



SARS-CoV-2 Inactivation Testing: Interim Report

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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	Coronavirus Ag Rapid Test Cassette (Swab) Buffer
Manufacturer	Orient Gene/Healgen
Product code	Not known
Manufacturer's recommended ratio of sample to product	Swab rotated in tube containing 10 drops of buffer (approximately 300µl volume)

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 3 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. 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)	5.6	
	Mean virus titre in log ₁₀ TCID50/ml [95% confidence interval]	Titre reduction in log ₁₀ TCID50/ml [95% confidence interval]
PBS-treated	6.3 [6.0-6.5]	-
Test buffer-treated (1 minute)	5.5 [5.2-5.8]	0.8 [0.4-1.2]
Test buffer-treated (5 minutes)	4.9 [4.5-5.2]	1.4 [1.0-1.8]
Test buffer-treated (10 minutes)	4.7 [4.4-5.0]	1.6 [1.2-2.0]

†Limit of detection was 0.7 log₁₀ TCID50

Interpretation

Treatment with this product for 10 minutes reduced virus titre by 1.6 log₁₀ TCID₅₀/ml. Shorter treatment times of 1 and 5 minutes reduced virus titre by 0.8 and 1.4 log₁₀ TCID₅₀/ml, respectively.

These titre reductions are relatively modest in comparison with extraction buffers for non-rapid tests and suggest that while this product may partially reduce sample infectivity, it 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.

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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