Verbund für Angewandte Hygiene e.V.
Desinfektionsmittel-Kommission

Requirements and Methods for VAH-Certification of Chemical Disinfection Procedures

VAH Disinfectants Commission (ed.)

Continually updated edition, as of 1 November 2021

Verbund für Angewandte Hygiene e.V.
Desinfektionsmittel-Kommission

Association for Applied Hygiene
Disinfectants Commission

Requirements and Methods for VAH Certification of Chemical Disinfection Procedures

Edited by VAH Disinfectants Commission

Chapter 1 to 4: As of 1 November 2021

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1 Requirements and methods for VAH certification of chemical disinfection procedures

The present test methods and requirements were compiled by the Disinfectants Commission at the Association for Applied Hygiene (VAH). They completely replace the publications *Requirements and methods for VAH certification of chemical disinfection procedures,* as of 2 April 2015 with supplements [1] as well as the communications regarding changes in methods published since then in the journal *Hygiene & Medizin*.

Preliminary remarks

This revision of the requirements and test methods reflects the current state of science and these will be continually updated in future and published in the status valid at that particular time.

All currently relevant standardization projects undertaken by Working Group 1 (WG 1) of CEN/TC 216 have been integrated into these requirements [2]. If preliminary standards are applicable, their status is given.

The test methods described here do not allow conclusions to be drawn about additional properties such as e. g. cleaning efficacy, toxicity and environmental impact.

Like all preventative measures in the healthcare sector, disinfection measures are implemented for the protection of patients, staff and third parties. The intended fields of application are areas, rooms and situations in which disinfection is medically indicated. These indications apply in patient care, for example in hospitals, other medical establishments and in dental practices as well as in cases with a high incidence (outbreaks) of certain infectious diseases in schools, nurseries, nursing homes, care homes, health resorts as well as in the workplace or the home. They also include laundries and hospital ward kitchens supplying their products to patients. They may also be applied in service facilities, such as e.g. hairdressing salons, manicure and pedicure salons, optician practices, ear piercing and tattoo parlours and acupuncture practices. Large scale commercial kitchens with their rooms used for food preparation and for clearing up after serving food are subject to specific hygienic requirements governed by foodstuffs legislation because of the conditions prevailing in such settings (temperatures, demands). Products for this sector are generally tested and listed in accordance with the requirements of the German Veterinary Medical Society (DVG) [3].

The test methods described here should be construed as standard methods. They contain the experimental tests for efficacy testing of products and procedures for hand, surface, instrument and laundry disinfection as well as skin antisepsis. The expert accessor bears responsibility for ensuring the suitability

of these standard methods for testing the respective procedure as well as for modification of the method. Accordingly, on the one hand, methodological changes or expanded testing may be needed to demonstrate the efficacy of certain products, especially in the case of new active substances or established products known to have certain problems. On the other hand, modifications are permitted if they have been sufficiently standardised and validated, thus increasing the power of the tests. In all cases, any deviation from, or supplements to, the standard methods must be stated, described and justified in the test report.

References

1. Desinfektionsmittel-Kommission im VAH (Hrsg.). Anforderungen und Methoden zur VAH-Zertifizierung chemischer Desinfektionsverfahren. Stand: 2.4.2015 mit Ergänzungen. Wiesbaden: mhp Verlag. [English version available online from https://vah-online.de/files/download/ebooks/eBook_VAH_RequirementsandMethods.pdf , accessed 20 December 2021]
2. DIN EN 14885:2019-10. Chemische Desinfektionsmittel und Antiseptika – Anwendung Europäischer Normen für chemische Desinfektionsmittel und Antiseptika, Deutsche Fassung EN 14885:2018.
3. DVG. Voraussetzung für die Desinfektionsmittelprüfung und Aufnahme in die Desinfektionsmittellisten der DVG. Stand 1.2.2015. Abrufbar über https://www.desinfektion-dvg.de/index.php?id=1809

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2 Principles of disinfectant testing

2.1 Test method

The microbicidal and virucidal activity (efficacy) is determined in quantitative tests, such that in this way a statement can be made on the inactivation kinetics. The disinfectant efficacy of the different application procedures is determined in two steps:

– In vitro tests (phase 2, step 1)

– Tests under simulated-use conditions (phase 2, step 2).

