

Study Title:
Quantitative suspension test for evaluation of virucidal activity in the medical area (Phase 2, Step1)

Product Name: Blulyte Surface Sanitizer

ITA Job No.: ITA 24543

Laboratory Reference No.: J002802

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Period of Analysis: 20/05/2021

Date of Report: 28 May 2021



Scope

The standard method BS EN 14476 describes a test method and the minimum requirements for virucidal activity of a chemical disinfectant and antiseptic products that form a homogenous physically stable preparation when diluted with hard water – or in the case of ready to use products that are not diluted when applied, - with water. Products can only be tested at a concentration of 80% (97% with a modified method for special cases) as some dilution is always produced by adding the test organisms and interfering substances. This European Standard applies to products that are used in the medical area in the fields of hygienic handrub, hygienic handwash, instrument disinfection by immersion, surface disinfection by wiping, spraying, flooding or other means and textile disinfection.

This European standard applies to areas and situations where disinfection is medically indicated. Such indication occurs in patient care, for example: In hospitals, in community medical facilities and in dental institutions or in clinics of schools, of kindergartens and of nursing homes, and may occur in the workplace and in the home. It may also include services such as laundries and kitchens supplying products directly for patients.

Outline of Test Method (Obligatory Test Conditions)

A sample of the test product is diluted in synthetic hard water in products diluted at point of use or water in the case of ready to use products is added to a test suspension of viruses in a solution of interfering substance. The mixture is maintained at one of the temperatures and contact times specified in the standard. At the end of this contact time, an aliquot is taken; the virucidal action in this portion is immediately suppressed by a validated method (dilutions of the sample in ice-cold cell maintenance medium). The dilutions are transferred into cell culture units either using monolayer or cell suspension. Infectivity tests are done either by plaque test or quantal tests. After incubation, the titres of infectivity are calculated according to Spearman and Käber or by plaque counting. Reduction of virus infectivity is calculated from differences of Ig virus titres before (virus control) and after treatment with the product. The standard minimum spectrum of test organisms is Poliovirus, Adenovirus and Murine Norovirus.

Acceptance Criteria

The product when tested as above shall demonstrate at least a 4 log₁₀ reduction against the test virus. The test is deemed valid where all control requirements are met.



Test information		Deviation
Name of Product	Blulyte Surface Sanitizer	/
Batch Number & Expiry Date	N/S	
Date of Delivery	03/03/2021	
Period of Analysis	20/05/2021	
Manufacturer / Supplier	Intertek Deutschland GmbH	
Storage Conditions	Ambient	
Appearance of the Product	Clear liquid	
Neutralisation Method	Dilution	
Product Diluent	Distilled water	
Test Concentrations	500ppm, 300ppm and 200ppm (Prediluted concentrations provided)	
Experimental Conditions	Clean	
Interfering Substance	Clean 0.3g/l Bovine Albumin	
Test Temperature	20°C ± 1°C	
Temperature of Incubation	37°C ±1°C	
Identification of the Viral Strains:	Poliovirus type 1, LSc 2ab Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine norovirus, strain S99 Berlin Porcine Parvovirus, Strain NADL2 (Full spectrum)	1
Contact Times	30 Seconds ± 5s	
Stability and Appearance During Test	No Change Observed (Homogenous)	

Deviations from Standard Method

1 – The product was tested against non standard organism Porcine Parvovirus, therefore reference inactivation controls were not performed due to no acceptance criteria available.

Test Result Summary

The test product received has achieved a 4-log reduction against Poliovirus, Adenovirus, Murine Norovirus and Porcine parvovirus when tested under the condition stipulated in this report.

See page 2 for acceptance criteria and raw data tables below for complete test results.



