

Steriplex Disinfectant Efficacy

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Thanks to...

- Grace Gardner, ASI
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- Chuck Loveday, sBioMed
- Brian Larson, sBioMed
- Dr. Rich Robison, Brigham Young University

Reference

- United States Pharmacopeia 36 <1072>

Evaluating Disinfectants

- AOAC and EPA required tests—typically performed or commissioned by the Disinfectant Manufacturer (test tube tests), and data supplied to the user
- Disinfectant Efficacy—laboratory study
- Sanitizer Effectiveness tests...*in situ*
Mapping Studies

Disinfectant Efficacy:

Evaluates the anti-microbial effectiveness of disinfectants used on representative surfaces from pharmaceutical facilities and equipment on specific microorganisms...

OR...

Chemically, will a solution/suspension kill specific microorganisms on defined surfaces in X time (“Contact Time”)

Contact Time

- The time that a disinfectant remains wet on a sanitized surface
- Disinfectants are not antimicrobial once the surfaces dry!

Disinfectant Efficacy

- Nothing to do with how a disinfectant is applied: spraying, mopping, wiping, soaking, fogging...

That is a different test: *In situ*...

- Disinfectant Efficacy is how effective chemically is a sanitizer, on a given surface, against specific microorganisms, at a controlled contact time

Sanitizer—Steriplex SD

Part A:

- Active Ingredient:
Elemental Silver (0.015%)
- Ethanol (10%)
- Inert Food Grade
Ingredients
- Water



Sanitizer—Steriplex SD

Part B (Activator):

- H_2O_2 (22.0%)
- Peroxyacetic Acid (15%)
- Acetic Acid (15%)
- Water
- We evaluated 5 different lots of both solutions



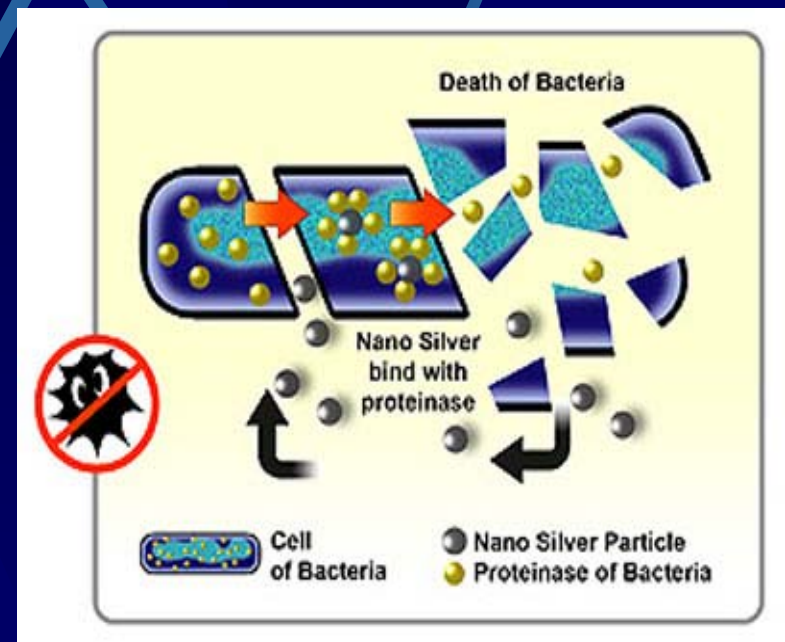
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History of Silver as an Antimicrobial

- Ancient times used for drinking water containers
- Mentioned in Roman Pharmacopoeia (69 B.C.)
- Silver nitrate drops in newborn's eyes
- Silver sulfadiazine for burns

Mode of Action

- Not completely understood:
- Extracellular binding of Ag^+ to negatively charged peptidoglycans in bacterial cell walls
- Binding of Ag^+ to cellular proteins, including cellular enzymes



Mode of Action

- Binds to DNA base pairs—prevents replication
- See “Silver as a Disinfectant,” Silvestry-Rodriguez, et al, Rev Environ Contam Toxicol, 191: 23-45, 2007



Surface Types

(All Autoclavable)

- 316L Stainless Steel
- Mipolam® Vinyl Floor Material
- Plexiglas used on Barrier Systems
(Lexan Polycarbonate, 9030 Series)
- Curtain Vinyl Material