The in vitro tests are intended to provide insights into the microbicidal properties of the test procedure at different concentrations, contact times and, if necessary, exposure temperatures. Furthermore, changes in the kill (inactivation) kinetics when using interfering substances tailored to the application procedure (e. g. protein or blood), is also recorded. The structure of the in vitro tests described here comply with phase 1 and phase 2/step 1 tests of the comparable European standards or preliminary standards. The results of the in vitro tests alone provide no clear conclusions on the likely efficacy of the test product when used under everyday conditions. Rather, the results of the in vitro tests or fulfilment of the requirements for the respective application procedures are a prerequisite for determination of the concentration-time (temperature) relations with which tests are to be carried out under simulated-use conditions.

Tests under simulated-use conditions help conclude whether, as per the current state of knowledge, the efficacy of a product under the conditions of the application procedure can be classified as suitable. Due to the vast number of influencing factors coming into play in such test series, larger scatter ranges are to be expected. Therefore, the reliability of the insights afforded is increased by performing a higher number of individual tests per test batch or by using reference procedures or reproducibility testing. The structure of the simulated-use tests is in accordance with phase 2/step 2 tests of the comparable European standards or preliminary standards. If instrument disinfectants are used as an immersion procedure for reprocessing medical devices, it should be noted that the entire reprocessing process must be validated, i.e. all individual steps executed for medical devices classified as “semi-critical” or higher.

2.2 Overview of the test methods for the different fields of application

Details of testing for the different fields of application as well as the requirements to be met by the results are given below. These include “screening”, "obligatory" and "optional" tests.

Screening tests are not obligatory and are not taken into account when stipulating the use recommendations for the disinfection procedure. However, the results of the screening tests can provide important insights and facilitate decision-making for the further course of action and may reduce the investment needed for the obligatory tests.

The results from the obligatory tests are the basis for assessment of the disinfection procedure. Quantitative suspension tests and the simulated-use test must be conducted as obligatory tests for the respective field of application.

Furthermore, additional optional tests permitting more extensive insights into the product’s activity spectrum (**see Table 2.1**) can be performed. Other methods must be used in special, appropriately justified, cases – in accordance with the current state of knowledge.

Certifiable procedures

1) *Hygienic hand washing*
   Contact time 30 seconds or 1 minute

2) *Hand disinfection*
   a) Hygienic hand disinfection: Contact time 30 seconds or 1 minute
   b) Surgical hand disinfection: Contact time 1 / 1.5 / 2 / 2.5 / 3 or 5 minutes

3) *Skin antisepsis / Skin disinfection*
   Depending on the skin area, contact time 15 seconds, 30 seconds or 1 minute for skin with a low density of sebaceous glands and 1 / 1.5 / 2 / 2.5 / 3 / 3.5 / 4 / 4.5 / 5 and 10 minutes for skin with a high density of sebaceous glands

4) *Surface disinfection*
   Contact time 1, 5, 15, 30, 60 and 240* minutes
   Additionally: disinfection of fungi on unprocessed wood, potential contact times as above

5) *Instrument disinfection as immersion disinfection*
   Contact time 5, 15, 30, 60 minutes

6) *Textile disinfection, chemical or chemothermal*
   Contact time from 5 to 20 minutes. Application method dependent on procedure.

* Only for surface disinfection without mechanical action

Table 2.1: Summary of the test methods and their EN equivalents for different claims in the VAH List. All procedures must be tested for bactericidal and yeasticidal activity and be found effective.

Field of application	Phase/ Step	Activity spectrum								
		Bactericidal	**Yeasticidal**	**Fungicidal** *optional*	**Tuberculocidal** *optional*	**Mycobactericidal** *optional*	**Active against enveloped viruses** *optional*	**Limited spectrum virucidal activity** *optional*	**Virucidal** *optional*	**Sporicidal** ***C. difficile*** *optional*
Hygienic hand washing		Method 7 *screening*	Method 7 *screening*							
		Method 8 *screening*	Method 8 *screening*							
	2 / 1	Method 9 *or EN 13727*	Method 9 or EN 13624				DVV, RKI 2015 *or EN 14476* [a]			
	2 / 2	Method 10 *or EN 1499*								
Hygienic hand disinfection		Method 7 *screening*	Method 7 *screening*							
		Method 8 *screening*	Method 8 *screening*							
	2 / 1	Method 9 *or EN 13727*	Method 9 *or EN 13624*				DVV, RKI 2015 *or EN 14476* [a]	DVV, RKI 2015 *or EN 14476*	DVV, RKI 2015 *or EN 14476* [b]	
	2 / 2	Method 11 *or EN 1500*							prEN 17430	
Surgical hand disinfection		Method 7 *screening*	Method 7 *screening*							
		Method 8 *screening*	Method 8 *screening*							
	2 / 1	Method 9 *or EN 13727*	Method 9 *or EN 13624*							
	2 / 2	Method 12 *or EN 12791*	Method 12 *or EN 12791*							

