

# AIHP - Does it behave like a Gas?

Miguel A. Grimaldo, M.Eng.  
University of Texas Medical Branch

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# Conflict of Interest

- Member of TOMI Environmental Solutions - Scientific Advisory Board.

## Our Decontamination Experience

- Formaldehyde gas decontamination – the “Gold Standard”.
- Decontamination with other technologies:
  - Vaporized Hydrogen Peroxide (Bioquell).
  - Chlorine Dioxide (ClorDiSys Solutions & DRS Laboratories).
- Goal – Looking for a suitable replacement for formaldehyde gas.

# H2O2 – Atmospheric Cold Plasma Activation



# Initial Tests in 2015

# Initial Test



# L-Shape Room - Results – Initial Test

## G. stearothersophilus

	3 Nozzles Tyvek-Tyvek Package G. stearothersophilus 03Mar2015
Positive	25
Negative	15
Total	40

### Some Negative for Growth Locations

Corner - Low

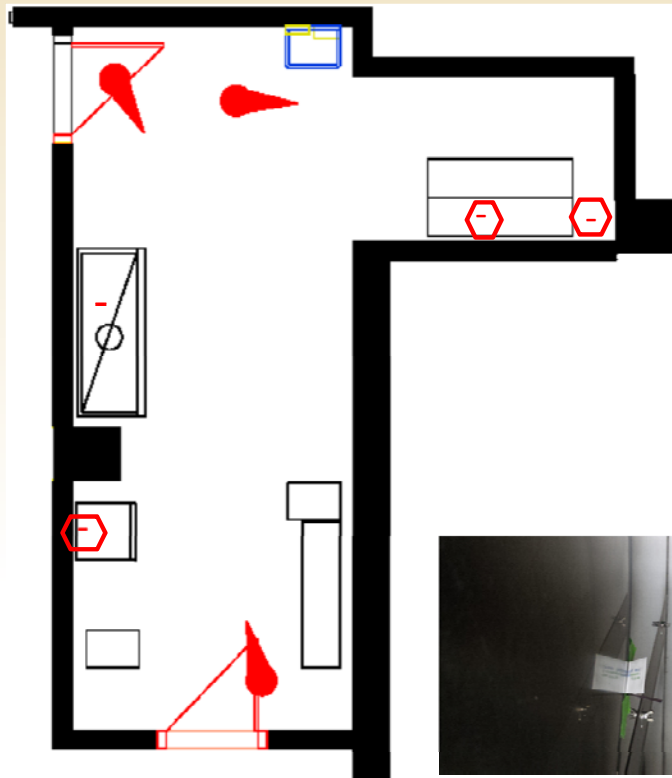
Over Allentown Exhaust

Intake Plenum - Allentown Cage

Under Bottom of BSC

BSC Back Wall

Behind Fridge

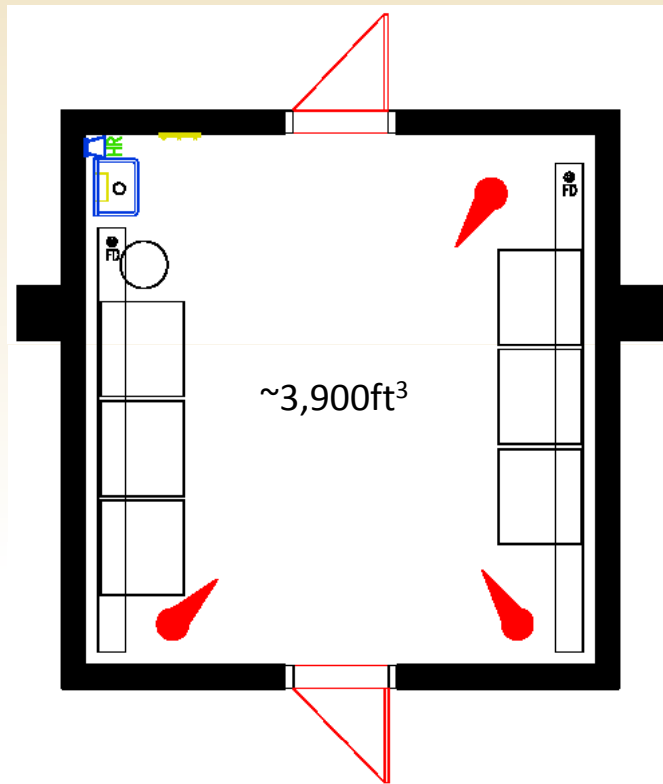


# Questions After Initial Test

- Does it behave like a gas??
- Does the wetting of the Tyvek packaging affect the penetration of the disinfectant?
- Does the number of nozzles utilized have an impact on the results (spray time)?



