



Monkeypox Virus Inactivation Testing Report

Report identifier	HCM/MPx/009/v1
Report date	30 June 2022
Testing laboratory	High Containment Microbiology, UK Health Security Agency (UKHSA)

Product details	
Product name	Panther Fusion Specimen Lysis Tubes, containing Specimen Transport Media (STM)
Product code	PRD-04339
Batch number	319007
Manufacturer	Hologic
Storage conditions	Ambient temperature
Active substances and concentrations (if known)	Not available
Instructions for use	500µL sample added to tube containing 0.71mL Specimen Transport Medium

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Experimental conditions	
Period of analysis	22 June – 30 June 2022
Product test concentrations	1.42 volumes product to 1 volume(s) 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	<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	1.63x10 ⁶	6.2 [6.1-6.3]	-	-
10-minute treatment	≤13	≤1.1 [†]	≥5.1 [4.9-5.2]	99.999%

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 Hologic STM (1.42 volumes product to 1 volume sample) for 10 minutes reduced monkeypox virus titre to below the limit of detection of the titration assay. This equates to a $\geq 5.1 \log_{10}$ reduction in virus titre, or a reduction of $\geq 99.999\%$.

This study evaluated inactivation of monkeypox virus by STM under conditions compatible with the instructions for use of Hologic Panther Fusion Specimen Lysis Tubes, e.g. 500 μ L liquid specimen into a Panther Fusion Specimen Lysis Tube. Hologic STM is also a component of the Aptima Multitest Swab Specimen Collection Kit (PRD-03546), which requires a swab to be collected directly into a tube containing 2.9mL of STM. Based on data presented in this study, Aptima transport tubes are therefore also likely to inactivate monkeypox virus effectively.

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.

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Summary of revisions

Version 1: New document