B|BRAUN
SHARING EXPERTISE

Microbiological standard (EN) in instruments disinfectant

Objectives

1) To provide an overview of European Standards on chemical disinfection testing focusing on instruments disinfectant.

What is the role of an disinfectant?

What is the role of an disinfectant?

A disinfectant **role is to reduce the number of microorganisms** on an instrument or surface **before they can be used on another patient**.

Why is it important to understand EN Standards?

It is not uncommon for manufacturers of disinfectants to advertise a long list of antimicrobial claims on their product labels. A common reason is to outnumber the claims of competitors and prove the superiority of their products.

It is therefore important in medical settings to understand how these claims are supported by independent laboratory tests.

Introduction

In Europe, the process of making claims for a disinfectant intended for use in the area of human medicine, veterinary or food, industrial, domestic and institutional areas is guided by **EN 14885:2018.**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 14885

November 2018

ICS 11.080.20; 71.100.35

Supersedes EN 14885:2015

English Version

Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 14885

November 2018

ICS 11.080.20; 71.100.35

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English Version

Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics

Can be applied on 3 areas:

1) Medical
2) Veterinary
3) Food, industrial, domestic & institutional

Introduction

This guideline lists basic laboratory tests that a particular chemical disinfectants must pass, in order to validate antimicrobial claims by manufacturers. This would include:-

1) test methods
2) specific test microorganisms
3) test conditions
4) Log reduction requirements.

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EN 14885

November 2018

ICS 11.080.20; 71.100.35

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Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

Formulation of New EN Standards

Draft standard drawn by working group(WG)

↓

Approved by Technical Committee(TC)

↓

Public comment (“enquiry”, comment by National Standards bodies – after consultation)

↓

Redrafting

↓

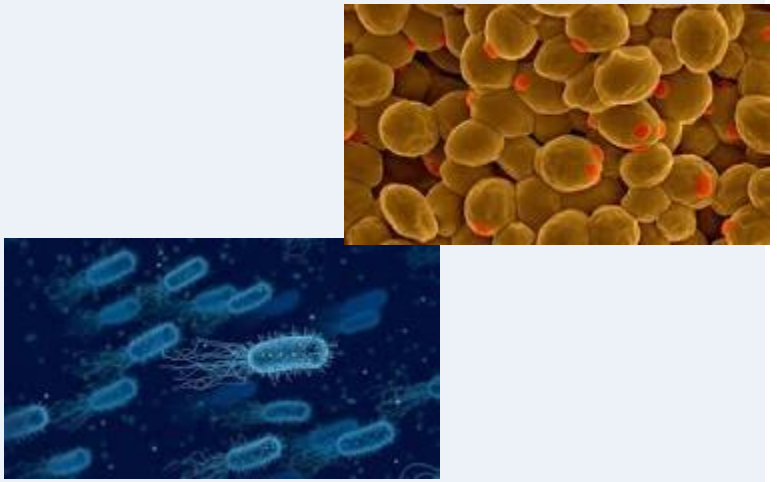
Formal vote → **Publication as EN by CEN (European Committee for Standardization**

Instrument disinfectants

According to EN 14885:2018, all instrument disinfectants intended for use in the medical area must pass the:-

1) bactericidal and
2) yeasticidal activity tests

In order to meet the minimum requirements.



Instrument disinfectants

Bactericidal activity tests

EN 13727: Quantitative suspension test for the evaluation of bactericidal activity in the medical area (Phase 2, Step 1)

EN 14561: Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area (Phase 2, Step 2).

Yeasticidal activity tests

EN 13624: Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area (Phase 2 Step 1)

EN 14562: Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area (Phase 2, Step 2).

Disinfectant Testing according to CEN-TC 216 – EN 14885 - 3-Phase-Model

Phase 1: Basis test

Phase 2 / Step 1 Suspension test

Phase 2 / Step 2 Carrier test

Phase 3: Field trials

Adapted from: Dr. J. Gebel, Association for Applied Hygiene e.V. Institute for Hygiene and Public Health, University-Hospital Bonn

Phase 1: Basic Test

Quantitative suspension test to establish that active substances or products under development have bactericidal, fungicidal or sporicidal activity without regard to specific areas of application. Eg EN 1040:2005, EN 1275:2005.

This test are usually done during development stage of a disinfectant and **cannot be used for efficacy claims.**

Phase 2 – Step 1

Quantitative **suspension test** to establish that a product has bactericidal, funicidal, yeasticidal, mycobactericidal, tuberculocidal, sporicidal or virucidal activity under stimulated practical conditions appropriate to its intended use.

It is to prove the irreversible inactivation of microorganisms. It provides relevant information about the activity of the products against microorganisms in suspension.

Phase 2 – Step 2

Quantitative laboratory tests to establish that a product has bactericidal, fungicidal, yeasticidal, mycobactericidal, tuberculocid, sporicidal or virucidal activity **when applied to a surface or skin under stimulated practical conditions (eg surface, instrument, handwash and handrub test).**

It provide information about the activity against desiccated(dried out) microorganisms on inanimate surfaces or on living tissues or against non-desiccated microorganisms on living tissues.

Phase 3 - Field Test

Field test under practical conditions performed in addition to phase, step 1 and phase 2, step 2. Validated methodology for this type of test is not available, maybe developed in the future.