Summary Poliovirus:

Controls					
Conditions	Concentration	Contact time	log TCID50	log reduction	Control validation
Virus control (water)	N/A	30 seconds	7.42	N/A	Validated
Cytotoxicity (product)	500 ppm	N/A	2.50	N/A	Validated
Product suppression control	500 ppm	N/A	7.75	-0.33	Validated
Reference virus inactivation (formaldehyde)	1.4%	30 minutes	4.92	2.50	Validated
Reference virus inactivation (formaldehyde)	1.4%	60 minutes	4.29	3.13	Validated
Cytotoxicity (formaldehyde)	1.4%	N/A	2.50	N/A	Validated

Interference controls					
Condition	Concentration	Contact time	log TCID50	Log difference	Control validation
Interference control (untreated)	N/A	N/A	8.21	N/A	N/A
Interference control (treated)	500 ppm	N/A	8.00	0.21	Validated

Test Results					
Condition	Concentration	Contact time	log TCID50	log reduction	Pass/Fail
Test product	500 ppm	30 seconds	3.08	>4	Pass
Test product	300 ppm	30 seconds	3.58	3.83	Fail
Test product	200 ppm	30 seconds	3.75	3.67	Fail



Summary Adenovirus :

Controls					
	Concentration	Contact time	log TCID50	log reduction	Control validation
Conditions					
Virus control (water)	N/A	30 seconds	7.67	N/A	Validated
Cytotoxicity (product)	500 ppm	N/A	2.50	N/A	Validated
Product supression control	500 ppm	N/A	7.75	-0.08	Validated
Reference virus inactivation (formaldehyde)	1.4%	30 minutes	3.75	3.92	Validated
Reference virus inactivation (formaldehyde)	1.4%	60 minutes	3.54	4.13	Validated
Cytotoxicity (formaldehyde)	1.4%	N/A	2.50	N/A	Validated

Interference controls					
Condition	Concentration	Contact time	log TCID50	Log difference	Control validation
Interference control (untreated)	N/A	N/A	7.92	N/A	N/A
Interference control (treated)	500 ppm	N/A	7.75	0.17	Validated

Test Results					
Condition	Concentration	Contact time	log TCID50	log reduction	Pass/Fail
Test product	500 ppm	30 seconds	2.50	>4	Pass
Test product	300 ppm	30 seconds	2.50	>4	Pass
Test product	200 ppm	30 seconds	3.83	3.83	Fail



Summary Murine norovirus:

Controls					
Conditions	Concentration	Contact time	log TCID50	log reduction	Control validation
Virus control (water)	N/A	30 seconds	7.33	N/A	Validated
Cytotoxicity (product)	500 ppm	N/A	2.50	N/A	Validated
Product supression control	500 ppm	N/A	7.38	-0.04	Validated
Reference virus inactivation (formaldehyde)	1.4%	30 minutes	4.71	2.63	Validated
Reference virus inactivation (formaldehyde)	1.4%	60 minutes	3.67	3.67	Validated
Cytotoxicity (formaldehyde)	1.4%	N/A	2.50	N/A	Validated

Interference controls					
Condition	Concentration	Contact time	log TCID50	Log difference	Control validation
Interference control (untreated)	N/A	N/A	7.71	N/A	N/A
Interference control (treated)	500 ppm	N/A	7.67	0.04	Validated

Test Results					
Condition	Concentration	Contact time	log TCID50	log reduction	Pass/Fail
Test product	500 ppm	30 seconds	2.50	>4	Pass
Test product	300 ppm	30 seconds	3.38	3.96	Fail
Test product	200 ppm	30 seconds	4.21	3.13	Fail



Summary Porcine Parvovirus:

Controls					
Conditions	Concentration	Contact time	log TCID50	log reduction	Control validation
Virus control (water)	N/A	30 seconds	6.92	N/A	Validated
Cytotoxicity (product)	500 ppm	N/A	2.50	N/A	Validated
Product supression control	500 ppm	N/A	7.08	-0.17	Validated

Interference controls					
Condition	Concentration	Contact time	log TCID50	Log difference	Control validation
Interference control (untreated)	N/A	N/A	7.25	N/A	N/A
Interference control (treated)	500 ppm	N/A	7.25	0.00	Validated

Test Results					
Condition	Concentration	Contact time	log TCID50	log reduction	Pass/Fail
Test product	500 ppm	30 seconds	2.50	>4	Pass
Test product	300 ppm	30 seconds	3.00	3.92	Fail
Test product	200 ppm	30 seconds	3.79	3.13	Fail



Raw data

Virus control (water)				Contact time		30 seconds		% CPE	p(1-p)
Dilution	Counts								
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	4	1	0
-7	3	3	3	3	3	3	3	0.75	0.1875
-8	1	1	1	1	1	0	0	0.16666667	0.138889
-9	0	0	0	0	0	0	0	0	0

