

## STUDY REPORT

### STUDY TITLE

Evaluation of Antimicrobial Effectiveness of a UVC Generating Device  
on Hard Nonporous Surfaces

### **Test Organisms:**

Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33592)  
*Clostridium difficile* - spore form (ATCC 43598)  
Vancomycin Resistant *Enterococcus faecalis* – VRE (ATCC 51575)

### PRODUCT IDENTITY

Aseptix

### AUTHOR

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### STUDY COMPLETION DATE

January 17, 2014

### PERFORMING LABORATORY

ATS Labs  
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### SPONSOR

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### PROJECT NUMBER

A15984

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## STUDY REPORT

### GENERAL STUDY INFORMATION

**Study Title:** Evaluation of Antimicrobial Effectiveness of a UVC Generating Device on Hard Nonporous Surfaces

**Project Number:** A15984

**TRF Number:** SXT01121613.CUST

### TEST SUBSTANCE IDENTITY

**Test Device Name:** Aseptix

### STUDY DATES

**Date Sample Received:** December 27, 2013  
**Study Initiation Date:** December 27, 2013  
**Experimental Start Date:** January 8, 2014  
**Experimental End Date:** January 13, 2014  
**Study Completion Date:** January 17, 2014

Test Organism	ATCC #	Culture Medium	Incubation Parameters
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA	33592	Synthetic Broth	35-37°C, aerobic
<i>Clostridium difficile</i> - spore form	43598	CDC Anaerobic Blood Agar	35-37°C, anaerobic
Vancomycin Resistant <i>Enterococcus faecalis</i> – VRE	51575	Fluid Thioglycollate Medium	35-37°C, aerobic

The test organisms to be used in this study were obtained from the American Type Culture Collection (ATCC), Manassas, Virginia.

**Exposure Times:** 5 minutes, 10 minutes and 15 minutes

**Exposure Temperature:** Room temperature (20.3°C)

**Number of Carriers Tested:** 2 per organism per location

**Soil Load Description:** No organic soil load required

**Neutralizer:** Lethen Broth

**Agar Plate Medium:** Tryptic Soy Agar with 5% Sheep Blood (BAP) [for MRSA and VRE]  
BHI-HT Agar [for *Clostridium difficile* – spore form]

## **EXPERIMENTAL DESIGN**

Glass carriers (1" x 3") inoculated with a dry film of the test organism were placed into the testing room and exposed to the UV generating device(s) for the Sponsor specified exposure times. Duplicate carriers per organism per location were placed around the testing area as indicated by the Sponsor. Briefly, two carriers per organism were placed on the bedrail of a hospital bed approximately 3 feet off the floor and approximately 2 feet from a UV device. The second set of carriers was located on the opposite side of the hospital bed, on a hospital table approximately 4 feet off the ground and approximately 5 feet from a UV device. Each test carrier was oriented so that the inoculated area of the carrier was perpendicular to the ground, parallel to the device and as vertical as possible. After exposure, the carriers were transferred to vessels containing subculture media and assayed for survivors. Appropriate culture purity, media sterility, carrier sterility, carrier quantitation, HCl resistance (for *Clostridium difficile*) and neutralization confirmation controls were performed.

Per Sponsor's direction, the study was not required to be conducted under US EPA 40 CFR Part 160 or US FDA 21 CFR Part 58.

## **STUDY RESULTS**

**TABLE 1: CONTROL RESULTS**

The following results from controls confirmed study validity:

Type of Control	Results		
	Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	<i>Clostridium difficile</i> - spore form (ATCC 43598)	Vancomycin Resistant <i>Enterococcus faecalis</i> – VRE (ATCC 51575)
Purity Control	Pure	Pure	Pure
Neutralizer Sterility Control	No Growth		
Carrier Sterility Control	No Growth		