Continuation Table 2.1: Summary of the test methods and their EN equivalents for different claims in the VAH List. All procedures must be tested for bactericidal and yeasticidal activity and be found effective. (This table reflects the status of **1 November 2021**).

Field of application	Phase/ Step	Activity spectrum								
		Bactericidal	**Yeasticidal**	**Fungicidal** *Optional*	**Tuberculocidal** *optional*	**Mycobactericidal** *optional*	**Active against enveloped viruses** *optional*	**Limited spectrum virucidal activity** *optional*	**Virucidal** *optional*	**Sporicidal** ***C. difficile*** *optional*
Skin antisepsis		Method 7 *screening*	Method 7 *screening*							
		Method 8 *screening*	Method 8 *screening*							
	2 / 1	Method 9 *or EN 13727*	Method 9 *or EN 13624*				DVV, RKI 2015 *or EN 14476* [a]			
	2 / 2	Method 13	Method 13							
Surface disinfection		Method 7 *screening*	Method 7 *screening*							
		Method 8 *screening*	Method 8 *screening*							
	2 / 1	Method 9 *or EN 13727*	Method 9 *or EN 13624*	Method 9 *or EN 13624*	Method 9 *or EN 14348*	Method 9 *or EN 14348*	DVV, RKI 2015 *or EN 14476* [a]	DVV, RKI 2015 *or EN 14476*	DVV, RKI 2015 *or EN 14476*	Method 18 *or EN 17126* [g]
Surface disinfection without mechanical action	2 / 2	Method 14.1 *or EN 17387* [h]	Method 14.1 *or EN 17387* [i]	Method 14.1 *or EN 17387* [i]	Method 14.1	Method 14.1	DVV 2012 *or EN 16777* [c]	DVV 2012 *or EN 16777* [d]	DVV 2012 *or EN 16777* [e]	
with mechanical action	2 / 2	Method 14.2 *or EN 16615*	Method 14.2 *or EN 16615*	Method 14.2	Method 14.2	Method 14.2	*Simulated-use tests by CEN under development*	*Simulated-use tests by CEN under development*	*Simulated-use tests by CEN under development*	Method 19
Instrument disinfection		Method 7 *screening*	Method 7 *screening*							
		Method 8 *screening*	Method 8 *screening*							
	2 / 1	Method 9 *or EN 13727*	Method 9 *or EN 13624*	Method 9 *or EN 13624*	Method 9 *or EN 14348*	Method 9 *or EN 14348*	DVV, RKI 2015 *or EN 14476* [a]		DVV, RKI 2015 *or EN 14476* [b] *to 40 °C or DVV, RKI 2015 or EN 14476* [f] *≥40 °C*	Method 18 *or EN 17126* [g]
	2 / 2	Method 15 *or EN 14561*	Method 15 *or EN 14562*	Method 15 *or EN 14562*	Method 15 *or EN 14563*	Method 15 *or EN 14563*	*EN 17111*		*EN 17111*	

Continuation Table 2.1: Summary of the test methods and their EN equivalents for different claims in the VAH List. All procedures must be tested for bactericidal and yeasticidal activity and be found effective. (This table reflects the status as of **1 November 2021**).