Organism <i>Poliovirus type 1</i> Lsc 2ab	
d	1
sum px	1.92
n	8
SD50	-7.42
SE	0.22
xp	-6

Cytotoxicity (product)				Product concentration		500 ppm		% CPE	p(1-p)
Dilution	Counts								
-2	4	4	4	4	4	4	4	1	0
-3	0	0	0	0	0	0	0	0	0
-4	0	0	0	0	0	0	0	0	0
-5	0	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0	0

Organism <i>Poliovirus type 1</i> Lsc 2ab	
d	1
sum px	1.00
n	8
SD50	-2.50
SE	0.00
xp	-2

Product supression control				Product concentration		500 ppm		% CPE	p(1-p)
Dilution	Counts								
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	4	1	0
-7	4	4	4	4	4	4	4	1	0
-8	2	2	1	1	0	0	0	0.25	0.1875
-9	0	0	0	0	0	0	0	0	0

Organism <i>Poliovirus type 1</i> Lsc 2ab	
d	1
sum px	1.25
n	8
SD50	-7.75
SE	0.16
xp	-7

Interference control (untreated)				Product concentration		Neat		% CPE	p(1-p)
Dilution	Counts								
-1	4	4	4	4	4	4	4	1	0
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	4	1	0
-7	4	4	4	4	4	4	4	1	0
-8	3	3	3	2	2	2	2	0.625	0.234375
-9	1	1	0	0	0	0	0	0.08333333	0.076389
-10	0	0	0	0	0	0	0	0	0

Organism <i>Poliovirus type 1</i> Lsc 2ab	
d	1
sum px	1.7083
n	10
SD50	-8.208
SE	0.1858
xp	-7



Raw data

Interference control (treated)			Product concentration				500 ppm	
Dilution	Counts					% CPE	p(1-p)	
-1	4	4	4	4	4	4	1	0
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	1	0
-7	4	4	4	4	4	4	1	0
-8	2	2	2	2	2	2	0.5	0.25
-9	0	0	0	0	0	0	0	0
-10	0	0	0	0	0	0	0	0

Organism <i>Poliovirus type 1</i> Lsc 2ab	
d	1
sum px	1.5
n	10
SD50	-8
SE	0.1667
xp	-7

Reference virus inactivation (formaldehyde)			Contact time				30 minutes	
Dilution	Counts					% CPE	p(1-p)	
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	1	0
-5	2	2	4	1	1	0	0.41666667	0.243056
-6	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0

Organism <i>Poliovirus type 1</i> Lsc 2ab	
d	1
sum px	1.42
n	8
SD50	-4.92
SE	0.19
xp	-4

Reference virus inactivation (formaldehyde)			Contact time				60 minutes	
Dilution	Counts					% CPE	p(1-p)	
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	3	3	3	3	3	3	0.75	0.1875
-5	1	0	0	0	0	0	0.04166667	0.039931
-6	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0

Organism <i>Poliovirus type 1</i> Lsc 2ab	
d	1
sum px	1.79
n	8
SD50	-4.29
SE	0.18
xp	-3

Cytotoxicity (formaldehyde)								
Dilution	Counts					% CPE	p(1-p)	
-2	4	4	4	4	4	4	1	0
-3	0	0	0	0	0	0	0	0
-4	0	0	0	0	0	0	0	0
-5	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0

Organism <i>Poliovirus type 1</i> Lsc 2ab	
d	1
sum px	1.00
n	8
SD50	-2.50
SE	0.00
xp	-2



Raw data

Test product		Product concentration				500 ppm	Contact time		30 seconds	
Dilution	Counts						% CPE	p(1-p)		
-2	4	4	4	4	4	4	4	1	0	
-3	2	2	2	2	2	2	2	0.5	0.25	
-4	1	1	0	0	0	0	0	0.08333333	0.076389	
-5	0	0	0	0	0	0	0	0	0	
-6	0	0	0	0	0	0	0	0	0	
-7	0	0	0	0	0	0	0	0	0	
-8	0	0	0	0	0	0	0	0	0	
-9	0	0	0	0	0	0	0	0	0	

Organism <i>Poliovirus type 1</i> Lsc 2ab	
d	1
sum px	1.58
n	8
SD50	-3.08
SE	0.22
xp	-2

