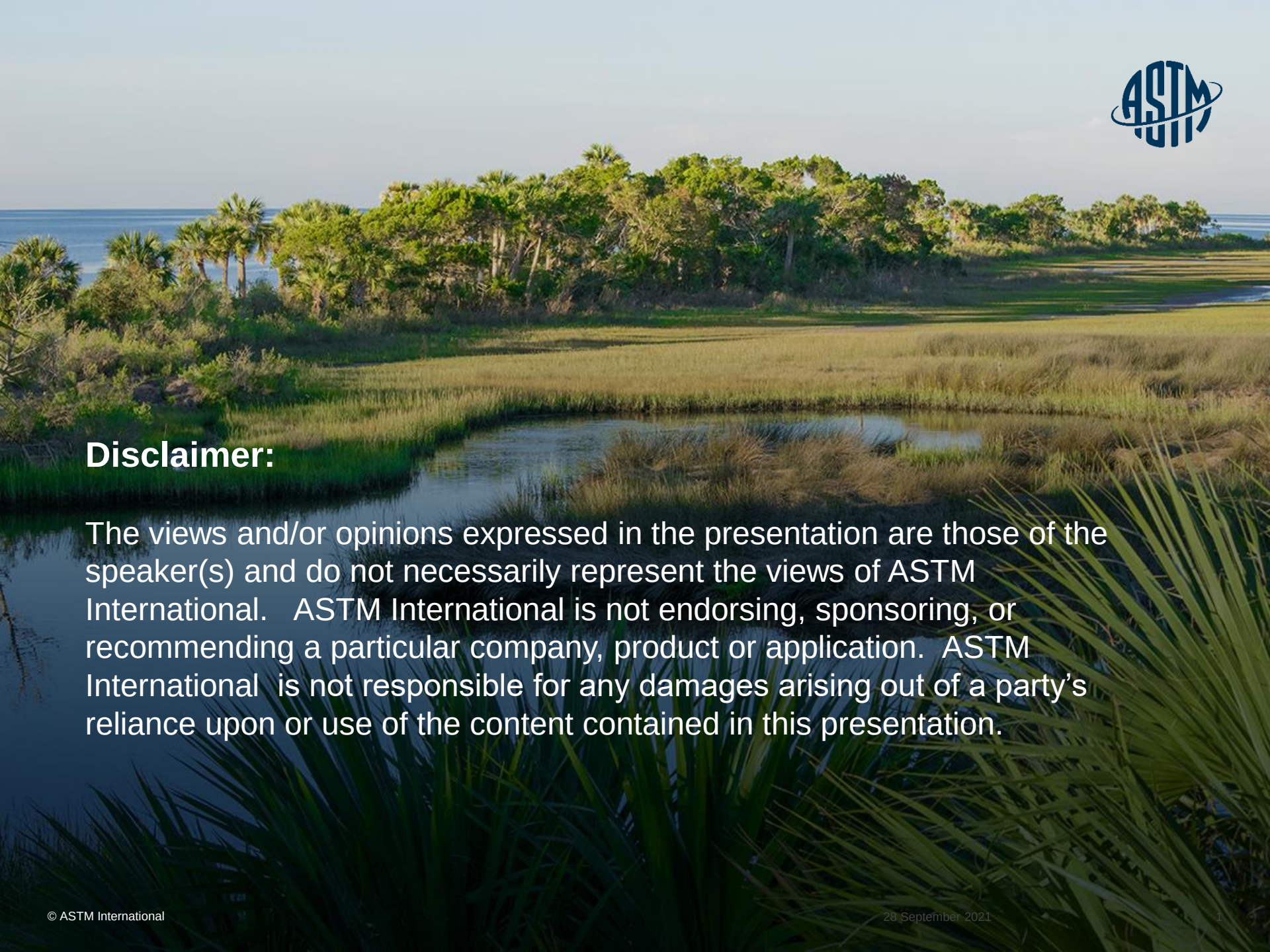


Disclaimer:

The views and/or opinions expressed in the presentation are those of the speaker(s) and do not necessarily represent the views of ASTM International. ASTM International is not endorsing, sponsoring, or recommending a particular company, product or application. ASTM International is not responsible for any damages arising out of a party's reliance upon or use of the content contained in this presentation.

ASTM INTERNATIONAL
Helping our world work better

Regulations Pertaining to Hand and Surface Sanitizers in the U.S. Market and a High-Level Review of Relevant ASTM International Standards

ASTM/JSMO Technical Training (IFC Program)

18 August 2021

.

www.astm.org

ASTM INTERNATIONAL
Helping our world work better

Regulatory Agencies, Regulation and Permissible Claims for Sanitizers in the U.S. Market

18 August 2021

Mary Czaplicki, MS.
R&D Microbiology Sr. Scientist, GOJO Industries, Inc.

www.astm.org

Contents

Sanitizer Categories

Hand sanitizers

- Antiseptic products applied to the skin that are not rinsed off with water after use (leave on products)
- Gels, sprays, wipes

Surface sanitizers

- Products applied to reduce, but not necessarily eliminate, microorganisms from the inanimate environment to levels considered safe as determined by public health codes or regulations.
- Liquids, sprays, wipes

2 separate regulatory agencies and approval processes

FDA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Hand Sanitizers: Regulations and Categories

U.S. Regulatory Agency:

- Regulated by the **FDA** (Food and Drug Administration) as over the counter drug products (OTC's)

Categories of hand sanitizers:

- Healthcare Antiseptics (Hand Rub and Surgical Scrub)
- Consumer Antiseptic Rubs
- Food Handler Antiseptics (Pre-Regulation)

  -Scope of efficacy requirements and allowable claims TBD

Hand Sanitizers: Claims

Allowable Claims:

– Claims for bacteria kill only

☑ "Reduces bacteria that can potentially cause disease"

☑ "Kills 99.99 percent of most common germs that may cause illness"

Unacceptable Claims:

– Viral claims

– Organism specific claims*

– Persistence

☒ " Kills Norovirus"

☒ "Kills MRSA"

☒ "Kills for 6, 12, 24 hours"

*Note: Can test for specified organisms relevant to the intended market but can't make organism specific claims on the label or marketing material

Allowable Hand Sanitizer Claim Example

“KILLS 99.99% OF ILLNESS CAUSING GERMS”

Hand Sanitizers: Pathways to Market

OTC MONOGRAPH ACTIVE

- A “rule book” listing approved active ingredients for each therapeutic category
- Lists **Generally Recognized As Safe and Effective (GRASE) a**ctive ingredients and specified dosage ranges
- Standard Labeling:
  - Uses (indications)
  - Warnings
  - Directions
- Requires final formulation testing for some categories
- Timing: No approval needed but must notify FDA about manufacturer and product details
- Cost: No regulatory/registration cost
- *Deferred actives for approval include:
  - **Ethanol**
  - **Isopropyl Alcohol**
  - **Benzalkonium Chloride**

NEW DRUG APPROVAL (NDA)

- Data demonstrating that a specific formulated **drug product** is safe and effective for use as directed for its approved indication
- FDA reviews sponsor’s submitted quality, safety and efficacy data and approves the product before it can be legally sold
- Changes to formulation, manufacturing process, or other approved specifications must also be FDA reviewed and approved before marketing
- Timing: Approximately 12 months after submission
- Cost: 1-1.5 million to file + testing costs
- Examples include Avagard (dual active=CHG/EtOH)
- Products approved through the NDA process are not subject to monograph review

Note: Safety and efficacy data are currently being collected to facilitate the approval process for the deferred actives mentioned above.