**TABLE 2: NEUTRALIZATION CONFIRMATION CONTROL RESULTS**

Test Device	Test Organism	Neutralization Confirmation (CFU/plate)		±1.0 Log <sub>10</sub> Pass/Fail
		Numbers Control	Results	
Aseptix	Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	20,13	21,14	-0.03 (Pass)
	<i>Clostridium difficile</i> - spore form (ATCC 43598)	40,36	40,34	0.01 (Pass)
	Vancomycin Resistant <i>Enterococcus faecalis</i> – VRE (ATCC 51575)	17,11	15,15	-0.03 (Pass)

CFU = Colony Forming Unit

**TABLE 3: CARRIER QUANTITATION CONTROL RESULTS**

Test Organism	Carrier #	Result	Average Log <sub>10</sub>	Geometric Mean
		CFU/Carrier (Log <sub>10</sub> )		
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	1.5 x 10 <sup>6</sup> (6.18)	6.18	1.51 x 10 <sup>6</sup>
	2	1.5 x 10 <sup>6</sup> (6.18)		
<i>Clostridium difficile</i> - spore form (ATCC 43598)	1	9.0 x 10 <sup>6</sup> (6.95)	6.95	8.91 x 10 <sup>6</sup>
	2	9.0 x 10 <sup>6</sup> (6.95)		
Vancomycin Resistant <i>Enterococcus faecalis</i> – VRE (ATCC 51575)	1	1.7 x 10 <sup>5</sup> (5.23)	5.17	1.48 x 10 <sup>5</sup>
	2	1.3 x 10 <sup>5</sup> (5.11)		

CFU = Colony Forming Unit

**TABLE 4: EVALUATION OF TEST CARRIER DATA – 5 Minute Exposure**

<b>Test Device: Aseptix</b>							
<b>Carrier Location: Bedrail (approximately 3 feet off ground and 2 feet from device)</b>							
<b>Test Organism</b>	<b>Carrier #</b>	<b>Number of Survivors (CFU)</b>					
		<b>Dilution</b>					
		<b>Filtered 10<sup>0</sup></b>	<b>10<sup>0</sup> (1.00 mL)</b>	<b>10<sup>0</sup></b>	<b>10<sup>-1</sup></b>	<b>10<sup>-2</sup></b>	<b>10<sup>-3</sup></b>
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	0	0,0	0,0	0,0	0,0	0,0
	2	0	0,0	0,0	0,0	0,0	0,0
<i>Clostridium difficile</i> – spore form (ATCC 43598)	1	3	0,0	0,0	0,0	0,0	0,0
	2	52	3,8	0,0	0,0	0,0	0,0
Vancomycin Resistant <i>Enterococcus faecalis</i> – VRE (ATCC 51575)	1	0	0,0	0,0	0,0	0,0	0,0
	2	0	0,0	0,0	0,0	0,0	0,0
<b>Carrier Location: Table (approximately 4 feet off ground and 5 feet from device)</b>							
<b>Test Organism</b>	<b>Carrier #</b>	<b>Number of Survivors (CFU)</b>					
		<b>Dilution</b>					
		<b>Filtered 10<sup>0</sup></b>	<b>10<sup>0</sup> (1.00 mL)</b>	<b>10<sup>0</sup></b>	<b>10<sup>-1</sup></b>	<b>10<sup>-2</sup></b>	<b>10<sup>-3</sup></b>
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	0	0,0	0,0	0,0	0,0	0,0
	2	0	0,0	0,0	0,0	0,0	0,0
<i>Clostridium difficile</i> – spore form (ATCC 43598)	1	TNTC	30,20	3,2	0,0	0,0	0,0
	2	TNTC	46,40	3,9	0,0	0,0	0,0
Vancomycin Resistant <i>Enterococcus faecalis</i> – VRE (ATCC 51575)	1	14	1,1	1,0	0,0	0,0	0,0
	2	2	1,0	0,0	0,0	0,0	0,0

CFU = Colony Forming Unit

TNTC = Too Numerous To Count

A value of <1 was used in place of zero for calculation purposes only.