# Large Animal Room Setup *G. stearothermophilus*



# Large Animal Room Results

## G. stearothermophilus



3 Nozzles	
Bare SS	
G. stearothermophilus	
3/16/2015	
Positive	0
Negative	38
Total	38



**BI's Used on the Test:**  
SBC-327 – Bare metal BI - G.  
stearothermophilus (#12980) >10E6

# Other Studies 2016

# Other Studies – Surface Spray Test

**Ionized Hydrogen Peroxide  
Decontamination Cycle Validations  
Biological Indicator Test Results Form**

Validation for: Manual Decon of Samples

Volume: N/A cu. ft. No. of Nozzles: 1

Injection Time: 7 sec ± 3 min (Min) Dwell Time:      (Min)

Spores Recovered/Inoculated in Broth By: M. Gammuto

Decon Date: Feb 8, 2016 Inoculation Date: Feb 8, 2016

**Biological Indicator (BI) Results**  
(+) = POSITIVE (Spore Growth Visible). (-) = NEGATIVE (Spore Growth is not Visible).  
(N.O.) = Not Observed. (N.A.) = Not Applicable.

	Day 1	Day 2	Day 3	Day 4	Day 5
Date	Feb 9	Feb 10	Feb 11	Feb 12	
BI 1	(-)	(-)	(-)	(-)	
BI 2	(-)	(-)	(-)	(-)	
BI 3	(-)	(-)	(-)	(-)	
BI 4	(-)	(-)	(-)	(-)	
BI 5	(-)	(-)	(-)	(-)	
BI 6	(-)	(-)	(-)	(-)	
BI 7	(-)	(-)	(-)	(-)	
BI 8	(-)	(-)	(-)	(-)	
BI 9	(-)	(-)	(-)	(-)	
BI 10	N.A.	N.A.	N.A.	N.A.	
Positive Control	(+)	(+)	(+)	(+)	
Media (Negative)	(-)	(-)	(-)	(-)	

Spore Type: Geobacillus stearothermophilus #12980 Ues6

Lot No. \_\_\_\_\_ Exp Date \_\_\_\_\_

Decon Passed: YES or NO Results Approved By: \_\_\_\_\_

*Samples 1 to 6 were sprayed for 7 seconds. The spray was done directly above the samples for approx 1 minute. Samples 7 to 9 were sprayed inside the base as part of a surface decon of the base for 3 min.*

*Original BI were also used with 6 samples Feb 9. The visual indicates a > 10<sup>6</sup> CFU reduction.*

	7 Sec Spray Decon 19" above samples Base SS GS 2/8/2016	3 min BSC Spray Decon Bare SS GS 2/8/2016
Sample No./Date		
1	-	
2	-	
3	-	
4	-	
5	-	
6	-	
7		-
8		-
9		-

**BIs Used on the Test:**  
SBC-327 – Bare metal BI - G.  
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Injection Time: 7 sec @ 3 min (Min) Dwell Time: — (Min)

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BI 4	(-)	(-)	(-)	(-)	
BI 5	(-)	(-)	(-)	(-)	
BI 6	(-)	(-)	(-)	(-)	
BI 7	(-)	(-)	(-)	(-)	
BI 8	(-)	(-)	(-)	(-)	
BI 9	(-)	(-)	(-)	(-)	
BI 10	N.A.	N.A.	N.A.	N.A.	
Positive Control	(+)	(+)	(+)	(+)	
Media (Negative)	(-)	(-)	(-)	(-)	

