Assessing the efficacy of high level chemical disinfectant / sterilant

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TOTACIDE 28
COLD
STERILISER
4 litre 7·04 pints
ASEP
idex.

CONSIDERATIONS WHEN CHOOSING A DISINFECTANT

Range of activity

Rate of kill at use dilution

Toxicity, irritancy, sensitization

Compatibility

Inactivation by organic matter

Stability

Cost

MANUFACTURERS CLAIMS

99.9%

"Stay back, you guys! This stuff has killed 99.99% of our fellow germs!"

99.99%

BUT WHAT DOES THIS MEAN?

90%	1 Log_{10} reduction
99%	2 Log_{10} reduction
99.9%	3 Log_{10} reduction
99.99%	4 Log_{10} reduction
99.999%	5 Log_{10} reduction
99.9999%	6 Log_{10} reduction

Log Reductions

Log reduction	% reduction	Number left from 1,000,000
0	0.00	1,000,000
1	90	100,000
2	99	10,000
3	99.9	1,000
4	99.99	100
5	99.999	10
6	99.9999	1

FIRST UK STANDARDISED TEST

1903 Samuel Rideal & JT Ainslie Walker

“Phenol co-efficient” establishing the lowest concentration of phenol and of disinfectant capable of killing Salmonella typhi.

Concentration found for disinfectant was divided by the concentration found for phenol. The co-efficient obtained indicated if the disinfectant was more or less effective than phenol.

1908 Chick & Martin modified this test to introduce yeast as an organic load.

KELSEY – SYKES TEST (1965)

Capacity test designed to assess the ability of the disinfectant to remain active during the addition of successive microbial loads.

Pseudomonas aeruginosa used as the test strain.

Performed under clean (no organic load) and dirty conditions (presence of yeast).

WHY STANDARDS FOR DISINFECTANT TESTING

To ensure minimum quality

CE marking/BPR

- Necessary before placing a product on the market in EU

How does a company and/or user validate a claim?

- Bactericidal, virucidal, sporicidal
- tuberculocidal/mycobactericidal,

WHO ARE CEN

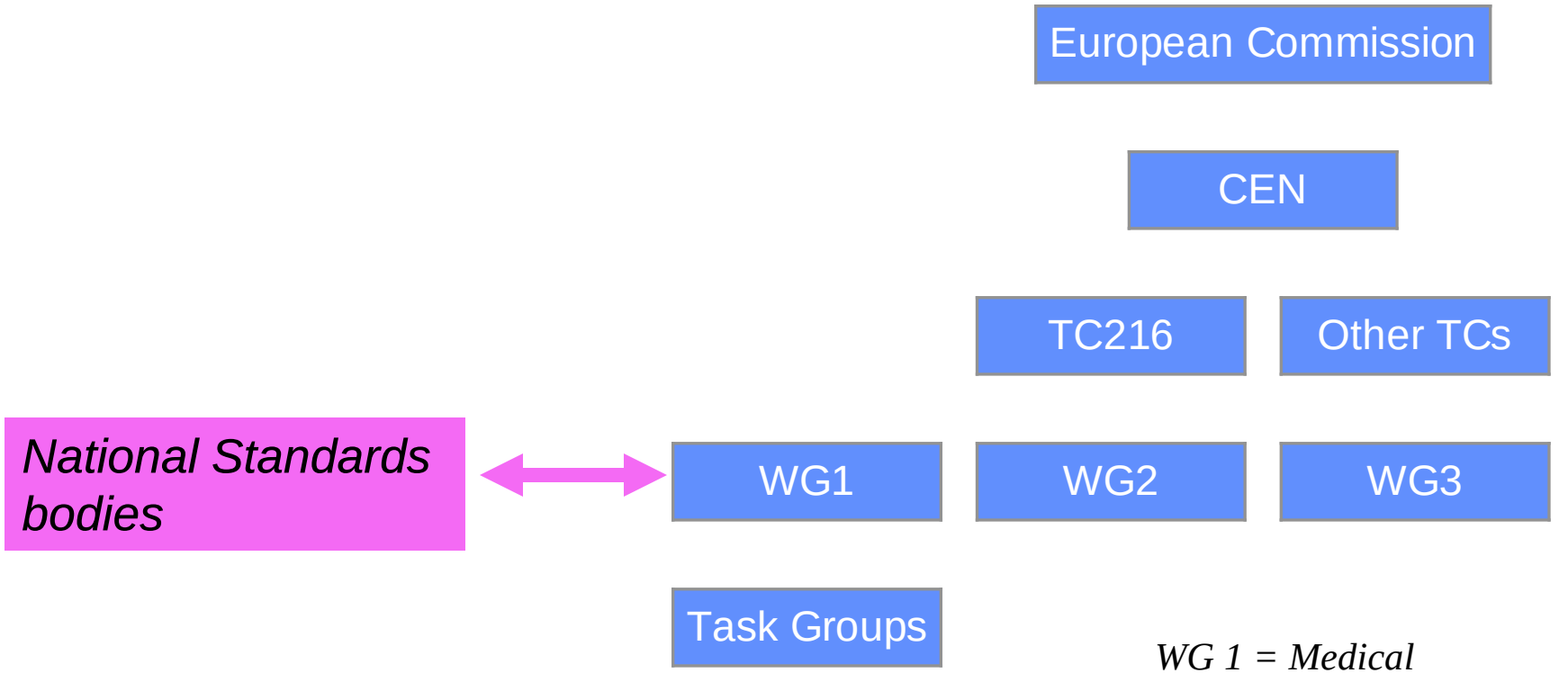
CEN Management Centre (Brussels)

a system of formal processes to produce standards

28 National Members (standards bodies e.g. BSI, DIN, AFNOR)

works closely with CENELEC and ISO

CEN COMMITTEES - STRUCTURE



WG 1 = Medical
WG 2 = Veterinary
WG3 = Food, domestic etc

PROGRESS OF A NEW STANDARD

Draft standard drawn up by WG

Approved by TC (prEN)