Field of application	Phase/ Step	Activity spectrum								
		Bactericidal	**Yeasticidal**	**Fungicidal** *optional*	**Tuberculocidal** *optional*	**Mycobactericidal** *optional*	**Active against enveloped viruses** *optional*	**Limited spectrum virucidal activity** *optional*	**Virucidal** *optional*	**Sporicidal** ***C. difficile*** *optional*
Chemical laundry disinfection (manual immersion procedure)		Method 7 *screening*	Method 7 *screening*							
		Method 8 *screening*	Method 8 *screening*							
	2 / 1	Method 9 *or EN 13727*	Method 9 *or EN 13624*	Method 9 *or EN 13624*	Method 9 *or EN 14348*	Method 9 *or EN 14348*				Method 18 *or EN 17126* [g]
	2 / 2	Method 16	Method 16	Method 16	Method 16	Method 16				
Automated chemo-thermal textile disinfection		Method 7 *screening*	Method 7 *screening*							
		Method 8 *screening*	Method 8 *screening*							
	2 / 1	Method 9 *or EN 13727*	Method 9 *or EN 13624*	Method 9 *or EN 13624*	Method 9 *or EN 14348*	Method 9 *or EN 14348*			*EN 14476* [f]	Method 18 *or EN 17126* [g]
	2 / 2	Method 17 *or EN 16616*	Method 17 *or EN 16616*	Method 17 *or EN 16616*	Method 17 *or EN 16616*	Method 17 *or EN 16616*				

If European standards are applied, tests must be carried out in duplicate while calculating the mean confidence interval as per DVV, RKI 2015.

a. EN 14476 only with MVA (Modified vaccinia virus Ankara)

b. EN 14476 + SV40

c. EN 16777 only with MVA (Modified vaccinia virus Ankara)

d. Low level: EN 16777 only with adenovirus + murine norovirus

e. High level: EN 16777 only with adenovirus + murine norovirus + murine parvovirus

f. EN 14476 only with murine parvovirus

g. EN 17126 only with *C. difficile*

h. or EN 13697 or EN 14349 mod. as per EN 14885

i. or EN 13697 or EN 16438 mod. as per EN 14885

References

All standards, preliminary standards and guidelines given in Table 2.1 are listed by topic in the following overview:

General standards for disinfection

DIN EN 14885:2019-10. Chemische Desinfektionsmittel und Antiseptika – Anwendung Europäischer Normen für chemische Desinfektionsmittel und Antiseptika. Deutsche Fassung EN 14885:2018.

DIN EN 13727:2015-12. Chemische Desinfektionsmittel und Antiseptika – Quantitativer Suspensionsversuch zur Prüfung der bakteriziden Wirkung chemischer Desinfektionsmittel im humanmedizinischen Bereich – Prüfverfahren und Anforderungen (Phase 2/Stufe 1). Deutsche Fassung EN 13727:2012+A2:2015.

DIN EN 13624:2013-12. Chemische Desinfektionsmittel und Antiseptika – Quantitativer Suspensionsversuch zur Prüfung der fungiziden Wirkung chemischer Desinfektionsmittel im humanmedizinischen Bereich – Prüfverfahren und Anforderungen (Phase 2/Stufe 1). Deutsche Fassung EN 13624:2013.

DIN EN 14348:2005-04. Chemische Desinfektionsmittel und Antiseptika – Quantitativer Suspensionsversuch zur Bestimmung der mykobakteriziden Wirkung chemischer Desinfektionsmittel im humanmedizinischen Bereich einschließlich der Instrumentendesinfektion – Prüfverfahren und Anforderungen (Phase 2/Stufe 1). Deutsche Fassung EN 14348:2005

DVV/RKI. Leitlinie der Deutschen Vereinigung zur Bekämpfung der Viruskrankheiten (DVV) e.V. und des Robert Koch-Instituts (RKI) zur Prüfung von chemischen Desinfektionsmitteln auf Wirksamkeit gegen Viren in der Humanmedizin – Fassung vom 1. Dezember 2014. Bundesgesundheitsbl 2015; 58:493–504.

DIN EN 14476:2019-10. Chemische Desinfektionsmittel und Antiseptika - Quantitativer Suspensionsversuch zur Bestimmung der viruziden Wirkung im humanmedizinischen Bereich – Prüfverfahren und Anforderungen (Phase 2/Stufe 1); Deutsche und Englische Fassung EN 14476:2013+A2:2019.

DIN EN 17126:2019-02. Chemische Desinfektionsmittel und Antiseptika – Quantitativer Suspensionsversuch zur Bestimmung der sporiziden Wirkung im humanmedizinischen Bereich – Prüfverfahren und Anforderungen (Phase 2/Stufe 1); Deutsche Fassung EN 17126:2018

Hygienic hand washing, Hygienic hand disinfection

DIN EN 1499:2017-10. Chemische Desinfektionsmittel und Antiseptika – Hygienische Händewaschung – Prüfverfahren und Anforderungen (Phase 2/Stufe 2); Deutsche Fassung EN 1499:2013.