Hand Sanitizers: Efficacy Requirements

Efficacy Regulations/Requirements for Monograph Actives:

- Final formulation needs to show efficacy against key organisms using approved test methods

In vivo testing (**ASTM E2755**):

- Superiority to a Negative Control (saline)
- Non-Inferiority to the Active Control (CHG/EtOH product)

In vitro testing (**ASTM E 2783**):

- For selected specified organisms
- *Specific organisms can NOT be listed on the label

Surface Sanitizers: Regulations and Categories

U.S. Regulatory Agency:

- Regulated by the **EPA** (Environmental Protection Agency) as **antimicrobial pesticides**

Categories of surface sanitizers:

- **Food contact products** - Used on sites where consumable food products are placed and stored.

  -dishes and cooking utensils
  -equipment and utensils found in: dairies, food-processing plants, eating and drinking establishments

- **Non-food contact products**

  - hard nonporous surfaces (counter tops, desks, bed rails)
  - carpet sanitizers
  - air sanitizers
  - laundry additives
  - in-tank toilet bowl sanitizers

Surface Sanitizers: Claims

Claims:

- Allow claims for **bacteria** only
- All claims must be approved by the EPA before use in marketing material (websites/ literature) or on the label

Acceptable Claim Examples:

- 99.9% reduction of relevant bacteria (Ex. *Staphylococcus aureus, Pseudomonas aeruginosa, E. coli*, etc.)

Note: Must be classified as a disinfectant to make viral claims

Surface Sanitizers: Pathway to Market

Required Regulatory Approvals:

1. **Federal EPA** (6- 9 months)
    - Required to market in the US
2. **State EPA** (~18 months)
    - Required for each state that product is sold into

Efficacy Regulations/Requirements:

– Must show efficacy against key organisms using approved test methods

Non-Food Contact Sanitizers: Efficacy Requirements

ASTM E 1153: Efficacy of Sanitizers Recommended for Inanimate, Hard, Nonporous Non-Food Contact Surfaces

- 3 lots tested at Lower Concentration Limit (LCL)
- All test product must have a GLP Certificate of Analysis (CofA) for use in testing
- 3 log reduction (99.9%)
- 2 key organisms required

  -*S. aureus* and *K. pneumoniae or E. aerogenes*
- 2 out of 3 surfaces

  -Glass, Stainless Steel, unglazed ceramic tile

No Rinse Food Contact Sanitizers: Efficacy Requirements

AOAC 960.09 /EPA MB-27

- 3 lots tested at LCL (in triplicate)
- All test product must have a GLP C of A for use in testing
- 5 log reduction (99.999%)
- 2 key organisms required (*S. aureus* and *E. coli*)
- 2 surfaces (rough plastic and glass or Stainless steel)

All ingredients approved for antimicrobials used in food establishments are found in **40CFR 180.940**

Additional References

Hand Sanitizers

- Healthcare Antiseptics: Federal Register :: Safety and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use
- Consumer Antiseptic Rubs: Federal Register :: Safety and Effectiveness of Consumer Antiseptic Rubs; Topical Antimicrobial Drug Products for Over-the-Counter Human Use

Surface Sanitizers

- EPA 810 guidelines: https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-810-product-performance-test-guidelines

- 40CFR 180.940: 40 CFR 180.940 - Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions). (govregs.com)

ASTM INTERNATIONAL
Helping our world work better

Thank you

Mary Czaplicki – GOJO Industries
CzaplicM@GOJO.COM

www.astm.org

ASTM INTERNATIONAL
Helping our world work better

Overview of In vitro Time Kill Standards against Bacteria Overview of In vitro Surface Sanitizer/Disinfectant Standards

18 August 2021

Lisa Hellickson
Lead Microbiologist, Ecolab

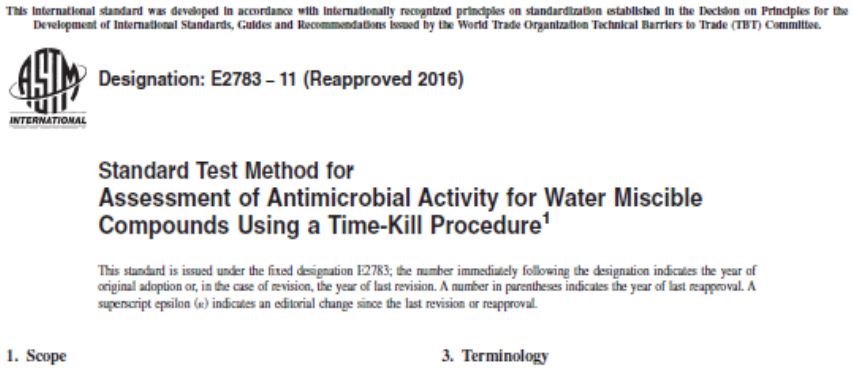
www.astm.org

ASTM Standards for hand care and surface efficacy testing

- ASTM E2783-11 (reapproved 2016)
  - Standard Test Method for Assessment of Antimicrobial Activity for Water Miscible Compounds Using a Time-Kill Procedure
- ASTM E2315-16
  - Standard Guide for Assessment of Antimicrobial Activity Using a Time-Kill Procedure
- ASTM E1153-14^{e1}
  - Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate, Hard, Non-porous Non-Food Contact Surfaces
- ASTM E2362-15
  - Standard Practice for Evaluation of Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection

E2783-11(2016): STM Time Kill Procedure

- Scope
  - *In vitro* suspension test to evaluate aerobic or anaerobic microorganism populations when exposed to antimicrobial test material for a contact time.
  - Purpose is to provide a set of standardized test conditions and organisms for comparative evaluations of aqueous antimicrobial test materials
  - Options to test 10 mL or 100 mL of test article
- Significance and use
  - "This procedure may be used to assess the *in vitro* reduction of a microbial population of test organisms after exposure to a test material."[1]
- Types of products evaluated using this method
  - Antibacterial hand washes
  - Hand sanitizers
  - Other aqueous products



This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Designation: E2783 – 11 (Reapproved 2016)

Standard Test Method for Assessment of Antimicrobial Activity for Water Miscible Compounds Using a Time-Kill Procedure[1]

This standard is issued under the fixed designation E2783; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

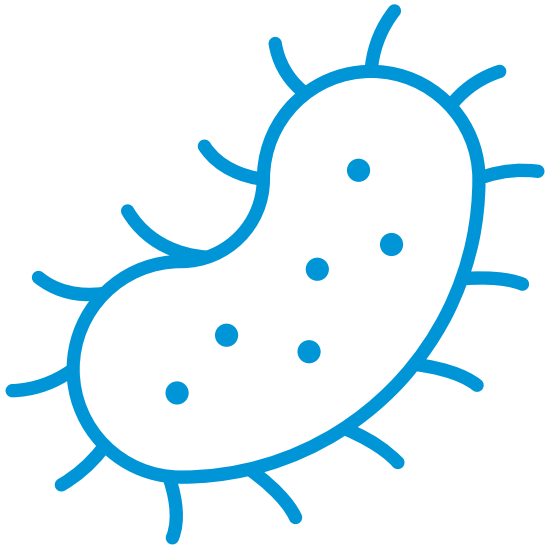
3. Terminology

[1] Source: ASTM E2783-11(2016)