Public comment

- “Enquiry”
- Comment by National Standards bodies (after consultation)

Redrafting

Formal vote ➔ publication as EN

NEW STANDARDS – NATIONAL ADOPTION

EN published by CEN

Adopted by national bodies

- BSI, DIN, AFNOR

Published as British Standard

- e.g. EN 1499 becomes BS EN 1499

Test Methods must be:

Reproducible

Repeatable

Standardized

Simulate practical conditions

Easy to perform

Test Report

Should include

- Objective
- Product details – concentration tested etc.
- Test method
  - Organic load
  - Contact times
  - Test temperature
- Validation testing
- Results
- Conclusion
- Test requirement

DISINFECTANT TESTING : VARIABLES

Test organisms

Test requirements

Inoculum

Organic load

Neutralization

TEST ORGANISMS

Varied

- Pseudomonas, Staph, E. coli, Enterococcus
- Mycobacterium terrae
- Viruses – enveloped and non-enveloped
- Spores – Bacillus, Clostridium
- Chosen according to likely pathogens in area of application

Surrogates used in testing

Organism	Category	Pathogen	Comments
S. aureus	Gram-positive coccus	Yes	Frequently used surrogate for testing microbicides against vegetative bacteria. Survives well on drying of inocula on carriers
Acinetobacter baumannii	Gram-negative bacillus	Yes	Higher intrinsic resistance to microbicides than other gram negatives, also withstands drying well. Increasingly important as a pathogen
Candida albicans	Nonfilamentous or yeast-like fungus	Yes	An opportunistic nosocomial pathogen. Widely used as a surrogate for testing ESD and topicals against nonfilamentous fungi
Aspergillus niger	Filamentous fungus	Yes	Aspergillus and other species of filamentous fungi are emerging pathogens. Conidia of A niger are used in testing against filamentous fungi

Surrogates used in testing

Organism	Category	Pathogen	Comments
Mycobacterium terrae	Environmental mycobacterium	Rarely	Several species of nontuberculous or environmental mycobacteria are increasingly being incriminated in HCAI. Mycobacteria have higher resistance to ESD
Bacillus subtilis	Aerobic spore former	No	Commonly used surrogate to test chemicals against aerobic spore-forming bacteria
Clostridium difficile	Anaerobic spore former	Yes	Significant nosocomial pathogen. EPA now requires ESD to be tested against nontoxigenic strains for label claims of sporicidal activity
Feline calicivirus	Small, nonenveloped virus	No	Safe and relatively easy to culture and assay for infectivity in vitro; withstands drying well, also shows relatively high resistance to ESD; good surrogate for viral pathogens including noroviruses

Inoculum

5 $\log_{10}$ reductions required if possible

May not be possible as initial inoculum must be high enough to show this level of reduction

- Virucidal
- Tuberculocidal

CONTACT TIME

Tests, including accepted standards, can have unrealistically long exposures

- Remember: disinfectants will only work when wet

Example: EN 13704 – the European sporicide test has a test time of 60 minutes

- Additional, shorter times can also be used

Look for exposure times that are relevant for your use situation(s)

Temperature

Check the temperature of the test – must be relevant to the setting

Should normally be room temperature (around 20^{o}C)

Tests described for the veterinary area use 4^{o}C

Organic matter

Some non-standard tests are done without organic matter. How does this simulate real life use?

Standard tests have standard clean & dirty conditions (usually 0.3% and 3% protein)

Organic Load

Clean conditions

- 0.03% BSA (final concentration)
  - BSA = Bovine Serum Albumin @ 0.3g/l

Dirty conditions

- 0.3% BSA (final concentration) (3g/l) plus:
- Early standards
  - Yeast
- Later standards
  - Sheep blood

Neutralization

Very important step

Essential to stop the activity of the test product at the time of sampling

All neutralizers should have demonstrated efficacy for the particular experimental conditions (disinfectant, concentration etc.) in use and that they are non-toxic to the test organism(s)

Neutralizers

Variety of agents suggested

- Lecithin/tween/thiosulphate/saponin
- Tween/lecithin/sodium lauryl sulphate
- Histidine/cysteine
- Thioglycollate
- Catalase
- Etc

Must be validated for neutralization ability and non-toxicity to the test organism

EN Disinfectant Testing

Phase 1

Suspension test for the basic activity of the product (EN 1040)

Phase 2/step 1

Suspension test under conditions representative of practical use

Phase 2/step 2

Other laboratory tests e.g. handwash/rub and surface tests simulating practical conditions

Phase 3

Field tests under practical conditions

PHASE 1 TESTS

EN1040 –

- Basic bactericidal activity
- Suspension test
- Ps. aeruginosa + S. aureus
- Exposure followed by neutralization
- 5 log reduction to pass

EN 1275 (fungicidal activity)

EN 14347 (sporicidal activity)

EN 14885 (2015)

Chemical disinfectants and antiseptics – application of European Standards for chemical disinfectants and antiseptics

Three areas of use –

- Medical
- Veterinary
- Food, industrial, domestic and institutional

EN 14885 (2015)

