

INTRODUCTION

The Cobas® SARS-CoV-2, Abbott RealTime SARS-CoV-2 and TaqPath™ COVID-19 Combo Kit are among most widely used Emergency Use Authorized RT-PCR tests for the detection of SARS-CoV-2. The Cobas® SARS-CoV-2 detects 2 targets (ORF1a/b, E-gene); Abbott RealTime SARS-CoV-2 assay detects 2 targets (RdRp, N genes); TaqPath™ COVID-19 Combo kit detects 3 targets (Orf1a/b, N, S-genes). In this study, we performed a 3-way comparison among the three above-mentioned tests and determined clinical performance using the 2-out-of-3 infected-patient “gold standard” as reference.

METHODS

A retrospective study was conducted on left-over nasal and nasopharyngeal specimens collected as part of routine clinical testing at TriCore Reference laboratory, Albuquerque, NM between September and October 2020. All specimens were transported in 3 ml of viral transport medium and stored at 4° C for up to 72 hours before testing. Specimens were first tested using the Roche SARS-CoV-2 assay on the Cobas 6800. A total of 305 nasal and nasopharyngeal specimens (66 positive and 239 negative) were used for the 3-way comparison. Left-over banked specimens were subsequently thawed and tested using TaqPath™ COVID-19 Kit on the Applied BioSystems 7500 FastDx as well as the Abbott RealTime SARS-CoV-2 on the M2000. Positive percent agreement (PPA) and negative percent agreement (NPA) for each of the assays was assessed against the 2-out-of-3 infected-patient “gold standard”.