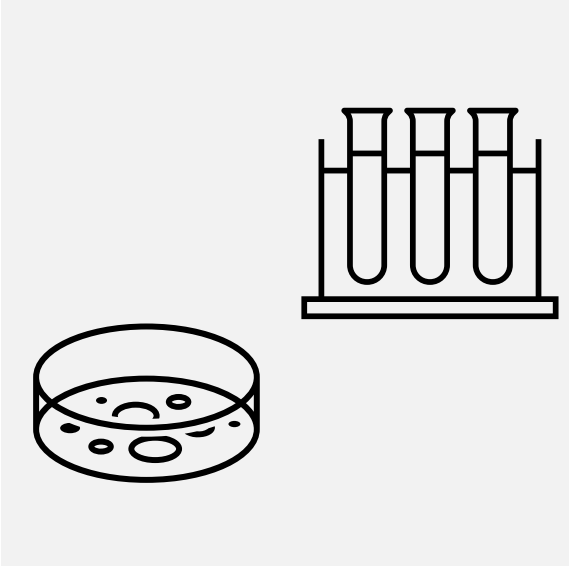
E2783-11(2016): STM Time Kill Procedure

Test Organisms

- *Acinetobacter* species
- *Candida albicans* ATCC 10231
- *Enterobacter* species
- *Enterococcus faecalis* ATCC 29212
- *Enterococcus faecium*
- *Escherichia coli* ATCC 8739, 11229 or 25922
- *Klebsiella pneumoniae* ATCC 10031, or 51504
- *Micrococcus yunnanensis* ATCC 7468 (formerly known as *Micrococcus luteus*)
- *Pseudomonas aeruginosa* ATCC 9027, 15442 or 27853
- *Proteus mirabilis* ATCC 4675 or 7002
- *Salmonella enterica* ATCC 10708
- *Serratia marcescens* ATCC 14756
- *Shigella* species
- *Staphylococcus aureus* ATCC 6538, 29213, 33591 or 33592
- *Staphylococcus epidermidis* ATCC 12228
- *Staphylococcus haemolyticus*
- *Staphylococcus hominis*
- *Staphylococcus saprophyticus*
- *Streptococcus pyogenes*
- *Streptococcus pyogenes*
- *Streptococcus pneumoniae*

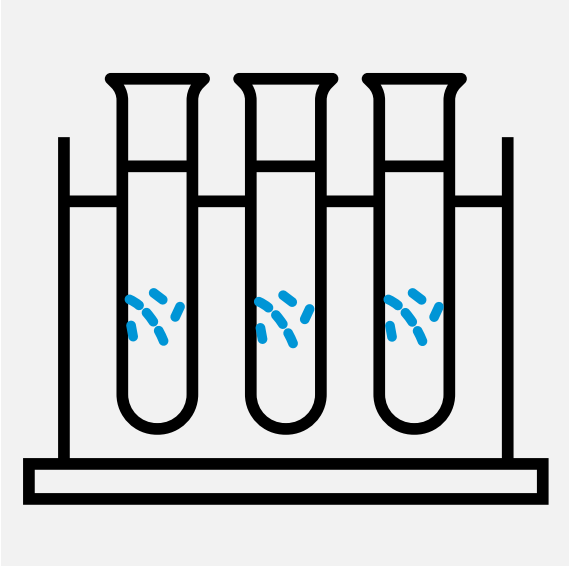


E2783-11(2016): STM Time Kill Procedure



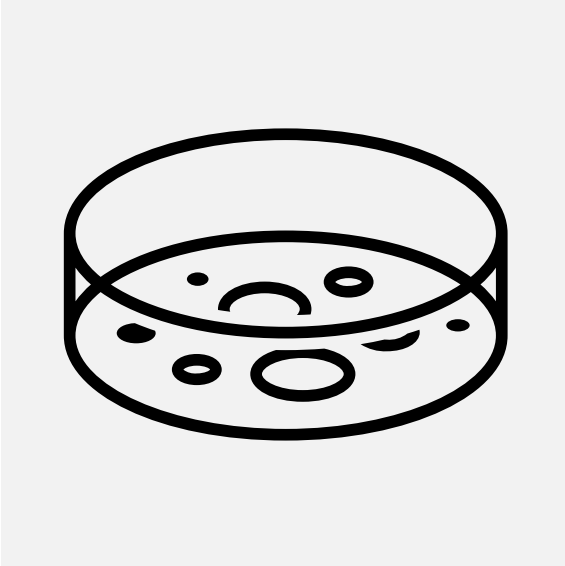
Prepare test organism

Test organisms prepared via an agar or broth method. The growth is resuspended in sterile saline. The inoculum is prepared at a minimum of 1.0×10^8 CFU/mL.



Inoculate test article

The test is performed at room temperature with a short contact time. An aliquot of the test organism is added to a sample of the test article and held for the contact time.

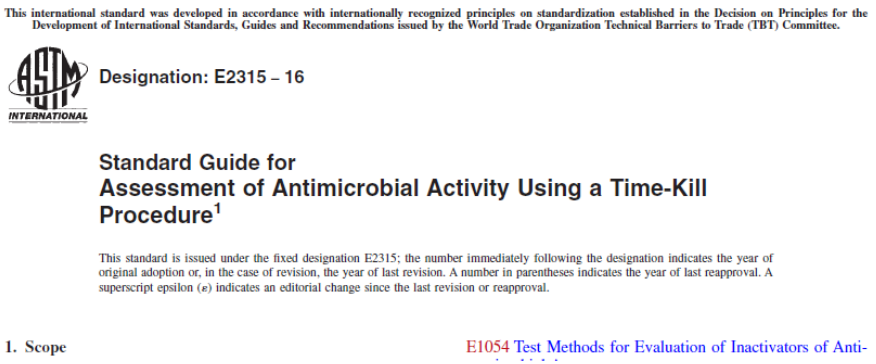


Neutralize and enumerate

The inoculated sample is mixed, and an aliquot is removed and added to neutralizer. The neutralizer is then plated on agar and incubated. The survivors are counted and compared to the survivors of a control sample to determine the log reduction.

E2315-16: SG Time Kill Procedure

- Scope
  - An example of an *In vitro* suspension test to evaluate microorganism populations when exposed to antimicrobial test material for a contact time.
  - Several options are provided for different aspects of the method including organism selection and growth.
  - Antimicrobial activity evaluated using this standard may vary depending on the variables selected.
- Significance and use
  - "This procedure may be used to assess the *in vitro* reduction of a microbial population of test organisms after exposure to a test material."[2]
- Products that could be evaluated using this standard
  - Antimicrobial hand washes, hand sanitizers, any aqueous product



This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Designation: E2315 – 16

Standard Guide for
Assessment of Antimicrobial Activity Using a Time-Kill Procedure[1]

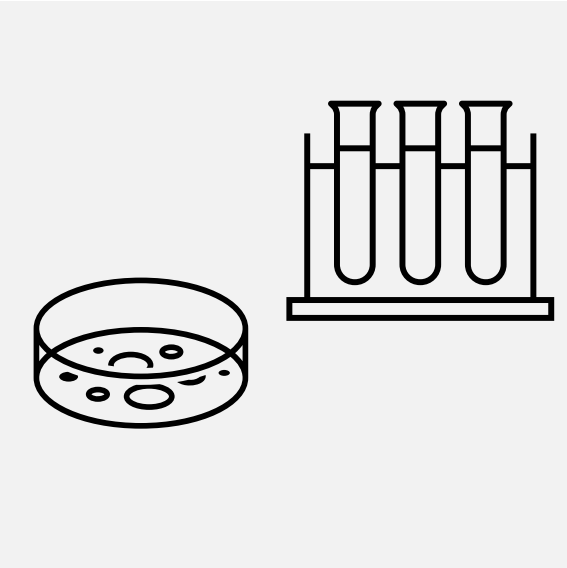
This standard is issued under the fixed designation E2315; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