Test product		Product concentration				300 ppm	Contact time		30 seconds	
Dilution	Counts						% CPE	p(1-p)		
-2	4	4	4	4	4	4	4	1	0	
-3	4	4	4	4	4	4	4	1	0	
-4	1	1	0	0	0	0	0	0.08333333	0.076389	
-5	0	0	0	0	0	0	0	0	0	
-6	0	0	0	0	0	0	0	0	0	
-7	0	0	0	0	0	0	0	0	0	
-8	0	0	0	0	0	0	0	0	0	
-9	0	0	0	0	0	0	0	0	0	

Organism <i>Poliovirus type 1</i> Lsc 2ab	
d	1
sum px	1.08
n	8
SD50	-3.58
SE	0.10
xp	-3

Test product		Product concentration				200 ppm	Contact time		30 seconds	
Dilution	Counts						% CPE	p(1-p)		
-2	4	4	4	4	4	4	4	1	0	
-3	4	4	4	4	4	4	4	1	0	
-4	1	1	1	2	1	0	0.25	0.1875		
-5	0	0	0	0	0	0	0	0	0	
-6	0	0	0	0	0	0	0	0	0	
-7	0	0	0	0	0	0	0	0	0	
-8	0	0	0	0	0	0	0	0	0	
-9	0	0	0	0	0	0	0	0	0	

Organism <i>Poliovirus type 1</i> Lsc 2ab	
d	1
sum px	1.25
n	8
SD50	-3.75
SE	0.16
xp	-3



Raw data

Virus control (water)				Contact time		30 seconds			
Dilution	Counts						% CPE	p(1-p)	
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	4	1	0
-7	4	4	4	4	4	4	4	1	0
-8	1	1	1	1	0	0	0.16666667	0.138889	
-9	0	0	0	0	0	0	0	0	0

Organism <i>Adenovirus type 5</i> Adenoid 75, ATCC VR-5	
d	1
sum px	1.17
n	8
SD50	-7.67
SE	0.14
xp	-7

Cytotoxicity (product)				Product concentration		500 ppm			
Dilution	Counts						% CPE	p(1-p)	
-2	4	4	4	4	4	4	4	1	0
-3	0	0	0	0	0	0	0	0	0
-4	0	0	0	0	0	0	0	0	0
-5	0	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0	0

Organism <i>Adenovirus type 5</i> Adenoid 75, ATCC VR-5	
d	1
sum px	1.00
n	8
SD50	-2.50
SE	0.00
xp	-2

Product supression control				Product concentration		500 ppm			
Dilution	Counts						% CPE	p(1-p)	
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	4	1	0
-7	4	4	4	4	4	4	4	1	0
-8	2	2	1	1	0	0	0.25	0.1875	
-9	0	0	0	0	0	0	0	0	0

Organism <i>Adenovirus type 5</i> Adenoid 75, ATCC VR-5	
d	1
sum px	1.25
n	8
SD50	-7.75
SE	0.16
xp	-7

Interference control (untreated)				Product concentration		Neat			
Dilution	Counts						% CPE	p(1-p)	
-1	4	4	4	4	4	4	4	1	0
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	4	1	0
-7	4	4	4	4	4	4	4	1	0
-8	3	2	2	1	1	1	0.41666667	0.243056	
-9	0	0	0	0	0	0	0	0	0
-10	0	0	0	0	0	0	0	0	0

Organism <i>Adenovirus type 5</i> Adenoid 75, ATCC VR-5	
d	1
sum px	1.4167
n	10
SD50	-7.917
SE	0.1643
xp	-7



Raw data

Interference control (treated)				Product concentration			500 ppm		
Dilution	Counts						% CPE	p(1-p)	
-1	4	4	4	4	4	4	4	1	0
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	4	1	0
-7	4	4	4	4	4	4	4	1	0
-8	4	1	1	0	0	0	0	0.25	0.1875
-9	0	0	0	0	0	0	0	0	0
-10	0	0	0	0	0	0	0	0	0

Organism <i>Adenovirus type 5</i> Adenoid 75, ATCC VR-5	
d	1
sum px	1.25
n	10
SD50	-7.75
SE	0.1443
xp	-7