4.2.6 Where in EN 14885 no standard exists for a specific activity in an area (e.g. medical), a standard from another area (e.g. veterinary) may be used and test conditions modified for relevance to the area of application to match the specific application

In certain cases it may be necessary or recommendable to modify even the test organism(s) to match the requirements of the area

- These choices shall be scientifically justified taking into account the field of application and the intended use of the product
- In the test report the European Standard shall be referenced as modified; details of and the reasons for the modification shall be reported and highlighted
- Conformity to the standard used shall not be claimed, but it should be stated that the product was tested in accordance with the standard

Table 1 — Medical area – Standard test methods to be used to substantiate claims for products

Type of activity	Phase step	Product Claim / Field of Application							
		Hygienic Handrub	Hygienic Handwash	Surgical Handrub or -wash	Surface Disinfection		Instrument Disinfection	Textile Disinfection	Water Treatment for Control of Legionella
					mechanical action				
					without	with			
Bacteri-cidal	2,1	EN 13727 (handrub products under clean, handwash products under dirty conditions)			EN 13727		EN 13727	EN 13727	***
	2,2	EN 1500	EN 1499	EN 12791	EN 13697 [a]	*	EN 14561	*	***
Yeasticidal	2,1	EN 13624 (handrub products under clean, handwash products under dirty conditions)			EN 13624		EN 13624	EN 13624	***
	2,2	***			EN 13697 [a]	*	EN 14562	*	***
Fungicidal	2,1	***			EN 13624		EN 13624	EN 13624	***
	2,2	***			EN 13697 [a]	**	EN 14562	*	***

Type of activity	Phase step	Product Claim / Field of Application							
		Hygienic Handrub	Hygienic Handwash	Surgical Handrub or -wash	Surface Disinfection		Instrument Disinfection	Textile Disinfection	Water Treatment for Control of Legionella
					mechanical action				
					without	with			
Tuber culocidal	2,1	EN 14348	EN 14348	***	EN 14348		EN 14348	EN 14348	***
	2,2	***			**	**	EN 14563	*	***
Myco-bacteri-cidal	2,1	EN 14348	EN 14348	***	EN 14348		EN 14348	EN 14348	***
	2,2	***			**	**	EN 14563	*	***
Virucidal	2,1	EN 14476	EN 14476	***	EN 14476		EN 14476	EN 14476	***
	2,2	**	**	***	*		**	*	***
Sporicidal aerobic	2,1	***			*		*	**	***
	2,2	***			*	**	**	***	***
Sporicidal anaerobic	2,1	***			*		*	**	***
	2,2	***			*	**	**	***	***
Legionella	2,1	***			***		***	***	EN 13623

[a] See 4.3.2.6.

* Work item approved.

** No work item yet approved but relevant standards may become available in the future

*** No intention to develop a test.

EN 13727 (2013)

- Phase 2/step 1
- Ps. aeruginosa, E. hirae, S. aureus
- Interfering substances
  - 0.03% BSA (clean)
  - 0.3% BSA + 0.3% erythrocytes (dirty)
- Neutralizer
- 5 $\log_{10}$ reduction required

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time	Interfering substances	Reduction (lg)
EN 13727 2,1	Hygienic handwash and handrub				
	Staphylococcus aureus ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* K12 NCTC 10538 *Enterococcus hirae* ATCC 10541	at 20 °C	between 30 s and 1 min	Clean conditions (handrub): bovine albumin: 0,3 g/L Dirty conditions (handwash): bovine albumin: 3,0 g/L plus sheep erythrocytes: 3 ml/l	≥ 5,0 for handrub products ≥ 3,0 for handwash products
	Surgical handwash and handrub				
	Staphylococcus aureus ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* K12 NCTC 10538 *Enterococcus hirae* ATCC 10541	at 20 °C	between 1 min and 5 min	Clean conditions (handrub): bovine albumin: 0,3 g/L Dirty conditions (handwash): bovine albumin: 3,0 g/L plus sheep erythrocytes: 3 ml/l	≥ 5,0
	Instrument disinfection				
	Staphylococcus aureus ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Enterococcus hirae* ATCC 10541 When temperature is 40 °C or higher: only *Enterococcus faecium* ATCC 6057	between 20 °C and 70 °C	no longer than 60 min	Clean conditions bovine albumin: 0,3 g/L Dirty conditions bovine albumin: 3,0 g/L plus sheep erythrocytes: 3 ml/l	≥ 5,0
	Surface disinfection				
	Staphylococcus aureus ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Enterococcus hirae* ATCC 10541	between 4 °C and 30 °C	no longer than 5 min (for surfaces in contact with patient or medical staff **or** no longer than 60 min (for other surfaces)	Clean conditions bovine albumin: 0,3 g/L Dirty conditions bovine albumin: 3,0 g/L plus sheep erythrocytes: 3 ml/l	≥ 5,0
	Additional conditions (all uses)				
	any relevant test organism	-	-	any relevant interfering substance	-

EN 14476

- Phase 2 / step 1 test
  - Virucidal quantitative suspension test
  - Poliovirus
  - Adenovirus
- Interfering substances
  - 0.03% BSA or PBS (clean)
  - 0.3% BSA + 0.3% erythrocytes (dirty)
- Neutralizer
- 4 log reduction required (0.5, 1, 5 or 60 min)