E1054 Test Methods for Evaluation of Inactivators of Anti-

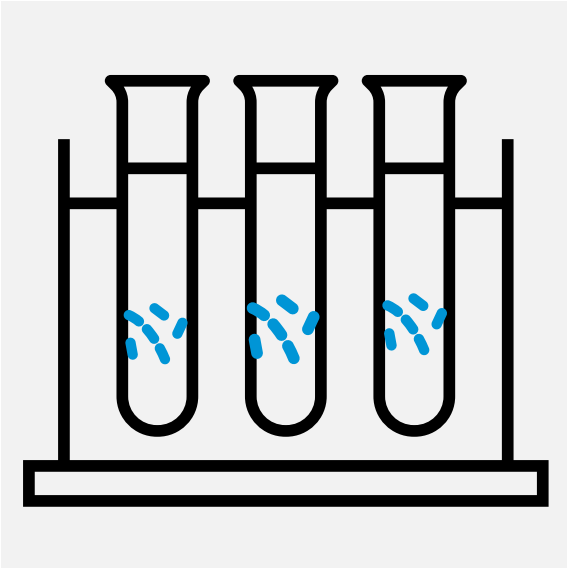
[2] Source: ASTM E2315-16

E2315-16: SG Time Kill Procedure



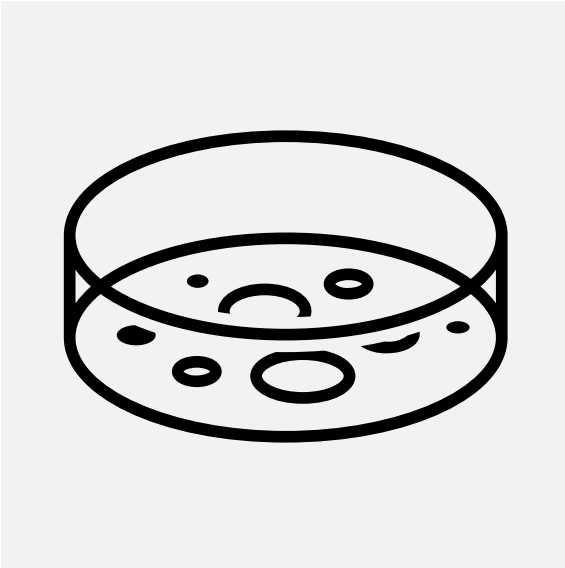
Prepare test organism

Test organisms may be propagated via an agar or broth method. The inoculum is prepared at a minimum level of 1.0×10^6 CFU/mL.



Inoculate test article

The test is performed at the selected temperature for a specified contact time. An aliquot of the test organism is added to a sample of the test article and held for the contact time.



Neutralize and enumerate

The inoculated sample is mixed, and an aliquot is removed and added to neutralizer. The neutralizer is then plated on agar and incubated. The survivors are counted and compared to the survivors of a control sample to determine the log reduction.

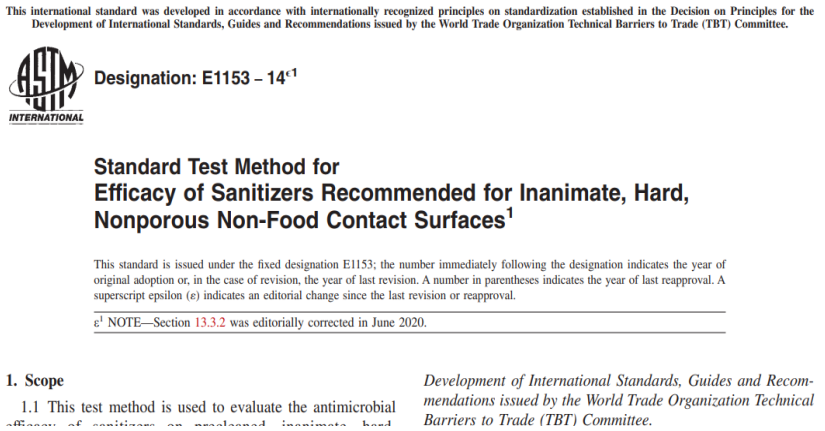
Time Kill Standards Comparison

How do I select which standard to use?

	ASTM E2783-11(16)	ASTM E2315-16
Type of Standard	Standard Test Method – Specific test procedure is described	Standard Guide –An example of a test procedure to be used to develop a protocol
Type of Test	*In vitro* Suspension Test	*In vitro* Suspension Test
Products Tested	Hand washes, hand sanitizers, any aqueous product	Hand washes, hand sanitizers, any aqueous product
Test Organisms	Several specified	No organisms specified
Test Temperature and Contact Time	Room temperature, short contact times	Any applicable temperature and contact time
Type of Result	Quantitative –log reduction	Quantitative –log reduction

E1153-14^{e1} : Non-Food Contact Sanitizer

- Scope
  - Carrier test to evaluate the antimicrobial efficacy of sanitizers on inanimate, hard, non-porous, non-food surfaces.
  - Test organisms: *Staphylococcus aureus* ATCC 6538, *Klebsiella pneumoniae* ATCC 4352 or *Klebsiella aerogenes* ATCC 13048
  - Options for sanitizer only or cleaner-sanitizer products (additional organic soil load)
  - Can be modified for additional test organisms, carrier materials and product forms (sprays, towelettes)
- Significance and use
  - "This test method shall be used to determine if a chemical intended for use as a non-food contact sanitizer or as a one-step cleaner-sanitizer provides percent reductions of the selected test organisms on treated carriers as compared to control."[3]
- Products that could be evaluated using this standard
  - Any product intended for use on hard, non-porous non-food contact surfaces: liquids, towelettes



This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Designation: E1153 – 14$^{\varepsilon 1}$

Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate, Hard, Nonporous Non-Food Contact Surfaces[1]

This standard is issued under the fixed designation E1153; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

ε^1 NOTE—Section 13.3.2 was editorially corrected in June 2020.

