Public Health England

SARS-CoV-2 Inactivation Testing: Interim Report

Report identifier	HCM/CoV2/046/v2
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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	VitaPCR SARS-CoV-2 Assay Sample Collection Buffer
Manufacturer	Credo Diagnostics
Product code	From kit PCRAE0114
Manufacturer's recommended ratio of sample to product	Swab to be added directly to tube containing approximately 4.5ml extraction buffer

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 10 volumes product
Contact time/s	1 minute; 5 minutes; 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 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. In parallel, purified samples were seeded onto Vero E6 monolayers in flasks to amplify any remaining virus by serial passage. Virus amplification over each passage was detected by visual (microscopic) examination of monolayers for cytopathic effect, and confirmed by SARS-CoV-2-specific real-time PCR. This test is qualitative and reports either the presence or absence of virus amplification. This test may detect levels of virus that are below the detection limit of the titration assay due to a greater sample plating volume and the opportunity for any virus present to amplify over serial passages.

Table of results			
Maximum possible virus reduction detectable in titration (log_{10} TCID50/ml)		5.3-6.3†	
	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 or passage: Yes/No (no. of replicates positive)
PBS-treated	7.0 [6.7-7.3]	-	Yes (3/3)
Test buffer-treated (1 minute)	≤2.0†*	≥5.0 [4.7-5.3]	Yes (3/3)
Test buffer-treated (5 minutes)	0.8†	6.2 [5.9-6.5]	Yes (3/3)
Test buffer-treated (10 minutes)	≤1.6†*	≥5.5 [5.2-5.7]	Yes (2/3)

†Limit of detection for sample replicates varied between 0.7 and 1.7 log_{10} TCID50/ml due to residual buffer cytotoxicity

*Mean titres are reported as ≤ when at least one replicate was below the limit of detection.

Interpretation

Treatment with this product for 1, 5 or 10 minutes reduced virus titre by ≥5.0 log_{10} TCID50/ml.

Low levels of residual virus were detectable by virus titration and/or passages in all sample replicates by virus titration after 1 or 5 minute treatment times, and in 2/3 sample replicates after 10 minute treatment.

Demonstrating complete inactivation is dependent on the starting titre of virus used for testing. Complete inactivation is likely if samples contained lower levels of infectious virus than those tested here, but 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
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Summary of revisions
Version 1: New document Version 2: Addition of new data; update of description of tests performed and interpretation

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