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FINAL DRAFT
EN 13727:2012+A1:2013

FprA2

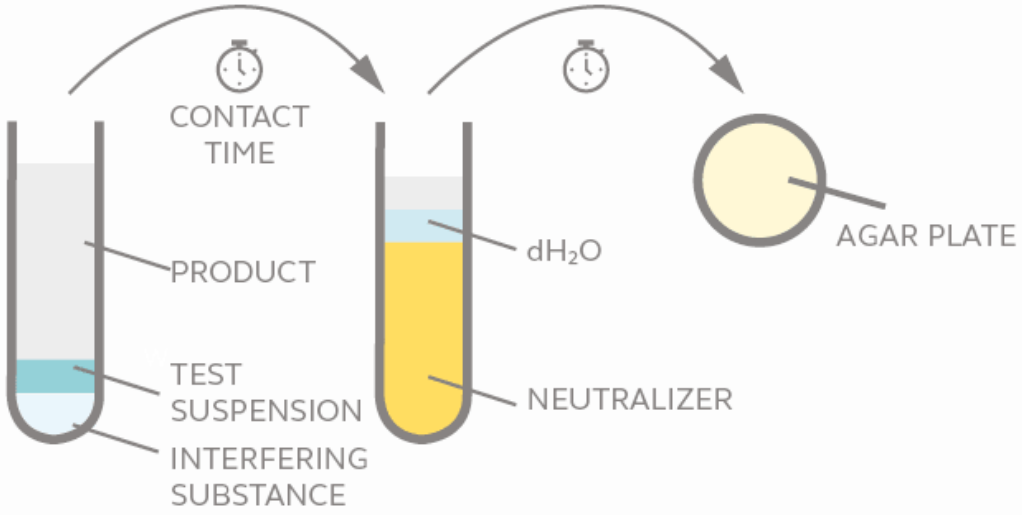
April 2015

ICS 11.080.20

English Version

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)

Diagram 1: EN 13727 test method



a) 8 parts of the test product is added to 1-part test microorganism and 1-part interfering substance.

b) The mixture is allowed to interact for the duration of the contact time.

c) One part of the mixture is added to 8 parts of neutralizer and 1-part water for 5 minutes to halt bactericidal activity.

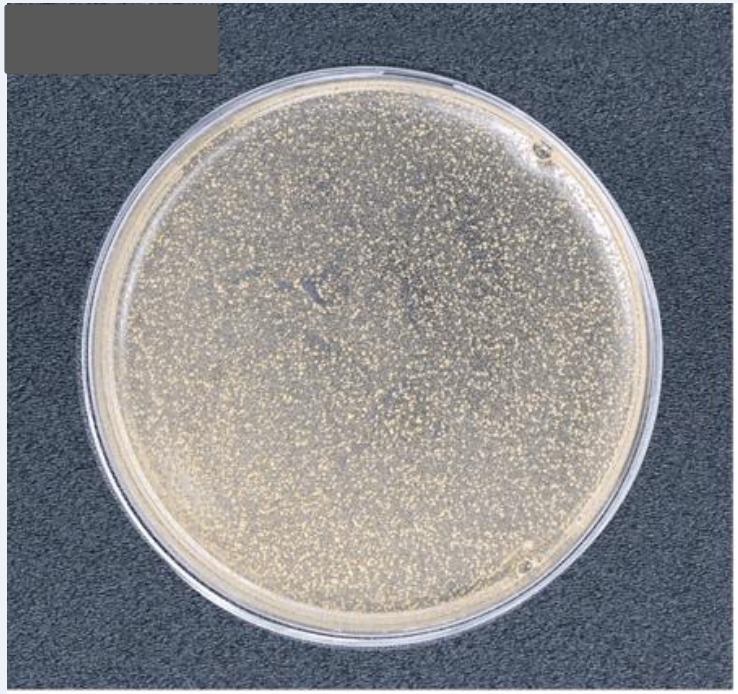
d) The final mixture is then acquired and incubated for 2 days to allow surviving bacteria (if any) to proliferate.

e) The bacterial colony is counted and compared against the original culture size.

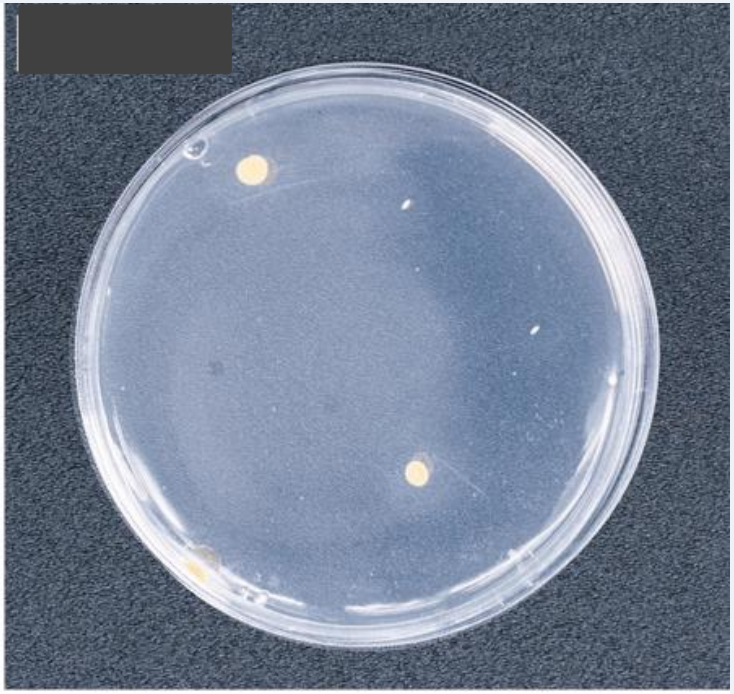
Diagram adapted from https://www.viroxylabs.com/microbiological-testing-services/disinfectant-efficacy-testing/en

For a product to pass EN 13727, it must be able to achieve 5-log reduction against the respective test microorganisms.

