Public Health England

SARS-CoV-2 Inactivation Testing: Interim Report

Report identifier	HCM/CoV2/038/v4
Report date	07 January 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 **This report replaces the previous report for Standard Q COVID-19 Ag Assay Diluent (HCM/CoV2/038/v2). HCM/CoV2/038/v2 should not be used to inform risk assessments for use of the Standard Q COVID-19 Ag Test, and assessments based on information in this superseded report should be updated.**	

Product/treatment details	
Product/treatment	Standard Q COVID-19 Ag Extraction Buffer
Manufacturer	SD Biosensor
Product code	No product code given
Available information on product composition, as supplied	No information available
Manufacturer's recommended ratio of sample to product	Swab or 350µl sample fluid to be added to extraction buffer tube containing 350µl buffer

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 2 volumes test buffer
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.

Table of results		
Maximum detectable virus reduction in test (log_{10} TCID50/ml)		4.4*
	Mean virus titre in log_{10} TCID50/ml [95% confidence interval]	Titre reduction in log_{10} TCID50/ml [95% confidence interval]
PBS-treated	6.1 [5.8-6.4]	-
Test buffer-treated (1 minute)	4.4 [4.1-4.6]	1.7 [1.3-2.1]
Test buffer-treated (5 minutes)	3.7 [3.4-4.0]	2.4 [2.0-2.8]
Test buffer-treated (10 minutes)	3.3 [3.0-3.5]	2.9 [2.4-3.3]

*Limit of detection was 1.7 log_{10} TCID50/ml due to residual buffer cytotoxicity

Interpretation

1 minute treatment with Standard Q COVID-19 Ag Extraction Buffer reduced virus titre by 1.7 log_{10} TCID50/ml. Longer treatment times reduced titres further, by 2.4 and 2.9 log_{10} TCID50/ml after 5 and 10 minutes, respectively. While this represents a small reduction in virus titre, this product should not be relied upon to completely inactivate infectious samples.

Standard Q COVID-19 Ag Extraction Buffer was assessed using one volume of sample to two volumes of product. The final concentration of active ingredients is likely to be higher than this in an extraction tube post-swab sampling when used according to the manufacturer's instructions; inactivation of swab samples is therefore likely to be at least as effective as demonstrated in our testing. For inactivation of fluid specimens (e.g. specimens in transport media), the manufacturer recommends a 1:1 ratio of sample to product, therefore inactivation of this sample type may be less effective than indicated 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. 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 Version 2: Addition of new information about buffer volumes and update of interpretation Version 3: Addition of new data and update of interpretation Version 4: Clarification of interpretation

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