Reference virus inactivation (formaldehyde)				Contact time			30 minutes		
Dilution	Counts						% CPE	p(1-p)	
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	1	1	1	1	2	0	0.25	0.1875	
-5	0	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0	0

Organism <i>Adenovirus type 5</i> Adenoid 75, ATCC VR-5	
d	1
sum px	1.25
n	8
SD50	-3.75
SE	0.16
xp	-3

Reference virus inactivation (formaldehyde)				Contact time			60 minutes		
Dilution	Counts						% CPE	p(1-p)	
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	1	0	0	0	0	0	0	0.04166667	0.039931
-5	0	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0	0

Organism <i>Adenovirus type 5</i> Adenoid 75, ATCC VR-5	
d	1
sum px	1.04
n	8
SD50	-3.54
SE	0.08
xp	-3

Cytotoxicity (formaldehyde)									
Dilution	Counts						% CPE	p(1-p)	
-2	4	4	4	4	4	4	4	1	0
-3	0	0	0	0	0	0	0	0	0
-4	0	0	0	0	0	0	0	0	0
-5	0	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0	0

Organism <i>Adenovirus type 5</i> Adenoid 75, ATCC VR-5	
d	1
sum px	1.00
n	8
SD50	-2.50
SE	0.00
xp	-2



Raw data

Test product		Product concentration				500 ppm	Contact time		30 seconds	
Dilution	Counts						% CPE	p(1-p)		
-2	4	4	4	4	4	4	4	1	0	
-3	0	0	0	0	0	0	0	0	0	
-4	0	0	0	0	0	0	0	0	0	
-5	0	0	0	0	0	0	0	0	0	
-6	0	0	0	0	0	0	0	0	0	
-7	0	0	0	0	0	0	0	0	0	
-8	0	0	0	0	0	0	0	0	0	
-9	0	0	0	0	0	0	0	0	0	

Organism <i>Adenovirus type 5</i> Adenoid 75, ATCC VR-5	
d	1
sum px	1.00
n	8
SD50	-2.50
SE	0.00
xp	-2

Test product		Product concentration				300 ppm	Contact time		30 seconds	
Dilution	Counts						% CPE	p(1-p)		
-2	4	4	4	4	4	4	4	1	0	
-3	0	0	0	0	0	0	0	0	0	
-4	0	0	0	0	0	0	0	0	0	
-5	0	0	0	0	0	0	0	0	0	
-6	0	0	0	0	0	0	0	0	0	
-7	0	0	0	0	0	0	0	0	0	
-8	0	0	0	0	0	0	0	0	0	
-9	0	0	0	0	0	0	0	0	0	

Organism <i>Adenovirus type 5</i> Adenoid 75, ATCC VR-5	
d	1
sum px	1.00
n	8
SD50	-2.50
SE	0.00
xp	-2

Test product		Product concentration				200 ppm	Contact time		30 seconds	
Dilution	Counts						% CPE	p(1-p)		
-2	4	4	4	4	4	4	4	1	0	
-3	4	4	4	4	4	4	4	1	0	
-4	2	2	2	2	2	0	0.33333333	0.222222		
-5	0	0	0	0	0	0	0	0	0	
-6	0	0	0	0	0	0	0	0	0	
-7	0	0	0	0	0	0	0	0	0	
-8	0	0	0	0	0	0	0	0	0	
-9	0	0	0	0	0	0	0	0	0	

Organism <i>Adenovirus type 5</i> Adenoid 75, ATCC VR-5	
d	1
sum px	1.33
n	8
SD50	-3.83
SE	0.18
xp	-3



Raw data

Virus control (water)				Contact time		30 seconds			
Dilution	Counts						% CPE	p(1-p)	
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	4	1	0
-7	3	3	3	3	3	3	3	0.75	0.1875
-8	1	1	0	0	0	0	0	0.08333333	0.076389
-9	0	0	0	0	0	0	0	0	0

Organism <i>Murine norovirus</i> S99 Berlin	
d	1
sum px	1.83
n	8
SD50	-7.33
SE	0.19
xp	-6

Cytotoxicity (product)				Product concentration		500 ppm			
Dilution	Counts						% CPE	p(1-p)	
-2	4	4	4	4	4	4	4	1	0
-3	0	0	0	0	0	0	0	0	0
-4	0	0	0	0	0	0	0	0	0
-5	0	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0	0