Challenge Microorganisms

- *Bacillus megaterium*-environmental isolate
- *Bacillus cereus*—environmental isolate
- *Bacillus subtilis*—ATCC strain
- *Aspergillus niger*—ATCC strain
- Gram positive cocktail (*S. aureus* & *S. epidermidis*—ATCC cultures)
- Gram negative cocktail (*E. coli* & *P. aeruginosa*—ATCC cultures)

Procedure—Prepare Challenge Cultures

- Grow cultures for 24-48 hours @ 32°C (TSA or AK Sporulation Agar)
- Mold--4 days @ RT
- Flood plates with saline (or IPA)
- Scrape colonies and place in a sterile tube
- Verify counts

Procedure—Prepare Challenge Cultures



Test Procedure

- Sterilize coupons; move to a BSC
- Inoculate (100 μ L) + & “test” coupons with high numbers of microorganism suspensions
--dry in the BSC
- Expose “test” coupons & Neutralization test coupons to Activated Steriplex for **1 minute**
- Expose + and uninoculated negative controls to sterile saline for 1 minute

Procedure--Autoclave



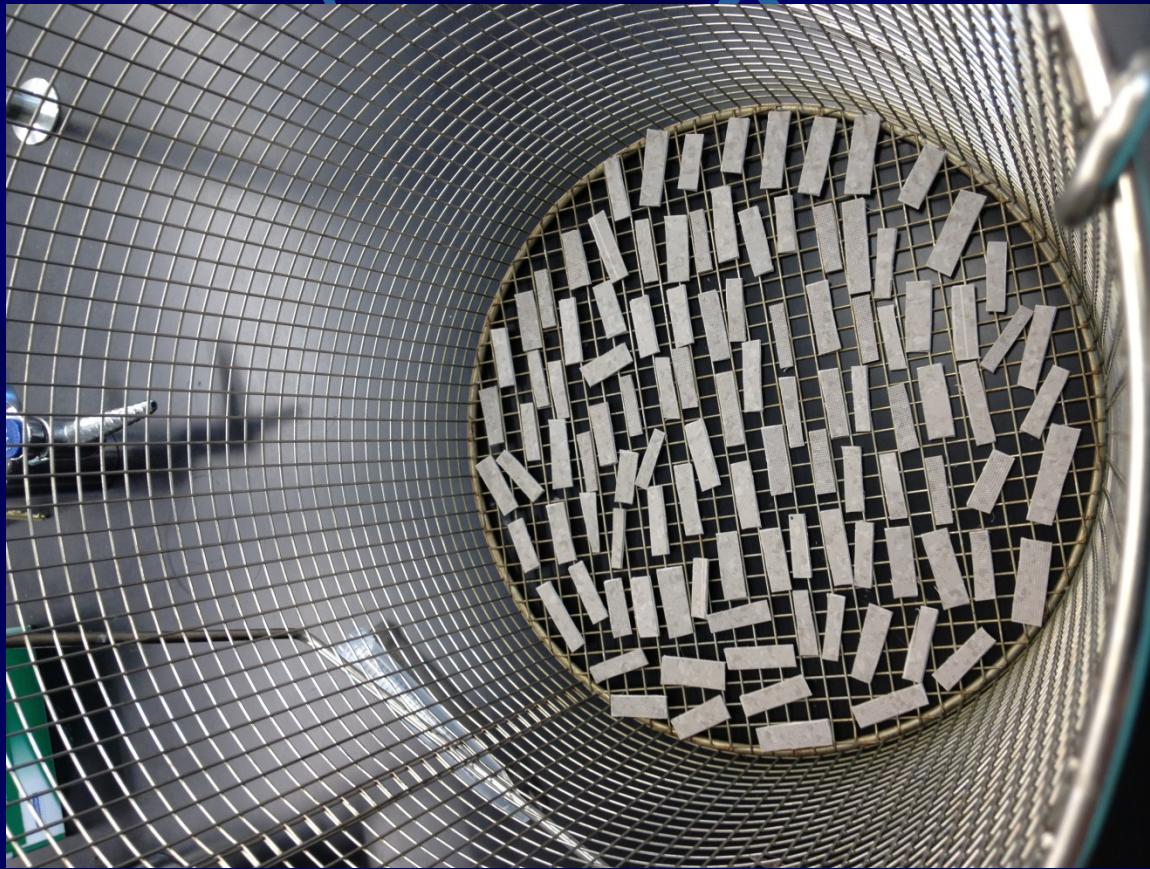
Procedure--BSC



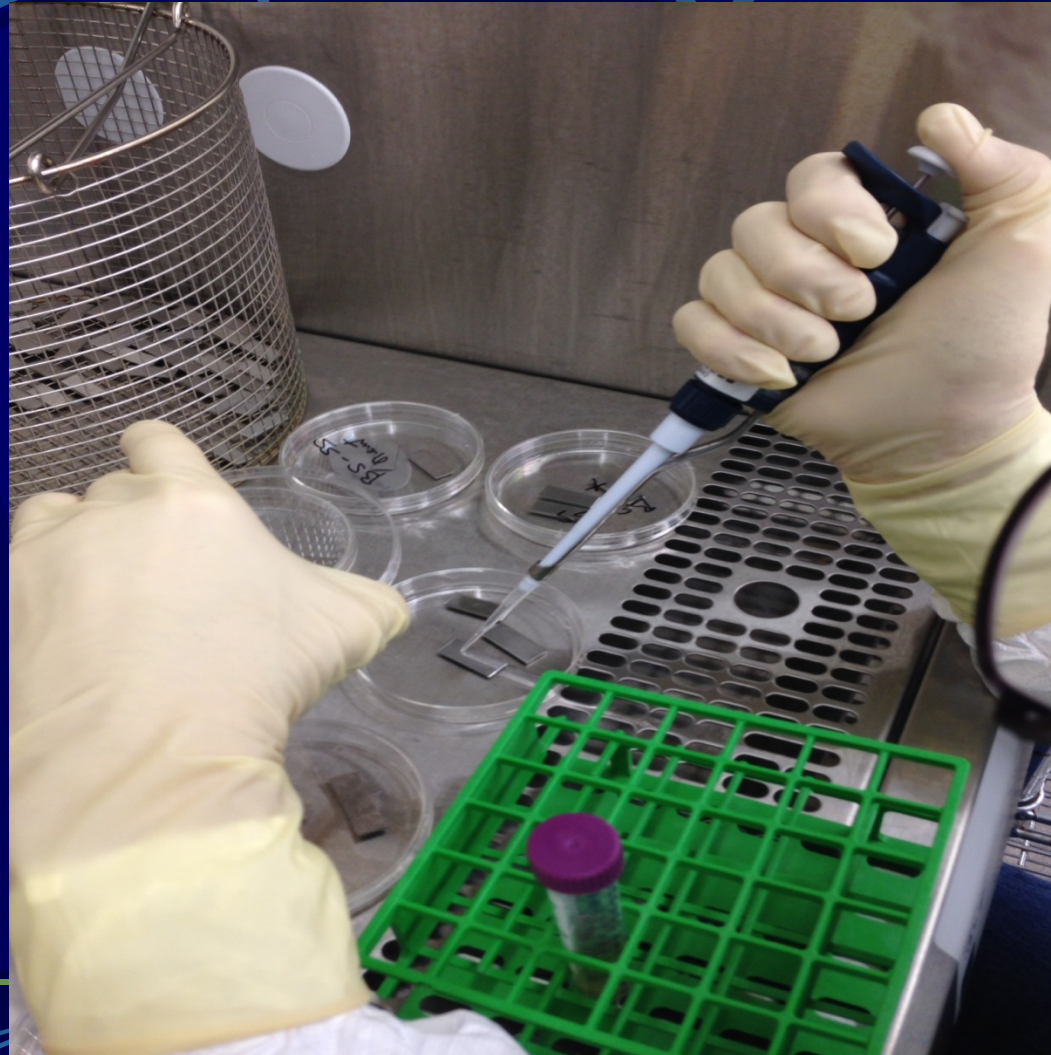
Procedure--SS



Procedure--Mipolam



Inoculating Coupons



Procedure—Inoculate Coupons



Adding Steriplex or Saline



Procedure

- After 1 minute exposure place coupons into 4 mL Neutralization Broth



Neutralization Broth

(from Dr. R. Robison. BYU)

Ingredients:

- Tween 80
- Tamol (Dispersing Agent)
- Lecithin
- Peptone
- Cysteine
- Tris Buffer
- H₂O

Issues:

- Must be made day of testing
- Order of addition critical
- Tamol is critical ingredient—but which Tamol????