DIN EN 1500:2017-10. Chemische Desinfektionsmittel und Antiseptika – Hygienische Händedesinfektion – Prüfverfahren und Anforderungen (Phase 2/Stufe 2); Deutsche Fassung EN 1500:2013.

DIN EN 17430:2019-09 Entwurf Chemische Desinfektionsmittel und Antiseptika – Viruzide hygienische Händedesinfektion – Prüfverfahren und Anforderungen (Phase 2/Stufe 2); Deutsche und Englische Fassung prEN 17430:2019.

DIN EN 12791:2018-01. Chemische Desinfektionsmittel und Antiseptika – Chirurgische Händedesinfektionsmittel – Prüfverfahren und Anforderungen (Phase 2/Stufe 2); Deutsche Fassung EN 12791:2016+A1:2017.

Surface disinfection

DIN EN 17387:2021-10. Chemische Desinfektionsmittel und Antiseptika - Quantitativer Versuch zur Bestimmung der bakteriziden und levuroziden und/oder fungiziden Wirkung chemischer Desinfektionsmittel im humanmedizinischen Bereich auf nicht porösen Oberflächen ohne mechanische Einwirkung - Prüfverfahren und Anforderungen (Phase 2, Stufe 2); Deutsche Fassung EN 17387:2021

DIN EN 13697:2019-10. Chemische Desinfektionsmittel und Antiseptika – Quantitativer Oberflächen-Versuch nicht poröser Oberflächen zur Bestimmung der bakteriziden und/oder fungiziden Wirkung chemischer Desinfektionsmittel in den Bereichen Lebensmittel, Industrie, Haushalt und öffentliche Einrichtungen – Prüfverfahren und Anforderungen ohne mechanische Behandlung (Phase 2/Stufe 2); Deutsche Fassung EN 13697:2015+A1:2019.

DIN EN 14349:2013-02. Chemische Desinfektionsmittel und Antiseptika – Quantitativer Oberflächenversuch zur Bestimmung der bakteriziden Wirkung chemischer Desinfektionsmittel und Antiseptika für den Veterinärbereich auf nicht-porösen Oberflächen ohne mechanische Wirkung – Prüfverfahren und Anforderungen (Phase 2/Stufe 2); Deutsche Fassung EN 14349:2012.

DIN EN 16438:2014-07. Chemische Desinfektionsmittel und Antiseptika – Quantitativer Oberflächenversuch zur Bestimmung der fungiziden oder levuroziden Wirkung chemischer Desinfektionsmittel und Antiseptika für den Veterinärbereich auf nicht-porösen Oberflächen ohne mechanische Wirkung – Prüfverfahren und Anforderungen (Phase 2/Stufe 2); Deutsche Fassung EN 16438:2014.

DIN EN 16615:2015-06. Chemische Desinfektion und Antiseptika – Quantitatives Prüfverfahren zur Bestimmung der bakteriziden und levuroziden Wirkung auf nicht-porösen Oberflächen mit mechanischer Einwirkung mit Hilfe von Tüchern oder Mops im humanmedizinischen Bereich (4-Felder-Test) – Prüfverfahren und Anforderungen (Phase 2/Stufe 2); Deutsche Fassung EN 16615:2015.

DVV. Quantitative Prüfung der viruziden Wirksamkeit chemischer Desinfektionsmittel auf nicht-porösen Oberflächen (Anwendung im Bereich Humanmedizin). HygMed 2012;37(3): 78–85.

DIN EN 16777:2019-03. Chemische Desinfektionsmittel und Antiseptika – Quantitativer Versuch auf nicht porösen Oberflächen ohne mechanische Einwirkung zur Bestimmung der viruziden Wirkung im humanmedizinischen Bereich – Prüfverfahren und Anforderungen (Phase 2/Stufe 2); Deutsche Fassung EN 16777:2018.

Instrument disinfection as immersion procedure

DIN EN 14561:2006-08. Chemische Desinfektionsmittel und Antiseptika – Quantitativer Keimträgerversuch zur Prüfung der bakteriziden Wirkung für Instrumente im humanmedizinischen Bereich – Prüfverfahren und Anforderungen (Phase 2/Stufe 2); Deutsche Fassung EN 14561:2006.

