



Monkeypox Virus Inactivation Testing Report

Report identifier	HCM/MPx/002/v3
Report date	5 July 2022
Testing laboratory	High Containment Microbiology, UK Health Security Agency (UKHSA)

Product details	
Product name	PrimeStore Molecular Transport Medium
Product code	R13907 (Thermo Fisher Scientific)
Batch number	R272210381
Manufacturer	Longhorn Vaccines & Diagnostics
Storage conditions	Ambient temperature
Active substances and concentrations (if known)	20-30% guanidine thiocyanate 19-25% ethanol <0.7% N-Lauroylsarcosine Na+
Instructions for use	Swab collected directly into tube containing 2mL PrimeStore Molecular Transport Medium

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Experimental conditions	
Period of analysis	8 June – 13 June 2022
Product test concentrations	10 volumes product to 1 volume test sample
Test temperature	Ambient temperature
Treatment times tested	2 minutes; 10 minutes
Sample type tested and virus details	Monkeypox virus stock: monkeypox virus isolate UK2 (GenBank entry MT903344), in tissue culture fluid containing 5% foetal bovine serum
Description of test	<p>Triplicate samples of monkeypox virus tissue culture fluid were treated with product at the indicated test concentration for indicated contact times. Mock-treatments were carried out in triplicate using an equivalent volume of phosphate-buffered saline (PBS) instead of product. After treatment, all samples were subjected to a filtration step to reduce cytotoxic buffer components, using Pierce Detergent Removal Spin Columns in accordance with the manufacturer's instructions. PBS-treated samples were subjected to the same filtration procedure in parallel. All samples were immediately titrated on Vero E6 cells and plates immunostained using an anti-vaccinia virus antibody to establish virus titre. Product only controls (purified and unpurified) were additionally titrated to determine product cytotoxicity before and after filtration.</p> <p>This test is quantitative and reports the virus titre for each treatment condition in focus forming units (FFU)/mL. Reduction in virus titre following treatment is given as the difference between the mean \log_{10} FFU/mL for treated conditions and the PBS control.</p>

Table of results				
Treatment condition	Mean virus titre in FFU/mL	Mean virus titre in log₁₀ FFU/mL [95% CI]	Titre reduction in log₁₀ FFU/mL [95% CI]	% reduction in virus titre
PBS-treated	4.5x10 ⁵	5.7 [5.6-5.7]	-	-
2-minute treatment	≤13	≤1.1 [†]	≥4.5 [4.4-4.6]	≥99.997%
10-minute treatment	≤13	≤1.1 [†]	≥4.5 [4.4-4.6]	≥99.997%

Mean titres are reported as ≤ when at least one replicate was below the limit of detection
[†]95% confidence interval cannot be calculated

Results interpretation and limitations

Treatment with PrimeStore Molecular Transport Medium for 2 minutes or more reduced monkeypox virus titre to below the limit of detection of the titration assay. This equates to a $\geq 4.5 \log_{10}$ reduction in virus titre, or a reduction of $\geq 99.997\%$.

A previous version of this report showed that treatment with PrimeStore Molecular Transport Medium for 30 minutes or more reduced monkeypox virus titre by $\geq 4.4 \log_{10}$, or $\geq 99.996\%$.

Demonstrating complete inactivation is dependent on the starting titre of virus used for testing. Complete inactivation may occur if samples contain lower levels of infectious virus than those tested here, but sample treatments that inactivate virus effectively in these tests 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 monkeypox virus may vary when used to inactivate clinical samples or other types of sample matrix.

Nucleic acid stability in this product has not been examined, nor has the suitability of this product for inactivation of other pathogens been evaluated in this study. The effectiveness of this product against SARS-CoV-2 has previously been assessed by this laboratory and a treatment time of 10 minutes or more reduced virus titre by $\geq 5.1 \log_{10}$ (Welch SR et al. (2020). Analysis of Inactivation of SARS-CoV-2 by Specimen Transport Media, Nucleic Acid Extraction Reagents, Detergents, and Fixatives. *Journal of Clinical Microbiology* 58(11):e01713-20. doi: 10.1128/JCM.01713-20).

Disclaimer

UKHSA does not in any way recommend any particular product for virus inactivation; and UKHSA shall not be responsible for the choice of product or treatment for virus inactivation, and it is the responsibility of users of the product to ensure that any such product or treatment implemented has undergone the necessary verification and validation; and UKHSA 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

Version 2: Replacement of 30-, 60- and 120-minute treatment data with shorter treatment times

Version 3: Minor edits to disclaimer