Table 1c — Medical area – Test conditions and requirements of standard test methods to be used to substantiate claims for virucidal activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time	Interfering substances	Reduction (lg)
EN 14476 2,1	Hygienic handrub and handwash				
	Poliovirus type 1, LSc-2ab (Picornavirus) *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 *Murine Norovirus*, strain S99 Berlin **Limited spectrum virucidal activity:** *Adenovirus*, strain Adenoid 75, ATCC VR-5 *Murine Norovirus*, strain S99 Berlin	at 20 °C	between 30 s and 2 min	Clean conditions (handrub): bovine albumin 0,3 g/L Dirty conditions (handwash): bovine albumin 3,0 g/L + sheep erythrocytes 3 ml/l	≥ 4,0
	Instrument disinfection				
	Poliovirus type 1, LSc-2ab (Picornavirus) *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 *Murine Norovirus*, strain S99 Berlin **when Temperature is 40°C or higher, only** *Murine Parvovirus*, minute virus of mice, strain Crawford, ATCC VR-1346	between 20 °C and 70 °C	no longer than 60 min	Clean conditions: bovine albumin 0,3 g/L and/or Dirty conditions: bovine albumin 3,0 g/L + sheep erythrocytes 3 ml/l	≥ 4,0
	Surface disinfection				
	Poliovirus type 1, LSc-2ab (Picornavirus) *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 *Murine Norovirus*, strain S99 Berlin	between 4 °C and 30 °C	no longer than 5 min (for surfaces in contact with patient or medical staff) **or** no longer than 60 min (for other surfaces)	Clean conditions: bovine albumin 0,3 g/L and/or Dirty conditions: bovine albumin 3,0 g/L + sheep erythrocytes 3 ml/l	≥ 4,0
	Textile disinfection				
	Murine Parvovirus, minute virus of mice, strain Crawford, ATCC VR-1346	between 30 °C and 70 °C	no longer than 20 min	Dirty conditions: bovine albumin 3,0 g/L + sheep erythrocytes 3 ml/l	≥ 4,0
	Additional conditions (all uses)				
	any relevant test organism	-	-	any relevant interfering substance	n.a.

EN 14348

- Phase 2 / step 1 test
- Tuberculocidal/mycobactericidal quantitative suspension test
  - M. terrae – tuberculocidal
  - M. avium intracellulare & M. terrae - mycobactericidal
- Interfering substances
  - 0.03% BSA (clean)
  - 0.3% BSA + 0.3% erythrocytes (dirty)
- Neutralizer
- 4 log reduction required (60 min)

EN 14561

- Phase 2 / step 2 test
- Surface disinfectants – bactericidal activity
- P. aeruginosa, E. hirae, S. aureus
- Interfering substances
  - 0.03% BSA (clean)
  - 0.3% BSA + 0.3% erythrocytes (dirty)
- Placed on stainless steel discs and exposed
- Neutralizer
- 5 log reduction required (60 minutes)
- (5, 15 and 30 minutes may be added)

SPORICIDAL

Basic sporicidal method

- EN 14347
- B. subtilis, B. cereus

Phase 2/step 1 & phase 2/step 2

- Not accepted as work items
- EN 13704 Phase 2 step 1 test for use in food, domestic and industrial

Sporicidal task group working on development of standards

C. difficile?

SPORICIDAL TEST : EN 13704 (Food, industrial, domestic and institutional areas)

Test organism: Bacillus subtilis

Interfering substance : 0.03% BSA

Neutralizer

60 min obligatory contact time

Table 3d — Food, industrial, domestic and institutional area – Test conditions and requirements of standard test methods to be used to substantiate claims for sporicidal activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time (min)	Interfering substances	Reduction (lg)
	Obligatory test conditions				
EN 13704 2,1	Spores of *Bacillus subtilis* ATCC 6633	20	60	Clean conditions: 0,3 g/L bovine albumin	≥ 3,0
	The following additional test conditions are permitted:				
	Spores of *Bacillus cereus* ATCC 12826 Spores of *Clostridium sporogenes 51* CIP 7 939	4 or 10 or 40 75	5 or 15 or 30		≥ 3,0

PHASE 2 / STEP 1 SPORICIDAL TEST MODIFIED TO INCLUDE DIRTY CONDITIONS

EN13704

- Sporicidal activity
- B subtilis & B cereus
- Additional – C sporogenes or “any other relevant spore”
- Interfering substances
  - 0.03% BSA (clean conditions)
  - 0.3% BSA + erythrocytes (dirty conditions)
- Neutraliser
- 3 $\log_{10}$ reduction required to pass

RELIABILITY AND REPRODUCIBILITY OF METHODOLOGY

C difficile spores difficult to produce

- Need high titre to demonstrate log kill
- May have vegetative organisms and not spores

Neutralisers

- Need to be validated
- Ensure full neutralisation
- No toxicity
- No standard neutraliser described in EN
- Trial and error

Journal of Hospital Infection 89 (2015) 2–15

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevierhealth.com/journals/jhin

Development of a sporicidal test method for *Clostridium difficile*

A.P. Fraise [a,*], M.A.C. Wilkinson [a], C.R. Bradley [a], S. Paton [b], J. Walker [b], J.-Y. Maillard [c], R.L. Wesgate [c], P. Hoffman [d], J. Coia [e], C. Woodall [f], C. Fry [g], M. Wilcox [h]

PROPOSED UK METHOD

Clostridium difficile NCTC 11209 (non-toxigenic strain.