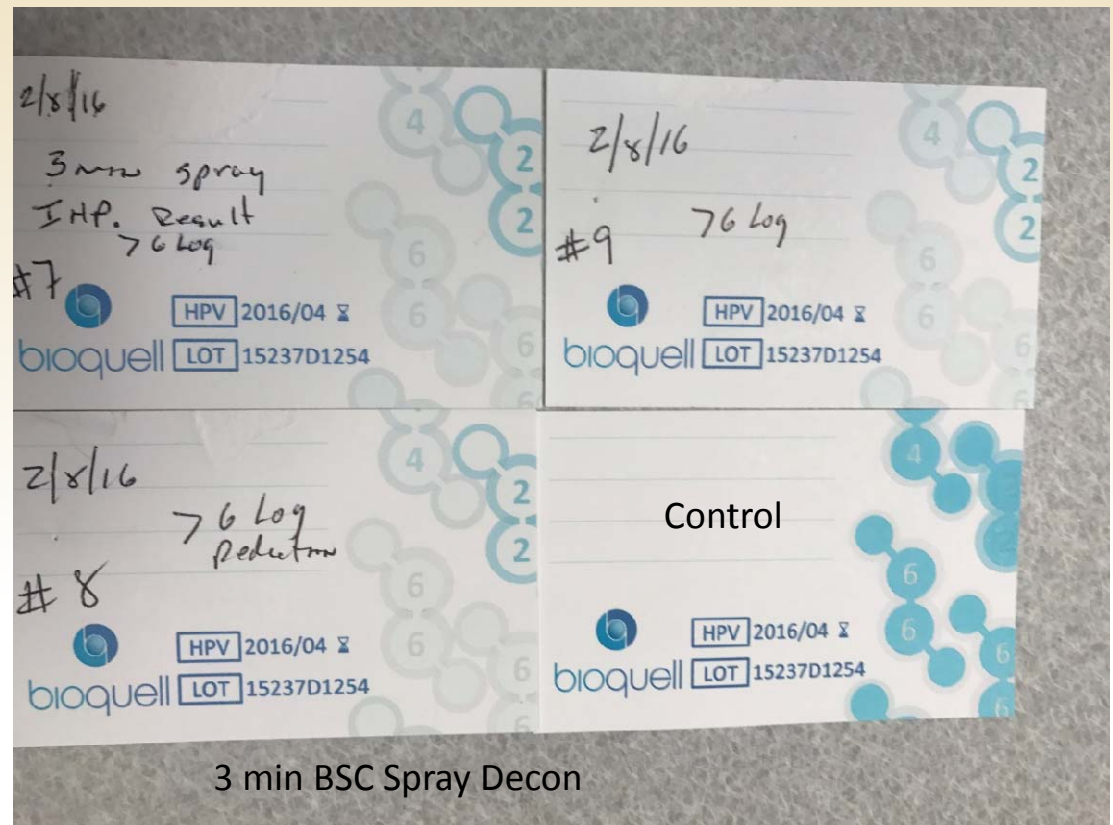
Spore Type: Cocci bacillus, Streptococcus Str. Ureca

Lot No. \_\_\_\_\_ Exp Date \_\_\_\_\_

Decon Passed: YES or NO Results Approved By: \_\_\_\_\_

*Original BI were also used with 6 samples 7-12. The visual indicates a > 6 log reduction.*

*Samples 1 to 6 were sprayed for 7 seconds. The spray was done directly above the samples for approx 1 minute. Samples 7 to 9 were sprayed inside the base as part of a surface decon of the base for 3 min.*