In other words, the product must be able to kill 99.999% bacteria while meeting all the other requirements of the European standard



Test product that failed EN 13727
S. aureus



Test product that passed EN 13727
S. aureus

Annex C
(informative)

Graphical representation of test procedures

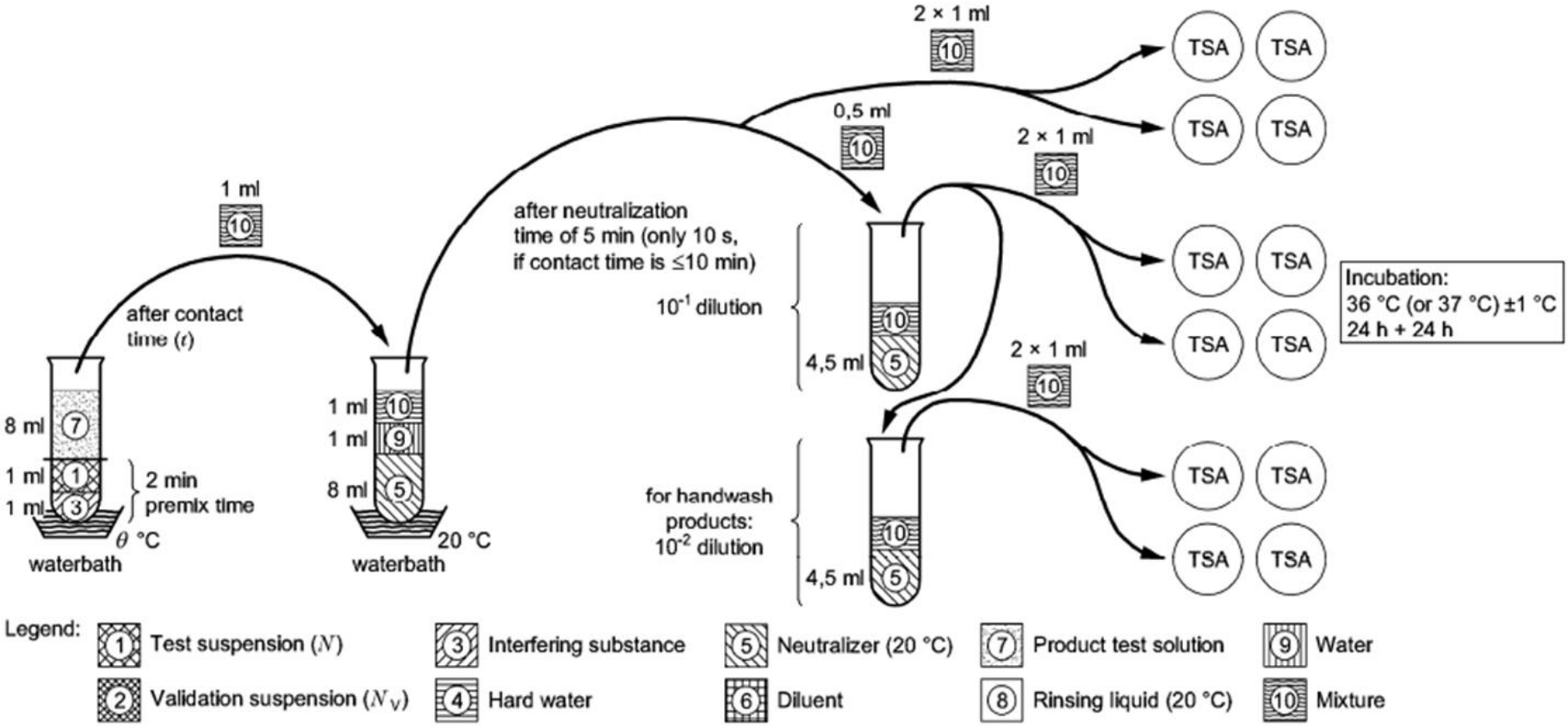


Figure C.1 – Dilution – neutralization method – Test procedure (N_a)