Clean and dirty conditions as for other tests

Clospore method for spore production

5 $\log_{10}$ reduction in 5 minutes

500 pm chlorine solution as control – 1 and 60 mins

NaDCC 1000 ppm

Log 10 Initial count (Challenge)	Contact time	Log $_{10}$ Reduction achieved	
		Clean conditions	Dirty Conditions
6.98	5 min	5.19	0.92
	10 min	5.38	0.93
	15 min	5.53	1.26
	60 min	5.83	0.89

Journal of Hospital Infection 91 (2015) 319–325

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevierhealth.com/journals/jhin

Disinfectant wipes are appropriate to control microbial bioburden from surfaces: use of a new ASTM standard test protocol to demonstrate efficacy

S.A. Sattar [a], C. Bradley [b], R. Kibbee [a], R. Wesgate [c], M.A.C. Wilkinson [b], T. Sharpe [d], J-Y. Maillard [c,*]

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[b] *Hospital Infection Research Laboratory, Queen Elizabeth Hospital Birmingham, Birmingham, UK*
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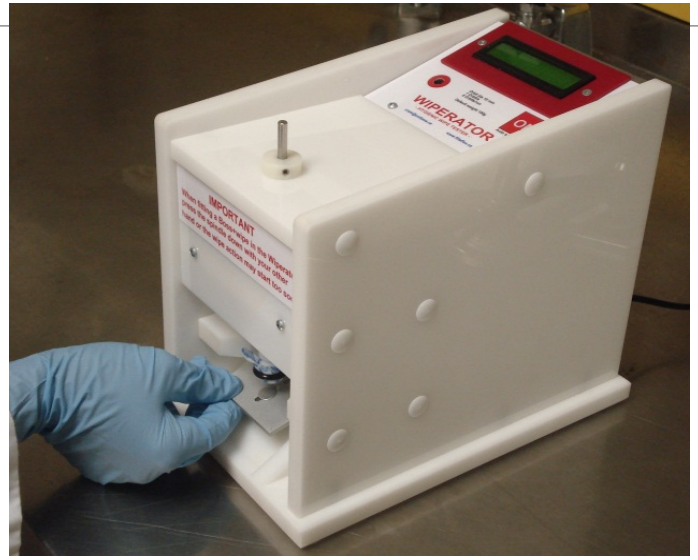
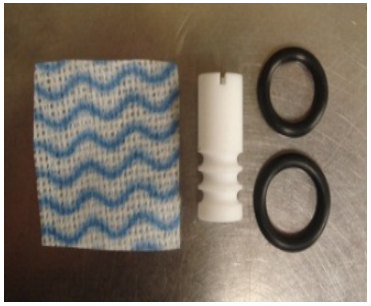
SUMMARY

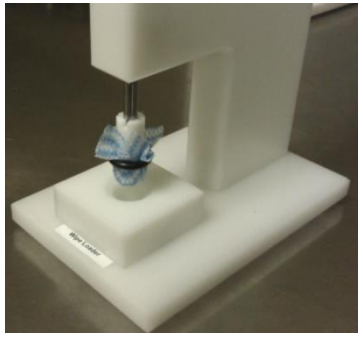
Background: The use of disinfectant pre-soaked wipes (DPW) to decontaminate high-touch environmental surfaces (HTES) by wiping is becoming increasingly widespread in the healthcare environment. However, DPW are rarely tested using conditions simulating their field use, and the label claims of environmental surface disinfectants seldom include wiping action.