Organism <i>Murine norovirus</i> S99 Berlin	
d	1
sum px	1.00
n	8
SD50	-2.50
SE	0.00
xp	-2

Product supression control				Product concentration		500 ppm			
Dilution	Counts						% CPE	p(1-p)	
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	4	1	0
-7	3	3	3	3	3	3	3	0.75	0.1875
-8	2	1	0	0	0	0	0	0.125	0.109375
-9	0	0	0	0	0	0	0	0	0

Organism <i>Murine norovirus</i> S99 Berlin	
d	1
sum px	1.88
n	8
SD50	-7.38
SE	0.21
xp	-6

Interference control (untreated)				Product concentration		Neat			
Dilution	Counts						% CPE	p(1-p)	
-1	4	4	4	4	4	4	4	1	0
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	4	1	0
-7	4	4	4	4	4	4	4	1	0
-8	4	1	0	0	0	0	0	0.20833333	0.164931
-9	0	0	0	0	0	0	0	0	0
-10	0	0	0	0	0	0	0	0	0

Organism <i>Murine norovirus</i> S99 Berlin	
d	1
sum px	1.2083
n	10
SD50	-7.708
SE	0.1354
xp	-7



Raw data

Interference control (treated)				Product concentration			500 ppm		
Dilution	Counts						% CPE	p(1-p)	
-1	4	4	4	4	4	4	4	1	0
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	4	1	0
-7	4	4	4	4	4	4	4	1	0
-8	2	2	0	0	0	0	0	0.16666667	0.138889
-9	0	0	0	0	0	0	0	0	0

Organism <i>Murine norovirus</i> S99 Berlin	
d	1
sum px	1.1667
n	10
SD50	-7.667
SE	0.1242
xp	-7

Reference virus inactivation (formaldehyde)				Contact time			30 minutes		
Dilution	Counts						% CPE	p(1-p)	
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	1	1	1	1	1	1	0	0.20833333	0.164931
-6	0	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0	0

Organism <i>Murine norovirus</i> S99 Berlin	
d	1
sum px	1.21
n	8
SD50	-4.71
SE	0.15
xp	-4

Reference virus inactivation (formaldehyde)				Contact time			60 minutes		
Dilution	Counts						% CPE	p(1-p)	
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	2	1	1	0	0	0	0	0.16666667	0.138889
-5	0	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0	0

Organism <i>Murine norovirus</i> S99 Berlin	
d	1
sum px	1.17
n	8
SD50	-3.67
SE	0.14
xp	-3

Cytotoxicity (formaldehyde)									
Dilution	Counts						% CPE	p(1-p)	
-2	4	4	4	4	4	4	4	1	0
-3	0	0	0	0	0	0	0	0	0
-4	0	0	0	0	0	0	0	0	0
-5	0	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0	0

Organism <i>Murine norovirus</i> S99 Berlin	
d	1
sum px	1.00
n	8
SD50	-2.50
SE	0.00
xp	-2



Raw data

Test product		Product concentration				500 ppm	Contact time		30 seconds	
Dilution	Counts						% CPE	p(1-p)		
-2	4	4	4	4	4	4	4	1	0	
-3	0	0	0	0	0	0	0	0	0	
-4	0	0	0	0	0	0	0	0	0	
-5	0	0	0	0	0	0	0	0	0	
-6	0	0	0	0	0	0	0	0	0	
-7	0	0	0	0	0	0	0	0	0	
-8	0	0	0	0	0	0	0	0	0	
-9	0	0	0	0	0	0	0	0	0	

Organism <i>Murine norovirus</i> S99 Berlin	
d	1
sum px	1.00
n	8
SD50	-2.50
SE	0.00
xp	-2

Test product		Product concentration				300 ppm	Contact time		30 seconds	
Dilution	Counts						% CPE	p(1-p)		
-2	4	4	4	4	4	4	4	1	0	
-3	4	4	4	3	3	3	0.875	0.109375		
-4	0	0	0	0	0	0	0	0	0	
-5	0	0	0	0	0	0	0	0	0	
-6	0	0	0	0	0	0	0	0	0	
-7	0	0	0	0	0	0	0	0	0	
-8	0	0	0	0	0	0	0	0	0	
-9	0	0	0	0	0	0	0	0	0	

