

Interpreting SARS-CoV-2 Positive Test Comparing Two Abbott PCR Real Time Systems: Alinity m and m2000

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Abstract

We compared two SARS-CoV-2 PCR Real Time methods automatized on Alinity m and m2000 Abbott instruments. We ascertained the optimal efficiency of both observing the threshold cycle (Ct) correlation on the whole clinical range. Overall we showed a systematic overestimate of Alinity Ct on average of 8.00 compared to m2000 Ct values. Nevertheless we noted that several samples with Ct > 36.80 on Alinity were not amplified using m2000. In our hands these discordances could be considered in monitoring asymptomatic subjects suspected carrying SARS-CoV-2 virus, concerning the PCR method to be used.

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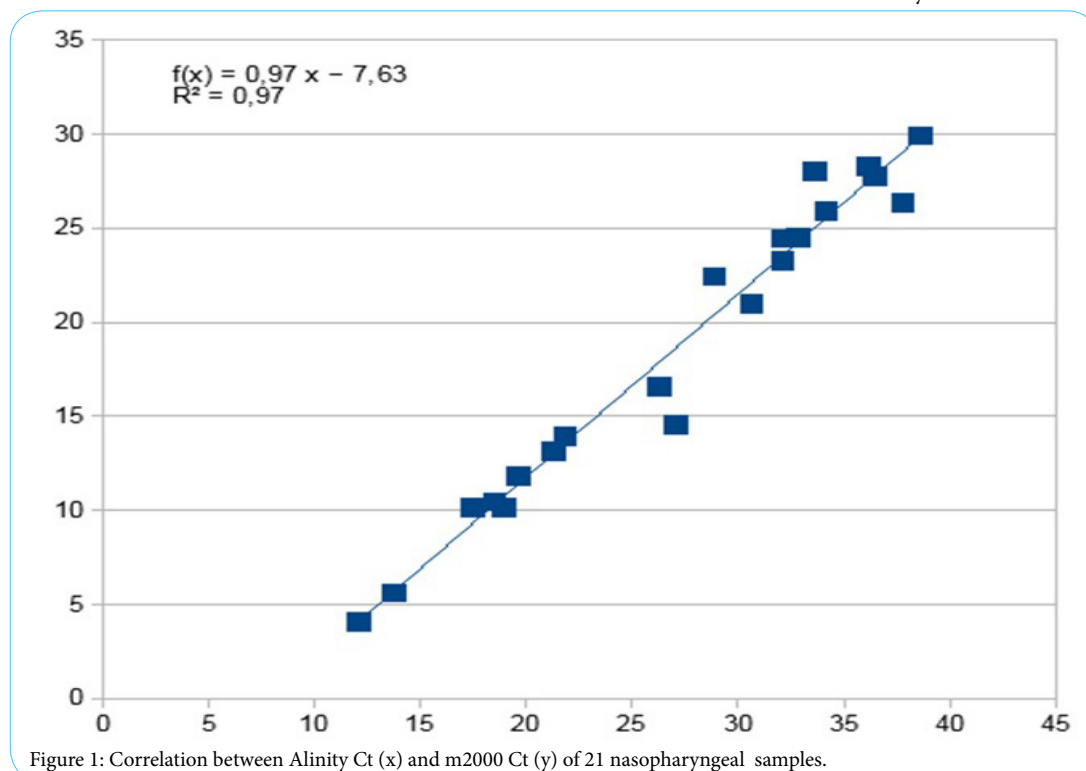
SARS-CoV-2 /PCR, Molecular diagnostics, Analytical sensitivity

Introduction

Real Time PCR to detect SARS-CoV-2 is widely used to diagnose viral infection and to monitor healing patients. We compared two automated Abbott PCR Real Time systems to ascertain the

Results

Overall we noted that the Alinity test overestimated on average 8.07 amplification cycles (Ct) compared to m2000 Ct values (Figure1). The Ct differences between Alinity-m and m2000 methods, both



viral presence on nasopharyngeal swabs from symptomatic and asymptomatic subjects suspected of having Covid19 disease.

Materials and Methods

The methods Resp-4-Plex AMP Kit and Abbott Real Time SARS-CoV-2 Amplification kit were automatized on m Alinity and m2000sp and m2000rt respectively following the instructions provided by manufacturer, Abbott Molecular Diagnostics, Roma, Italy.

Biological samples stored in UTM medium (Copan, Italy) were analyzed not over 24 hours after the collection.