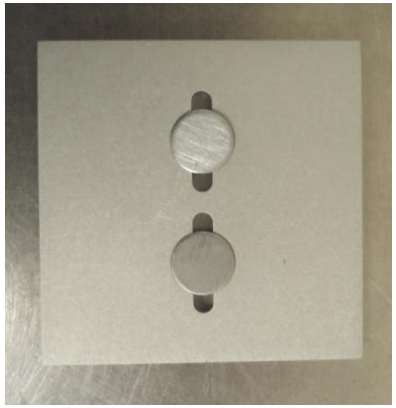
WIPERATOR STUDY

ASTM Standard E2967-15



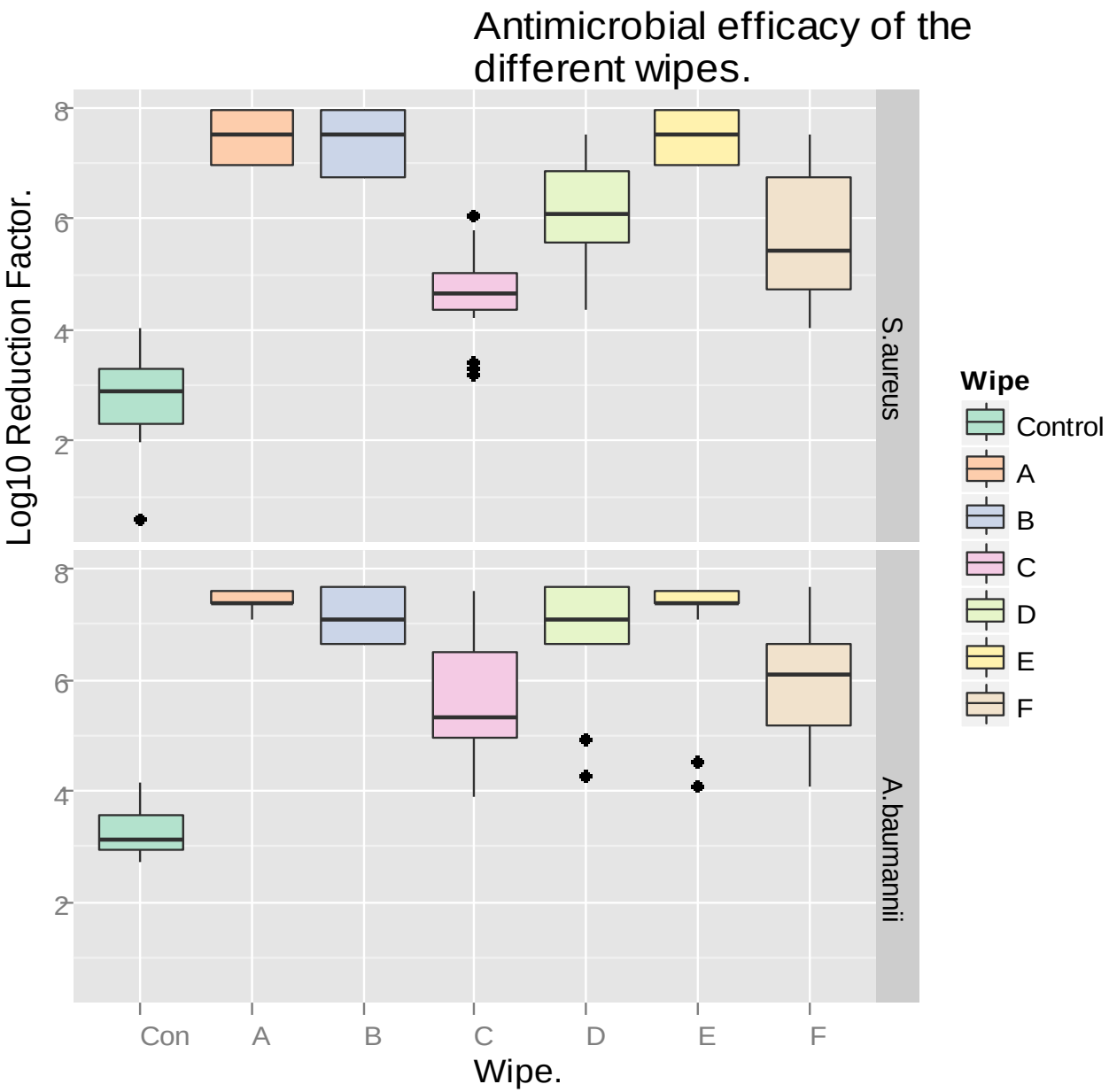






WIPERATOR STUDY

Test microorganism	Test		Total number of carriers/number positive*					
		Control	A	B	C	D	E	F
Staphylococcus aureus	Removal	15/15	15/0	15/0	15/15	15/13	15/0	15/12
	Transfer	15/15	15/0	15/0	15/15	15/6	15/0	15/6
Acinetobacter baumannii	Removal	11/11	15/0	15/0	15/12	15/9	15/11	15/13
	Transfer	11/11	15/0	15/0	15/0	15/0	15/0	15/3


Antimicrobial efficacy of the different wipes.
Log10 Reduction Factor.
8
6
4
2
S.aureus
A.baumannii
Con
A
B
C
D
E
F
Wipe.
Wipe
Control
A
B
C
D
E
F

HAND DISINFECTANT TESTING

EN 1499 – Hygienic handwash

EN 1500 – Hygienic handrub

EN 12791 – Surgical hand disinfection

PRINCIPLE OF THE TESTS

The number of test organisms released from artificially or naturally contaminated hands is assessed before and after application of the product

Results compared with a reference product

Necessary precision achieved by repeating the test on 18-22 subjects (18-20 for surgical skin disinfectants)

TEST AND REFERENCE PRODUCTS

EN 1499 - Soft soap

EN 1500 - Propan-2-ol 60% (v/v)

EN 12791 – Propan-1-ol 60% (v/v)

The effectiveness of reference and test products are assessed

EN 1499

Surface test for hygienic handwashes

- 12 – 15 volunteers; hands immersed in E. coli K12 broth
- Reference Product vs Test Product
- Reference non-antimicrobial soft soap, 5 ml for 60 seconds
- Log_{10} Reduction Factors calculated (RF)
- Traditional superiority test, $p = 0.01$

EN1500: Hygienic Hand Rub Overview

Challenge organism: E. coli

Single product cross-over design:

- Each volunteer uses test product and an internal reference product

Product application for defined volume, contact time

- Typical: 3 ml for 30 sec

Must show non-inferiority to internal reference

- 2 x 3 ml of 60% isopropyl alcohol
- 60 second total rub time
- Non-inferiority test, $p = 0.025$

Could a hand wipe be an alternative?

Wilkinson, M. A. C., M. Kiernan, J. Wilson, H. Loveday and C. Bradley (2017). "Assessment of the efficacy of a patient hand wipe; development of a test method." Journal of Hospital Infection

Hybrid test

Based on EN 1499 and EN 1500.

- 20 volunteers; hands immersed in E. coli K12 broth.
- Reference Product vs Test Product
- Reference non-antimicrobial soft soap, 5 ml for 60 seconds.
- Log10 Reduction Factors calculated (RF)

Products

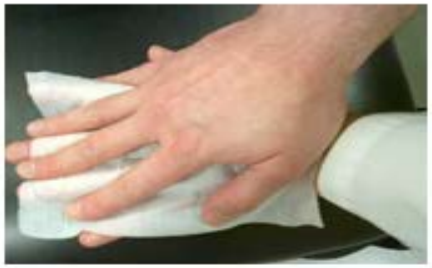
- P2 antimicrobial handwipe (benzalkonium chloride & didecyldimonium chloride; Clinell©)
- P1 = P2 − quat compounds.