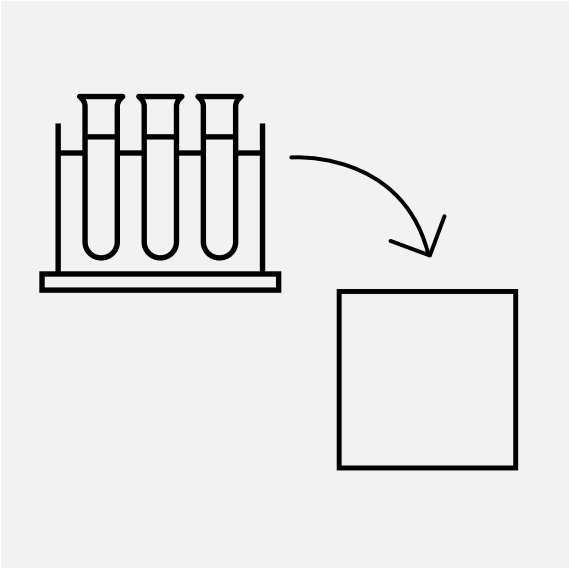
1. Scope

1.1 This test method is used to evaluate the antimicrobial

Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

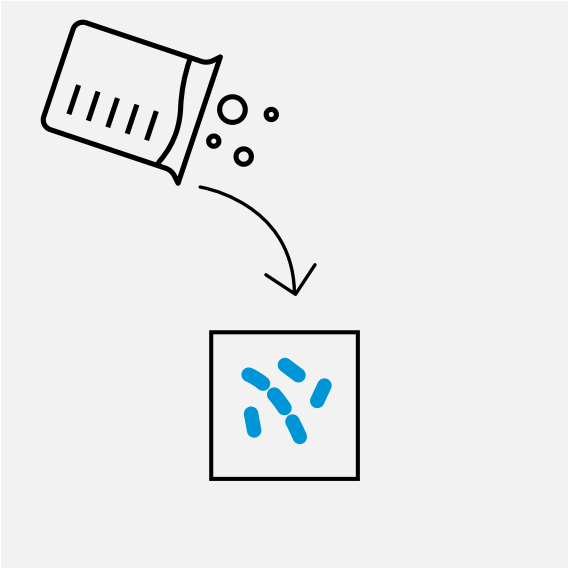
[3] Source: ASTM 1153-14^{e1}

E1153-14^{e1} : Non-Food Contact Sanitizer



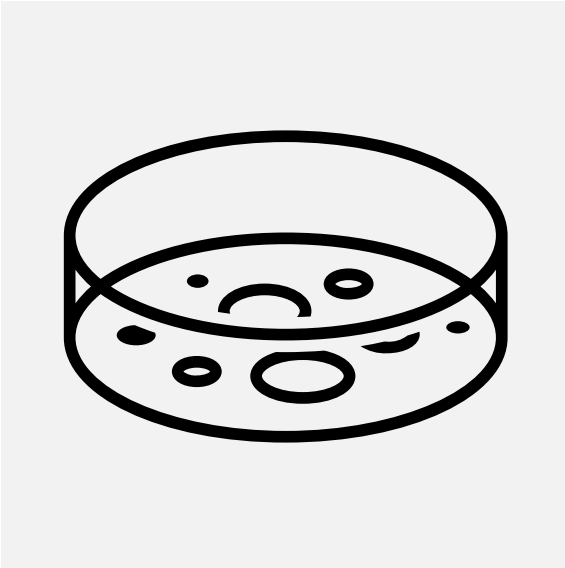
Prepare test organism and carriers

Test organisms are grown in broth media. If required, add a 5% Fetal Bovine Serum organic soil load to the culture and mix. An aliquot of the culture (0.01 – 0.03 mL) is spread evenly on each carrier (25 x 25 mm glass slide or other surface) and dried in an incubator with humidity for 20 to 40 minutes.



Treat carriers with test substance

The test is performed at room temperature with a contact time of 5 minutes or less according to the intended use. One dried, inoculated carrier is placed in a jar and treated with 5 mL of the test substance. Five carriers are treated per test substance.

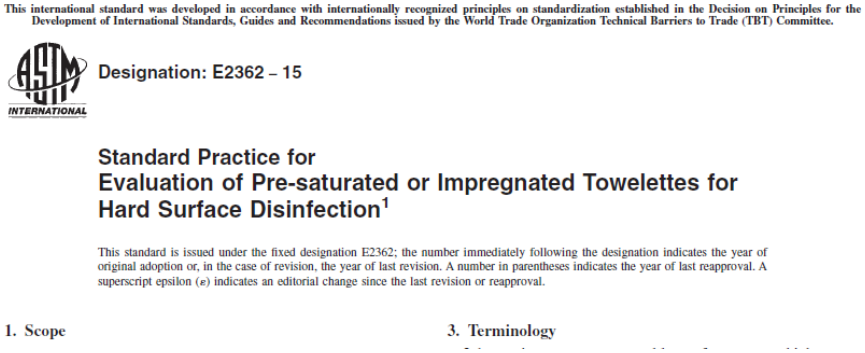


Neutralize and enumerate

At the end of the contact time, 20 mL of neutralizer is added to the treated carrier/jar and vortex mixed. The neutralizer is then plated on agar and incubated. The survivors of the test substance are compared to the survivors of a control sample to determine the log reduction.

E2362-15: SP Hard Surface Towelette Disinfection

- Scope
  - Carrier test to evaluate the antimicrobial activity of pre-saturated or impregnated towelettes as a hard surface disinfectant
  - Test organisms include *Staphylococcus aureus* ATCC 6538, *Salmonella enterica* ATCC 10708 and *Pseudomonas aeruginosa* ATCC 15442, mycobacteria and fungi
  - Options for disinfectant only or cleaner-disinfectant products (additional organic soil load)
- Significance and use
  - Can be used to determine if a pre-saturated or impregnated towelette is an effective disinfectant on hard surfaces
  - Test results are qualitative (growth/no growth) and do not provide a quantitative (log) reduction value
- Products that could be evaluated using this standard
  - Pre-saturated disinfectant towelettes or impregnated towelettes



This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Designation: E2362 – 15

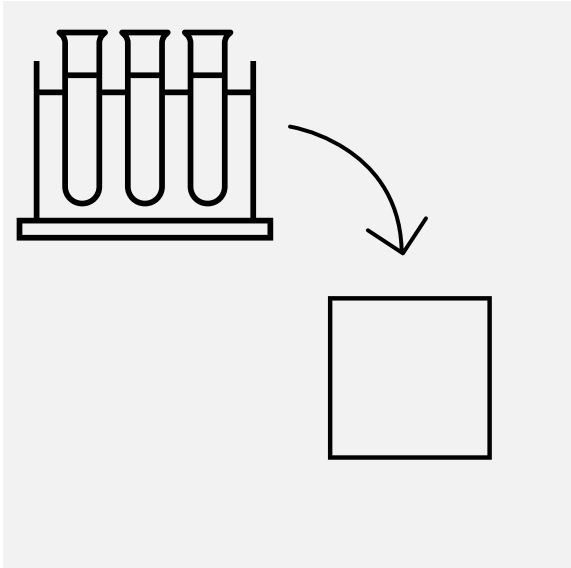
Standard Practice for Evaluation of Pre-saturated or Impregnated Towelettes for Hard Surface Disinfection[1]

This standard is issued under the fixed designation E2362; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

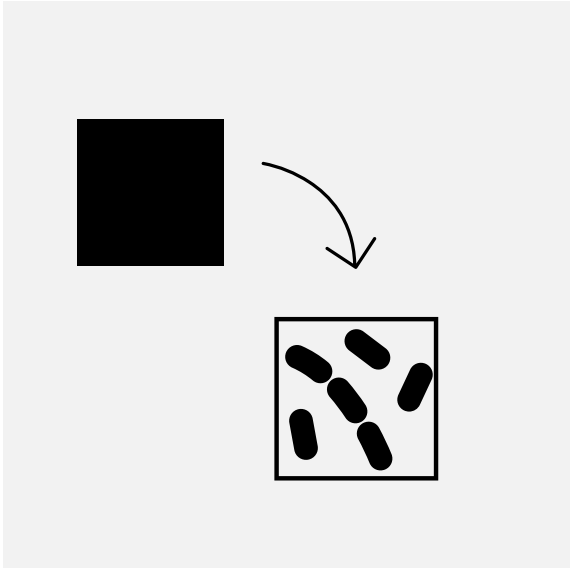
3. Terminology

E2362-15: SP Hard Surface Towelette Disinfection



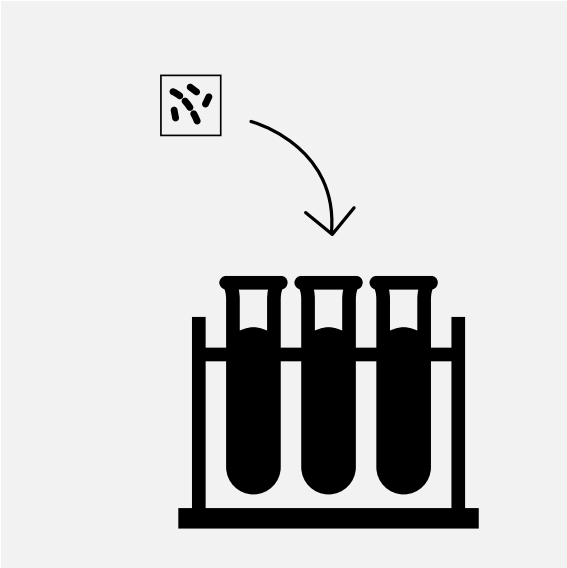
Prepare test organism and carriers

Test organisms are grown in broth media. If required, add a 5% Fetal Bovine Serum organic soil load to the culture and mix. A 0.01 mL aliquot of the culture is spread evenly on each carrier (25 x 25 mm glass slide) and dried in an incubator for 30 to 40 minutes.



Treat carriers with test substance

The test is performed at room temperature with a contact time of 10 minutes or less. The test substance towelette is used to wipe the dried, inoculated carrier and allowed to sit for the contact time. Typically, ten carriers are treated with one towelette.



Neutralize and incubate

At the end of the contact time, the carrier is transferred to a tube of neutralizer/growth medium. Each carrier tested is transferred to a tube of neutralizer/growth medium. The carriers/tubes are incubated and read for growth, no growth.

