

Antimicrobial
Water-Base for PU & Silicone



Aqua 65JL
Aqua 87JL

Water-Based
Hydrophilic Coating

**Highly Lubricious,
Non-Eluting,
Antimicrobial
surface coating
for the reduction
of biofilm adhesion.**

Aqua 65JL
US FDA
MAF-1785

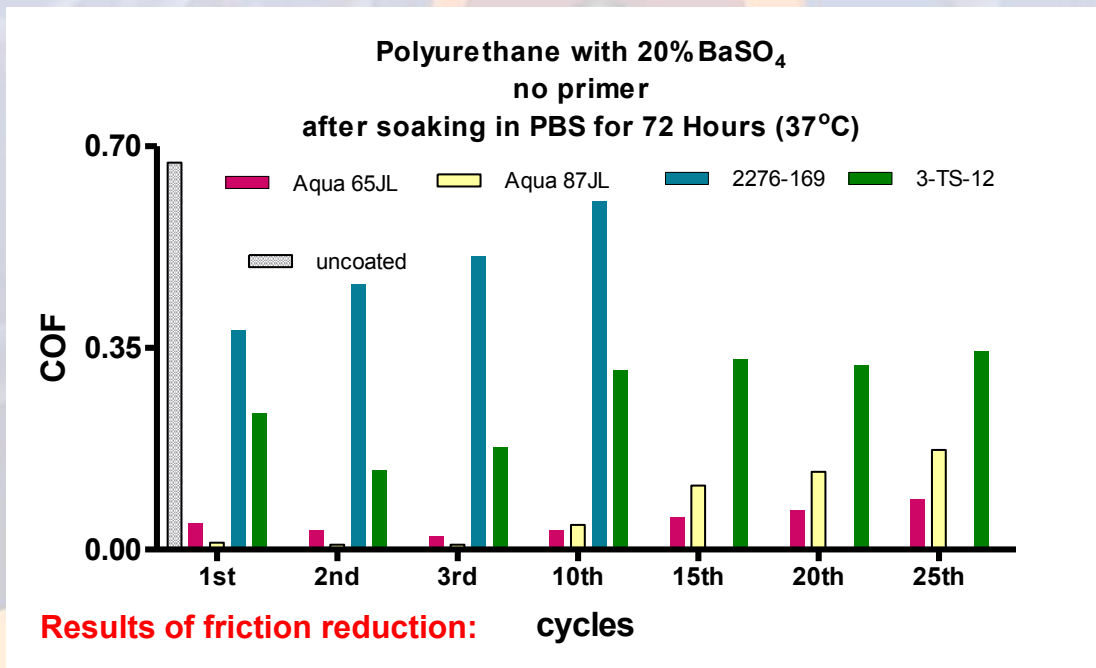
Polyurethane

Coating process for polyurethane

- Wipe (sealed edge, knitted polyester wipe) catheter with heptane followed by IPA
- air dry at R.T.
- Dip into top coat formula Aqua 65JL or Aqua 87JL (R.T. humidity 40 - 50%)
 - 30 sec. for clear PU
 - 1min. for white PU (NEUTHANE 80AE with 20% BaSO₄)
- Air dry at Room Temperature for 15 min
- Cure at 60°C for 4 hours

Test for Lubricity of Water-Based Top Coat on polyurethane

- Coated tubes were tested for lubricity after soaking in PBS at 37°C for 72 hours.
- Place tubes in the test bed filled with water and a 350 gram weight was placed on the tubing
- Move the weight back and forth for 25 cycles and the force required to slide the weight was recorded and is proportional to the lubricity or Coefficient of Friction (COF).



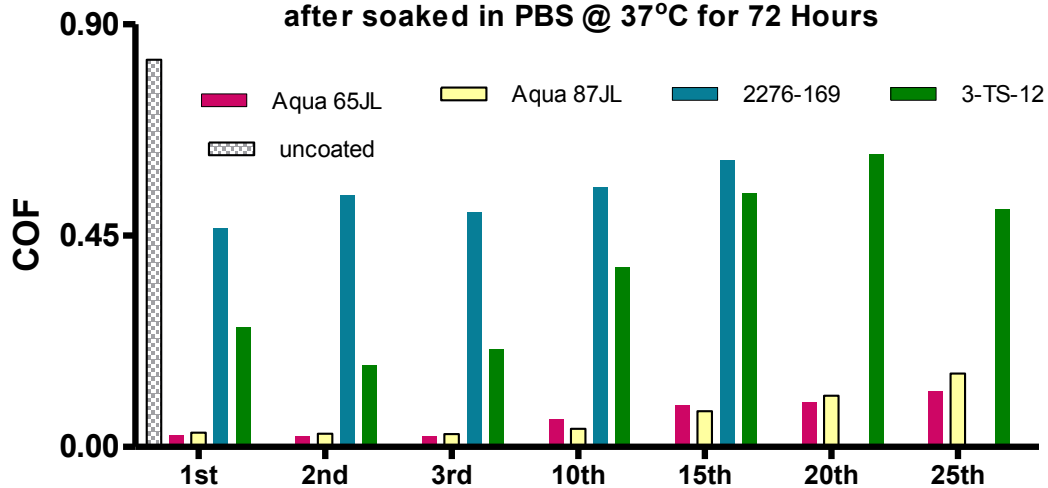
	Aqua 65JL	Aqua 87JL	2276-169	3-TS-12
Avg. of 1,2,3 cycles	95%	98%	33.00%	73%
25th cycles	87%	74%	N/D	49%