OR....

Neutralization Broth

Just use DE Broth!!

Procedure

- Vortex at high revolution for 1 minute
- Make serial dilutions (1 mL from Neutralization Broth into 9 mL sterile saline) of positive control (2- 4 dilutions)
- No dilutions of the coupons from the Neutralization Broth or negative control

Procedure

- Place two Neutralization Coupons in Neutralization Broth
- Inoculate Neutralization Broth plus a tube containing 4 mL saline with < 100 CFU challenge dilution in 0.1 mL

Procedure

- Place 0.1 mL of the last 2-3 test dilutions onto each of three TSA plates [and MacConkey Agar for Gram (-) tests]
- Place 0.1 mL of 10^0 and 10^{-1} dilutions onto three plates
- Spread the inoculum so the entire plate is covered

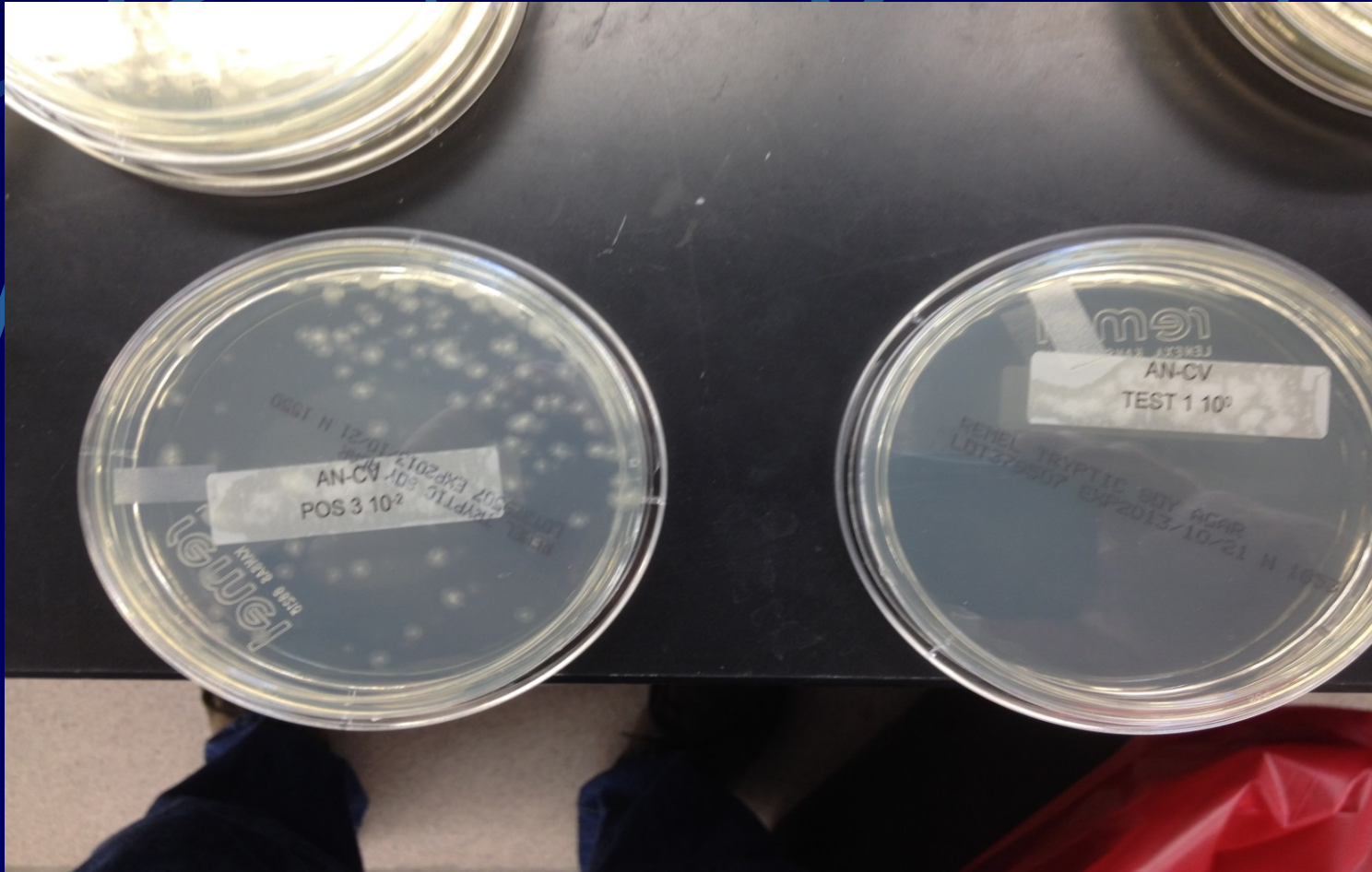


Procedure

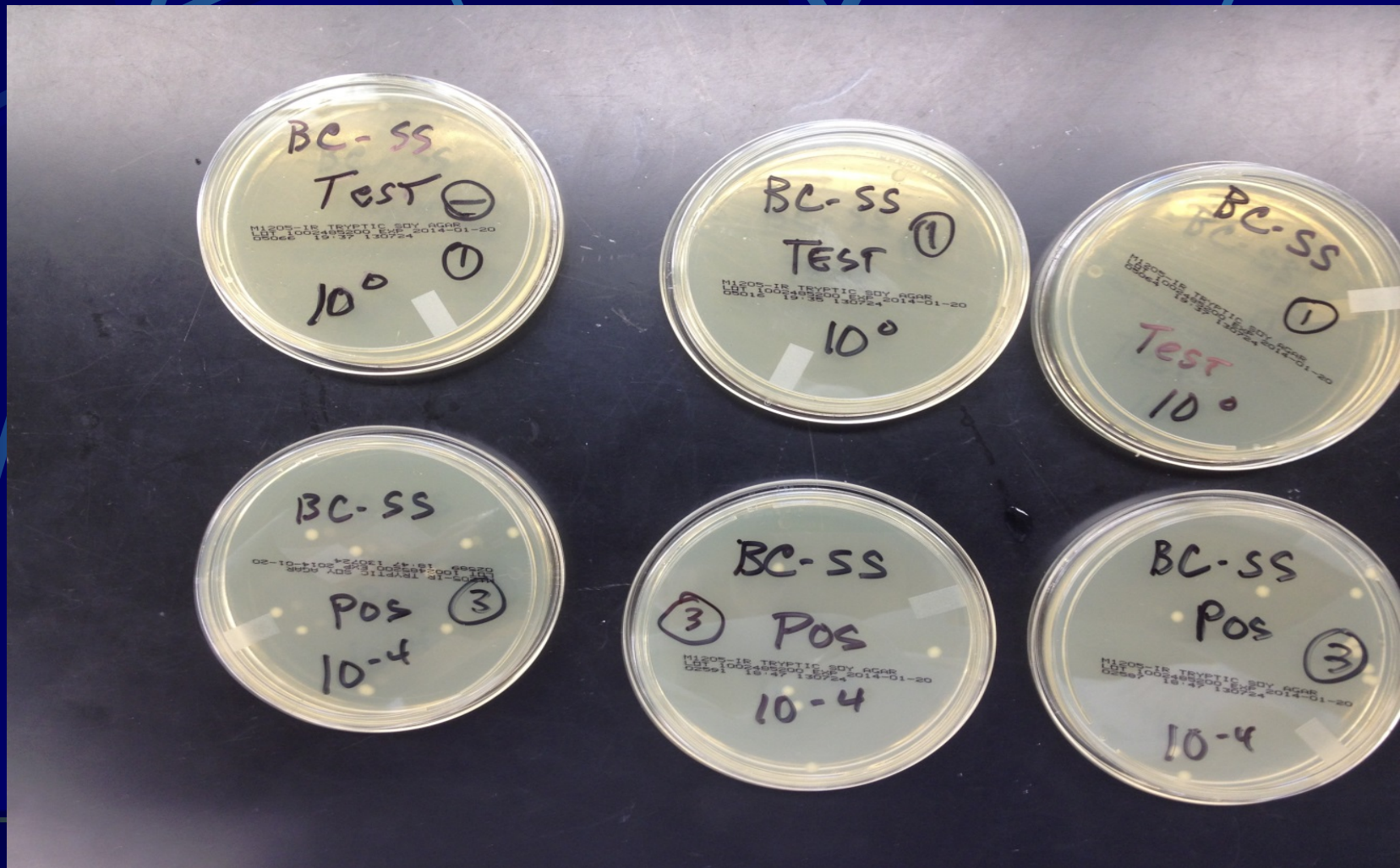
- Incubate plates at $32^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 24-48 hours or until growth is observed (3-4 days @ $25^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for *Aspergillus*)