DIN EN 14562:2006-08. Chemische Desinfektionsmittel und Antiseptika – Quantitativer Keimträgerversuch zur Prüfung der fungiziden oder levuroziden Wirkung für Instrumente im humanmedizinischen Bereich – Prüfverfahren und Anforderungen (Phase 2/Stufe 2); Deutsche Fassung EN 14562:2006.

DIN EN 14563:2009-02. Chemische Desinfektionsmittel und Antiseptika – Quantitativer Keimträgerversuch zur Prüfung der mykobakteriziden oder tuberkuloziden Wirkung chemischer Desinfektionsmittel für Instrumente im humanmedizinischen Bereich – Prüfverfahren und Anforderungen (Phase 2/Stufe 2); Deutsche Fassung EN 14563:2008.

DVV/GfV, RKI. Mitteilung des Fachausschusses Virusdesinfektion der DVV/GfV und des RKI zur Untersuchungstemperatur bei der Prüfung von chemischen bzw. chemothermischen Instrumentendesinfektionsverfahren entsprechend der DVV/RKI-Leitlinie in der Fassung vom 01.12.2014. Bundesgesundheitsbl 2015;58(8):888.

DIN EN 17111:2018-12. Chemische Desinfektionsmittel und Antiseptika – Quantitativer Keimträgerversuch zur Prüfung der viruziden Wirkung für Instrumente im humanmedizinischen Bereich – Prüfverfahren und Anforderungen (Phase 2/Stufe 2); Deutsche Fassung EN 17111:2018.

Textile disinfection

DIN EN 16616:2015-10. Chemische Desinfektionsmittel und Antiseptika – Chemothermische Wäschedesinfektion – Prüfverfahren und Anforderungen (Phase 2/Stufe 2); Deutsche Fassung EN 16616:2015.

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3 Assessment procedure for VAH certification

3.1 Application submission

The following documents must be sent by post for certification of a product:

1. Application form in quadruplicate for award/renewal of a certificate.
2. Two independent expert opinions in triplicate with test reports.
3. Labels or draft labels, product information, safety data sheet. For new products at least a complete description of the recommended application method must be submitted.

Send to:

Disinfectants Commission im VAH

c/o Institut für Hygiene and Öffentliche Gesundheit

des Universitätsklinikums Bonn

Venusberg-Campus 1, Gebäude 63

53127 Bonn

Germany

More detailed information and **application forms** can be downloaded from the VAH homepage, under VAH List for Manufacturers

3.2 Requirements for test report, expert opinion and expert assessor

3.2.1 Test report

Test reports must contain the results of all tests in tabular form. Details are given under the respective test methods. No description of the method is needed if it is conducted according to these standard methods or to a relevant European standard. However, any deviation from the method should be declared and justified. For each test a reference should be made to one of the standard methods or standards with date of issue.

Unless stated otherwise, the baseline colony count should be stated in cfu per ml for the test suspensions used. Each test series must contain an assessment of the results showing the extent to which the efficacy requirements are fulfilled in terms of the standard methods or the standards.

Test reports must contain the following:

- Name and address of the test laboratory,
- Product name of the original trade packaging or a clear test sample name that can be traced back to the customer,
- Customer,
- Date of order / receipt of samples,
- Test period,
- Batch number and/or date of manufacture, if applicable expiry date,
- Description of product, e.g. liquid or powder, colour, appearance, scent,
- pH value of concentrate and of a 1% product solution,
- Active substances according to type and amount based on the manufacturer's information in line with the applicable legally binding provisions.

3.2.2 Expert opinion

The expert opinion must feature the expert accessor's personal letterhead and be signed by the expert accessor concerned. The name of the product, a reference to the test reports and the recommendation for use with area of application and effective concentration-time relations must be clearly stated based on the test results obtained, taking account of the current state of scientific knowledge.

3.2.3 Expert assessor

The expert accessor must have experience as an expert in the area of disinfectant testing and hospital hygiene. Expert accessors who have a degree in medicine or a related science degree and a minimum of more than two years of experimental experience in the disinfectant testing sector can be regarded as an expert assessors.

A list of expert assessors who issue expert opinions according to the requirements for certification of chemical disinfection procedures by the VAH can be found on the VAH homepage.

3.3 Quality assurance

Each test laboratory must be accredited and undergo regular quality control organized by the VAH Disinfectants Commission by taking part in ring trials. It must also be guaranteed that representatives appointed by the Disinfectants Commission are granted access to the test laboratory with the right to inspect the laboratory facilities and the VAH-relevant laboratory protocols.