N/D: not determined

Test for Lubricity of Water-Based Top Coat on polyurethane

Polyurethane (Dow 2363-80AE) no primer

after soaked in PBS @ 37°C for 72 Hours

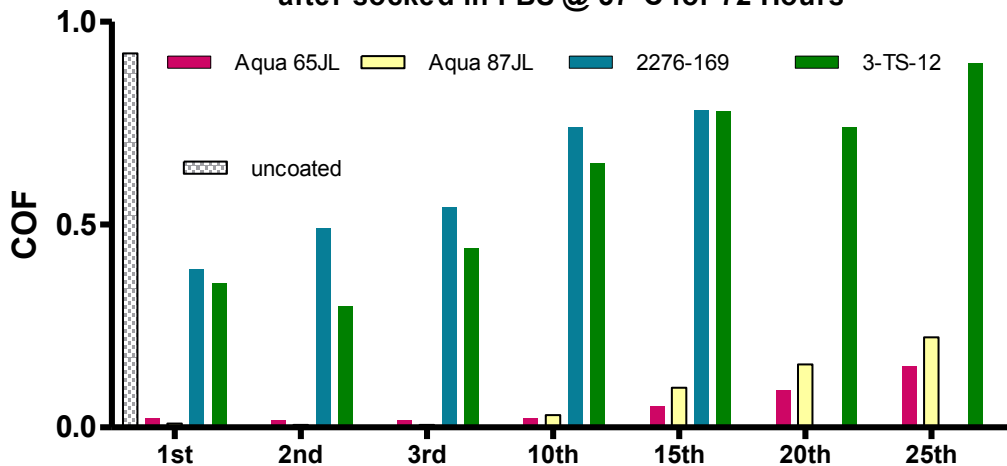


Results of friction reduction: cycles

	Aqua 65JL	Aqua 87JL	2276-169	3-TS-12
Avg. of 1,2,3 cycles	97%	96%	33.00%	74%
25th cycles	85%	81%	NA	39%

Polyurethane (ICO RALLY, ProFLO, medical grade) no primer

after soaked in PBS @ 37°C for 72 Hours



Results of friction reduction: cycles

	Aqua 65JL	Aqua 87JL	2276-169	3-TS-12
Avg. of 1,2,3 cycles	98%	99%	33.00%	60%
25th cycles	84%	76%	NA	3%

Test for cytotoxicity of
Water-Based Top coat on
Polyurethane with 20% BaSO₄
(NEUTHANE 80AE RO20 with 20% BaSO₄)

Uncoated & coated Polyurethane tubes (no pre-wash) were extracted for 24 hours in cell culture medium (MEM) containing 5% FBS.

The extracts are then placed in duplicate 35mm wells with L929 cells at ~10% confluence.

The monolayers were incubated at 37°C in the presence of 5% CO₂. Cells were examined by light microscopy at 72 hours for signs of toxicity.



