

Vaccinia virus (VR-1549) Elstree strain Control Data

EN14476:2013 + A2:2019 Suspension test for the efficacy of XtraProtect, BT-AQA-03FT(2) from Aqua Air against Vaccinia virus VR-1549 under DIRTY conditions												
Controls												
Virus Recovery 0 min		Virus Recovery 2 min		Virus Recovery 15 min		Cytotoxicity		Disinfectant Suppression VS		Disinfectant Suppression VS2		
raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	
4.83	2.15E+06	4.67	1.47E+06	4.83	2.15E+06	1.00	3.16E+02	1.33	6.81E+02	4.33	6.81E+05	
666650	2.15E+06	666640	1.47E+06	666650	2.15E+06	600000	3.16E+02	620000	6.81E+02	666620	6.81E+05	
	6.33		6.17		6.33		2.50		2.83		5.83	
									3.33		0.33	
Formaldehyde reference inactivation controls							No column Control					
Cytotoxicity		Exposure time	0.7% Formaldehyde				2 mins					
raw data	TCID ₅₀ /ml		5 mins		15 mins		raw data	TCID ₅₀ /ml				
2.00	3.16E+03		raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	5.00	3.16E+06				
660000	3.16E+03		3.00	3.16E+04	2.00	3.16E+03	666651	3.16E+06				
	3.50	log	666000	3.16E+04	660000	3.16E+03		6.50				
		log difference		4.50		3.50						
				1.83		2.83						
Interference control		Virus dilution						Stock Virus (TCID ₅₀)				
		-3	-4	-5	-6	-7	-8	6.00				
		1	1	1	1	0.17	0	3.16E+07				
PBS Control		3.16E+02	3.16E+02	3.16E+02	3.16E+02	4.68E+01	3.16E+01	6666660000				
		2.50	2.50	2.50	2.50	1.67	1.50					
Raw Data		6	6	6	6	1	0					
		1	1	1	0.67	0.5	0					
Product		3.16E+02	3.16E+02	3.16E+02	1.48E+02	1.00E+02	3.16E+01					
		2.50	2.50	2.50	2.17	2.00	1.50					
Raw Data		6	6	6	4	3	0					
Log Difference		0.00	0.00	0.00	0.33	-0.33	0.00					
Product Cyt Dilution		-2	-2	-2	-2	-2	-2					
PBS Dilution		Neat	Neat	Neat	Neat	Neat	Neat					

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Parallel Control Test												
Controls						Test Results						
Virus Recovery 0 min		Virus Recovery 2 min		Virus Recovery 15 min		Concentration	1.0% (v/v)		4.0% (v/v)		8.0% (v/v)	
raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	Exposure Time	data	TCID ₅₀ /ml	data	TCID ₅₀ /ml	data	TCID ₅₀ /ml
4.83	2.15E+06	4.67	1.47E+06	4.83	2.15E+06	t = 2 minutes	2.33	6.81E+03	0.00	3.16E+01	1.00	3.16E+02
666650	2.15E+06	666631	1.47E+06	666650	2.15E+06	Raw data	662000	6.81E+03	000000	3.16E+01	600000	3.16E+02
	6.33		6.17		6.33	log		3.83		1.50		2.50
						log difference		2.33		4.67		3.67

CONCLUSION

Verification of the methodology

A test is only valid if the following criteria are fulfilled:

- a) The titre of the test suspension of at least 10^8 TCID₅₀ /ml is sufficiently high to at least enable a titre reduction of 4 lg to verify the method.
- b) Detectable titre reduction is at least 4 log₁₀.
- c) Difference of the logarithmic titre of the virus control minus the logarithmic titre of the test virus in the reference inactivation test is between:
 - Between 0.5 and 2.5 after 30 min and between 2.0 and 4.5 after 60 min for poliovirus
 - Between 3.0 and 5.0 after 30 min and between 3.5 and 5.5 after 60 min for adenovirus
 - Between 1.0 and 3.0 after 30 min and between 2.0 and 4.0 after 60 min for murine norovirus
 - Between 0.0 and 2.0 after 30 min and between 0.5 and 2.5 after 60 min for parvovirus
 - Between 0.75 and 3.5 after 5 min and between 2.0 and 4.0 after 15 min for Vaccinia virus
- d) Cytotoxicity of the product solution does not affect cell morphology and growth or susceptibility for the test virus in the dilutions of the test mixtures which are necessary to demonstrate a 4 log₁₀ reduction of the virus.
- e) The interference control result does not show a difference of < 1.0 log₁₀ of virus titre for test product treated cells in comparison to the non-treated cells.
- e) Neutralisation validation. This is called the disinfectant suppression test in this protocol. The disinfectant was neutralised by column chromatography through an Illustra Microspin S-400 HR column to achieve the best possible neutralisation available for this test. The difference for virus is greater than 0.5 log₁₀ indicating rapid irreversible virucidal activity of the disinfectant by dilution at a concentration of 8.0% v/v for VS1. This neutralisation validation has been verified by VS2, which shows the product has been successfully neutralised.

According to EN 14476:2013 + A2:2019, **XtraProtect POSSESSES VIRUCIDAL** activity at a concentration of **4.0% v/v** as tested after **2 MINUTES** at **20°C** under **DIRTY** conditions (3.0 g/l bovine albumin + 3.0 ml/l erythrocytes) against *Vaccinia virus* VR-1549 Elstree strain / Vero cells.

The cytotoxicity of the product has prevented at 4.0 log reduction being observed at 8.0% v/v.

This product therefore is effective against all enveloped viruses as defined in EN 14476:2013 + A2:2019 Annex A*. This therefore includes all coronaviruses and SARS-CoV-2.

Signed



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DISCLAIMER

The results in this test report only pertain to the sample supplied.

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***EN 14476 2013 + A2 2019 Annex A (informative – Enveloped viruses)**

Poxviridae
Herpesviridae
Filoviridae (e.g. Ebola, Marburg)
Flavivirus
Hepatitis C Virus (HCV)
Hepatitis Delta Virus (HDV)
Influenza Virus
Paramyxoviridae
Rubella Virus
Measles Virus
Rabies Virus
Coronavirus (e.g. SARS, MERS)
Human Immunodeficiency Virus (HIV)
Human T Cell Leukemia Virus (HTLV)
Hepatitis B virus (HBV)

Reference: Van Regenmortel MHV et al.,Eds.: Virus Taxonomy, Classification and Nomenclature of Viruses, seventh report of the international committee on taxonomy of viruses. Academic Press, San Diego, 2000