附表１．in vivo標準試験法の比較

	EN1499	EN1500	EN12791	ASTM E1174	ASTM E2276	ASTM E2613
試験概要	医療従事者対象の衛生的手洗い	医療従事者対象の衛生的手指擦式	外科的衛生手洗いおよび手指擦式	医療従事者対象の手洗い製剤の有効性評価	成人の指腹を使用する衛生的手洗い/手指擦式剤の細菌除去効果を決定するための標準試験法	成人の指腹を使用する衛生的手洗い/手指擦式剤の真菌除去効果を決定するための標準試験方法
適用製品形状	固形、溶液	固形、溶液	固形、液体	液体	液体、ジェル、泡	液体、ジェル、泡
評価項目（即効性）	消毒直後のみ評価	消毒直後のみ評価	消毒直後	Log10の減少率	乾燥後の生存細菌の数の差	乾燥後の生存真菌の数の差
（持続性）	記載なし	記載なし	3時間後	各回復間隔/洗浄でのLog10の減少率	一定時間後後の生菌数の差	一定時間後の生菌数の差
使用する微生物（ウイルスを含む）	*Escherichia coli K12* (NCTC 10538)	*Escherichia coli K12* (NCTC 10538)	健常人ボランテイアの皮膚常在菌	*Serratia marcescens* (ATCC 14756) *Escherichia. Coli* (ATCC 11229)	no	*Candida albicans* (ATCC 10231) *Aspergillus niger* (ATCC 64958)
試験の手順	メーカー推奨量で30ないし60秒間スクラブ（対照；5mL、60秒間スクラブ）	メーカー推奨量で30ないし60秒間ラビング（対照；3mL、30秒間ラビングを2回）	メーカー推奨量で最長5分間ラビング（対照；3mL、2回、3分間ラビング）	グローブジュース法により行う。 試験微生物で汚染された手に試験品を適用し、残存した微生物をグローブに回収する。	Finger pad test	Finger pad test
評価の指標	ログ削減が対照（非薬用石鹸）よりも優れる	ログ削減が対照（60%v/vイソプロパノール）より劣らない	ログ削減が対照（60%v/vイソプロパノール）より劣らない	菌数の初発菌数に対する対数減少	乾燥による細菌の生存能力の喪失	乾燥による真菌の生存能力の喪失
参考文献番号	1～7	1～5, 8	1, 8	74～78	13～18	17, 19～23, 36

附表２．in vitro標準試験法の比較

	EN1040	EN13727	EN13624	ASTM E2315
試験概要	基本的な殺菌活性を評価するための定量的懸濁試験	医療分野での化学消毒剤の殺細菌活性を評価するための定量的懸濁試験	医療分野での化学消毒剤の殺真菌活性、殺酵母活性を評価するための定量的懸濁試験	タイムキルプロシージャを使用する抗菌活性評価のための標準ガイド
適用製品形状	固形、溶液	液体	液体	液体
評価項目（即効性）	Log10の減少率	Log10の減少率	Log10の減少率	Log10の減少率
使用する微生物（ウイルスを含む）	*Pseudomonas aeruginosa*（ATCC 15442） *Staphylococcus aureus*（ATCC 6538）	*Pseudomonas aeruginosa*（ATCC 15442） *Staphylococcus aureus*（ATCC 6538） *Enterococcus hirae*（ATCC 10541） *Escherichia coli K12*（NCTC 10538）	*Candida albicans*（ATCC 10231, CIP 4872, DSM 1386, CBS 6431, NCTC 3179）	特記なし
試験の手順	薬液：蒸留水：菌液を8：1：1で混合して作用	薬液：負荷物質：菌液を8:1:1で混合して作用 負荷物質： 0.3g/Lウシアルブミン溶液（擦式消毒剤） 3g/Lウシアルブミン溶液3mL/Lヒツジ赤血球（洗浄消毒剤）	薬液：負荷物質：菌液を8:1:1で混合して作用 負荷物質： 0.3g/Lウシアルブミン溶液（擦式消毒剤） 3g/Lウシアルブミン溶液と3mL/Lヒツジ赤血球（洗浄消毒剤）	Time-Kill test
評価の指標	5log10以上	5log10以上	4log10以上（洗浄手指消毒剤の場合は2log10以上）	細菌、真菌に対する処理ののち何秒でどのくらいが死滅するか
その他		微生物種は擦式手指消毒剤及び洗浄手指消毒剤の試験のための最小スペクトラム	微生物種は擦式手指消毒剤及び洗浄手指消毒剤の試験のための最小スペクトラム（酵母の指定はない）	
参考文献番号	9	9	9	24～33