3.3.1 Test laboratories

A list of test laboratories issuing test reports according to the requirements for certification of chemical disinfection procedures by the VAH can be found on the VAH homepage.

3.3.2 Spot checks by the Disinfectants Commission

The Disinfectants Commission head office will regularly conduct or commission spot checks of commercially available products. The certificate holder must not be informed in advance of the time of the spot check. The following parameters must be checked: pH of the concentrate (excluding alcohols), pH of the use concentration of the product solution in WSH, refractive index, density. Additionally, the content of active substances can be tested using the manufacturer's methods (see III Section 2 [1]). In the case of deviations, the applicant will be asked for a commentary. The Disinfectants Commission will then decide if microbiological retesting is needed, in particular of the test results in the submitted test reports, which were decisive for the concentration / contact time relations, including the neutralisation parameters. The test findings will be presented to the Disinfectants Commission with an evaluation. If the Disinfectants Commission endorses the assessment or unanimously amends it, the head office will inform the certificate holder of this outcome.

References

1. Verbund für Angewandte Hygiene (VAH) (2013). Geschäftsordnung der Desinfektionsmittel-Kommission im VAH. Stand 1. Juli 2013. Download über: www.vah-online.de [English translation available from the website]

4 Efficacy against specific pathogens

4.1 Bacterial spores

The VAH in cooperation with the 4+4 Working Group has published as **VAH Method 18** a quantitative suspension test for testing sporicidal activity against anaerobic sporulating microbes, while using *Clostridium difficile* ribotype R027 spores.

This test method has also been submitted via DIN to WG 1 of CEN TC 216 and published as DIN EN 17126 [1].

Contrary to the test procedures commonly used for declaration purposes, this suspension test stipulates, among other things, a higher level of spore reduction. Accordingly, reduction by 4 lg levels (in the previously published test methods only by 3 lg levels) must be demonstrated.

A simulated-use 4-field test – surface disinfection with mechanical action – for efficacy testing against *C. difficile* spores has been investigated by the VAH for feasibility and robustness and established as **VAH Method 19**. Hence, listing of sporicidal surface disinfectants with mechanical action against *C. difficile* spores is possible.

On receipt of an application from a company, the product test reports and expert opinions will be reviewed by independent experts. For the conformity assessment procedure two independent expert opinions, including test reports and data on sensitivity testing of the spore suspension used, confirming the claimed concentration-time relation must be submitted.

There are no established, simulated-use test methods for the other fields of application in the medical setting, e.g. instrument immersion disinfection or textile disinfection. Until such time as listing of sporicidal products is possible in these fields of applications, users should at least request tests based on VAH Method 18 or prEN 17126 [1].

4.2 Efficacy against viruses

The inclusion of virucidal properties in the VAH List is intended as a means of giving the user the opportunity to select disinfectants which, based on the current state of knowledge, have demonstrated activity against enveloped viruses, limited spectrum virucidal activity and/or virucidal activity in the quantitative suspension test and in the test under simulated-use conditions (if available).

On receipt of a corresponding application from a company for certification (of a product), the test reports and expert opinions relating to the respective products will be reviewed by independent experts.

For the conformity assessment procedure two independent expert opinions, including test reports, confirming efficacy in the claimed concentration-time relation must be submitted.

The test methods with the associated test viruses, interfering substances and test conditions are specified for the respective fields of application.

Likewise, for tests carried out in accordance with a European standard the effective concentration-time relation must be confirmed in a second independent test. The reproducibility test (second test batch) must be performed using at least the use concentration and must include as controls the virus control, the cytotoxicity test and the reference test.

Since European standards and the corresponding DVV guidelines may be used as test methods, the test report must clearly state which method was used for testing. To improve interpretation of the results all deviations from the respective method must be clearly described. If a large volume-plating method is used, the dilutions and volumes used for all test and control batches must be specified.

The bactericidal and yeasticidal (levoricidal) activity confirmed by the VAH by means of a conformity assessment procedure or confirmed additionally during this procedure is a prerequisite for certification.

The contact time for activity against viruses featured in the VAH List must not be shorter than that specified for the bactericidal/yeasticidal efficacy. The test concentrations and contact times must be selected such that the relationship between the disinfectant virucidal activity and the concentration and contact time is evident from the test results (kinetics).