Procedure



Procedure



Calculation

- Determine the minimum population reduction (efficacy) of the test carriers
- (Log of the mean surviving population from the positive controls) minus (Log of the mean surviving population from the test carriers)

Acceptance Criteria

- The average recovery from the positive control carrier must be sufficient to demonstrate the required Log reduction
- No growth should be recovered from the negative control

Acceptance Criteria

- The minimum population reduction must be ≥ 3 -log reduction for bacteria, spores and fungi (USP now says 2-log bacterial spore reduction is adequate)
- The two Neutralization Challenge samples should be close to the same count as the saline control

Results—*B. cereus*

- Stainless Steel: >6.88 Spore Log Reduction
- Curtain Vinyl: >5.66 Spore Log Reduction
- Mipolam: >5.98 Spore Log Reduction
- Plexiglas: 5.95 Spore Log Reduction

Results—*B. megaterium*

- Stainless Steel: >6.56 Spore Log Reduction
- Curtain Vinyl: >6.56 Spore Log Reduction
- Mipolam: 4.52 Spore Log Reduction
- Plexiglas: >6.56 Spore Log Reduction

Results—*B. subtilis*

- Stainless Steel: >5.34 Spore Log Reduction
- Curtain Vinyl: >4.90 Spore Log Reduction
- Mipolam: >5.15 Spore Log Reduction
- Plexiglas: >5.20 Spore Log Reduction

Results—*A. niger*

- Stainless Steel: >4.86 Log Reduction
- Curtain Vinyl: >4.41 Log Reduction
- Mipolam: >4.81 Log Reduction
- Plexiglas: 4.19 Log Reduction

Results—Gram Positive Cocktail (Combined Results)

- Stainless Steel: >5.54 Log Reduction
- Curtain Vinyl: >5.81 Log Reduction
- Mipolam: >5.32 Log Reduction
- Plexiglas: >5.71 Log Reduction

Results—Gram Positive Cocktail



Results—Gram Negative Cocktail (Combined Results on MacConkey Agar)

- Stainless Steel: >4.13 Log Reduction
- Curtain Vinyl: >4.85 Log Reduction
- Mipolam: >4.46 Log Reduction
- Plexiglas: >4.50 Log Reduction

Results—Gram Negative Cocktail



Neutralization Test: Stainless Steel Challenged with *A. niger*

	Avg. CFU per 3 Counts
Carrier 1	69.3
Carrier 2	74.7
Saline Control	70.0

DE Broth vs Steriplex Neutralization Broth (*A. niger* Challenge)

Surface Substrate	Log Reduction	
	Steriplex Broth	DE Broth
Stainless Steel	> 4.86	> 5.20
Mipolam	> 4.81	> 4.86
Curtain Vinyl	> 4.41	> 4.32
Plexiglas	4.19	> 4.99

In situ Testing :

Baseline—Prior to Cleaning					
Location/Sa mple Type	No. Sampled	No. Positive	% Positive	No. Mold	% Mold
RODACs	150	106	71	47	31
Swabs	32	15	47	1	3
After Cleaning (Detergent) & Steriplex					
Surfaces	100	0	0	0	0

Recommendations:

Disinfectant Rotation??? See USP <1072>

Why???

Change the Sanitization Paradigm

Comment

- This was an independent study.
- I did not get paid to do these evaluations.
- sBioMed only paid for expenses and materials for these studies
- The opinions I have expressed are based on my objective experience with this product.

Thank you!



Questions????????

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