Public Health England

SARS-CoV-2 Inactivation Testing: Interim Report

Report identifier	HCM/CoV2/077/v1
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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	LIAISON SARS-CoV-2 Ag Inactivation Buffer
Manufacturer	DiaSorin
Product code	Not known
Manufacturer's recommended ratio of sample to product	1 volume of sample to be added to 1 volume of product

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 1 volume product
Contact time/s	30 minutes; 60 minutes; 120 minutes; 24 hours
Temperature of incubation	Refrigerated temperature (range 6.5-8.0°C) for 24-hour treatment only) Ambient temperature (all other contact times)
Brief description of tests performed	Triplicate samples were treated with test buffer for indicated contact time/s, or mock-treated in triplicate with an equivalent volume of PBS and incubated for the indicated times and temperature. All samples were then subjected to a purification step to remove cytotoxic buffer components. PBS-treated samples were subjected to the same purification procedure in parallel. Purified samples were 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.

Table of results (30-, 60- and 120-minute contact times)			
	Mean virus titre in log_{10} TCID50/ml [95% confidence interval]	Titre reduction in log_{10} TCID50/ml [95% confidence interval]	Virus detectable in titration: Yes/No (no. of replicates positive)
PBS-treated	7.0 [6.6-7.3]	-	Yes (3/3)
Test buffer-treated (30 minutes)	5.9 [5.6-6.3]	1.1 [0.6-1.6]	Yes (3/3)
Test buffer-treated (60 minutes)	5.3 [5.0-5.6]	1.7 [1.2-2.1]	Yes (3/3)
Test buffer-treated (120 minutes)	4.8 [4.4-5.1]	2.2 [1.8-2.7]	Yes (3/3)

Table of results (24-hour contact time)			
	Mean virus titre in log_{10} TCID50/ml [95% confidence interval]	Titre reduction in log_{10} TCID50/ml [95% confidence interval]	Virus detectable in titration: Yes/No (no. of replicates positive)
PBS-treated (24 hours, 4°C)	6.9 [6.7-7.2]	-	Yes (3/3)
Test buffer-treated (24 hours, 4°C)	5.4 [5.1-5.7]	1.6 [1.2-1.9]	Yes (3/3)
PBS-treated (24 hours, ambient temperature)	6.7 [6.4-6.9]	-	Yes (3/3)
Test buffer-treated (24 hours, ambient temperature)	≤ 0.7*†	≥ 5.9 [5.7-6.2]	No (0/3)

*Limit of detection for test was 0.7 log10 TCID50/ml. Mean titres are reported as ≤ when at least one replicate was below the limit of detection.

†95% confidence interval cannot be calculated

Interpretation

Treatment with DiaSorin LIAISON SARS-CoV-2 Ag Inactivation Buffer using 1 volume sample to 1 volume product for 30, 60 or 120 minutes at ambient temperature reduced SARS-CoV-2 titre by 1.1, 1.7 and 2.2 $\log_{10}$ TCID50/mL respectively. Treatment with DiaSorin LIAISON SARS-CoV-2 Ag Inactivation Buffer using 1 volume sample to 1 volume product for 24 hours at refrigerated temperature reduced SARS-CoV-2 titre by 1.6 $\log_{10}$ TCID50/ml. These titre reductions are modest in comparison with other inactivation buffers and this product should not be relied upon to inactivate infectious samples at these contact times and temperature conditions.

Treatment with DiaSorin LIAISON SARS-CoV-2 Ag Inactivation Buffer using 1 volume sample to 1 volume product for 24 hours at ambient temperature reduced SARS-CoV-2 titre by ≥ 5.9 $\log_{10}$ TCID50/ml, to below the limit of detection of the test. These data indicate that treatment for 24 hours at ambient temperature is far more effective at inactivating SARS-CoV-2 in tissue culture fluid than at shorter times or at lower temperatures.

Demonstrating complete inactivation is dependent on the starting titre of virus used for testing. Sample treatments that inactivate virus effectively in our testing may fail to inactivate samples containing higher levels of virus than those evaluated in this study.

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

PHE's evaluations of commercial products and treatments for inactivating SARS-CoV-2 have been carried out primarily for PHE's own internal use and the reports of such evaluations are shared solely for readers information; PHE does not in any way recommend any particular product for virus inactivation; and PHE shall not be responsible for the choice of product or treatment for virus inactivation, and it is the responsibility of the testing laboratory to ensure that any such product or treatment implemented has undergone the necessary verification and validation; and PHE shall not be liable, to the greatest extent possible under any applicable law, for any claim, loss or damage arising out of or connected with use of this and related reports and choice of virus inactivation products or treatments.

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Summary of revisions

Version 1: New document

Queries regarding this report or HCM inactivation testing should be directed to HCMgroup@phe.gov.uk