Tested for non-inferiority (EN 1500)

- Subsequently tested for superiority (EN 1499)

HAND WIPE APPLICATION PROCEDURE

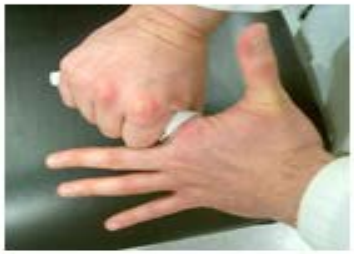
Palm to palm



Right palm over back of left hand

Left palm over back of right hand

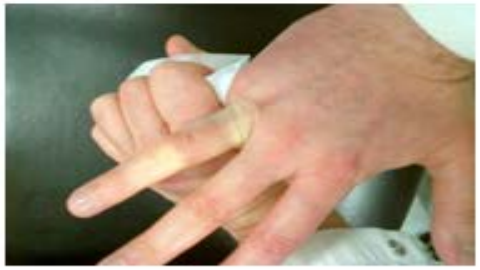
Rotational rubbing of thumb*



Rotational rubbing of index finger*

Rotational rubbing of middle finger*

Rotational rubbing of ring finger*

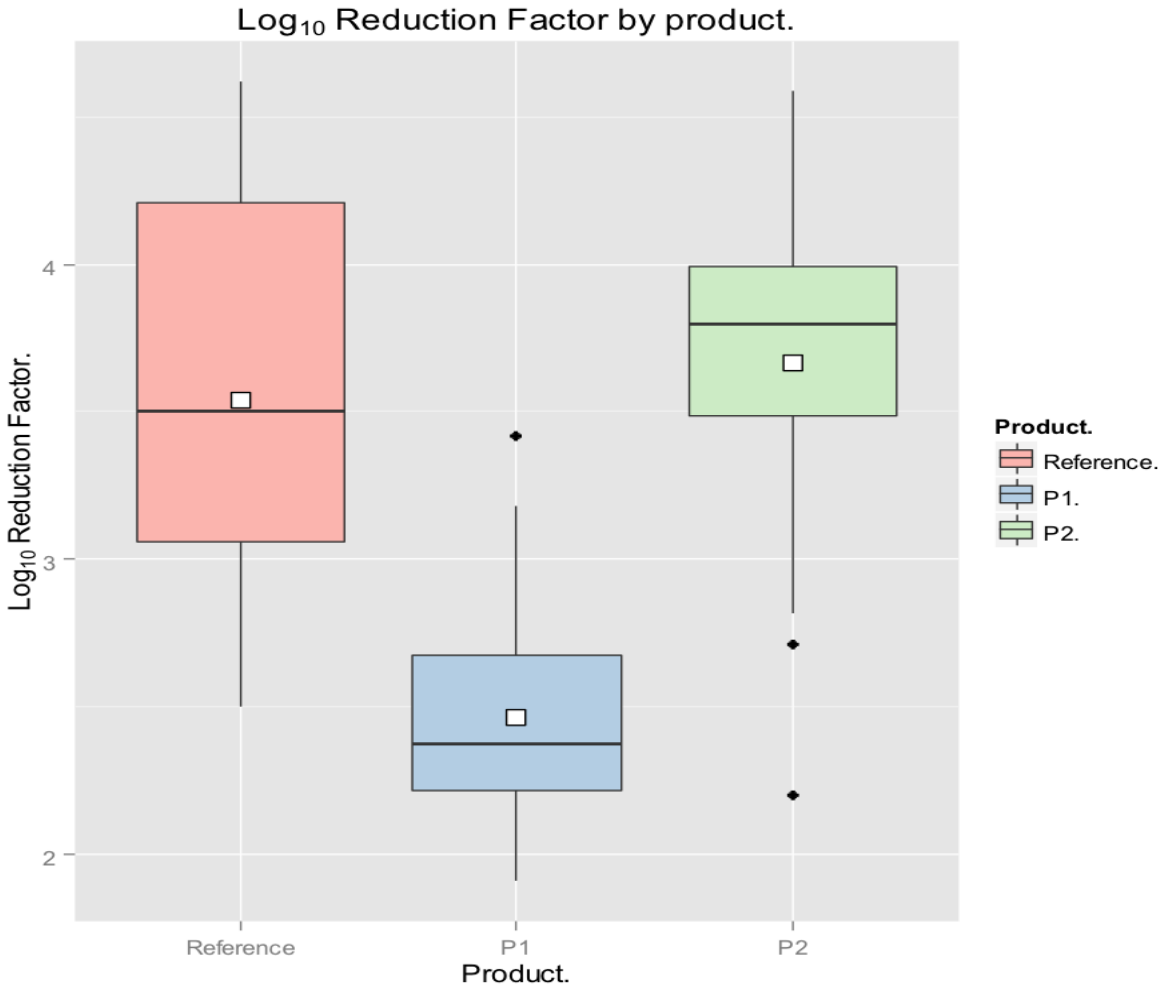


Rotational rubbing of little finger*

Rotational rubbing while scrunched between fingertips

*carryout for both hands

Results.


Log10 Reduction Factor by product.
Log10 Reduction Factor.
4
3
2
Reference
P1
P2
Product.
Product.
Reference.
P1.
P2.

