



SARS-CoV-2 Inactivation Testing: Interim Report

Report identifier	HCM/CoV2/045/v2
Report date	28 October 2020
Undertaken by High Containment Microbiology, NIS Laboratories, National Infection Service, Public Health England N.B. This is an interim report and may be updated as further results are obtained	

Product/treatment details	
Product/treatment	LumiraDx SARS-CoV-2 Antigen Extraction Buffer
Manufacturer	LumiraDx
Product code	Not known
Manufacturer's recommended ratio of sample to product	Swab to be added directly to tube containing approximately 750µl extraction buffer

Sample details	
Sample type tested	Tissue culture fluid containing 5% (v/v) foetal calf serum
Virus strain tested	SARS-CoV-2 England 2
Ratio of spiked virus stock to sample matrix	Not applicable; tissue culture fluid used undiluted

Experimental conditions	
Ratio of sample to product tested	1 volume sample to 7.5 volumes product
Contact time/s	1 minute; 5 minutes; 10 minutes
Temperature of incubation	Room temperature
Brief description of tests performed	<p>Triplicate samples were treated with test buffer for indicated contact time/s or mock-treated in triplicate with an equivalent volume of PBS. Samples were immediately titrated on Vero E6 cells to establish virus titre. This test is quantitative and reports the titre of virus in each treatment condition in TCID50 per ml. Reduction in virus titre following treatment is given as the difference between the mean \log_{10} TCID50/ml for treated conditions and the PBS control.</p>

Table of results		
	Mean virus titre in \log_{10} TCID50/ml [95% confidence interval]	Titre reduction in \log_{10} TCID50/ml [95% confidence interval]
PBS-treated	4.9 [4.6-5.2]	-
Test buffer-treated (1 minute)	4.8 [4.5-5.2]	0.0 [-0.4-0.5]
Test buffer-treated (5 minutes)	4.9 [4.5-5.2]	0.0 [-0.4-0.4]
Test buffer-treated (10 minutes)	4.8 [4.5-5.2]	0.1 [-0.4-0.5]

Interpretation

Treatment with LumiraDx SARS-CoV-2 Antigen Extraction Buffer had no effect on SARS-CoV-2 titre following a 1, 5 or 10 minute treatment time.

This buffer should not be relied upon to inactivate infectious samples.

This test has been performed using tissue culture fluid. The effectiveness of this treatment against SARS-CoV-2 may vary when used to inactivate clinical samples or other types of sample matrix. Any results of inactivation testing using other sample matrices will be released as they become available.

Inactivation reagents should not be assumed to be 100% effective against SARS-CoV-2.

Suitability of products and treatments for inactivation of other pathogens has not been evaluated in this study.

All COVID-19 laboratory testing workflows must be subjected to suitable and sufficient risk assessment, with consideration given to any inactivation step. Risk assessments should be reviewed regularly as new information on the inactivation of SARS-CoV-2 becomes available.

The impact of chosen inactivation method on the sensitivity of subsequent SARS-CoV-2 detection should also be assessed locally.

Disclaimer

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Summary of revisions

Version 1: New document

Version 2: Addition of confidence intervals; rewording of text in interpretation

Queries regarding this report or HCM inactivation testing should be directed to
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