UK Health Security Agency

Monkeypox Virus Inactivation Testing Report

Report identifier	HCM/MPx/015/v1
Report date	5 October 2022
Testing laboratory	High Containment Microbiology, UK Health Security Agency (UKHSA)

Product details	
Product name	NeuMoDx Vantage Viral Lysis Buffer
Product code	401500
Lot number	120980
Manufacturer	NeuMoDx
Storage conditions	Ambient temperature
Active substances and concentrations (if known)	50.5% guanidine hydrochloride 0.8% sodium tetraborate decahydrate 0.3% Tris(2-carboxyethyl)phosphine hydrochloride
Instructions for use	1 volume sample treated with 1 volume of product

Experimental conditions	
Period of analysis	23 September – 05 October 2022
Product test concentrations	1 volume product to 1 volume test sample
Test temperature	Ambient temperature
Treatment times tested	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	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 minimum essential medium (MEM) 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. MEM-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. 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.

Table of results

Treatment condition	Mean virus titre in FFU/mL	Mean virus titre in log_{10} FFU/mL [95% CI]	Titre reduction in log_{10} FFU/mL [95% CI]	% reduction in virus titre
MEM-virus control	$6.8x10^6$	6.8 [6.5-7.2]	-	-
30-minute treatment	≤ 133†	≤ 2.1†	≥ 4.7 [4.4-5.1]	99.998

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 NeuMoDx Vantage Viral Lysis Buffer (1 volume product to 1 volume sample) for 10 minutes reduced monkeypox virus titre to below the limit of detection for the test. This equates to ≥4.7 log_{10} reduction in virus titre, or a reduction of 99.998%.

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.

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. UKHSA is an executive agency of the Department of Health and Social Care. Unauthorised use of the UKHSA name and/or logo is prohibited.

Summary of revisions
Version 1: New document