Public Health England

SARS-CoV-2 Inactivation Testing: Interim Report

Report identifier	HCM/CoV2/054/v1
Report date	02 November 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	Lysis Buffer
Manufacturer	Biomonde
Product composition	Manufactured according to Boom R., Sol C. J., Salimans M. M., Jansen C. L., Wertheim-van Dillen P. M., van der Noordaa J. Rapid and simple method for purification of nucleic acids. *Journal of Clinical Microbiology*. 1990;28(3):495–503.
Product code	Not available
Manufacturer's recommended ratio of sample to product	Not available

Sample details	
Sample type tested	Tissue culture fluid containing 5% (v/v) foetal calf serum, concentrated through a 100KDa molecular weight cut-off centrifugal filter
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 4 volumes product
Contact time/s	10 minutes
Temperature of incubation	Room temperature
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. 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 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.

Table of results		
Maximum detectable virus reduction in test (log_{10} TCID50/ml)	5.8†	
	Mean virus titre in log_{10} TCID50/ml [95% confidence interval]	Titre reduction in log_{10} TCID50/ml [95% confidence interval]
PBS-treated	7.5 [7.2-7.7]	-
Test buffer-treated (10 minutes)	≤1.7	5.8 [5.5-6.0]

†Limit of detection was 1.7 log_{10} TCID50/ml

Interpretation
Treatment with this lysis buffer for 10 minutes reduced virus titre by ≥5.8 $log_{10,}$ to below the limit of detection for the test. Demonstrating complete inactivation is dependent on the starting titre of virus used for testing. While our data suggest complete inactivation by this product in our tests, 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 concentrated 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. PHE is an Executive Agency of the Department of Health and Social Care. Unauthorised use of the PHE name and/or logo is prohibited.

Summary of revisions
Version 1: New document

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