**TABLE 5: EVALUATION OF TEST CARRIER DATA – 10 Minute Exposure**

Test Device: Aseptix							
Carrier Location: Bedrail (approximately 3 feet off ground and 2 feet from device)							
Test Organism	Carrier #	Number of Survivors (CFU)					
		Dilution					
		Filtered 10 <sup>0</sup>	10 <sup>0</sup> (1.00 mL)	10 <sup>0</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	0	0,0	0,0	0,0	0,0	0,0
	2	0	0,0	0,0	0,0	0,0	0,0
<i>Clostridium difficile</i> – spore form (ATCC 43598)	1	1	0,0	0,0	0,0	0,0	0,0
	2	15	0,0	0,0	0,0	0,0	0,0
Vancomycin Resistant <i>Enterococcus faecalis</i> – VRE (ATCC 51575)	1	0	0,0	0,0	0,0	0,0	0,0
	2	0	0,0	0,0	0,0	0,0	0,0
Carrier Location: Table (approximately 4 feet off ground and 5 feet from device)							
Test Organism	Carrier #	Number of Survivors (CFU)					
		Dilution					
		Filtered 10 <sup>0</sup>	10 <sup>0</sup> (1.00 mL)	10 <sup>0</sup>	10 <sup>-1</sup>	10 <sup>-2</sup>	10 <sup>-3</sup>
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	0	0,0	0,0	0,0	0,0	0,0
	2	0	0,0	0,0	0,0	0,0	0,0
<i>Clostridium difficile</i> – spore form (ATCC 43598)	1	80	1,8	0,0	0,0	0,0	0,0
	2	52	2,5	0,0	0,0	0,0	0,0
Vancomycin Resistant <i>Enterococcus faecalis</i> – VRE (ATCC 51575)	1	39	3,2	0,0	0,0	0,0	0,0
	2	TNTC	36,46	1,0	0,0	0,0	0,0

CFU = Colony Forming Unit

TNTC = Too Numerous To Count

A value of <1 was used in place of zero for calculation purposes only.

**TABLE 6: EVALUATION OF TEST CARRIER DATA – 15 Minute Exposure**

<b>Test Device: Aseptix</b>							
<b>Carrier Location: Bedrail (approximately 3 feet off ground and 2 feet from device)</b>							
<b>Test Organism</b>	<b>Carrier #</b>	<b>Number of Survivors (CFU)</b>					
		<b>Dilution</b>					
		<b>Filtered 10<sup>0</sup></b>	<b>10<sup>0</sup> (1.00 mL)</b>	<b>10<sup>0</sup></b>	<b>10<sup>-1</sup></b>	<b>10<sup>-2</sup></b>	<b>10<sup>-3</sup></b>
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	0	0,0	0,0	0,0	0,0	0,0
	2	0	0,0	0,0	0,0	0,0	0,0
<i>Clostridium difficile</i> – spore form (ATCC 43598)	1	0	0,0	0,0	0,0	0,0	0,0
	2	0	0,0	0,0	0,0	0,0	0,0
Vancomycin Resistant <i>Enterococcus faecalis</i> – VRE (ATCC 51575)	1	0	0,0	0,0	0,0	0,0	0,0
	2	0	0,0	0,0	0,0	0,0	0,0
<b>Carrier Location: Table (approximately 4 feet off ground and 5 feet from device)</b>							
<b>Test Organism</b>	<b>Carrier #</b>	<b>Number of Survivors (CFU)</b>					
		<b>Dilution</b>					
		<b>Filtered 10<sup>0</sup></b>	<b>10<sup>0</sup> (1.00 mL)</b>	<b>10<sup>0</sup></b>	<b>10<sup>-1</sup></b>	<b>10<sup>-2</sup></b>	<b>10<sup>-3</sup></b>
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	0	0,0	0,0	0,0	0,0	0,0
	2	0	0,0	0,0	0,0	0,0	0,0
<i>Clostridium difficile</i> – spore form (ATCC 43598)	1	6	0,0	0,0	0,0	0,0	0,0
	2	18	0,0	0,0	0,0	0,0	0,0
Vancomycin Resistant <i>Enterococcus faecalis</i> – VRE (ATCC 51575)	1	0	0,0	0,0	0,0	0,0	0,0
	2	4	0,0	0,0	0,0	0,0	0,0

CFU = Colony Forming Unit

A value of <1 was used in place of zero for calculation purposes only.