Organism <i>Murine norovirus</i> S99 Berlin	
d	1
sum px	1.88
n	8
SD50	-3.38
SE	0.13
xp	-2

Test product		Product concentration				200 ppm	Contact time		30 seconds	
Dilution	Counts						% CPE	p(1-p)		
-2	4	4	4	4	4	4	4	1	0	
-3	4	4	4	4	4	4	4	1	0	
-4	3	3	2	2	2	2	0.625	0.234375		
-5	1	1	0	0	0	0	0.08333333	0.076389		
-6	0	0	0	0	0	0	0	0	0	
-7	0	0	0	0	0	0	0	0	0	
-8	0	0	0	0	0	0	0	0	0	
-9	0	0	0	0	0	0	0	0	0	

Organism <i>Murine norovirus</i> S99 Berlin	
d	1
sum px	1.71
n	8
SD50	-4.21
SE	0.21
xp	-3



Raw data

Virus control (water)				Contact time			30 seconds		% CPE	p(1-p)
Dilution	Counts									
-2	4	4	4	4	4	4	4	1	0	
-3	4	4	4	4	4	4	4	1	0	
-4	4	4	4	4	4	4	4	1	0	
-5	4	4	4	4	4	4	4	1	0	
-6	4	4	4	4	4	4	4	1	0	
-7	2	1	2	2	2	2	1	0.41666667	0.243056	
-8	0	0	0	0	0	0	0	0	0	
-9	0	0	0	0	0	0	0	0	0	

Organism <i>Porcine parvovirus</i> Strain NADL2	
d	1
sum px	1.42
n	8
SD50	-6.92
SE	0.19
xp	-6

Cytotoxicity (product)				Product concentration			500 ppm		% CPE	p(1-p)
Dilution	Counts									
-2	4	4	4	4	4	4	4	1	0	
-3	0	0	0	0	0	0	0	0	0	
-4	0	0	0	0	0	0	0	0	0	
-5	0	0	0	0	0	0	0	0	0	
-6	0	0	0	0	0	0	0	0	0	
-7	0	0	0	0	0	0	0	0	0	
-8	0	0	0	0	0	0	0	0	0	
-9	0	0	0	0	0	0	0	0	0	

Organism <i>Porcine parvovirus</i> Strain NADL2	
d	1
sum px	1.00
n	8
SD50	-2.50
SE	0.00
xp	-2

Product supression control				Product concentration			500 ppm		% CPE	p(1-p)
Dilution	Counts									
-2	4	4	4	4	4	4	4	1	0	
-3	4	4	4	4	4	4	4	1	0	
-4	4	4	4	4	4	4	4	1	0	
-5	4	4	4	4	4	4	4	1	0	
-6	4	4	4	4	4	4	4	1	0	
-7	2	2	2	2	2	2	2	0.5	0.25	
-8	1	1	0	0	0	0	0	0.08333333	0.076389	
-9	0	0	0	0	0	0	0	0	0	

Organism <i>Porcine parvovirus</i> Strain NADL2	
d	1
sum px	1.58
n	8
SD50	-7.08
SE	0.22
xp	-6

Interference control (untreated)				Product concentration			Neat		% CPE	p(1-p)
Dilution	Counts									
-1	4	4	4	4	4	4	4	1	0	
-2	4	4	4	4	4	4	4	1	0	
-3	4	4	4	4	4	4	4	1	0	
-4	4	4	4	4	4	4	4	1	0	
-5	4	4	4	4	4	4	4	1	0	
-6	4	4	4	4	4	4	4	1	0	
-7	3	3	3	3	3	3	3	0.75	0.1875	
-8	0	0	0	0	0	0	0	0	0	
-9	0	0	0	0	0	0	0	0	0	
-10	0	0	0	0	0	0	0	0	0	

Organism <i>Porcine parvovirus</i> Strain NADL2	
d	1
sum px	1.75
n	10
SD50	-7.25
SE	0.1443
xp	-6



Raw data

Interference control (treated)		Product concentration					500 ppm	
Dilution	Counts						% CPE	p(1-p)
-1	4	4	4	4	4	4	1	0
-2	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	1	0
-7	2	2	4	4	2	2	0.66666667	0.222222
-8	1	1	0	0	0	0	0.08333333	0.076389
-9	0	0	0	0	0	0	0	0
-10	0	0	0	0	0	0	0	0