CEN TC 216 – EN 13727 – Phase 2 / Step 1

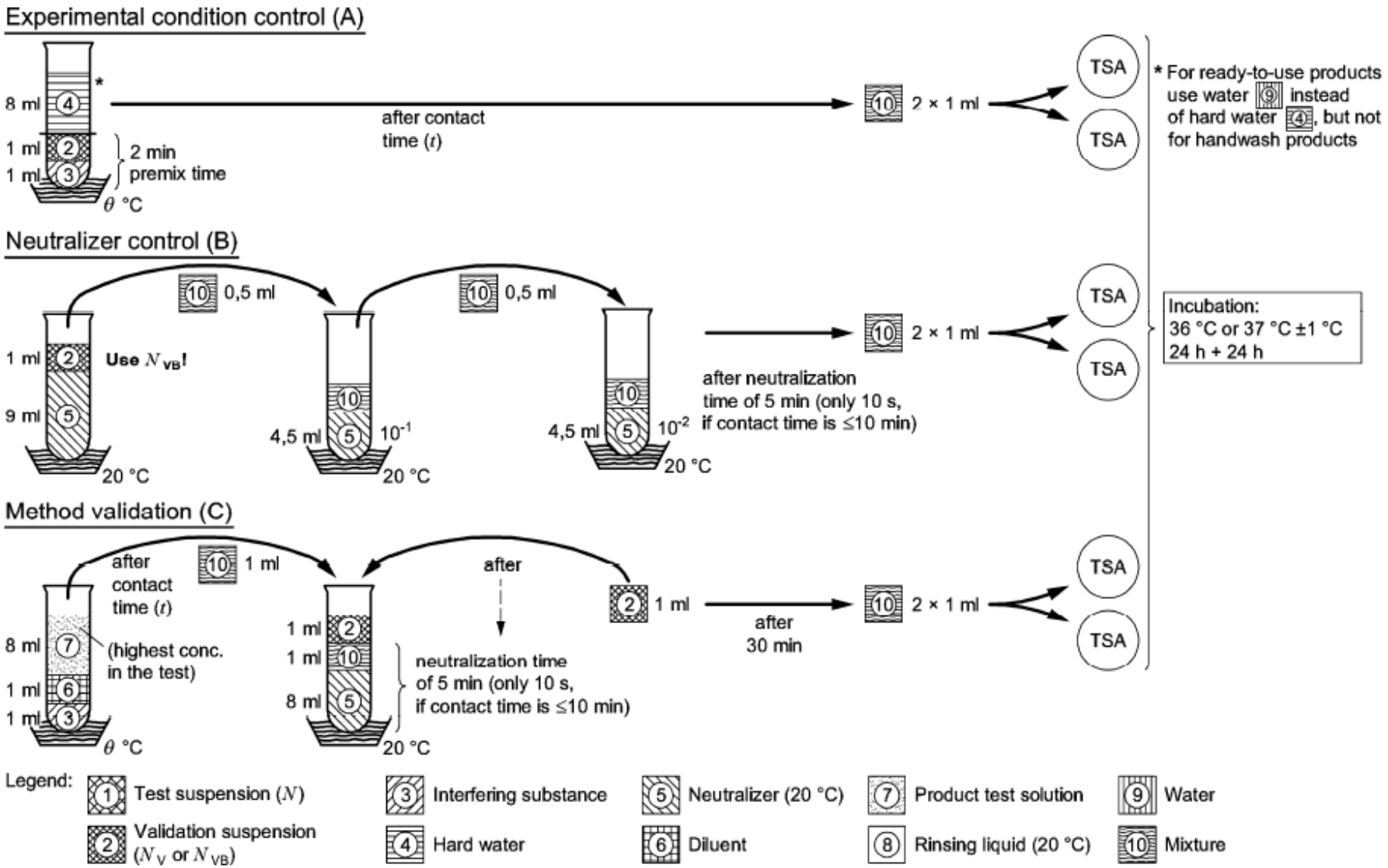


Figure C.2 – Dilution – neutralization method – Validation

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 14561

May 2006

ICS 11.080.20

English Version

Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)

Phase 2 / Step 2: carrier test

This test is to stimulate practical usage conditions.

1) **Bactericidal** - EN 14561:2006 (Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area)

2) **Fungicidal/Yeasticidal** - EN 14562:2006 (Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area)

3) **Mycobactericidal/Tuberculocidal** - EN 14563 (Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area).

Phase 2 / Step 2: carrier test (Process)

1) The test microorganism is mixed with bovine albumin (for clean conditions) and sheep blood (for dirty conditions)

2) It is then applied onto a 1cm 2 space of glass slide or metal disk for non-porous surface and wood for porous surface. These materials act as the actual surface (or carrier of microorganisms).