**TABLE 7: CALCULATED VALUES – 5 Minute Exposure**

<b>Test Device: Aseptix</b>					
<b>Carrier Location: Bedrail (approximately 3 feet off ground and 2 feet from device)</b>					
<b>Test Organism</b>	<b>Carrier #</b>	<b># Survivors/ Carrier (Log<sub>10</sub>)</b>	<b>Average Log<sub>10</sub></b>	<b>Geometric Mean</b>	<b>Percent Reduction (Log<sub>10</sub>)</b>
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	<1 (<0.00)	<0.00	<1	>99.9999% (>6.18)
	2	<1 (<0.00)			
<i>Clostridium difficile</i> - spore form (ATCC 43598)	1	4 (0.60)	1.20	1.58 x 10 <sup>1</sup>	>99.999% (5.75)
	2	6.2 x 10 <sup>1</sup> (1.79)			
Vancomycin Resistant <i>Enterococcus faecalis</i> – VRE (ATCC 51575)	1	<1 (<0.00)	<0.00	<1	>99.999% (>5.17)
	2	<1 (<0.00)			
<b>Carrier Location: Table (approximately 4 feet off ground and 5 feet from device)</b>					
<b>Test Organism</b>	<b>Carrier #</b>	<b># Survivors/ Carrier (Log<sub>10</sub>)</b>	<b>Average Log<sub>10</sub></b>	<b>Geometric Mean</b>	<b>Percent Reduction (Log<sub>10</sub>)</b>
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	<1 (<0.00)	<0.00	<1	>99.9999% (>6.18)
	2	<1 (<0.00)			
<i>Clostridium difficile</i> - spore form (ATCC 43598)	1	5.0 x 10 <sup>2</sup> (2.70)	2.82	6.60 x 10 <sup>2</sup>	99.99% (4.13)
	2	8.6 x 10 <sup>2</sup> (2.93)			
Vancomycin Resistant <i>Enterococcus faecalis</i> – VRE (ATCC 51575)	1	1.7 x 10 <sup>1</sup> (1.23)	0.77	5.89 x 10 <sup>0</sup>	>99.99% (4.40)
	2	2 (0.30)			



**TABLE 8: CALCULATED VALUES – 10 Minute Exposure**

<b>Test Device: Aseptix</b>					
<b>Carrier Location: Bedrail (approximately 3 feet off ground and 2 feet from device)</b>					
<b>Test Organism</b>	<b>Carrier #</b>	<b># Survivors/ Carrier (Log<sub>10</sub>)</b>	<b>Average Log<sub>10</sub></b>	<b>Geometric Mean</b>	<b>Percent Reduction (Log<sub>10</sub>)</b>
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	<1 (<0.00)	<0.00	<1	>99.9999% (>6.18)
	2	<1 (<0.00)			
<i>Clostridium difficile</i> - spore form (ATCC 43598)	1	1 (0.00)	0.63	4.27 x 10 <sup>0</sup>	>99.9999% (6.32)
	2	1.8 x 10 <sup>1</sup> (1.26)			
Vancomycin Resistant <i>Enterococcus faecalis</i> – VRE (ATCC 51575)	1	<1 (<0.00)	<0.00	<1	>99.999% (>5.17)
	2	<1 (<0.00)			
<b>Carrier Location: Table (approximately 4 feet off ground and 5 feet from device)</b>					
<b>Test Organism</b>	<b>Carrier #</b>	<b># Survivors/ Carrier (Log<sub>10</sub>)</b>	<b>Average Log<sub>10</sub></b>	<b>Geometric Mean</b>	<b>Percent Reduction (Log<sub>10</sub>)</b>
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	<1 (<0.00)	<0.00	<1	>99.9999% (>6.18)
	2	<1 (<0.00)			
<i>Clostridium difficile</i> - spore form (ATCC 43598)	1	9.5 x 10 <sup>1</sup> (1.98)	1.89	7.76 x 10 <sup>1</sup>	99.999% (5.06)
	2	6.2 x 10 <sup>1</sup> (1.79)			
Vancomycin Resistant <i>Enterococcus faecalis</i> – VRE (ATCC 51575)	1	4.6 x 10 <sup>1</sup> (1.66)	2.29	1.95 x 10 <sup>2</sup>	>99.8% (2.88)
	2	8.2 x 10 <sup>2</sup> (2.91)			