	GB 15981	ASTM E2197	AOAC Use-Dilution Methods
試験概要	消毒と滅菌効果の評価方法と標準	化学物質の殺菌、殺ウイルス、殺菌、殺マイコバクテリア、および殺胞子活性を決定するための標準的な定量的ディスクキャリア試験法	
適用製品形状	液体	液体	液体
評価項目（即効性）	Log10の減少率	Log10の減少率 ウイルスの場合は感染した宿主細胞のLog10の減少率	記載なし
使用する微生物 （ウイルスを含む）	*Escherichia coli* (ATCC 8099) *Staphylococcus aureus* (ATCC 6538) *Candida albicans* (ATCC 10231) ポリオウイルス Ⅰ型ワクチン株 ※手消毒剤の一般要件を定めたGB 27950による指定	*Styphylococcus aureus* (ATCC 6538) *Pseudomonas aeruginosa* (ATCC 15442) *Conidia of Trichophyton metagrophyton* (ATCC 9533) *Candida albicans* (ATCC 10231) *Candida of Aspergillus niger* (ATCC 64958) *Mycobacterium terrae* (ATCC 15755) *Spores of Bacillus subtilis* (ATCC 19659) *Spores of Closiridium sporogenes* (ATCC 7955) *Human adenovirus* (ATCC VR-1516) Hepatotis A virus strain HM-175 (ATCC VR-1402) Canine parvovirous strain Cornell 780916-80 (ATCC VR-2017) Feline calicivirus F9 (ATCC VR-782) Human Rhinovirus 37 or 14 (ATCC VR-1147, VR284) Human Rotavirus strain Wa (ATCC VR-2018) Murine Norovirus(strain S99 or MNV-1)	*Styphylococcus aureus* (ATCC 6538) *Pseudomonas aeruginosa* (ATCC 15442) *Salmonera enterica* (ATCC 10708)
試験の手順	懸濁法／キャリア法	標準定量ディスク担体検査方法	定性的試験法
評価の指標	懸濁法 E. coli ≧5.00 S. aureus ≧5.00 C. albicans ≧4.00 ポリオウイルス ≧4.00 キャリア法 E. coli ≧3.00 S. aureus ≧3.00 C. albicans ≧3.00 ポリオウイルス ≧4.00	汚染された表面における標的生物の生存能力の対数減少を評価 ウイルスの場合は宿主細胞に感染する力の対数減少を評価	培養後の菌の発育の有無
その他	懸濁法とキャリア法がある		菌の発育の有無評価
参考文献番号	なし	34～49	50～60(但し955.14は56,57を除く)

	EN 14476	ASTM E1052
試験概要	医療分野での殺ウイルス活性を評価するための定量的懸濁液試験	懸濁液中のウイルスに対する殺菌剤の活性を評価するための標準的な方法
適用製品形状	液体	液体
評価項目（即効性）	Log10の減少率	記載なし
使用する微生物（ウイルスを含む）	Poliovirus type 1, LSc 2ab (Picornavirus) Murine norovirus, strain S99 Berlin Adenovirus type 5, strain Adenoid 75 (ATCC VR-5) Murine Parvovirus, minute virus of mice, strain Crawford (ATCC VR-1346) Modified vaccinia virus Ankara (MVA) (ATCC VR-1508) or vaccinia virus strain Elstree (ATCC VR-1549)	Adenovirus, Type 2 or Type 5 (ATCC VR-846, VR-5) Cell line options: Human Lung Carcinoma (A549) [CCL-185], HEp-2. [CCL-23], Vero [CCL-81] Canine Parvovirus, Cornell-780916-80 strain (ATCC VR-2017) Cell line option: A72 [CRL-1542] Cytomegalovirus, strain AD-169 (ATCC VR-538) Cell line options: Human diploid lung (MRC-5 [CCL-171] or WI-38 [CCL-75]) Feline calicivirus, strain F-9 (ATCC VR-782) Cell line option: CRFK [CCL-94] Hepatitis A Virus, HM-175 strain (ATCC VR-2093) Cell line options: FRhK-4 [CRL-1688] Herpes simplex virus, Type 1, strain F (1) (ATCC VR-733) Cell line options: VERO [CCL-81], HEp-2 [CCL-23] Influenza A, A/Hong Kong/8/68, A/PR/8/34 (ATCC VR-544, VR-95) Cell line options: Madin-Darby Canine kidney (MDCK) [CCL-34]; Rhesus monkey kidney (LLC-MK2) [CCL-7] Murine Norovirus Cell line: RAW 264.7 [TIB-71] Respiratory syncytial virus, Long strain (ATCC VR-26) Cell line options: HEp-2 [CCL-23], MRC-5 [CCL-171] Rhinovirus, Type 14 or 37 (ATCC VR-284, VR-1607) Cell line options: MRC-5 [CCL-171], WI-38 [CCL-75], HeLa T4+ Rotavirus, Wa strain (ATCC VR-2018) Cell line options: MA-104 [CRL-2378.1] or African green monkey kidney (CV-1) [CCL-70]. Vaccinia, WR strain, (ATCC VR-119) Cell line options: VERO [CCL-81], HEp-2 [CCL-23]
試験の手順	薬液：負荷物質：ウイルス液を8:1:1で混合して作用 負荷物質： 0.3g/Lウシアルブミン溶液（擦式消毒剤） 3g/Lウシアルブミン溶液と3mL/Lヒツジ赤血球（洗浄消毒剤）	薬液：ウイルス液を9:1で混合して作用
評価の指標	4log10以上	記載なし
その他	微生物種は擦式手指消毒剤及び洗浄手指消毒剤の試験のための最小スペクトラム 試験微生物を維持する方法としてEN 12353を挙げている	ウイルスの他、宿主を指定している 土壌負荷が必要な場合は、ウイルス懸濁液に追加
参考文献番号	61～73	11,12

附表３．標準試験法の参照文献

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