3) The carrier is then left to air-dry to mimic actual medical surfaces before the disinfectant is applied for the duration of the claimed contact time.

4) It is then submerged into a neutralizer solution to prevent continued disinfection.

Phase 2 / Step 2: carrier test (Process)

5) The assumption here is that the microorganisms are suspended in the neutralizer upon immersion.

6) A sample of the neutralizer solution is then acquired, plated and incubated.

7) The number of test microorganisms recovered is compared to the number of microorganisms recovered from the control sample (where test microorganisms are exposed to water instead of disinfectant) to determine if the disinfectant is able to reduce relevant test microorganisms to an acceptable level as outlined in the norms.

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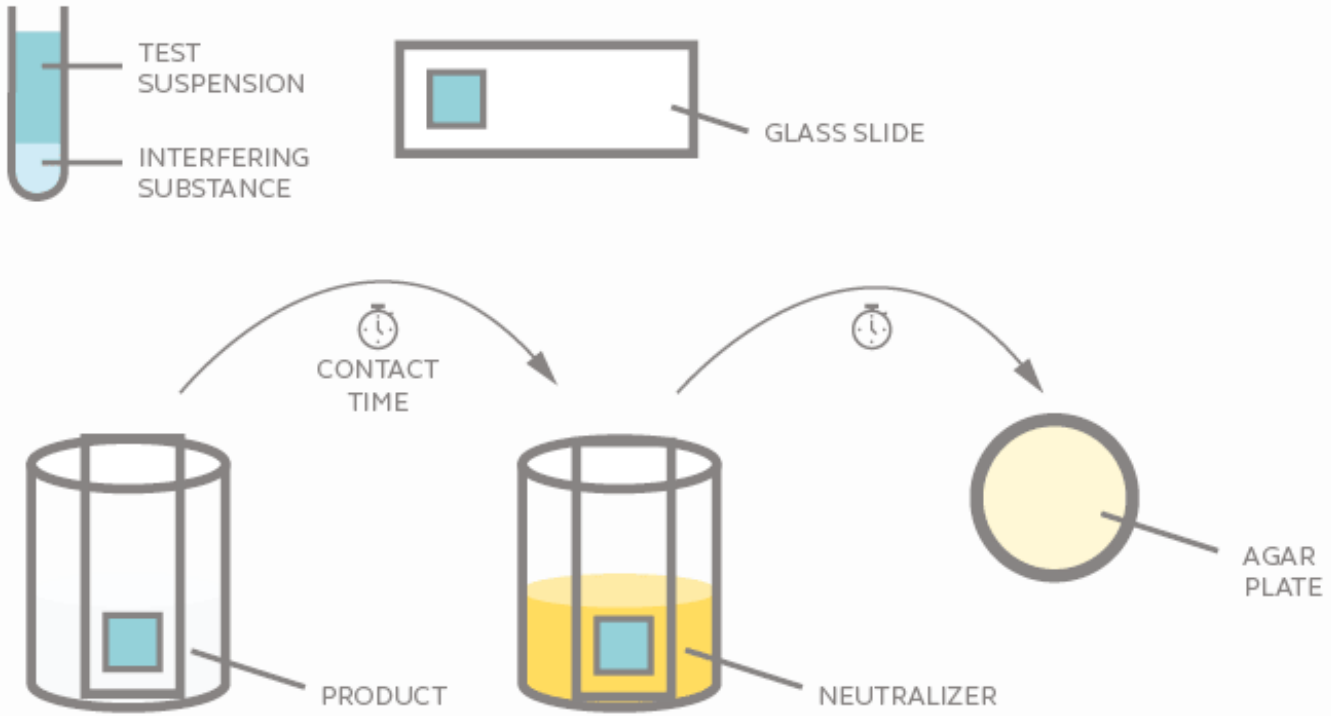
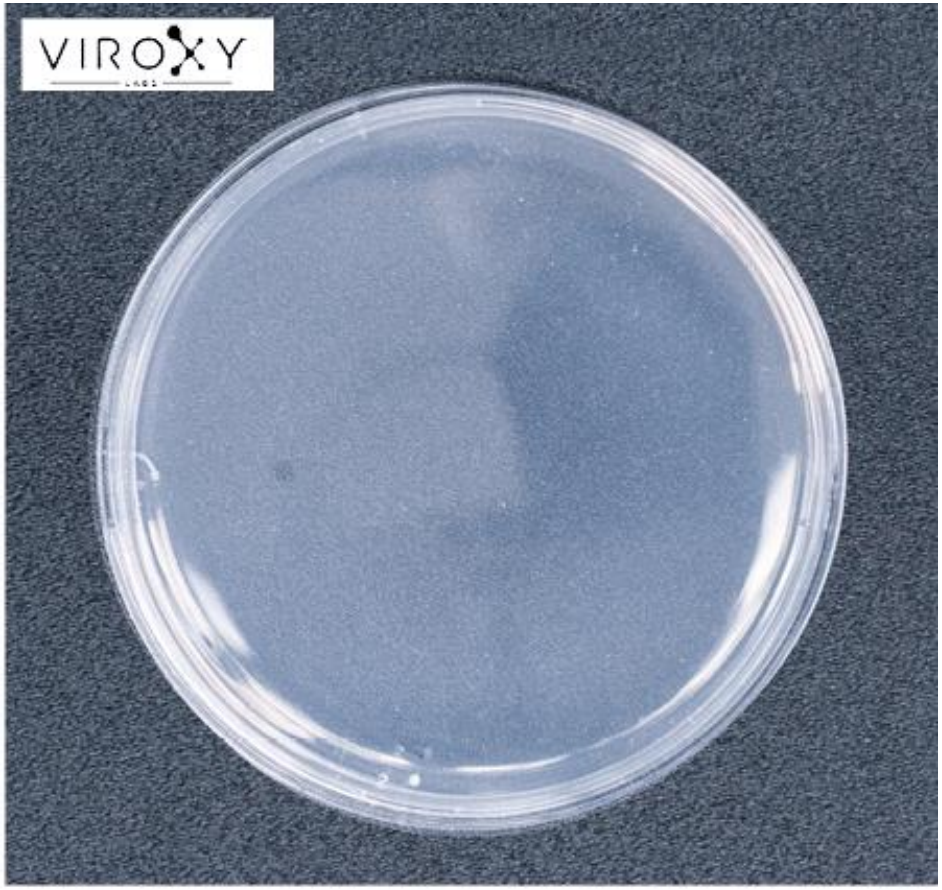
Diagram 1: EN 14561 test method