**TABLE 9: CALCULATED VALUES – 15 Minute Exposure**

<b>Test Device: Aseptix</b>					
<b>Carrier Location: Bedrail (approximately 3 feet off ground and 2 feet from device)</b>					
<b>Test Organism</b>	<b>Carrier #</b>	<b># Survivors/ Carrier (Log<sub>10</sub>)</b>	<b>Average Log<sub>10</sub></b>	<b>Geometric Mean</b>	<b>Percent Reduction (Log<sub>10</sub>)</b>
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	<1 (<0.00)	<0.00	<1	>99.9999% (>6.18)
	2	<1 (<0.00)			
<i>Clostridium difficile</i> - spore form (ATCC 43598)	1	<1 (<0.00)	<0.00	<1	>99.9999% (>6.95)
	2	<1 (<0.00)			
Vancomycin Resistant <i>Enterococcus faecalis</i> – VRE (ATCC 51575)	1	<1 (<0.00)	<0.00	<1	>99.999% (>5.17)
	2	<1 (<0.00)			
<b>Carrier Location: Table (approximately 4 feet off ground and 5 feet from device)</b>					
<b>Test Organism</b>	<b>Carrier #</b>	<b># Survivors/ Carrier (Log<sub>10</sub>)</b>	<b>Average Log<sub>10</sub></b>	<b>Geometric Mean</b>	<b>Percent Reduction (Log<sub>10</sub>)</b>
Methicillin Resistant <i>Staphylococcus aureus</i> - MRSA (ATCC 33592)	1	<1 (<0.00)	<0.00	<1	>99.9999% (>6.18)
	2	<1 (<0.00)			
<i>Clostridium difficile</i> - spore form (ATCC 43598)	1	7 (0.85)	1.09	1.23 x 10 <sup>1</sup>	>99.999% (5.86)
	2	2.1 x 10 <sup>1</sup> (1.32)			
Vancomycin Resistant <i>Enterococcus faecalis</i> – VRE (ATCC 51575)	1	<1 (<0.00)	<0.35	<2.24 x 10 <sup>0</sup>	>99.99% (>4.82)
	2	5 (0.70)			

**TABLE 10: VERIFICATION OF ANTIBIOTIC RESISTANCE – *Staphylococcus aureus* - MRSA**

Organism (ATCC)	Zone of Inhibition (mm)	CLSI* Resistant Range (mm)
Methicillin Resistant <i>Staphylococcus aureus</i> – MRSA (ATCC 33592)	6	≤ 10
Quality Control Organism (ATCC)	Zone of Inhibition (mm)	CLSI* Acceptable Range (mm)
<i>Staphylococcus aureus</i> (ATCC 25923)	20	18 - 24

\*CLSI = Clinical and Laboratory Standards Institute

**TABLE 11: VERIFICATION OF ANTIBIOTIC RESISTANCE – *Enterococcus faecalis* - VRE**

Quality Control Organism	Zone of Inhibition (mm)	CLSI* Acceptable Range (mm)
Vancomycin Resistant <i>Enterococcus faecalis</i> – VRE (ATCC 51575)	10	≤14
Test Organism	Zone of Inhibition (mm)	CLSI* Resistant Range (mm)
<i>Staphylococcus aureus</i> (ATCC 25923)	17	17-21

\*CLSI = Clinical and Laboratory Standards Institute

Interpretation of result and acceptable range are from the Clinical and Laboratory Standards Institute, Performance Standards for Antimicrobial Susceptibility Testing; Twenty-Second Information Supplement January 2012, Volume 31 Number 1, Approved Standard M02-A11 and M07-A9, Wayne, Pennsylvania.