The following activity spectrums may be listed: activity against enveloped viruses, limited spectrum virucidal activity, virucidal activity [2].

1. effective against enveloped viruses
2. effective against enveloped viruses and adenoviruses, norovirus and rotavirus [2]
3. effective against enveloped and non-enveloped viruses.

If the activity spectrum “limited spectrum virucidal activity” or “virucidal” is applied for in the absence of a listing for the activity spectrum against enveloped virudses, efficacy against enveloped viruses must as a rule be demonstrated in addition. This applies in particular for products containing active substances or active principles on which little information is available on the virucidal efficacy[†].

Table 4.1 gives a summary of the test viruses used and thus of the viruses covered.

[†] Information on this can be obtained from the head office

Table 4.1: Test viruses used for efficacy testing of disinfectants and selected viruses covered by the test viruses.

Test viruses		Activity spectrum (example) [a, b]
Virucidal activity: enveloped and non-enveloped viruses	- Adenovirus, non-enveloped (Adenovirus type 5, Adenoid 75 strain) - Murine norovirus, non-enveloped (MNV, S99 Berlin strain) - Poliovirus, non-enveloped (Poliovirus type 1, LSs-2ab strain) - Polyomavirus SV40, non-enveloped (Simian virus 40, 777 strain)	**Papillomaviruses** **Parvoviruses**[b] - Parvovirus B19 - Bocaviruses **Picornaviruses** - Enteroviruses: coxsackieviruses, echoviruses, polioviruses, rhinoviruses - Hepatovirus: hepatitis A virus (HAV)[b] - Parechoviruses: echovirus 22 and 23 **Additionally, activity spectrum against enveloped viruses and limited virucidal activity**
Limited spectrum virucidal activity: adeno-, noro-, rotavirus	- Adenovirus, non-enveloped (Adenovirus type 5, Adenoid 75 strain) - Murine norovirus, non-enveloped (MNV, S99 Berlin strain)	**Viruses causing gastroenteritis** - Adenovirus serotype 40 and 41 - Norovirus - Rotavirus **Viruses causing respiratory infections** - Adenovirus serotype 7 **Viruses causing keratoconjunctivitis** - Adenovirus serotype 8, 19 and 37 **Additionally, activity spectrum against enveloped viruses**
Activity against enveloped viruses	- BVDV*, enveloped (Bovine Viral Diarrhea Virus) *Surrogate virus for hepatitis C virus - Vaccinia virus, enveloped (Elstree or MVA strain)	**Viruses causing bloodborne infections** - Hepatitis B virus (HBV) - Hepatitis C virus (HCV) - Human immunodeficiency virus (HIV) **Viruses causing respiratory infections** - Human coronaviruses (HCoV) 229E and OC43 - Influenza virus A (e.g. H1N1, H3N2) and B - Metapneumovirus - Respiratory syncytial virus (RSV) **Viruses causing travel-associated infections** - Bunyavirus (sandfly fever) - Dengue virus, Ebola virus, yellow fever virus, hantavirus, Lassa virus,Marburg virus - Crimean-Congo haemorrhagic fever virus - Tick-borne encephalitis virus (TBEV) - SARS-CoV-2, MERS-CoV - Rabies virus - West Nile virus (West Nile fever) **Herpesviruses** - Cytomegalovirus (CVM) - Herpes simplex viruses type 1 and 2 (HSV-1, HSV-2) - Epstein Barr virus (EBV) - Varicella Zoster virus (VZV) **Paramyxoviruses** - Measles virus - Mumps virus **Rubella virus**
Chemot-hermal Textile disinfection	- Minute virus of mice (MVM, murine parvovirus), non-enveloped	Please see “virucidal activity” “limited spectrum virucidal activity” and “activity against enveloped viruses”

Restrictions:
a. This classification can only serve as an indicative estimate since there is an active substance dependency and the effect cannot always be fully estimated.
b. For particularly stabile non-enveloped viruses, e.g. HAV, parvoviruses or gene vectors such as adeno-associated viruses (AAV) additional testing may be needed with the corresponding viruses [2,3]

Annex V sets out in detail the requirements to be met for certification of virucidal procedures.

To date, the following documents have been published as an annex: Annex V1A *Hygienic Hand disinfection*, Annex V2A *Surface disinfection*, Annex V3A *Instrument disinfection* and Annex V4A *Textile disinfection*.

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