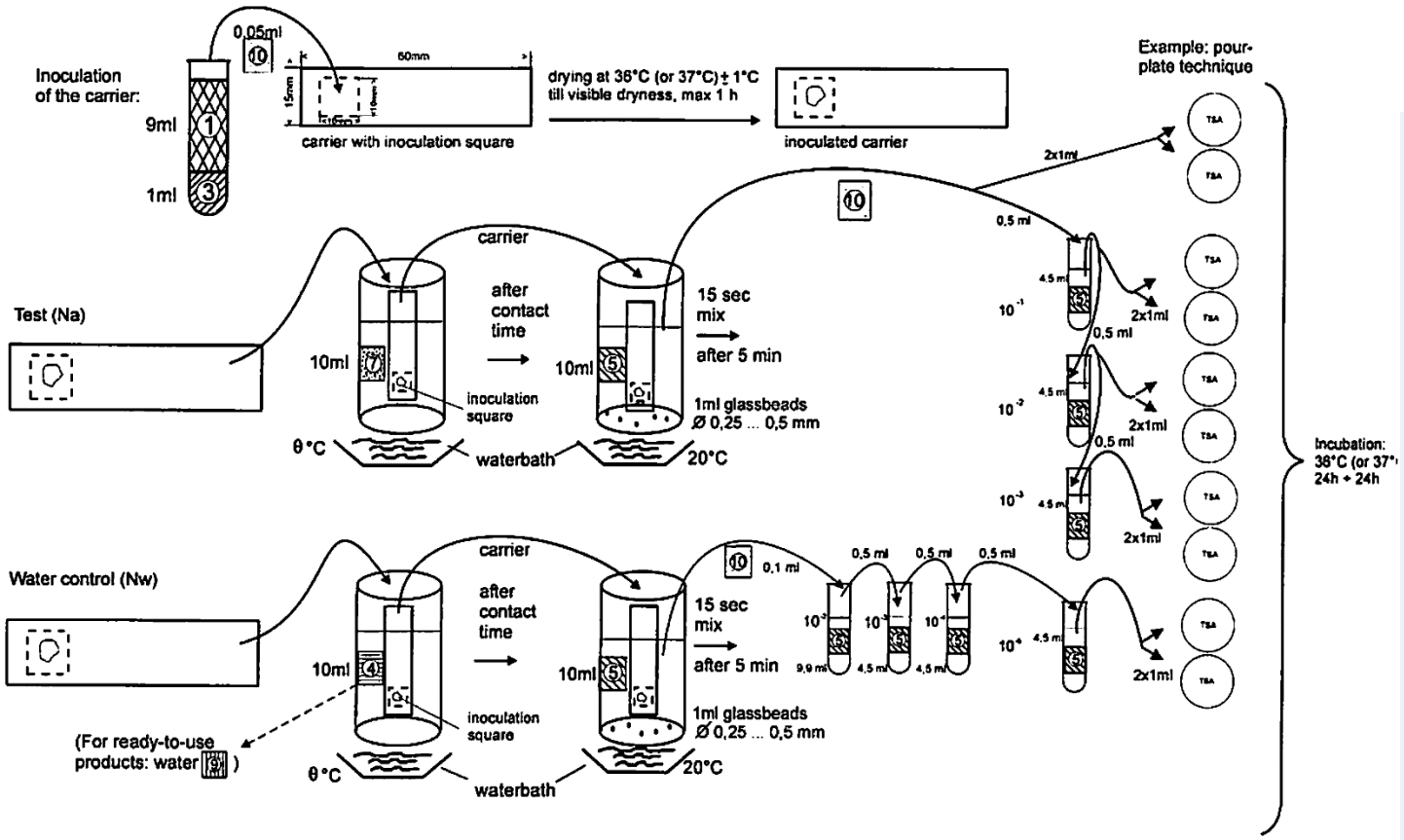


Test product that failed EN 14561
E. hirae



Test product that passed EN 14561
E. hirae

For test (N_a) and water control (N_W) see Figure C.1.

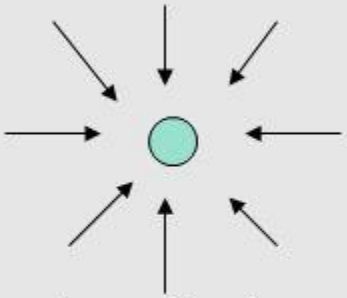


Key

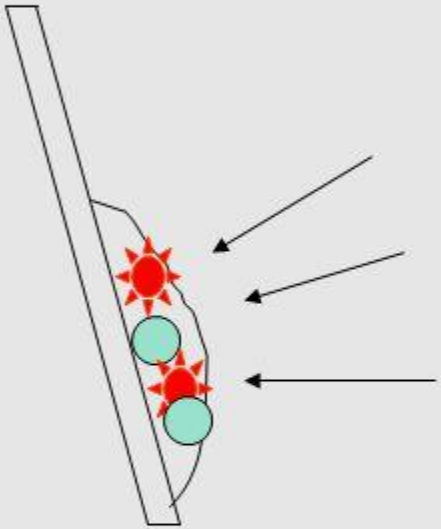
1 Test suspension (N)
2 Validation suspension (N_V)
3 Interfering substance
4 Hard water
5 Neutralizer (20 °C)
6 Diluent
7 Product test solution
9 Water
10 Mixture

Figure C.1 — Test (N_a) and water control (N_W)

Suspension test **vs.** **Practical Carrier test**



Active ingredients can attack germs form all directions



Active ingredients can attack from one direction, only!

What is the difference?

Difference between a suspension test &

	Pros	Cons
Suspension Test	Test product has better contact with the microorganisms in suspended state Test is easier to conduct Mircoorganisms count is maintained throughout the test.	May not represent actual environment as test microorganisms are not adhered to a specific surface or material The outcome of the test maybe influenced by dilution variation. Disinfectants with high viscosity may not be evenly distributed in the test suspension

Difference between a suspension test &

	Pros	Cons
Carrier Test	Test better represents actual conditions compared to suspension test Microorganisms are adhered to a carrier as they are in actual conditions	Death / loss of microorganisms during the drying process makes it difficult to control the number of microorganisms retrieved Surfaces are not truly identical and can pose a challenge in reproducing the same result Slightly more tedious than suspension test

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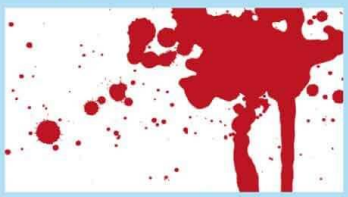
	SITUATIONS & LABORATORY CONDITIONS	BACTERIA REDUCTION	FUNGI REDUCTION	VIRUSES REDUCTION	MYCOBACTERIA REDUCTION	PERFORMANCE OF DISINFECTION	
PHASE 1	**CLEAN** SOLUTIONS 	**99,999%** **5 log** EN 1040 *P. aeruginosa* *S. aureus*	**99,990%** **4 log** EN 1275 *C. albicans* *A. niger*	Not applicable	Not applicable	LOW PERFORMANCE ★ Artificial evaluation	PHASE 1
PHASE 2 step 1	**DIRTY** SOLUTIONS 	**99,999%** **5 log** EN 13727 *P. aeruginosa* *S. aureus* *E. hirae*	**99,990%** **4 log** EN 13624 *C. albicans* *A. niger*	**99,990%** **4 log** EN 14476 *Poliovirus 1* *Adenovirus 5* *Norovirus*	**99,990%** **4 log** EN 14348 *M. avium* *M. terrae*	INTERMEDIATE PERFORMANCE ★★ Limited validation	PHASE 2 step 1
PHASE 2 step 2	**DIRTY AND DRY** SURFACES 	**99,999%** **5 log** EN 14561 *P. aeruginosa* *S. aureus* *E. hirae*	**99,990%** **4 log** EN 14562 *C. albicans* *A. niger*	Not applicable	**99,990%** **4 log** EN 14563 *M. avium* *M. terrae*	HIGH PERFORMANCE ★★★ Validation in practical condition	PHASE 2 step 2

EN: European Normative Standard Medical Devices

Every product has to be tested in phase 2, step 1 and phase 2, step 2

EN 14885

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 Hand-wash	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	**	***
	2,2	EN 1500	EN 1499	EN 12791	EN 13697 [a]	EN 16615	EN 14561	EN 16616	***
Yeasticidal	2,1	EN 13624 (handrub products under clean, handwash products under dirty conditions)			EN 13624		EN 13624	**	***
	2,2	***			EN 13697 [a]	EN 16615	EN 14562	EN 16616	***
Fungicidal	2,1	***			EN 13624		EN 13624	**	***
	2,2	***			EN 13697 [a]	**	EN 14562	EN 16616	***
Tuber culocidal	2,1	EN 14348	EN 14348	***	EN 14348		EN 14348	EN 14348	***
	2,2	***			**	**	EN 14563	EN 16616	***
Myco-bacteri-cidal	2,1	EN 14348	EN 14348	***	EN 14348		EN 14348	EN 14348	***
	2,2	***			**	**	EN 14563	EN 16616	***

