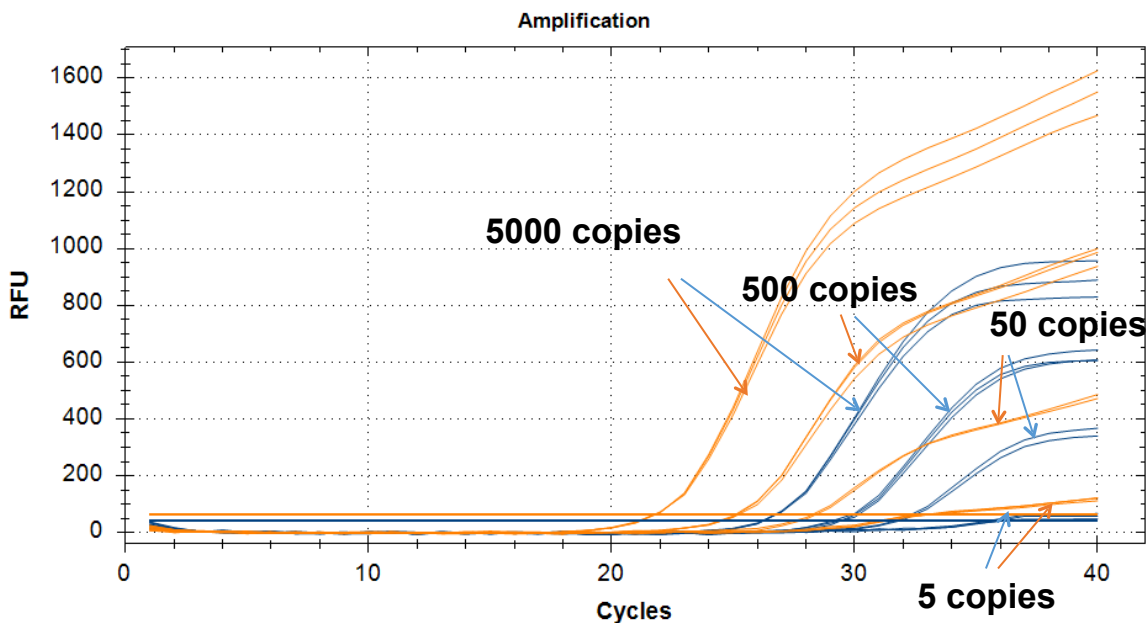


## LifeDireX - COVID-19 RT-qPCR Detection Kit Analytical Comparison

Table 1. Analytical comparisons of our LifeDirex COVID-19 Kit and CDC using DNA and IVT-RNA templates

Gene copies/ reaction	DNA( <i>IDT Cat. 10006625</i> )		IVT-RNA( <i>in vitro</i> transcription)	
	LifeDireX COVID-19 RT- qPCR Detection Kit (avg)	CDC	LifeDireX COVID-19 RT- qPCR Detection Kit (avg)	CDC
5000	22.63	24.91	20.70	22.66
500	25.90	28.24	24.30	26.19
50	28.90	30.32	28.24	29.50
5	32.72	35.18	32.53	32.84
0.5	36.06	37.37	33.53	35.00



\*Relative Fluorescence Unit (RFU)

\* The values make reference to the number of cycles conducted based on the number of copies.

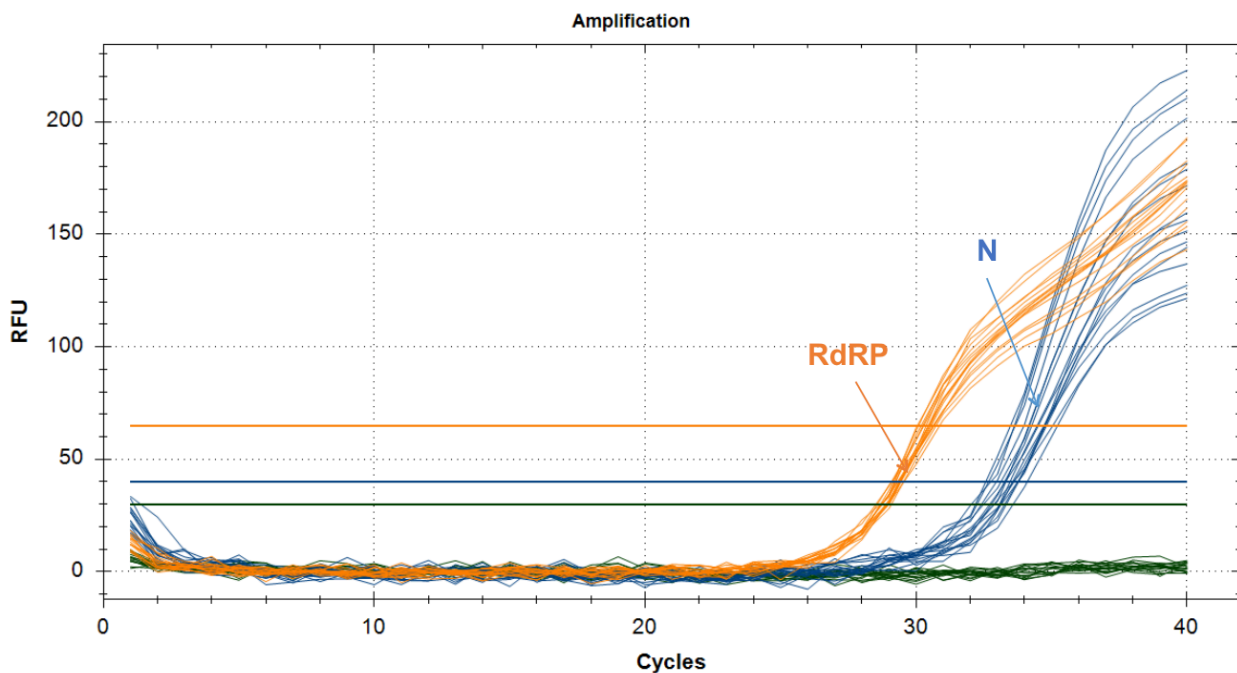
The serial diluted target sequences were tested within the N and RdRP genes and showed the positive signal with RdRP (orange) and N (blue), suggest the LoD is 5 copies/reaction for both targets.

## LifeDireX - COVID-19 RT-qPCR Detection Kit Analytical Comparison

Table 2. LoD verification study results

Target	Concentration (genomic copies/reaction)	Detection Rate	Mean Ct
CoV-N	5 gene copies	100% (20/20)	32.65
CoV-RDRP	5 gene copies	100% (20/20)	32.37

The preliminary LoD was determined to be 5 copies/reaction and was further confirmed by testing 20 additional replicates of samples at 5 copies/reaction by spiking them into nasopharyngeal (NP) clinical matrix, presuming negative. The study results showed that the LoD of the **LifeDirex COVID-19 RT-qPCR Detection Kit** assay is 5 cp/reaction.



### Specifications

- Dual-Gene Detection System: RdRP (same as ORF1ab) and N genes.
- To decrease pipetting step during PCR set up, we have combined the primer/probe tubes.
- "Negative Extraction Control" included for monitoring cross-contamination during the nucleic acid extraction step.
- Expected Performance of Controls and detailed result interpretation table included.
- Performance characteristics included for clinical and cross reactivity.