

**Summary of Analysis of non-medical sampling at Regional Testing Sites versus Liverpool Testing Sites**  
**Analysis 25/11/2020**

**This analysis compares the LFD performance at the Regional testing sites V Liverpool sites.**

**SUMMARY**

There is no statistically significant difference between the two studies. The viral load for the Liverpool participants were lower than for the RTS study (about 3 CT units). After adjusting for CT values, it is unlikely that the sensitivity of the Liverpool study is worse than for the RTS (self-trained) study described in the Technical Evaluation Report.

**Table 1. Comparison of RTS V Liverpool LFD results and PCR**

CT range	RTS	Liverpool	OR (95% )	2P
Lighthouse lab	LFD Pos (%)	LFD Pos /total		
<15	50/55 (90.1%)	2/2 (100%)	n/a	1.0
15-20	126/184 (68.5%)	17/20* (85%)	0.54 (0.12-1.79)	0.44
20-25	32/67 (47.8%)	2/8 (25%)	2.74 (0.44-29.3)	0.28
25-30	6/52 (11.5%)	2/9 (22.2%).	0.456(0.06—5.8)	0.34
>30	0/14 (0%)	0/8 (0%)	n/a	n/a
Total	214/372 (57.5%)	22/47 (46.9%)	1.54 (0.80-2.97)	0.21
Median (IQR)	19.0 (16.7-22.4)	22.1 (18.8-27.0)		<0.0001

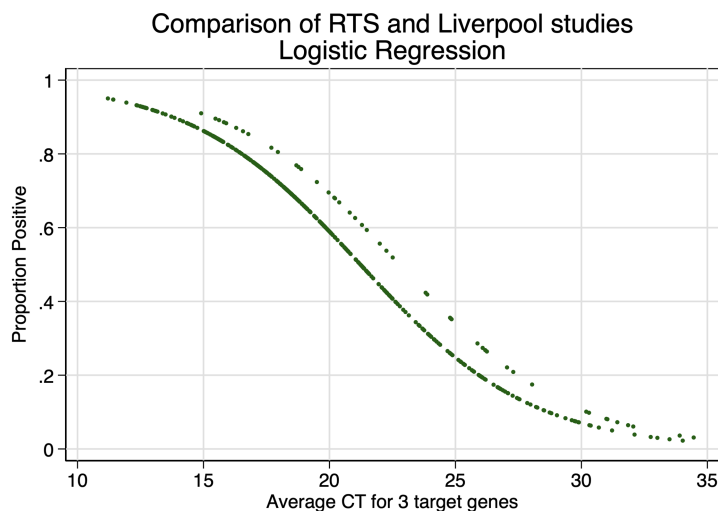
**Notes:**

1. Viral Loads in Liverpool were lower than in the RTS sites.
2. \*1 test was 'void' and is classified as negative in this analysis.
3. the Porton Cobas PCR test has CT values about 4-5 units higher than the Lighthouse labs used, the standardised data for the Lighthouse Lab is available in Appendix 1.

**Odds of positive result linearly related to average CT value**

Odds Ratio (Odds of Liverpool study having a positive result compared to RTS study)

1.54 (0.72-3.45) P=0.257



## Appendix 1. Lighthouse Labs: CT comparisons to viral loads

QNostic Sample ID	Copies/ml	Log10 Copies	Orf1ab	S Gene	N Gene
SCV2AQP01-S01	1000000	6	15.3 (100%)	16.5 (100%)	15.8 (100%)
SCV2AQP01-S02	100000	5	18.3 (100%)	20.5 (100%)	17.4 (100%)
SCV2AQP01-S03	10000	4	22.8 (100%)	24.9 (100%)	23.6 (100%)
SCV2AQP01-S04	5000	3.7	19.5 (100%)	24.8 (100%)	24.1 (100%)
SCV2AQP01-S05	1000	3	25.9 (100%)	28.6 (100%)	26.6 (100%)
SCV2AQP01-S06	500	2.7	25.8 (100%)	29.1 (100%)	25.8 (100%)
SCV2AQP01-S07	100	2	27.7 (33%)	30.3 (66%)	30.8 (100%)
SCV2AQP01-S08	50	1.7	29.3 (17%)	31.1 (27%)	29.1 (55%)
SCV2AQP01-S09	Negative	----	Negative	Negative	Negative

Analytical sensitivity and specificity of the Birmingham Turnkey lab RT-PCR pipeline. This was assessed against the commercial Qnostics SARS-CoV-2 analytical Q-panel – 01. Ct values are a median of 5 independent technical replicate, and figures in parentheses indicate the percentage of replicates returning a PCR positive for that given gene target (Ct < 35).