Performance comparison of TaqPath™ COVID-19 CE-IVD RT-PCR Kit and Lyra® SARS-CoV-2 Assay for detecting SARS-CoV-2 in upper respiratory specimens

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INTRODUCTION

The TaqPath™ COVID-19 CE-IVD RT-PCR Kit targets three SARS-CoV-2 genes (ORF1ab, N, S), whereas the Lyra® SARS-CoV-2 Assay targets a single SARS-CoV-2 gene (ORF1ab). (Fig.1) Both assays use an automated RNA extraction protocol and bacteriophage MS2 as an exogenous process control. In this study, we compared clinical performance of the two above-mentioned RT-qPCR diagnostic tests with clinical nasopharyngeal swabs, using the cobas® SARS-CoV-2 assay to resolve discordant results.

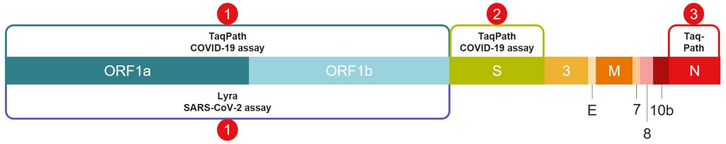

***Figure 1**. Design schematic for multi-target TaqPath and single-target Lyra assays for SARS-CoV-2*

METHODS

A retrospective study was conducted on residual nasopharyngeal specimens at Quantigen BioSciences in January 2021. A total of 240 samples were selected based upon results generated by an EUA-cleared test as part of routine clinical testing. Residual samples stored at -80˚ C were blinded and aliquoted at an independent site and shipped back to the testing site for parallel testing. Automated, magnetic-bead based RNA extraction was conducted according to each assay's EUA-approved protocol. RT-qPCR with both assays was performed on an Applied Biosystems 7500 Fast Dx Real-Time PCR instrument. Positive percent agreement (PPA) and negative percent agreement (NPA) were calculated. Discordant samples were evaluated using the cobas® SARS-CoV-2 Assay on a cobas® 6800 system at an independent facility (Poplar Healthcare, TN, USA). (Fig. 2)

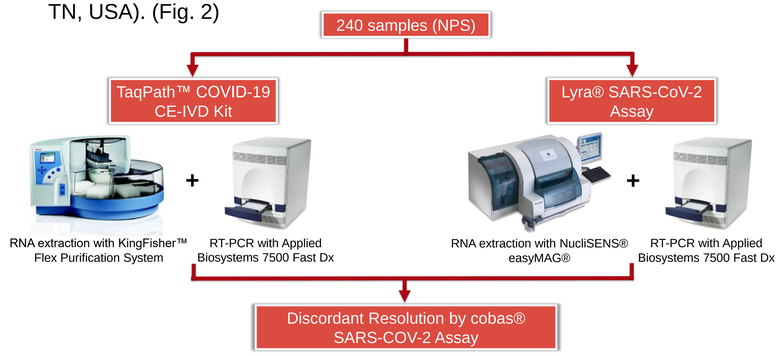

***Figure 2.** Experimental design for the performance comparison study*

RESULTS

Of the 240 samples, 14 samples were excluded from the cohort due to invalid / non-interpretable results generated by the Lyra® assay (12 samples) and inconclusive results generated by the TaqPath™ assay (2 samples). The final study cohort consisted of 226 samples.

The PPA between the two assays was 93.5% and the NPA was 93.3%, with a total of 15 discordant results between the two assays. (Table 1)

		Lyra® SARS-CoV-2 Assay		
		Positive	Negative	Total
TaqPath™ COVID-19 CE-IVD RT-PCR Kit	Positive	100	8	108
	Negative	7	111	118
	Total	107	119	226
Positive Percentage Agreement		**93.5%**	87.0% to 97.3%	
Negative Percentage Agreement		**93.3%**	87.2% to 97.1%	

***Table 1.** Concordance between TaqPath™ COVID-19 CE-IVD RT-PCR Kit and Lyra® SARS-CoV-2 Assay*

Of the 15 discordant samples, 3 samples did not produce conclusive results with the cobas® SARS-CoV-2 assay.

Sample ID	TaqPath™ Result	Lyra® Result	cobas® Result (Resolver)
CV95	Negative ✓	Positive	Negative
CV170	Negative ✓	Positive	Negative
CV187	Negative ✓	Positive	Negative
CV198	Negative	Positive ✓	Positive
CV201	Negative	Positive	Inconclusive
CV213	Negative ✓	Positive	Negative
CV220	Negative	Positive	Inconclusive
CV8	Positive ✓	Negative	Positive
CV29	Positive	Negative ✓	Negative
CV34	Positive	Negative	Inconclusive
CV64	Positive	Negative ✓	Negative
CV155	Positive ✓	Negative	Positive
CV159	Positive	Negative ✓	Negative
CV163	Positive	Negative ✓	Negative
CV184	Positive	Negative ✓	Negative

***Table 2.** Discordant sample resolution showing agreement of each of the assays with cobas® SARS-CoV-2 Assay*

RESULTS (Contd)

Of the remaining 12 discordant samples, arbitration was evenly split, with the resolver test agreeing with 50% of the discordant samples (6/12 samples each) for each assay. (Table 2)

After arbitration testing using the cobas® SARS-CoV-2 assay, the PPA and NPA for TaqPath assay was 99.03% and 95.83% respectively and for the Lyra assay was 98.06% and 96.67% respectively. (Table 3)

	TaqPath™ COVID-19 Combo Kit	Lyra® SARS-CoV-2 Assay
Adjusted Positive Percent Agreement	**99.0%**	**98.1%**
Adjusted Negative Percent Agreement	**95.8%**	**96.7%**

***Table 3.** Agreement of the 2 assays after blinded arbitration testing using cobas assay*

There were 5 samples that were positive by TaqPath and negative by, both, the Lyra assay as well as the cobas assays. Of these 4 out 5 samples showed high Ct values (Ct>30). (Table 4) These samples could be low positive samples that may not be able to be detected by other methods.

Sample ID	TaqPath™ COVID-19 Test			Lyra® SARS-CoV-2 Assay	cobas® SARS-CoV-2 Assay (Resolver)
	ORF1ab Ct	N gene Ct	S gene Ct		
CV29	32.34	32.19	33.11	Negative	Negative
CV64	36.65	34.51	40.00	Negative	Negative
CV159	34.49	34.48	40.00	Negative	Negative
CV163	25.73	29.56	32.42	Negative	Negative
CV184	36.17	30.98	36.59	Negative	Negative

***Table 4.** Ct values of the 5 cases that were positive by the TaqPath™ COVID-19 Test and negative by, both, Lyra® and cobas® SARS-CoV-2 Assays*

CONCLUSIONS

There is strong concordance between TaqPath™ COVID-19 CE-IVD RT-PCR Kit and Lyra® SARS-CoV-2 assay. Arbitration testing using an independent assay generated an even split between the two test methods. Both methods show very good agreement (>95%) using a 2-out-of-3 arbitration on the discordant samples.