24	27,35
	22	1172	pos	8,07	20,66	20,33	24,33
	23	1228	pos	14,32	26,24	25,91	29,96
	24	1187	pos	7,56	19,38	19,71	23,29
	25	1209	pos	10,99	24,5	23,16	26,86

SARS-CoV-2 Ct-group (pretest)	No.	Hologic Aptima (TMA total RLU)	Hologic Aptima pos/neg	Abbott RealTime Ct-value *)	Abbott Alinity M Ct-value	inhouse E-gene Ct-value	inhouse RdRP-g. Ct-value
Ct-value between 25 - 35	1	1221	pos	20,08	32,66	30,77	42,7
	2	1193	pos	23,62	36,51	35,72	na
	3	1182	pos	25,29	37,44	na	na
	4	1173	pos	17,89	31,13	29,77	37,65
	5	1228	pos	22,23	34,81	32,62	na
	6	1217	pos	13,9	26,49	26,43	30,01
	7	1234	pos	21,59	33,11	32,1	na
	8	1256	pos	14,88	27,76	26,76	30,41
	9	1207	pos	21,28	33,86	32,66	na
	10	1201	pos	14,62	28,05	26,86	30,06
	11	1205	pos	22,96	34,87	35,21	na
	12	1166	pos	25,31	37,7	na	na
	13	320	neg	28,57	40,77	na	na
	14	1204	pos	14,9	27,98	27,33	31,32
	15	1233	pos	23,05	36,35	35,07	na
	16	1181	pos	23,91	36,47	36,24	na
	17	1224	pos	19,6	32,17	30,64	42,15
	18	1198	pos	16,27	28,15	27,81	31,93
	19	1219	pos	20,58	32,36	31,49	na
	20	1236	pos	15,75	29,54	28,07	32,52
	21	1243	pos	13,68	26,29	26,14	29,66
	22	1210	pos	18,85	32,71	31,55	na
	23	1203	pos	18,03	30,84	29,95	42,3
	24	1217	pos	15,54	28,51	27,88	31,79
	25	1269	pos	17,9	29,9	29,18	39,89
Ct-value > 35	1	452	neg	28,01	39,25	na	na
	2	287	neg	nd	nd	na	***) na
	3	1002	pos	20,66	35,18	35,34	na
	4	285	neg	26,67	39,98	na	na
	5	701	pos	26,16	38,16	na	na
	6	727	pos	27,33	40,3	na	na
	7	1167	pos	24,72	37,5	38,97	na
	8	1166	pos	24,71	37,06	37,1	na
	9	356	neg	26,03	40,42	na	na
	10	767	pos	29,71	38,43	na	na
	11	700	pos	25,69	38,15	na	na
	12	287	neg	nd	40,78	na	na
	13	284	neg	nd	nd	na	***) na
	14	280	neg	29,54	40,94	na	na
	15	1208	pos	28,18	39,72	na	na
	16	1078	pos	24,85	37,66	na	na
	17	1199	pos	22,7	35,05	na	na
	18	1194	pos	23,17	36,23	35,87	na
	19	725	pos	26,11	38,46	na	na
	20	893	pos	26,6	39,56	45,59	na
	21	785	pos	nd	39,45	na	na
	22	290	neg	nd	40,26	na	na
	23	281	neg	25,54	37,22	na	na
	24	278	neg	nd	nd	na	***) na
	25	683	pos	27,88	39,39	na	na

*) due to uncounted precycles Ct-values are lower **) not included in analysis due to technical reasons ***) negative because diluted for parallel testing in 4 systems

Results

The 100 prospective samples were all tested negative with all four assays, except one invalid and one weak positive result (corrected Ct 41.04) with the RealTime assay. In September 2020 in Germany we had a very low incidence.
In the retrospective analysis a good correlation was observed.
In group one (negative pretest) all samples tested negative except one positive (Ct 43.22) E-gene in the inhouse test.
In the second group (pretest-Ct <25) 100% concordance was determined, one sample was not included in the analysis due to technical reasons.
In the third group (pretest-Ct between 25 and 35) one sample tested negative with the Panther and three were tested negative with the inhouse assay.
In the group with the highest Ct-values in the pre-test (above 35), the inhouse test detected 5/25, the Panther 15/25, RealTime 19/25 and Alinity m 22/25 samples positive. Three samples were negative on all four assays, probably due to the dilution required to perform the four re-tests.

Conclusions

The Hologic Aptima Sars-CoV-2 assay performed good with high specificity and sensitivity in the tested patient samples. It seems to be slightly less sensitive compared to the Abbott assays, however these high Ct-values are discussed controversial concerning infectiousity. The Hologic Aptima Sars-CoV-2 Assay is a reliable and safe test for routine diagnosis of SARS-CoV-2 and as a random access system a flexible and rapid tool.