UK Health Security Agency

SARS-CoV-2 inactivation testing report

Report identifier	HCM/CoV2/106/v2
Report date	11 November 2022
Undertaken by High Containment Microbiology, UK Health Security Agency (UKHSA)	

Product/treatment details	
Product/treatment	InhibiSURE Viral Inactivation Medium
Manufacturer	Thermo Fisher Scientific
Product code	EB1359A
Manufacturer's recommended ratio of sample to product	Swab to be directly added to tube containing 1.5mL 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	10 volumes product to 1 volume test sample (150µL test sample added to InhibiSURE tube containing 1.5mL product)
Contact time/s	5, 10 and 30 minutes
Temperature of incubation	Ambient temperature
Brief description of tests performed	Triplicate samples of SARS-CoV-2 virus tissue culture fluid were treated with product at the indicated test concentration for indicated contact times. Mock-treatments were carried out in triplicate using an equivalent volume of MEM instead of product. After treatment, all samples were subjected to a filtration step to reduce cytotoxic buffer components. MEM-treated samples were subjected to the same filtration procedure in parallel. All samples were immediately titrated on Vero E6 cells. Plates immunostained using an anti-SARS-CoV-2 virus antibody to establish virus titre. Product only controls (purified and unpurified) were additionally titrated to determine product cytotoxicity before and after filtration. This test is quantitative and reports the virus titre for each treatment condition in focus forming units (FFU)/mL. Reduction in virus titre following treatment is given as the difference between the mean log10 FFU/mL for treated conditions and the MEM control.

	Mean virus titre in log_{10} FFU/ml [95% confidence interval]	Titre reduction in log_{10} FFU/ml [95% confidence interval]	% virus reduction
PBS-treated	5.7 [5.3-6.0]	-	-
Test buffer-treated (5 minutes)	≤ 1.1†	≥ 4.5 [4.2-4.9]	≥ 99.997%
Test buffer-treated (10 minutes)	≤ 1.1†	≥ 4.5 [4.2-4.9]	≥ 99.997%
Test buffer-treated (30 minutes)	≤ 1.1†	≥ 4.5 [4.2-4.9]	≥ 99.997%

†95% confidence interval cannot be calculated
*Limit of detection for the buffer test was 1.1 log10 FFU/mL. Mean titres are reported as ≤ when at least one replicate was below the limit of detection.

Interpretation

Treatment with InhibiSURE Viral Inactivation Medium using 10 volumes product to 1 volume sample for at least 5 minutes reduced SARS-CoV-2 titre to below the limit of detection of the test. This was equivalent to a ≥ 4.5 $\log_{10}$ (≥ 99.997%) reduction in virus titre.

Demonstrating complete inactivation is dependent on the starting titre of virus used for testing. Complete inactivation may occur if samples contained lower levels of infectious virus than those tested here, but sample treatments that inactivate virus effectively in these tests may fail to inactivate samples containing higher levels of virus than those evaluated here.

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.

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
UKHSA does not in any way recommend any particular product for virus inactivation; and UKHSA shall not be responsible for the choice of product or treatment for virus inactivation, and it is the responsibility of the testing laboratories to ensure that any such product or treatment implemented has undergone the necessary verification and validation; and UKHSA 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. UKHSA is an executive agency of the Department of Health and Social Care. Unauthorised use of the UKHSA name and/or logo is prohibited.

Summary of revisions
Version 1: New document Version 2: Document converted to short report form for publication on gov.uk

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