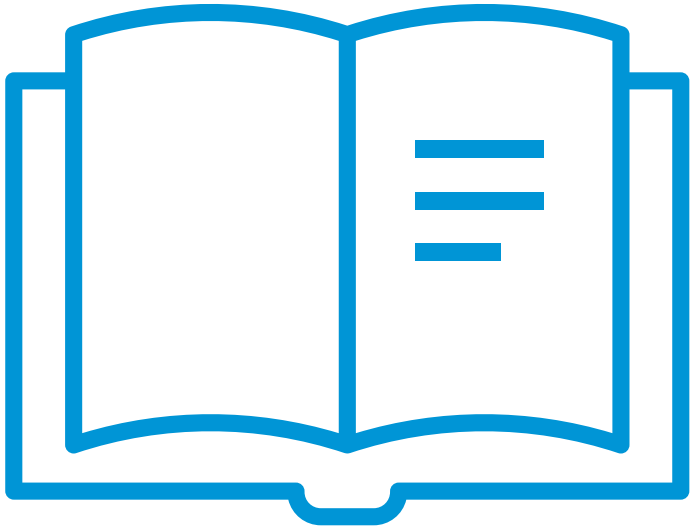
New Standards in Development

- Standards are reviewed and approved at regular intervals by the ASTM committee
- New standards are also in development by the ASTM committee
- A new standard for the evaluation of disinfectant towelettes is in development in collaboration with ASTM and U.S. EPA Scientists
  - Quantitative method
  - More applicable to how disinfectant towelettes are used

Other Standard Test Methods

Other Surface Standard Test Methods

- Use-dilution disinfectant standards
  - AOAC 964.02
  - AOAC 955.14
  - AOAC 955.15
- Germicidal spray disinfectant standard
  - AOAC 961.02
- Tuberculocidal standard
  - AOAC 965.12
- Fungicidal standard
  - AOAC 955.17 or modified use-dilution standards
- Sporicidal standard
  - AOAC 966.04
- Clostridioides difficile hard surface standard
  - ASTM E3218-21
- Biofilm standards
  - Several ASTM standards including E2871
- Food-contact sanitizer standard
  - AOAC 955.16 or AOAC 960.09
- Viral standards
  - ASTM standards E1052 and E1053



Summary

- ASTM standards E2783-11 and E2315-16 are both *In vitro* suspension tests used to evaluate antimicrobial hand care products
- E2783-11 is a standard test method, but E2315-16 is a standard guide, so it has several options for selecting test parameters
- Hard surface non-food contact sanitizers are evaluated using a quantitative carrier-based *In vitro* test ASTM E1153-14^{e1} using glass slide carriers
- Disinfecting towelettes are evaluated using E2362-15 which is a qualitative carrier-based *In vitro* test using glass slide carriers

ASTM INTERNATIONAL
Helping our world work better

Thank you

Lisa Hellickson – Ecolab
lisa.hellickson@ecolab.com

www.astm.org

ASTM INTERNATIONAL
Helping our world work better

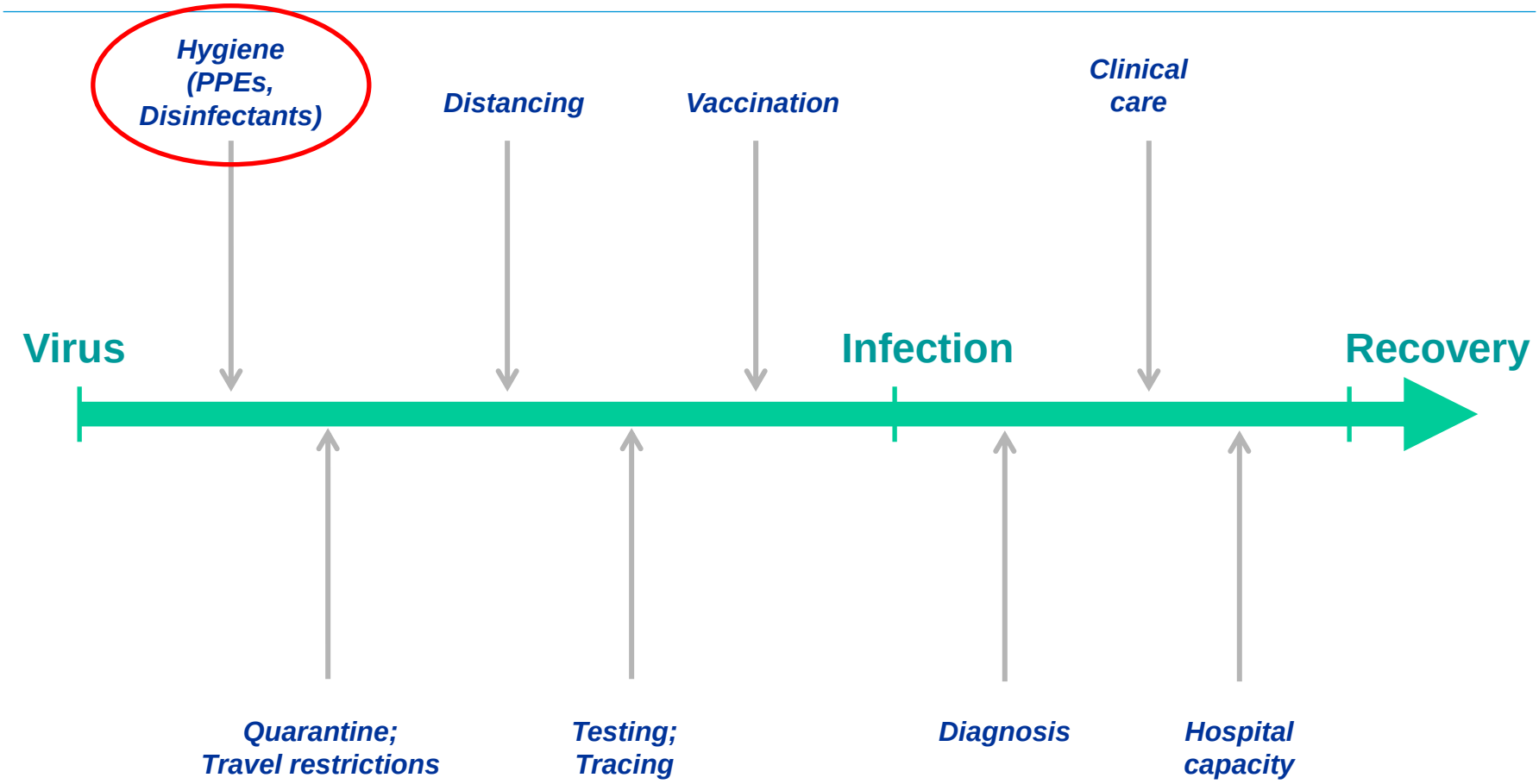
Overview of In Vitro Virucidal Efficacy Testing Methods for Disinfectants, Sanitizers and Treated Materials

18 August 2021

Steven Zhou, PhD
Director of Virology, Microbac Laboratories

www.astm.org

Defense Strategies against COVID



Routes of Transmission for COVID

Droplet transmission

- Respiratory droplets from infected individuals via coughing or sneezing

Aerosol transmission

- Tiny particles from talking, singing or breathing

Surface (fomite) transmission

- Individuals touching contaminated surfaces and touching eyes, nose, or mouth.