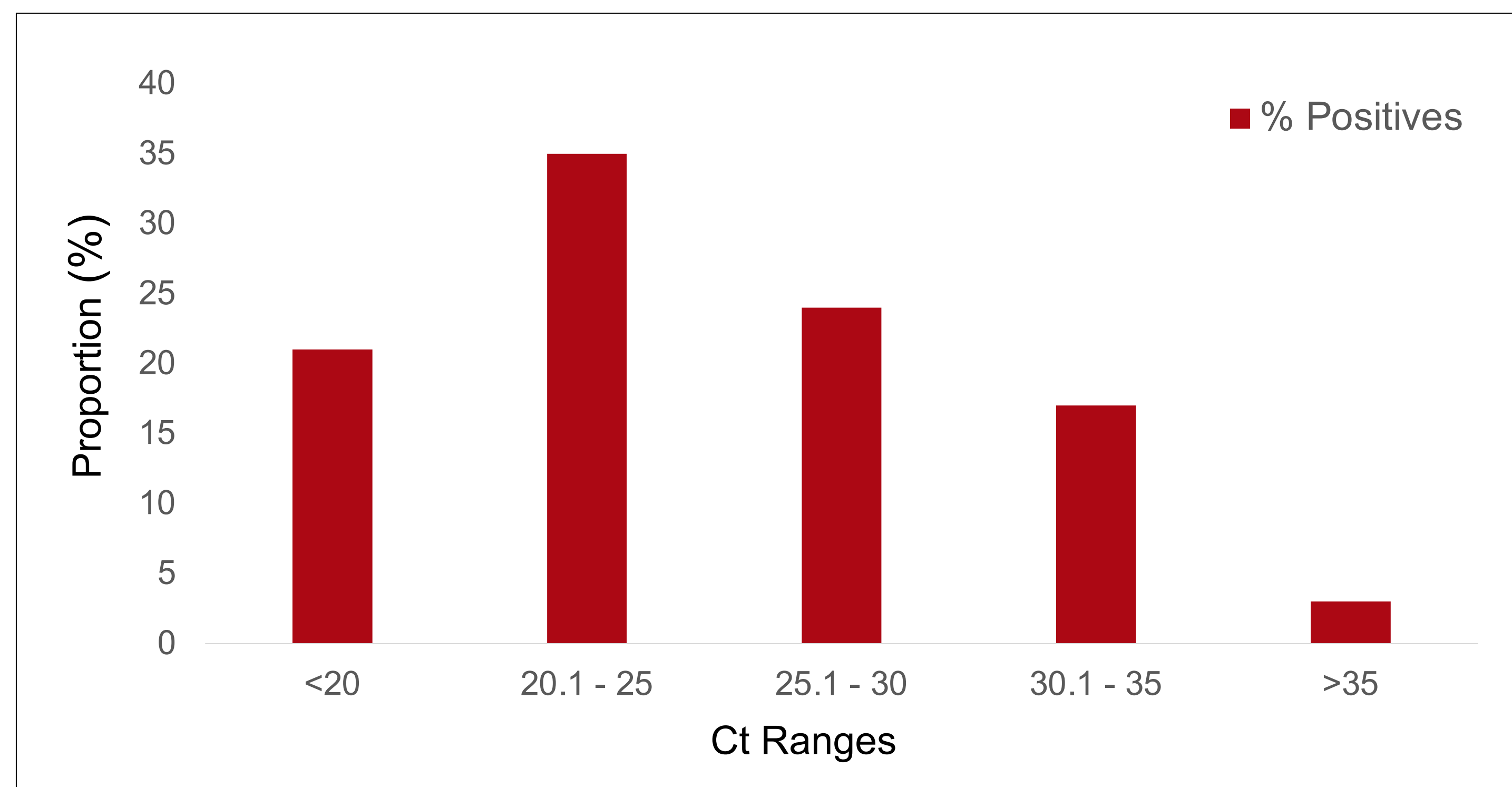


Figure 1. Distribution of Ct values for positive cohort based on initial Roche cobas testing

RESULTS

The average Roche Ct for positive samples ranged from 14.22 to 36.88. The distribution of positives is shown in Figure 1.

In the 3-way comparison, Roche SARS-CoV-2 and TaqPath™ COVID-19 Combo Kit showed 100% PPA, 99.58% NPA; Abbott RealTime SARS-CoV-2 and TaqPath™ COVID-19 Combo Kit showed 89% PPA, 98.29% NPA; Roche SARS-CoV2 and Abbott RealTime SARS-CoV-2 showed 95% PPA, 96.67% NPA. (Tables 1, 2, 3)

Roche SARS-CoV-2 cobas® 6800			
	Positive	Negative	Total
TaqPath™ COVID-19 Combo Kit			
Positive	66	1	67
Negative	0	238	238
Total	66	239	305*
PPA – 100%; NPA – 99.58% Overall Agreement – 99.67%			

Table 1. Concordance between TaqPath™ COVID-19 Combo Kit and Roche SARS-CoV-2 Assay

Abbott RealTimeSARS-CoV-2			
	Positive	Negative	Total
TaqPath™ COVID-19 Combo Kit			
Positive	63	4	67
Negative	8	230	238
Total	71	234	305*
PPA – 89%; NPA – 98.29% Overall Agreement – 96.07%			

Table 2. Concordance between TaqPath™ COVID-19 Combo Kit and Abbott Real-Time SARS-CoV-2 Assay

Roche SARS-CoV-2 cobas® 6800			
	Positive	Negative	Total
Abbott Real Time SARS-CoV-2			
Positive	63	8	71
Negative	3	232	235
Total	66	240	306
PPA – 95%; NPA – 96.67% Overall Agreement – 96.41%			

Table 3. Concordance between Abbott Real-Time SARS-CoV-2 Assay and Roche SARS-CoV-2 Assay

RESULTS (Contd)

Against the “2-out-of-3” reference, the TaqPath™ COVID-19 Combo Kit showed a PPA and NPA of 100% and 99.58% respectively; the Roche SARS-CoV2 showed a PPA and NPA, each of 100%, the Abbott RealTime SARS-CoV-2 showed a PPA and NPA of 95% and 96.65% respectively. (Table 4)

2-out-of-3 "gold standard"	TaqPath™ COVID-19 Combo Kit	Roche SARS-CoV-2	Abbott RealTime SARS-CoV-2
PPA	100%	100%	95.00%
NPA	99.58%	100%	96.65%

Table 4. Agreement of the 3 assays as compared to the 2-out-of-3 infected patient “gold standard”

The one sample that tested positive with TaqPath and negative with the other two assays had high Ct values (Ct values for all targets >30). Discordant results for each of the assays for which there was agreement between the other two are shown in Tables 5, 6.

Sub ID	ORF1ab	N Gene	S Gene	Avg
TRL039	33.04	32.88	35.01	33.64

Table 5. Discordant sample that was positive on TaqPath COVID-19 Combo Kit and negative on the other two assays.

Sub ID	TaqPath ORF1ab	TaqPath N	TaqPath S	Avg	Roche ORF1a/b	Roche E	Avg
TRL242	13.98	13.98	13.54	13.84	26.8	17.95	22.38
TRL243	9.00	9.45	10.49	9.645	16.96	17.38	17.17
TRL347	none	34.14	34.47	34.30	none	36.88	36.88

Table 6. Discordant samples that were negative on Abbott RealTime but positive on the other two assays. 2 of the 3 samples had low (<20) to medium (<30) Ct values

CONCLUSIONS

All three molecular assays have good concordance when compared against the 2-out-of-3 infected-patient “gold standard” (>95% PPA and NPA). TaqPath™ COVID-19 Combo kit and Roche cobas® SARS-CoV-2 assay show excellent concordance between each other (>99% PPA, NPA). Samples with low viral loads can result in disagreement between molecular tests.