



## SARS-CoV-2 Inactivation Testing: Interim Report

<b>Report identifier</b>	HCM/CoV2/073/v1
<b>Report date</b>	11 February 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	

<b>Product/treatment details</b>	
Product/treatment	Zeesan Saliva RNA Sample Collection Kit Buffer
Manufacturer	Xiamen Zeesan Biotech Co., LTD.
Product code	401115
Manufacturer's recommended ratio of sample to product	1 volume of saliva to be added to 2 volumes of product

<b>Sample details</b>	
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

<b>Experimental conditions</b>	
Ratio of sample to product tested	1 volume sample to 2 volumes product
Contact time/s	30 minute; 60 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 remove cytotoxic buffer components. PBS-treated samples were subjected to the same purification procedure in parallel.</p> <p>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 TCID<sub>50</sub> per ml. Reduction in virus titre following treatment is given as the difference between the mean log<sub>10</sub> TCID<sub>50</sub>/ml for treated conditions and the PBS control.</p>

<b>Table of results</b>			
	Mean virus titre in log <sub>10</sub> TCID <sub>50</sub> /ml [95% confidence interval]	Titre reduction in log <sub>10</sub> TCID <sub>50</sub> /ml [95% confidence interval]	Virus detectable in titration: Yes/No (no. of replicates positive)
PBS-treated	6.4 [6.1-6.7]	-	Yes (3/3)
Test buffer-treated (30 minute)	≤0.8 <sup>†</sup>	≥5.6 [5.3-5.9]	Yes (2/3)
Test buffer-treated (60 minutes)	0.8 <sup>†</sup>	5.6 [5.3-5.9]	Yes (3/3)

\*Limit of detection for test was 0.7 log<sub>10</sub> TCID<sub>50</sub>/ml. Mean titres are reported as ≤ when at least one replicate was below the limit of detection.

<sup>†</sup>95% confidence interval cannot be calculated

<b>Interpretation</b>
<p>Treatment with Zeesan Saliva RNA Sample Collection Kit Buffer reduced mean SARS-CoV-2 titre by ≥5.6 log<sub>10</sub> after 30 minute treatment. Low levels of residual virus were detectable by virus titration, even after 60 minute treatment.</p> <p>While this represents a considerable reduction in virus titre, this product should not be relied upon to completely inactivate infectious samples.</p> <p>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.</p> <p>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.</p>

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**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

Queries regarding this report or HCM inactivation testing should be directed to

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