Hygienic Interventions against COVID

Viral Inactivation

- Chemical (disinfectants, antiseptics)
- Physical (e.g., UV, Heat devices)

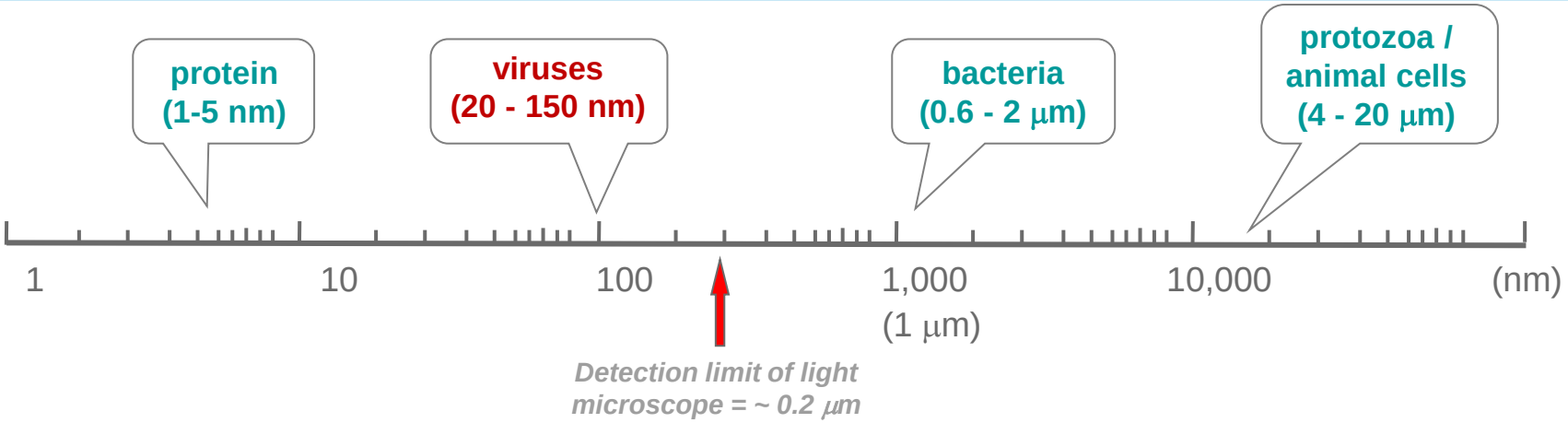
Viral Blocking or Removal

- Masking
- Cleaning
- Barrier (e.g., antiviral air filters)

Pre-treated Materials

- Coated surfaces
- Copper, Nanoparticles
- Treated textiles

How to “Kill” a Virus?



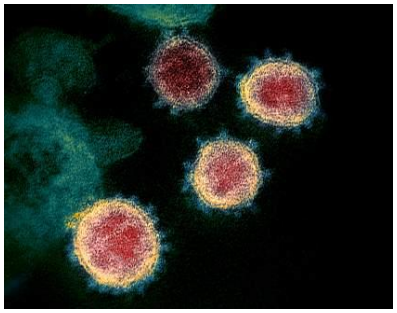
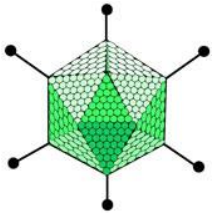
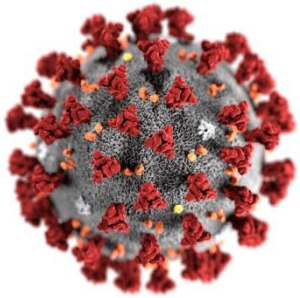
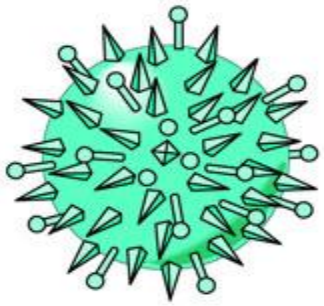


Image of SARS-CoV-2; NIH.gov

- **Common mechanisms of viral inactivation:**
  - **Disruption of lipid membrane (*env. viruses*)**
  - **Disruption of viral capsid**
  - **Damage of viral DNA/RNA**

Structure and Groups of Viruses

	Enveloped	Non-enveloped
DNA	 herpes simplex virus	 adenovirus  parvovirus
RNA	 SARS-CoV-2  influenza virus	 rotavirus  poliovirus

Viral Inactivation Approaches

Physical
- Heat
- HTST
- UV
- Gamma
- Electron beam
- High pressure

Halogens
- Chlorine
- Iodine

Aldehydes
- Glutaraldehyde
- Formaldehyde
- OPA

Peroxygens
- H_2O_2
- Peracetic Acid
- Ozone

Alcohols
- Ethanol
- IPA

Quats

Low/High pH

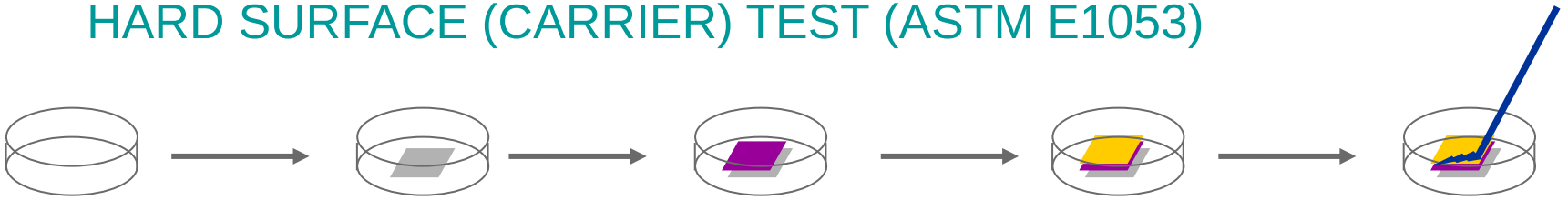
Phenolics

Biguanides
- Chlorhexidine
- PHMB

Solvent/Detergent

Heavy metals
- Silver
- Copper
- Zinc

HARD SURFACE (CARRIER) TEST (ASTM E1053)



Glass Petri dish

dry virus

Apply test substance

Hold for contact time; Add neutralizer

Elute sample, assay for virus

HARD SURFACE (CARRIER) TEST (EN 16777)

Stainless steel disc

Add virus and dry

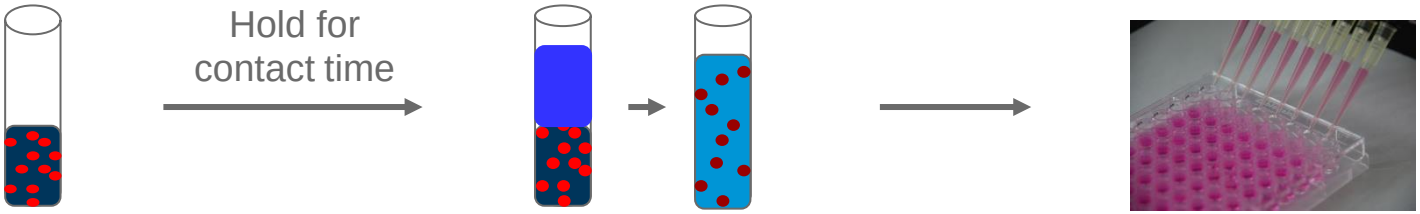
Apply test substance

Hold for contact time; Add neutralizer

Elute sample, assay for virus

Efficacy Test Methods for Sanitizers

SUSPENSION TEST (e.g., ASTM E1052, EN14476)



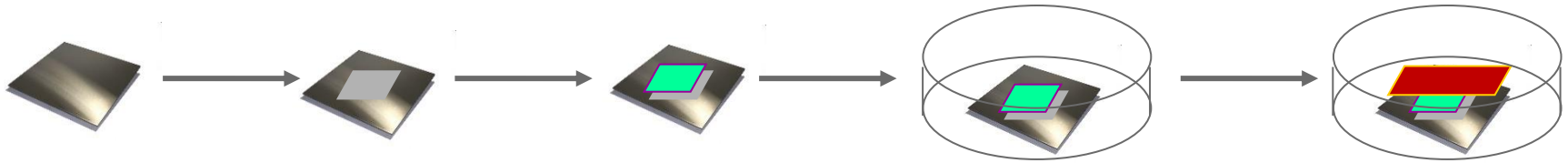
Mix virus with test substance in suspension

