UNIVERSITY OF LIVERPOOL

Innova Lateral Flow SARS-CoV-2 Antigen test accuracy in Liverpool Pilot: Preliminary Data

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The Liverpool Health Protection Board decided yesterday to pause plans to use Innova Lateral Flow SARS-COV-2 Antigen tests (LFT) in test-to-enable visitor access to care home settings due to the accuracy statistics presented below, derived from data received in the past 24h from DHSC who have been running a Quality Assurance programme.

Aim: To compare the classifications made using military supervised self-administered swabs with LFT made on site, vs those obtained by the same asymptomatic person using a second self-administered swab and assayed by a second LFT and reverse transcribed quantitative polymerase chain reaction (PCR) at a DHSC designated quality assurance (QA) laboratory and then investigate the association between LFT prediction and cycle threshold (Ct) values from a PCR test.

Ct number is inversely correlated with virus specific nucleic acid level in the sample, a surrogate marker of viral load.

Table 1: Comparison of LFT Site Results and LFT QA Results

		LFT Site Result		
		Negative	Positive	Void
LFT QA Result	Negative	3164	1	1
	Positive	0	25	0
	Void	0	0	8

There are paired data for **3199 patients**. A comparison of the LFT site results to the QA PCR results is shown in Table 2.

Table 2: Comparison of LFT Site Results and PCR Results

		PCR QA Result		
		Negative	Positive	Void
LFT Site Result	Negative	2979	23	162
	Positive	2	22	2
	Void	8	1	0

Accuracy measures (excluding VOID results), assuming PCR is gold standard: -

Including 95% confidence intervals: -

Sensitivity (true positive rate)
0.488889 (0.337034 to 0.64226), **48.89%** (**33.7%** to **64.23%)**

Specificity (true negative rate)
0.999329 (0.997579 to 0.999919), **99.93%** (**99.76%** to **99.99%)**

Predictive value of +ve test (post-test likelihood of disease)
0.916667 (0.730027 to 0.989744), **91.67%** (**73%** to **98.97%), change = 91%**

Predictive values of -ve test (post-test likelihood of no disease)
0.992338 (0.988526 to 0.995137), **99.23%** (**98.85%** to **99.51%**), **change = 0%**
(post-test disease likelihood despite -ve test)
0.007662 (0.004863 to 0.011474), 0.77% (0.49% to 1.15%), change = 0%

We compared the site LFT test result to the Ct value from the QA PCR test. This was calculated as the average of existing values for "N_gene", "S_gene" and "ORF lab"

Table 3: Comparison of LFT Site Results and QA PCR Ct values for positive PCR samples.

		Ct score from PCR test					
		<20	20-25	25-30	30-35	Negatives	Void
LFT Site Results	**Negative**	2	7	6	8	2979	162
	Positive	12	8	1	1	2	2
	Void	1	0	0	0	8	0
Cumulative Sensitivity (95% CI)		85.7 (57.2 to 98.2)	69.0 (49.2 to 84.7)	58.3 (40.8 to 74.5)	48.9 (33.7 to 64.2)		

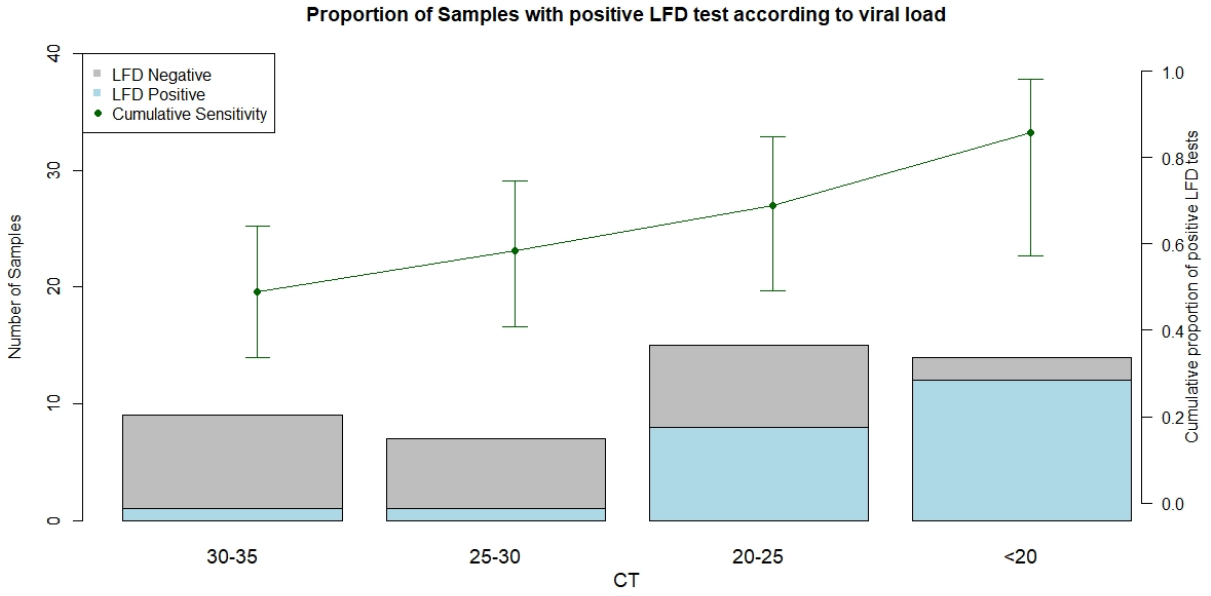

Figure 1: Number of samples (positive and negative by LFT) according to Ct value. Cumulative proportions and 95% CI are also displayed.

END