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Performance of the new Abbott Realti*me* SARS-CoV-2 assay

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BACKGROUND

The Abbott RealTi*me* SARS-COV-2 assay is a newly launched test combining RNA extraction, master mix pipetting and realtime PCR on the m2000sp/rt system with batch sizes of 24/48/72 or 96 samples including 2 controls. The test was designed as a dual target assay using the RdRP- and the N-gene of SARS-CoV-2. We here tested the performance on clinical samples, compared results of an EQA panel, checked for cross reactivity to other seasonal respiratory viruses from routine laboratory diagnostics and performed a limited dilution series to evaluate the detection limit.

METHODS

29 known negative and 29 positive pretested samples (with Seegene Allplex™ 2019-nCoV Assay) were retested with the Abbott system. 20 respiratory virus positive but SARS-COV-2 negative samples (pretested with Seegene Allplex™ Respiratory panel 1) containing influenza A or B and RSV A or RSV B positive samples were checked for cross-reactivity. A dilution series in 0.9% NaCl solution of the Abbott SARS-COV-2 positive control denoted with 1000 copies/mL was performed (1000, 500, 250, 100, 50, 10, 5, 2.5 copies/mL) in 10 replicates per step. 7 Samples of the German EQA samples from INSTAND were also tested.

RESULTS

Tab. 1: Clinical evaluation: 29 negative and 29 positive samples (pretested with Seegene Allplex™ 2019-nCoV Assay) were retested with the Abbott RealTi*me* SARS-CoV-2

		Seegene Allplex™ 2019-nCoV Assay	
		positive	negative
Abbott RealTi*me* SARS-CoV-2 Assay	positive	29	---
	negative	---	29

Tab. 2: Limit of detection: 10 replicates per nominal concentration of 1000, 500, 250, 100, 50, 10, 5, 2.5 copies/mL

Target concentration (copies/mL)	No. of replicates tested	No. of replicates detected by Abbott assay	Percentage of replicates detected by Abbott assay
1000	10	10	100%
500	10	10	100%
250	10	10	100%
100	10	10	100%
50	10	10	100%
10	10	5	50%
5	10	3	30%
2.5	10	2	20%

Tab. 3: Cross reactivity: 20 respiratory virus positive but SARS-CoV-2 negative samples (pretested with Seegene Allplex™ Respiratory panel 1)

Sample number	Respiratory Virus	Result RealTi*me* SARS-CoV-2
1	Influenza A (pdm09)	not detected
2	RSV B	not detected
3	Influenza B	not detected
4	RSV A	not detected
5	RSV A	not detected
6	Influenza A (pdm09)	not detected
7	Influenza A (H3)	not detected
8	Influenza A (H3)	not detected
9	Influenza A (H3)	not detected
10	Influenza A (H3)	not detected
11	Influenza A (H3)	not detected
12	Influenza A (pdm09)	not detected
13	Influenza A (pdm09)	not detected
14	Influenza A (pdm09)	not detected
15	Influenza A (H3)	not detected
16	Influenza B	not detected
17	Influenza B	not detected
18	Influenza B	not detected
19	Influenza B	not detected
20	Influenza B	not detected

Tab. 4: External Quality Assessment (EQA) Samples

4 samples containing serial dilutions of SARS-CoV-2 infected cell lysates (heat-inactivated virus of the strain BetaCoV/Munich/ChVir984/2020)

- Dilution 1:1,000
- Dilution 1:10,000
- Dilution 1:100,000
- Dilution 1:1,000,000

100% correct detection of true positive samples with Abbott RealTi*me* SARS-CoV-2

3 samples containing non-infected cell lysates or cell lysates infected with common coronavirus strains

- Non-infected
- HCoV OC43
- HCoV 229E

100% correct detection of true negative samples with Abbott RealTi*me* SARS-CoV-2

RESULTS

All clinical samples were confirmed with the Abbott RealTi*me* SARS-CoV-2 assay, resulting in a concordance of 100%. The Abbott C(t) values were always about 10 steps lower than the Seegene C(t) values due to a 10 cycle pre PCR in the Abbott protocol before starting realtime fluorescence measurement. This could also be observed for the EQA samples with regard to concordance of C(t) values. No cross-reactivity was found for samples positive for Influenza A (H3N2, H1N1 pdm09), Influenza B, RSV A or RSV B. The tested dilution series resulted in a lower limit of detection than stated by the manurfacturer, i.e. 38 copies/mL (95% CI: 15 – 91) as calculated by probit analysis (95% detection rate).

CONCLUSIONS

The Abbott RealTi*me* SARS-CoV-2 assay shows very high sensitivity with a low limit of detection of 38 copies/mL while still showing high specificity with no cross-reactivity to the tested respiratory virus positive samples. The EQA samples positive for Coronaviruses other than SARS-CoV-2 (OC43, 229E) showed no detectable signal. The highly automated workflow enables high throughput testing of respiratory samples with high quality on a widely available platform.

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