# Other Studies – Ebola Decon

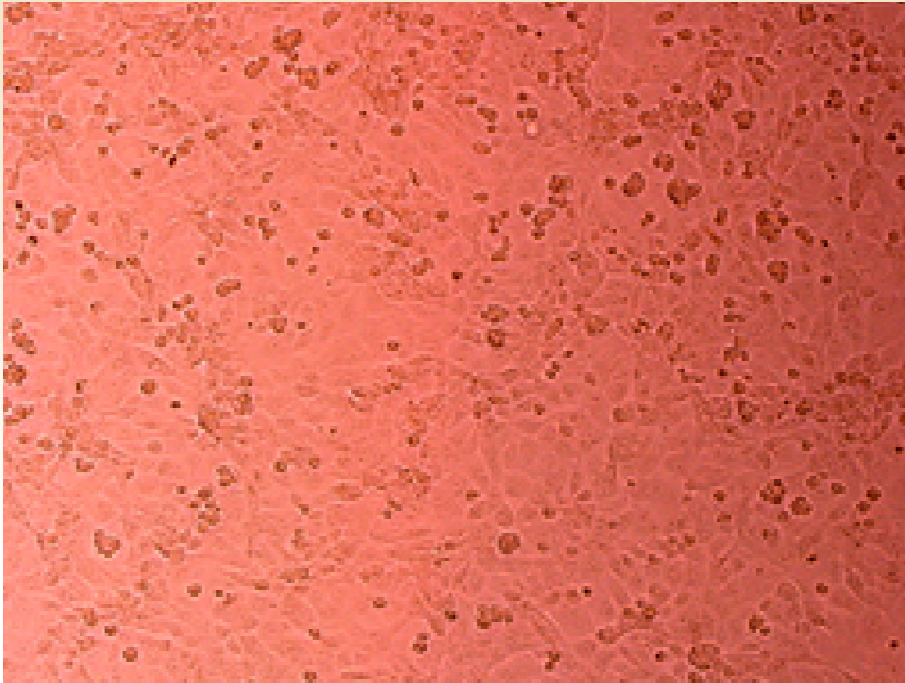


Test Plates Used During Trial – Positive Control

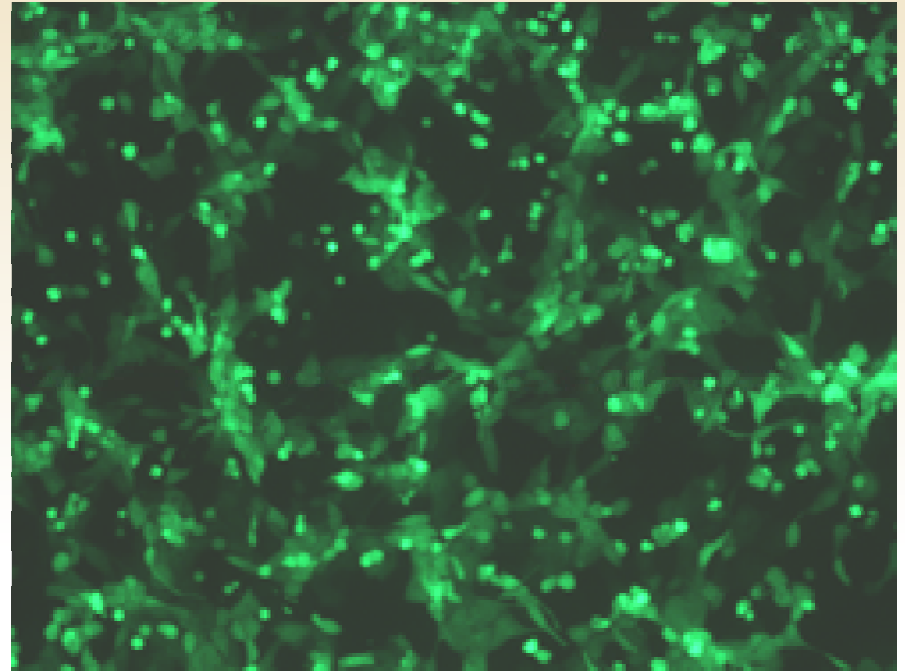


Biological Indicators Used

# Other Studies – Ebola Decon



Control EBOV-eGFP Expression – White light view



Control EBOV-eGFP Expression  
– UV Fluorescence light view

# Other Studies – Ebola Decon

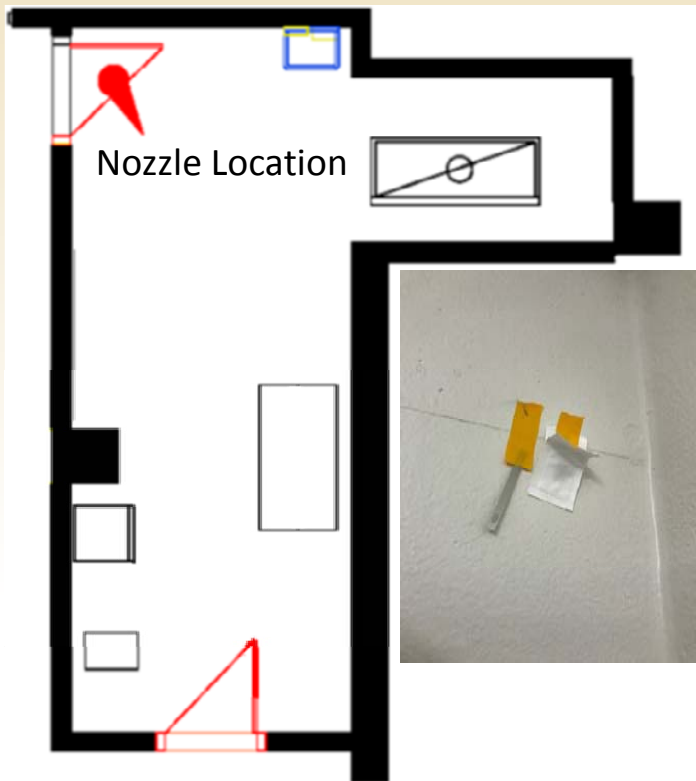
	Positive Control EBOV on plastic surface	EBOV on Unwashed TYVEK	EBOV on ETOH washed TYVEK	Spore strips in 6-well plate	Spore strips on plastic surface	Negative Control Media on plastic surface	Negative Control Media on Unwashed TYVEK	Negative Control Media on ETOH washed TYVEK
7 sec Spray (Duplicates)	No Cells <sup>1</sup>	No Cells <sup>1</sup>	No Cells <sup>1</sup>	Negative	Negative	No Cells <sup>1</sup>	No Data	No Cells <sup>1</sup>
3 min. 12sec Spray (Triplicates)	No Cells <sup>1</sup>	No Cells <sup>1</sup>	No Cells <sup>1</sup>	Negative	Negative	No Cells <sup>1</sup>	No Cells <sup>1</sup>	No Cells <sup>1</sup>
Unsprayed (Duplicates)	+ GFP <sup>2</sup>	+ GFP <sup>2</sup>	+ GFP <sup>2</sup>	Positive	No Data	Purple	Monolayer present	Monolayer present

- 1) No viable cells were detectable in the cell culture wells, likely due to cytotoxicity of the hydrogen peroxide.
- 2) Expression of eGFP correlates with replication of infectious EBOV.



# Diffusion Studies 2016

# L-Shape Room - Diffusion Study



# L-Shape Room - Diffusion Study



		L-Shape Room 1-Nozzle		
		Tyvek-Tyvek	Bare SS	Tyvek-Tyvek
		BA	GS	GS
Dwell Time	Hrs	16	16	16
Sample No./Date	Label	9/30/2016	9/30/2016	9/30/2016
1	1		-	
2	2		-	
3	3		-	
4	4		-	
5	1.			-
6	2.			-
7	3.			-
8	4.			-
9	A	-		
10	B	-		