CEN TC 216 – EN 14885

Type of activity	Phase step	Product Claim / Field of Application							
		Hygienic Handrub	Hygienic Hand-wash	Surgical Handrub or -wash	Surface Disinfection		Instrument Disinfection	Textile Disinfection	Water Treatment for Control of *Legionella*
					mechanical action				
					without	with			
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 14885

4.3.2.5 Instrument disinfection

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1), EN 14561 (2/2)
Yeasticidal activity	EN 13624 (2/1), EN 14562 (2/2)
Additional European Standards	
Fungicidal activity	EN 13624 (2/1), EN 14562 (2/2)
Tuberculocidal / Mycobactericidal activity	EN 14348 (2/1), EN 14563 (2/2)
Virucidal activity	EN 14476 (2/1)

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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	20	between 30 s and1 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	20	between 1 minand5 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 and 70	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 and 30	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	none	none	any relevant interfering substance	none

Test conditions and requirements - Fungicidal & Yeasticidal

Table 3 — Medical area – Test conditions and requirements of standard test methods to be used to substantiate claims for fungicidal and yeasticidal activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time	Interfering substances	Logarythmic (lg) reduction
EN 13624 2,1	Hygienic handwash and handrub				
	Candida albicans ATCC 10231 (yeasticidal)	20	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	≥ 4,0 for handrub products ≥ 2,0 for handwash products
	Surgical handwash and handrub				
	Candida albicans ATCC 10231 (yeasticidal)	20	between 1 minand5 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	≥ 4,0
	Instrument disinfection				
	Candida albicans ATCC 10231 and *Aspergillus brasiliensis* ATCC 16404 (fungicidal) or *Candida albicans* ATCC 10231 (yeasticidal)	between 20 and70	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	≥ 4,0

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Table 4 — 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	Logarythmic (lg) reduction
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 **Virucidal activity against enveloped viruses:** *Vaccinia virus*, strain Ankara (MVA), ATCC VR-1508	20	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 20and70	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 4and30	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 and 70	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.

Table 5 — Medical area – Test conditions and requirements of standard test methods to be used to substantiate claims for mycobactericidal and tuberculocidal activity of products

EN reference Phase, step	Test organisms	Temperature (°C)	Contact time	Interfering substances	Logarythmic (lg) reduction
EN 14348 2,1	Obligatory test conditions				
	mycobactericidal activity: *Mycobacterium avium* ATCC 15769 **and** *Mycobacterium terrae* ATCC 15755 **or tuberculocidal activity**: only *Mycobacterium terrae* ATCC 15755	20	60 min	Clean conditions: bovine albumin 0,3 g/l Dirty conditions: bovine albumin 3,0 g/l + sheep erythrocytes 3 ml/l	≥ 4,0
	The following additional test conditions are permitted:				
		10 °C-steps	5 min, 15 min, 30 min		
Remark EN 14348 can be used to demonstrate mycobactericidal and/or tuberculocidal activity for hygienic handrub (4.3.2.2) and – wash (4.3.2.3) products, surface disinfectants (4.3.2.6 and 4.3.2.7) and disinfectants for textile (4.3.2.8). In these cases the contact times shall be adapted according to the principles described in EN 13727 and EN 13624.					
EN 14563 2,2	**mycobactericidal activity:** *Mycobacterium avium* ATCC 15769 **and** *Mycobacterium terrae* ATCC 15755 **or tuberculocidal activity**: only *Mycobacterium terrae* ATCC 15755	20	60 min	Clean conditions: bovine albumin 0,3 g/l Dirty conditions: bovine albumin 3,0 g/l + sheep erythrocytes 3 ml/l	≥ 4,0
	The following additional test conditions are permitted:				
		10 °C-steps (max. 60)	5 min, 15 min, 30 min		

Difference between EN norms & TGA

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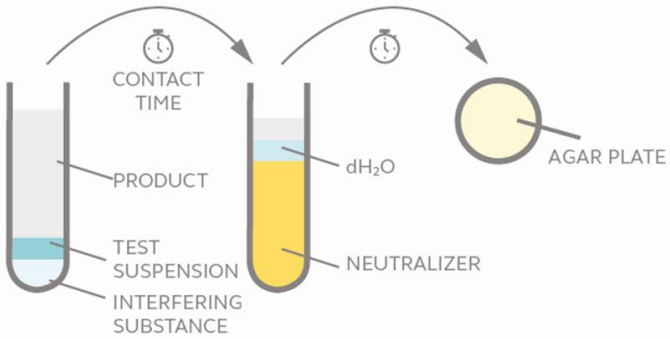
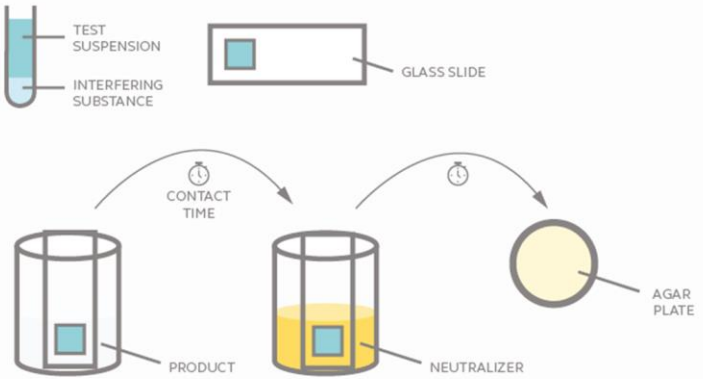
Diagram 1: EN 13727 test method