Add neutralizer; mix

Assay for virus

Efficacy Test Methods for Treated Materials

Treated Plastics or Other Hard, Non-Porous Materials (ISO 21702)



Treated hard surface

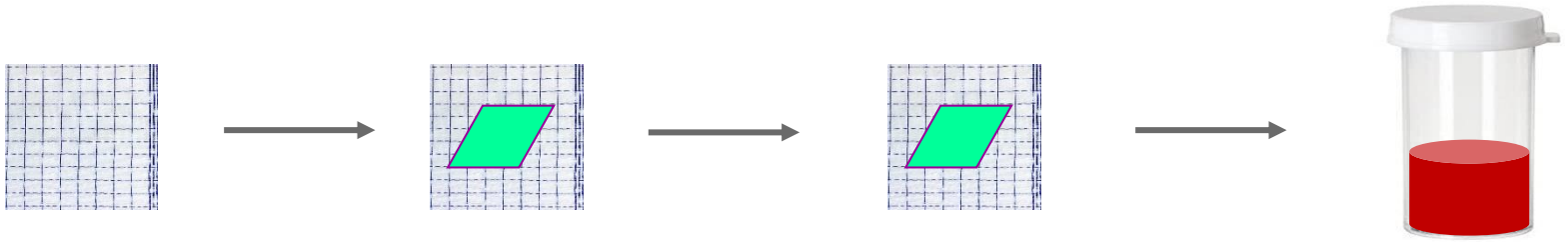
Add virus

Cover with film

Hold for contact time

Neutralize and elute sample; assay for virus

Treated Textiles or Other Soft, Porous Materials (ISO 18184)



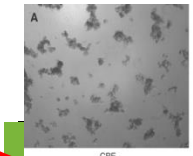
Treated hard surface

Add virus

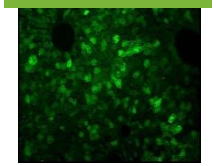
Hold for contact time

Neutralize and elute sample; assay for virus

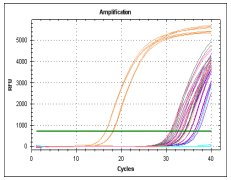
Viral Assays



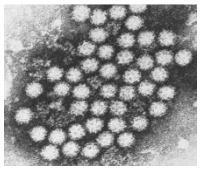
Cell culture
(TCID$_{50}$ or Plaque)



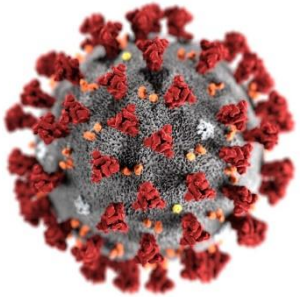
Cell culture - IFA

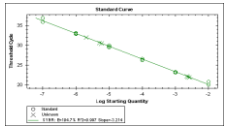


Polymerase Chain
Reaction (PCR)

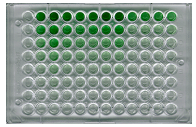


Electron
microscopy

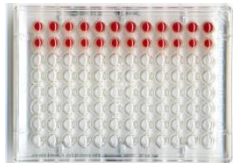




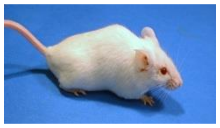
Enzymatic
(e.g., transcriptase)



ELISA



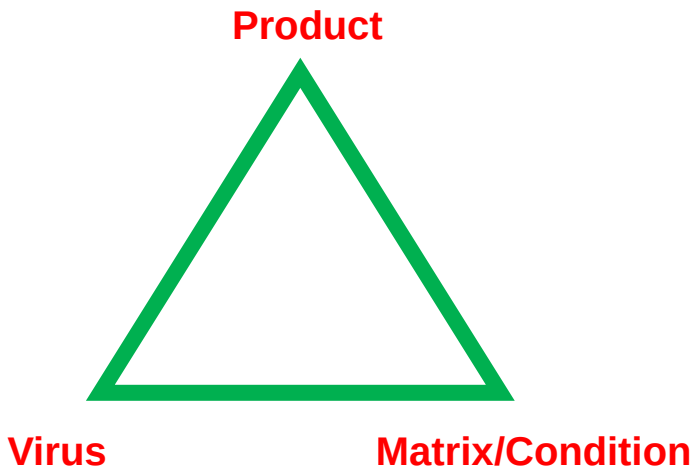
Hemagglutination



In vivo infectivity

What Factors Influence Efficacy?

- **Product**
  - Active ingredients
  - Dose (conc. and time)
  - Stability
- **Virus**
  - Structure
  - Resistance / Mutations
- **Matrix / Condition**
  - Contact time
  - Temperature
  - Organic soil
  - pH
  - Surface type
  - Synergistic or antagonistic agents
  - Product delivery



In Search for a “Perfect” Virucide…

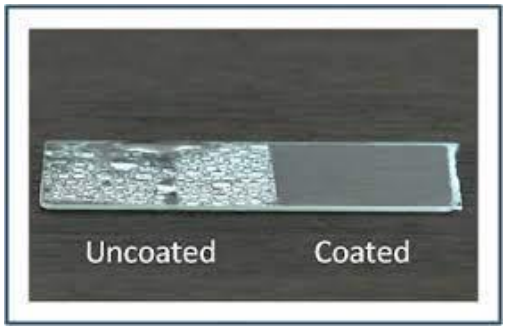
Safe... Effective… Economical… Easy to use.. Stable...

Active ingredient	Pros	Cons
Alcohol	inexpensive; safe	low activity on non-env. Viruses
Chlorhexidine gluconate	low toxicity	Cost
Glutaraldehyde	highly effective	toxicity; odor
Hydrogen peroxide	broad spec activity	non stable
o-phthaladehyde (OPA)	highly effective	cost
Peracetic acid	broad spec activity	skin irritation
Phenol	inexpensive	toxicity
Quats	low tox; broad spec activity	cost
Hypochlorite (bleach)	fast kill, convenient	corrosive; odor

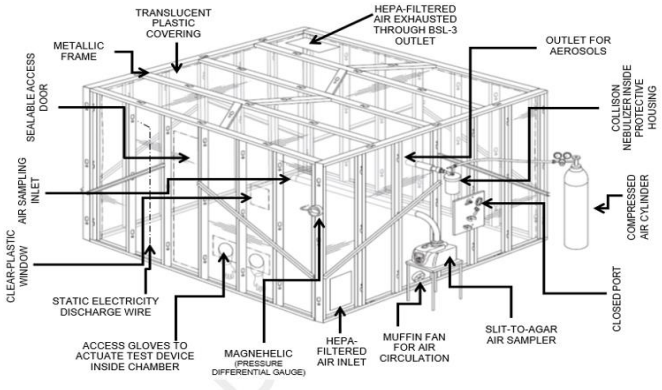
Newer Technologies

- Electrostatic Sprayers (ESS)

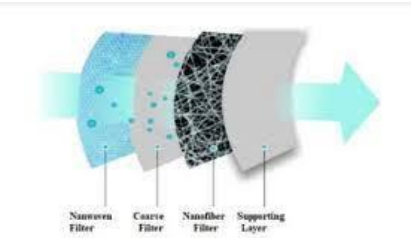
- Coated Surfaces / Residual Efficacy



- Air sanitizers / devices



- Antiviral fabrics / masks / filter media



ASTM INTERNATIONAL
Helping our world work better

Thank you

Steven Zhou - Microbac
steve.zhou@microbac.com

www.astm.org

ASTM INTERNATIONAL
Helping our world work better

Thank you

Questions for our experts?