Results

Log reductions

- Mean Log_{10} RF for soap was 3.54
- Mean Log_{10} RF for P1 was 2.46
- Mean Log_{10} RF for P2 was 3.67

Non-inferiority (Hodges – Lehmann test):

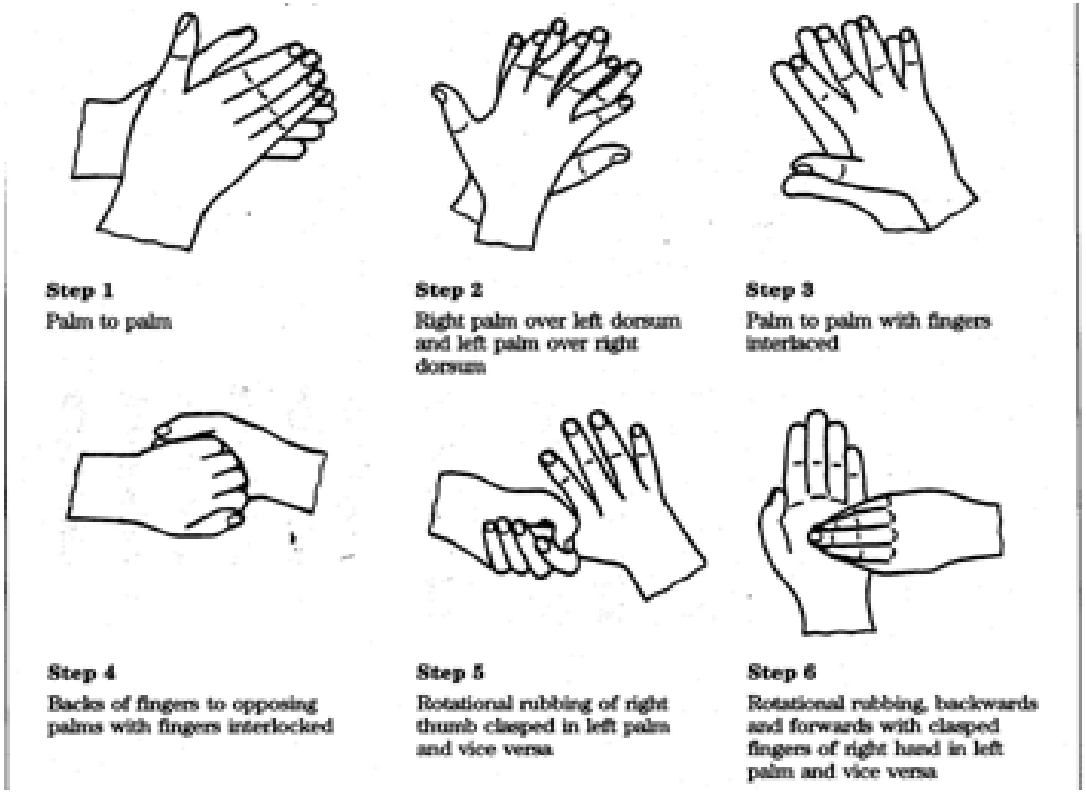
- P1 was not non-inferior to soap
- P2 was non-inferior

Superiority (Wilcoxon – Wilcox test):

- P2 was not superior to soap

Conclusion: The evidence suggests that the antimicrobial patient wipe, when applied for 60 seconds, is at least as good as soap and water, representing an acceptable alternative to handwashing from a bactericidal perspective

STANDARD APPLICATION TECHNIQUE



Step 1
Palm to palm

Step 2
Right palm over left dorsum and left palm over right dorsum

Step 3
Palm to palm with fingers interlaced

Step 4
Backs of fingers to opposing palms with fingers interlocked

Step 5
Rotational rubbing of right thumb clasped in left palm and vice versa

Step 6
Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa

ANALYSIS OF RESULTS

Log_{10} reduction obtained with the reference product is compared with that obtained when using the test product.

The values are compared statistically to the reference product

- EN 1499 – Wilcoxon Signed Ranked Pairs test (significance)
- EN 1500 – Hodges Lehmann test (non-inferiority)
- EN 12791 – Wilcoxon Signed Ranked Pairs Test (significance)

Table 1a — Medical area – Test conditions and requirements of standard test methods to be used to substantiate claims for bactericidal activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time	Interfering substances	Reduction (lg)
EN 1499 2,2	Minimum test conditions				
	Escherichia coli K12, NCTC 10538 (=NCIMB 10083)	Tested on the skin	between 30 s and 1 min	None	Product > reference soap with 1 min wash ($P = 0,01$)
EN 1500 2,2	Minimum test conditions				
	Escherichia coli K12, NCTC 10538	Tested on the skin	between 30 s and 1 min	None	Product not < Propan-2-ol 60 % vol with 2 × 3 ml/30 s each ($P = 0,1$)
EN 12791 2,2	Minimum test conditions				
	Normal skin flora	Tested on the skin	between 1 min and 5 min	None	<u>Immediate effect:</u> Product not < Propan-1-ol 60 % vol with n × 3 ml/3 min ($P = 0,1$)
					<u>3-hour effect:</u> Product not < Propan-1-ol 60 % vol ($2P = 0,01$)
	Additional test conditions				
	None	None	None	None	<u>Sustained effect</u>: Product > Propan-1-ol 60 % vol with n × 3 ml/3 min after 3 h ($2P = 0,01$)

DISINFECTANT TESTING : SUMMARY

Standards exist or are being written for most areas of chemical disinfection

Hierarchy of tests (phase 1, 2, 3)

Clean and dirty conditions should be included as relevant

Contact times should be relevant to actual practice

Ongoing process

THANK YOU FOR LISTENING