Phase 2, Step 1

Phase 2, Step 2

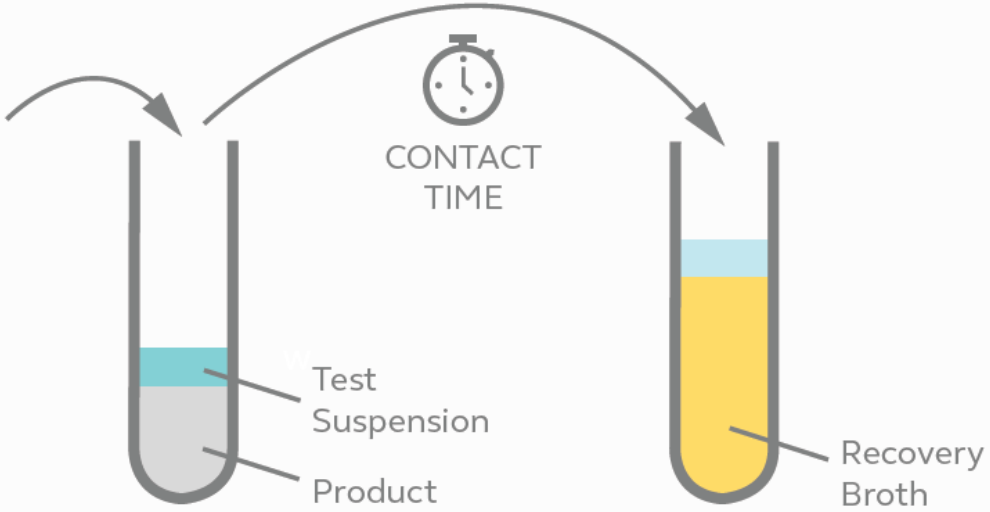
Diagram 1: EN 14561 test method



Overview of TGA

Challenge 1

Household & Commercial grade, skin antiseptics



1) 3ml of disinfectant is diluted according to manufacturer's recommendation.

2) 1 ml of bacteria is inoculated in the suspension.

3) 5 drops of the mixture is withdrawn after 8mins from the mixture.

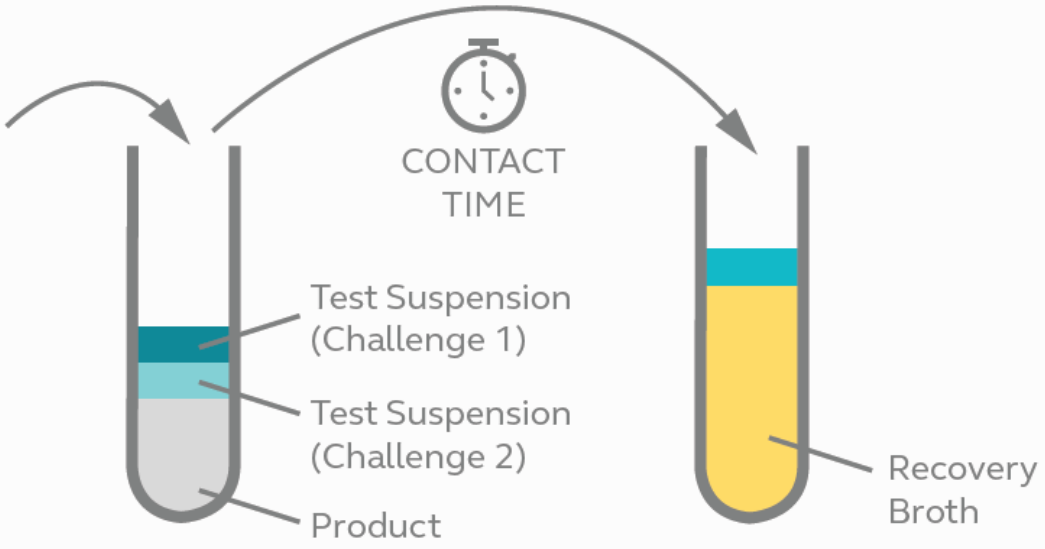
4) Cultured in 5 test tubes containing recovery broth and appropriate neutralizer.

5) After 48hours, challenge is passed if not visual growth is noted in at least 2 of the recovery broth.

Overview of TGA

Challenge 2

Hospital grade disinfectant



1) By inoculating additional 1ml of bacteria into challenge 1 mixture
2) 5 drops are withdrawn from the mixture after further 8 mins and cultured in 5 test tibes containing recovery broth & neutralizer
3) Test is passed if no visual growth after 48 hours in at least 2 of the recovery broth

Difference between EN & TGA

	EN Norms	TGA
Product Classification	Medical area Veteinary Area Food, industrial, domestic & Institutional area	Hospital Grade Household/Commercial Grade Antiseptic
Test Organisms	Enterococcus faecium Enterococcus hirae Escherichia coli Pseudomonas aeruginosa Staphylococcus aureus	Escherichia coli Proteus vulgaris Pseudomonas aeruginosa Staphylococcus aureus
Test	Quantitative Test (Bacterial Colony)	Qualitative Test (Visual Analysis)
Contact Time	Specific Contact Times	8 minutes for each challenge

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SHARING EXPERTISE

Difference between EN & TGA

	EN Norms	TGA
% of product in test (ready to use)	80% using Standard Method, 97% for modified method	75% for 1st Challenge, 60% fro second challenge
Interfering Substances	Bovine albumin – Clean condition Sheep erythrocyte – dirty condition	Option A: Sterile Water Option B: 4 parts yeast suspension + six parts sterile hard water Option C: Nutrient Broth Option D: Sterile hard water, dilute 1:100 with hard water and add 8ml of final dilution to 2ml sheep serum.
Test Temperature	Medical area Handwash/Handrub – 20 C Instrument disinfectant 20 C to 70 C Surface 4 to 30 C	21 C

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SHARING EXPERTISE

Summary

- The EN standard for making claim for a product should be based on EN 14885.
- This standards are established with consens from 36 europaen nations
- Every product has to be tested in phase 2, step 1 **and** phase 2, step 2