# L-Shape Room - Diffusion Study



# L-Shape Room - Diffusion Study



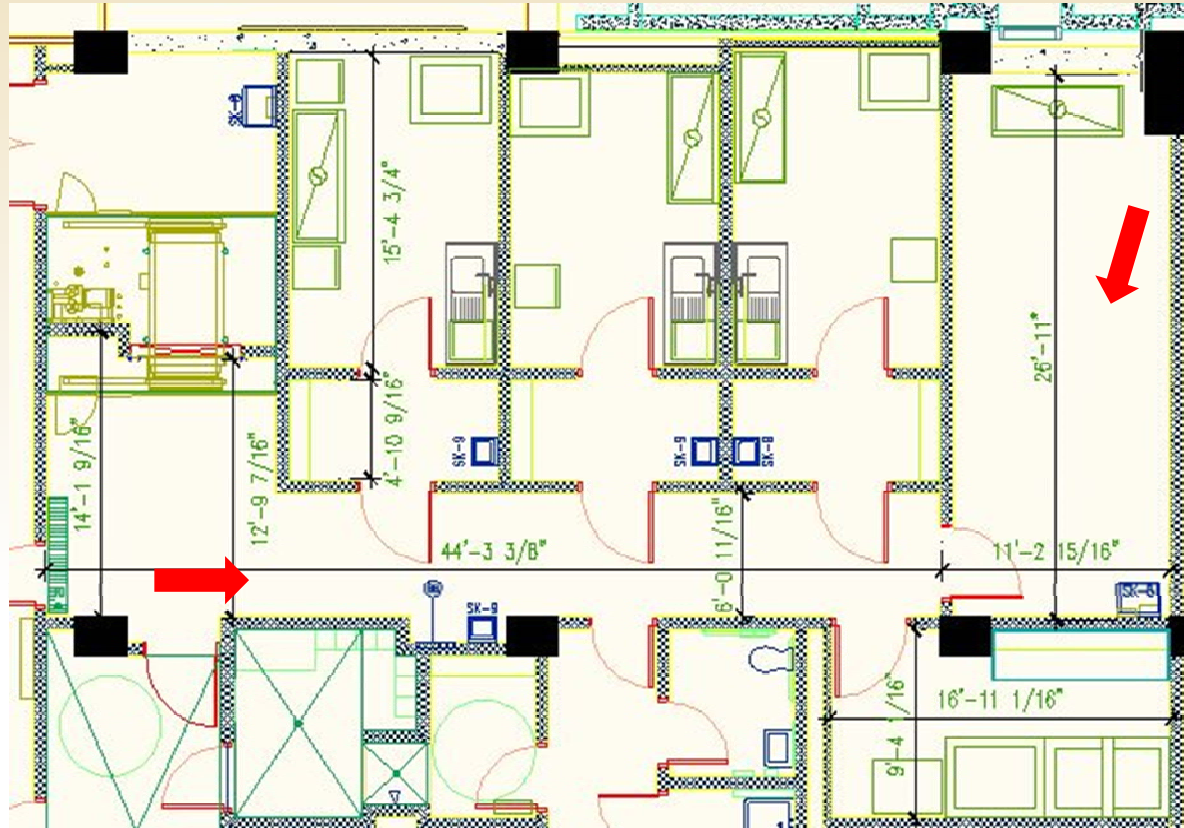
Sample No.	Spore Locations
1	Under the BSC where stand supports it.
2	At BSC Difusser
3	Under Sink
4	Attached to bottom of Animal Pen Tray
5	Attached to bottom of Fridge



	Diffusion Study - L-Shape Room	
	Tyvek-Tyvek	Bare SS
	BA	GS
<b>Dwell Time</b>	<b>17hrs</b>	<b>17hrs</b>
Sample No./Date	10/5/2016	10/5/2016
1	-	-
2	-	-
3	-	-
4	-	-
5	-	-

