



SARS-CoV-2 Inactivation Testing: Interim Report

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| Report identifier | HCM/CoV2/064/v1 |
| Report date | 15 December 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 | |

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| Product/treatment details | |
| Product/treatment | MicroLYSIS-RNA Direct to PCR Lysis Solution |
| Manufacturer | Clent Life Science |
| Product code | 2MLR |
| Manufacturer's recommended ratio of sample to product | 1 volume sample to 1 volume product |

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| 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 |

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| Experimental conditions | |
| Ratio of sample to product tested | 1 volume sample to 1 volume product |
| Contact time/s | 5 minutes; 20 minutes |
| Temperature of incubation | Ambient temperature |

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| 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 dilution and 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 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.</p> |
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| Table of results | | |
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| | Mean virus titre in \log_{10} TCID50/ml [95% confidence interval] | Mean titre reduction in \log_{10} TCID50/ml [95% confidence interval] |
| PBS-treated | 6.1 [5.8-6.4] | - |
| Test buffer-treated (5 minutes) | 5.1 [4.8-5.4] | 1.0 [0.6-1.4] |
| Test buffer-treated (20 minutes) | 4.2 [3.9-4.4] | 1.9 [1.6-2.3] |

| Interpretation |
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| <p>MicroLYSIS-RNA reduced mean SARS-CoV-2 titre by 1.0 \log_{10} and 1.9 \log_{10} TCID50/ml after 5 and 20 minutes treatment, respectively.</p> <p>This product should not be relied upon to completely inactivate infectious samples.</p> |

Demonstrating complete inactivation is dependent on the starting titre of virus used for testing. Complete inactivation may occur if samples contained much lower levels of infectious virus than those tested here, and 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

PHE's evaluations of commercial products and treatments for inactivating SARS-CoV-2 have been carried out primarily for PHE's own internal use and the reports of such evaluations are shared solely for readers information; PHE does not in any way recommend any particular product for virus inactivation; and PHE shall not be responsible for the choice of product or treatment for virus inactivation, and it is the responsibility of the testing laboratory to ensure that any such product or treatment implemented has undergone the necessary verification and validation; and PHE shall not be liable, to the greatest extent possible under any applicable law, for any claim, loss or damage arising out of or connected with use of this and related reports and choice of virus inactivation products or treatments.

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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