



SARS-CoV-2 Inactivation Testing: Interim Report

Report identifier	HCM/CoV2/069/v2
Report date	15 March 2021
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	VivaDiag SARS-CoV-2 Ag FIA Test Extraction Solution
Manufacturer	VivaChek Biotech (Hangzhou) Co., Ltd.
Product code	VID44-08-011
Manufacturer's recommended ratio of sample to product	Swab to be added directly to tube containing 0.3ml 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 3 volumes product
Contact time/s	1 minute; 5 minutes; 10 minutes
Temperature of incubation	Ambient temperature
Brief description of tests performed	<p>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 reduce 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 log₁₀ TCID₅₀/ml for treated conditions and the PBS control.</p>

Table of results		
	Mean virus titre in log ₁₀ TCID ₅₀ /ml [95% confidence interval]	Titre reduction in log ₁₀ TCID ₅₀ /ml [95% confidence interval]
PBS-treated	6.5 [6.2-6.8]	-
Test buffer-treated (1 minute)	3.5 [3.2-3.8]	3.0 [2.5-3.5]
Test buffer-treated (5 minutes)	2.5 [2.2-2.8]	4.0 [3.5-4.4]
Test buffer-treated (10 minutes)	2.5 [2.2-2.8]	4.0 [3.5-4.4]

Interpretation

Treatment with VivaDiag SARS-CoV-2 Ag FIA Test Extraction Solution for 1 minute reduced virus titre by 3.0 log₁₀ TCID₅₀/ml. Treatment for 5 and 10 minutes reduced SARS-CoV-2 titre by 4.0 log₁₀ TCID₅₀/ml. While this represents a considerable reduction in virus titre, this product should not be relied upon to completely inactivate infectious samples.

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 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

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Summary of revisions

Version 1: New document

Version 2: Previous results retracted (incorrect buffer for indicated test kit provided by requester) and replaced with results for correct buffer

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