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	Ct Alinity	Ct m2000	Ct Alinity-Ct m2000
CTRL native	30.75	24.28	6.47
	32.84	24.52	8.32
CTRL 1:10	34.29	27.12	7.17
	35.74	30.13	5.61
	36.17	28.27	7.9
	36.56	30.2	6.36
	36.84	n	
	37.07	n	
	37.37	n	
	37.51	n	
	37.79	n	
	37.9	n	
	38.03	n	
	38.03	n	
	38.07	n	
CTRL 1:100	38.17	30.33	7.84
	38.47	n	
	38.8	n	
	39.31	n	
CTRL 1:1000	N	n	
<i>mean</i>	36.8	27.8	
<i>DevSt</i>	2.1	2.6	
<i>CV</i>	5.8	9.4	

Table 1: Ct values of 20 samples with Ct > 30.00 on Alinity test compared to those of m 2000. In bold Control positive Abbott and its dilutions. n: Not Detected.

employing PCR real time technique, varied from 5.47 and 12.5. We selected 16 samples detected by Alinity with amplification cycles ranging 32.84-39.31. Of these specimens, characterized by a low viral load, 11 were not amplified by the m2000 test, and only 5 resulted positive on m2000 with Ct variation from 24.42 to 30.13 (Table 1). At this clinical range good concordance was observed with R² 0.86 (Figure 2) comparing Ct values to two systems, and variation coefficients of 5,8 % and 9,4 % for Alinity and m2000 respectively.

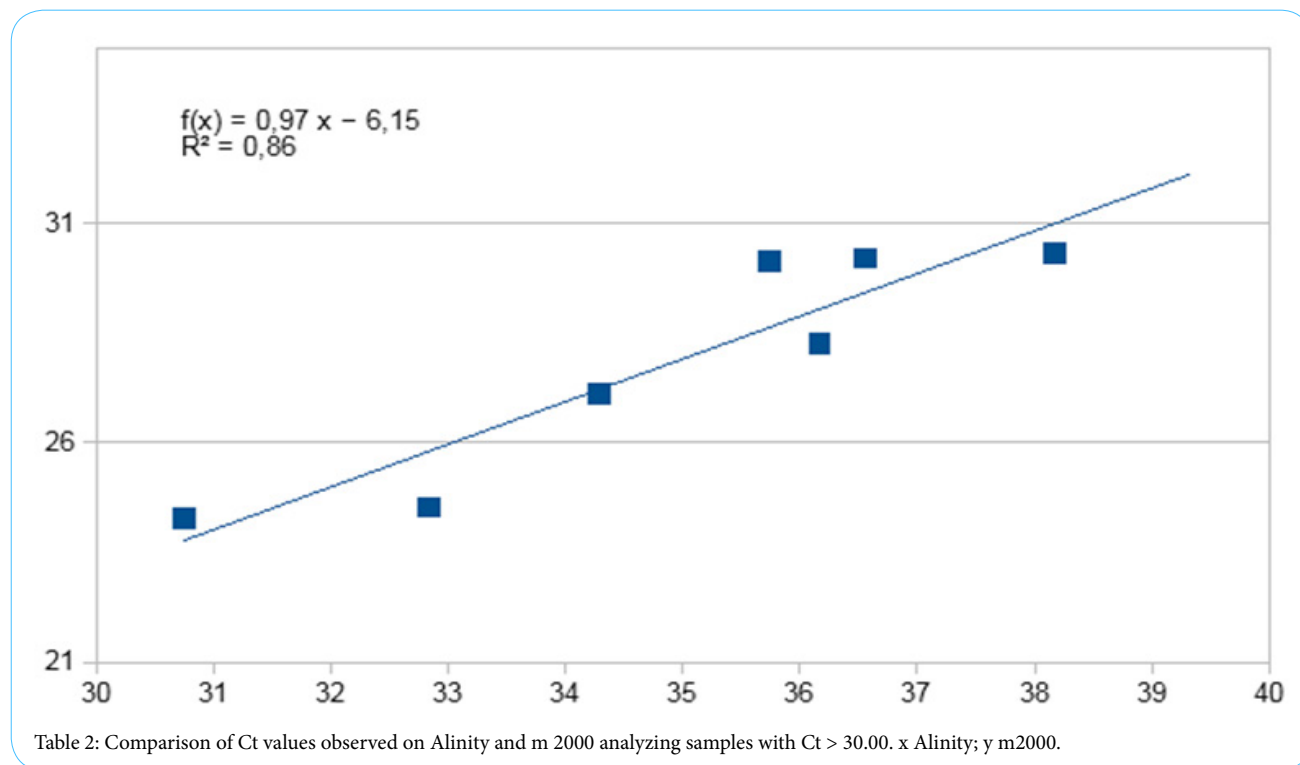
A similar analytical performance was found testing samples diluted from a high positive control provided by Abbott, showing Ct Alinity of 38.17 and Ct m2000 of 30.33 detected in sample diluted 1:100, values compatible with sensitivity of both methods, being around 100 copies/ml genomic RNA [3].

Discussion

In agreement with previous reports we confirmed the optimal analytical correspondence between the two PCR real time methods shown at different levels of viral loads, included the positive samples with low viral load. Nevertheless in our experience several samples positive above 36.84 Ct on Alinity resulted negative on the m2000 test. In this context it has been reported a superior performance of Alinity m SARS-CoV-2 assay to the parameters stated in the package insert [2]. Given that 50 copies /mL is the real analytical sensitivity of this method, we might suppose that the discordance found between the methods assayed, could be due to the lesser analytical sensitivity of m2000 in respect to Alinity m. In our hands, especially in monitoring subjects suspected carrying low SARS-CoV-2 load, this discrepancy could be taken into account.

Competing Interests

The authors declare that they have no competing interests.



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