**TABLE 12: HCL RESISTANCE VERIFICATION**

<b>Test Organism: <i>Clostridium difficile</i> – spore form (ATCC 43598)</b>						
<b>Exposure Time</b>	<b>10<sup>-2</sup></b>	<b>10<sup>-3</sup></b>	<b>10<sup>-4</sup></b>	<b>CFU/mL (Log<sub>10</sub>)</b>	<b>Log<sub>10</sub> Reduction from Control</b>	<b>Pass/Fail (≤ 2 log<sub>10</sub> difference)</b>
5 minutes (test)	184,204	27,27	6,1	1.94 x 10 <sup>5</sup> (5.29)	0.94	Not Applicable
10 minutes (test)	56,58	12,17	4,0	5.7 x 10 <sup>4</sup> (4.76)	1.47	Pass
20 minutes (test)	4,7	1,3	0,0	6 x 10 <sup>3</sup> (3.78)	2.45	Not Applicable
20 minutes (control)	T,T	142,200	29,37	1.71 x 10 <sup>6</sup> (6.23)	Not Applicable	Not Applicable

T = Too Numerous To Count (≥300 colonies)

**CONTROL RESULTS**

The results of controls run for purity, carrier sterility, neutralizer sterility, neutralization confirmation, HCl resistance control, antibiotic resistance and carrier quantitation were all acceptable.

**ANALYSIS**

The UV light generating device, Aseptix, demonstrated a >99.999% (>5.75 log<sub>10</sub>) reduction, >99.9999% (6.32 log<sub>10</sub>) and >99.9999% (>6.95 log<sub>10</sub>) reduction of *Clostridium difficile* – spore form on the test carriers located on the hospital bedrail following a 5, 10 and 15 minute exposure time, respectively, when tested at room temperature (20.3°C).

The UV light generating device, Aseptix, demonstrated a 99.99% (4.13 log<sub>10</sub>) reduction, 99.999% (5.06 log<sub>10</sub>) and >99.999% (5.86 log<sub>10</sub>) reduction of *Clostridium difficile* – spore form on the test carriers located on the hospital table following a 5, 10 and 15 minute exposure time, respectively, when tested at room temperature (20.3°C).

The UV light generating device, Aseptix, demonstrated a >99.9999% (>6.18 log<sub>10</sub>) reduction of Methicillin Resistant *Staphylococcus aureus* - MRSA on all test carriers following 5, 10 and 15 minute exposure times when tested at room temperature (20.3°C).

The UV light generating device, Aseptix, demonstrated a >99.999% (>5.17 log<sub>10</sub>) reduction of Vancomycin Resistant *Enterococcus faecalis* – VRE (ATCC 51575) on the test carriers located on the hospital bedrail following 5, 10 and 15 minute exposure times when tested at room temperature (20.3°C).

The UV light generating device, Aseptix, demonstrated a >99.99% (4.40 log<sub>10</sub>) reduction, >99.8% (2.88 log<sub>10</sub>) reduction and a >99.99% (>4.82 log<sub>10</sub>) reduction of Vancomycin Resistant *Enterococcus faecalis* – VRE (ATCC 51575) on the test carriers located on the hospital table following a 5, 10 and 15 minute exposure time, respectively, when tested at room temperature (20.3°C).

**PREPARED BY:**

  
\_\_\_\_\_  
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1-17-14  
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