Organism <i>Porcine parvovirus</i> Strain NADL2	
d	1
sum px	1.75
n	10
SD50	-7.25
SE	0.1822
xp	-6

Test product		Product concentration					500 ppm		Contact time	30 seconds
Dilution	Counts						% CPE	p(1-p)		
-2	4	4	4	4	4	4	1	0		
-3	0	0	0	0	0	0	0	0		
-4	0	0	0	0	0	0	0	0		
-5	0	0	0	0	0	0	0	0		
-6	0	0	0	0	0	0	0	0		
-7	0	0	0	0	0	0	0	0		
-8	0	0	0	0	0	0	0	0		
-9	0	0	0	0	0	0	0	0		

Organism <i>Porcine parvovirus</i> Strain NADL2	
d	1
sum px	1.00
n	8
SD50	-2.50
SE	0.00
xp	-2

Test product		Product concentration					300 ppm		Contact time	30 seconds
Dilution	Counts						% CPE	p(1-p)		
-2	4	4	4	4	4	4	1	0		
-3	2	2	2	2	2	2	0.5	0.25		
-4	0	0	0	0	0	0	0	0		
-5	0	0	0	0	0	0	0	0		
-6	0	0	0	0	0	0	0	0		
-7	0	0	0	0	0	0	0	0		
-8	0	0	0	0	0	0	0	0		
-9	0	0	0	0	0	0	0	0		

Organism <i>Porcine parvovirus</i> Strain NADL2	
d	1
sum px	1.50
n	8
SD50	-3.00
SE	0.19
xp	-2

Test product		Product concentration					200 ppm		Contact time	30 seconds
Dilution	Counts						% CPE	p(1-p)		
-2	4	4	4	4	4	4	1	0		
-3	4	4	4	4	4	4	1	0		
-4	1	1	1	2	2	0	0.29166667	0.206597		
-5	0	0	0	0	0	0	0	0		
-6	0	0	0	0	0	0	0	0		
-7	0	0	0	0	0	0	0	0		
-8	0	0	0	0	0	0	0	0		
-9	0	0	0	0	0	0	0	0		

Organism <i>Porcine parvovirus</i> Strain NADL2	
d	1
sum px	1.29
n	8
SD50	-3.79
SE	0.17
xp	-3



KEY

CPE	Cytopathic effect		
Counts	0-4 indicating degree of cytopathic effect		
	0 = No effect, 1 = 25% CPE, 2 = 50% CPE, 3 = 75% CPE, 4 = 100% CPE		
d	Dilution factor (log)		
Sum px	Sum of % CPE from the highest dilution showing 100% CPE to the lowest dilution assessed.		
n	Number of dilutions		
SD50	Dilution showing 50% of the end point according to Spearman-Kärber method		
SE	Standard error		
xp	Lowest dilution showing 100% CPE		
TCID50	Titre causing 50% of the end point according to Spearman-Kärber		
PASS	=	lg R greater than or equal to 4	
FAIL	=	lg R less than 4	
>	greater than		≥ equal to or greater than
<	less than		≤ equal to or less than

Calculation notes

In cases where the highest dilution assessed has not shown 100% CPE, the value has been calculated assuming the dilution above this would give 100% CPE and the corresponding value has been assigned as <x.

The standard requires the product suppression control to show a <0.5 log reduction in viral titre. In cases where the product has failed to achieve the required 4 log reduction, but the product suppression control shows a >0.5 log reduction the result has been deemed as valid for fail as the consequence of inadequate suppression would be a partially extended contact time which would generate false positives, but not false negatives.

A similar approach has been taken in regards to the cytotoxicity controls. The standard requires a 4-log difference between the cytotoxicity level and the viral titre. In cases where this is not obtained, but the log reduction observed by the product is within the difference between the cytotoxicity levels and the viral titre the result is deemed acceptable for a fail as there will be no impact on the determination of efficacy.

Reviewed by



Chris Brennan
Director
Intertek, Health Environmental & Regulatory Services
28th May 2021

Tests have been sub-contracted to an agent approved by Intertek.

END OF REPORT

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