# Multiple Rooms – Diffusion Study

~12,000 ft<sup>3</sup>



# Multiple Rooms – Diffusion Study



# Multiple Rooms – Diffusion Study

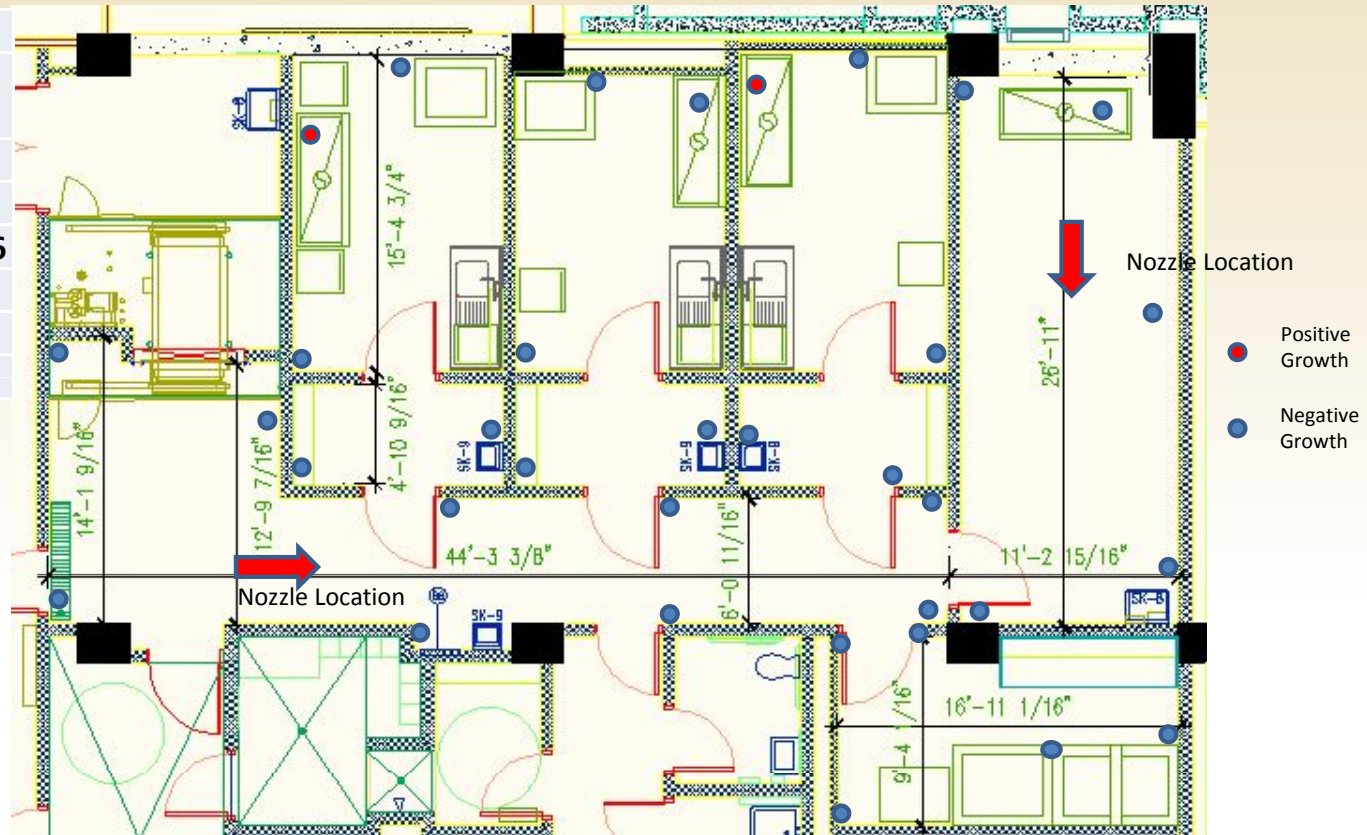




# Multiple Rooms – Diffusion Study

## Multiple Rooms - 2 Nozzles

	Tyvek-Tyvek	Bare SS
	BA	GS
Dwell Time (hrs)	16	16
Sample No./Date	10/19/2016	10/19/2016
Positive	0	2
Negative	34	32
Total	34	34



**BIs Used on the Test:**  
 SBC-327 – Bare metal BI - G.  
 stearotherophilus (#12980) >10E6

**BIs Used on the Test:**  
 GRS-090 – Tyvek/Tyvek packaged BI - B.  
 atrophaeus (#9372) >10E6

# Summary of Results

- It is important to perform decontamination studies to establish:
  - Number of nozzles needed
  - Contact time required
- The decontamination process is diffusing similarly to formaldehyde gas. No need to use fans.
- *Bacillus atrophaeus* spores in Tyvek-Tyvek envelopes are a good indicator for the decontamination process. Similar to Formaldehyde gas decontamination.

# Future Directions

- Continue with the diffusion studies to reduce the contact time for the same areas.
- Develop decontamination protocols for:
  - HEPA filter housings
  - Biological Safety Cabinets
- Do parametric analysis of the decontamination process.

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# Thank you...

**Miguel A. Grimaldo, M.Eng.**

Assistant Professor – Department of Pathology  
Director of Institutional Biocontainment Resources  
University of Texas Medical Branch  
301 University Boulevard  
Galveston, Texas 77555-0609  
Tel: (409) 266-6521  
E-mail: [magrimal@utmb.edu](mailto:magrimal@utmb.edu)