Grade	0	1	2	3	4
cytotoxic	none	slight	mild	moderate	severe

Conclusion: all three water-based top coats on pellethane are non-cytotoxic

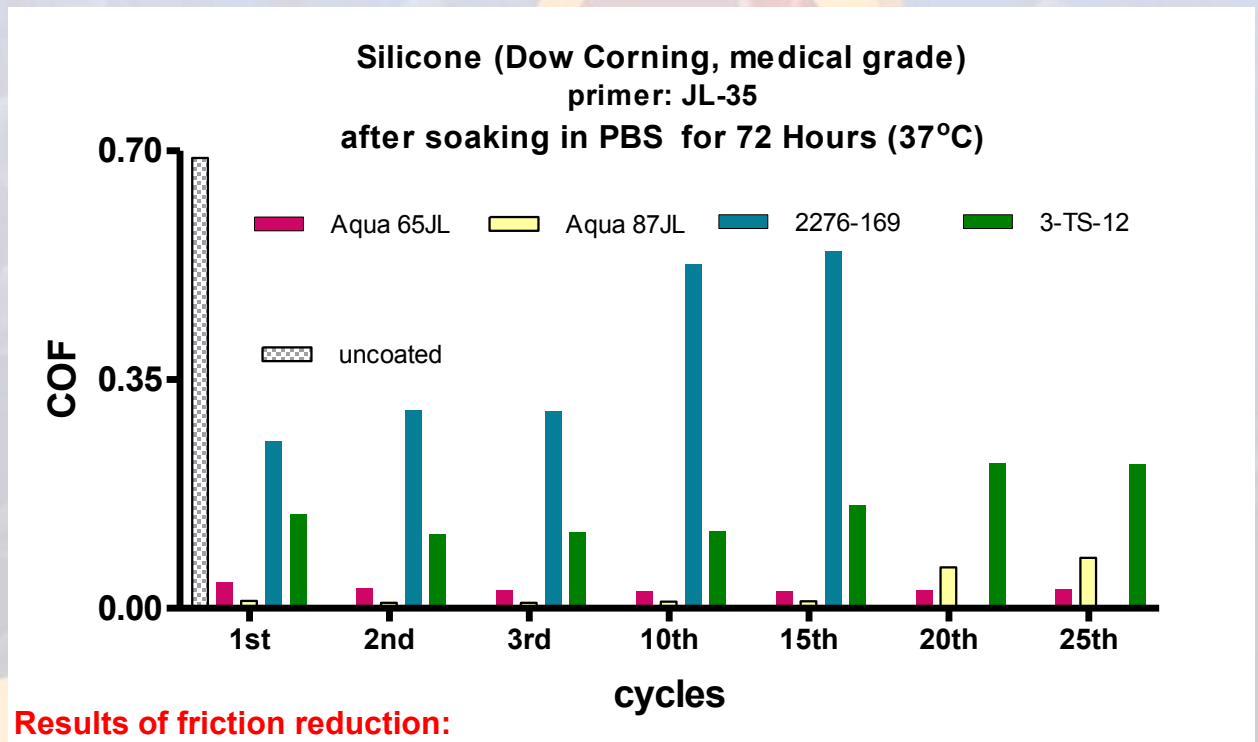
Silicone

Coating process for silicone:

- Wipe (sealed edge, knitted polyester wipe) catheter with heptane, air dry at R.T.
- Dip into primer solution Hydromer JL-35 (Heptane Base) for 2min
- Air dry for 15 - 30min
- Dip into formula Aqua 65JL or Aqua 87JL for 1min (R.T. humidity 40 - 50%)
- Air dry at R.T. for 15 min
- Cure at 60°C for 2 hours

Test for Lubricity of Water-Based Top Coat on silicone

- Coated tubes were tested for lubricity after soaking in PBS at 37°C for 72 hours.
- Place tubes in the test bed filled with water and a 350 gram weight was placed on the tubing.
- Move the weight back and forth for 25 cycles and the force required to slide the weight was recorded and is proportional to the lubricity or Coefficient of Friction (COF).



Results of friction reduction:

	Aqua 65JL	Aqua 87JL	2276-169	3-TS-12
Avg. of 1,2,3 cycles	95%	99%	58%	82%
25th cycles	96%	89%	N/D	68%

Cytotoxicity Test of Water-Based Top coat on Silicone

Uncoated & coated silicone tubes (no pre-wash) were extracted for 24 hours in cell culture medium (MEM) containing 5% FBS. The extracts are then placed in duplicate 35mm wells with L929 cells at ~10% confluence. The monolayers were incubated at 37°C in the presence of 5% CO₂. Cells were examined by light microscopy at 72 hours for signs of toxicity.

Silicone: Dow Corning (medical grade; Lot# 0005372633)
Primer: JL-35



Grade	0	1	2	3	4
cytotoxic	none	slight	mild	moderate	severe

Conclusion: Both water-based top coats on silicone are non-cytotoxic

Test Method for Antimicrobial Activity

All tested tubings were washed and soaked in PBS at 37°C for 24 hours before antimicrobial activity test.

METHOD:

- **Place tubing (5-6cm length, coated and uncoated control) into a disposable culture tube (16 x 100mm)**
- **Incubate in LB broth containing $\sim 1 \times 10^5$ CFU/ml for 24 hours with moderate shaking @ 37°C (bacteria) or 72 hours @ 25°C for fungal strains**
- **Remove tubing and rinse with PBS**
- **Cut off both ends and place 3 cm section of tubing into 5 ml of LB broth (for bacteria) or Malt Extract Broth (MEB) (for yeast)**
- **Sonicate for 7 minutes followed by vortexing for 1 minute**

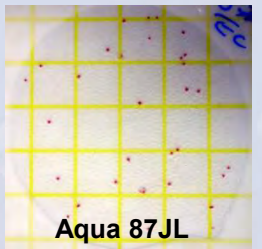
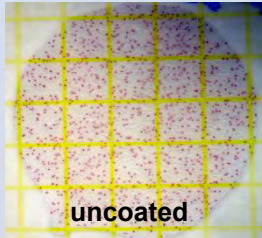
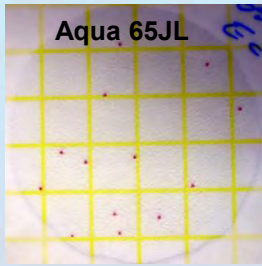
For bacterial

- **Mix 5-8 μ l of this broth and 1.5ml of LB then plate 1ml of this mixture onto 3M petrifilm**
- **Count colonies after incubation at 32°C for 24-48 hours.**

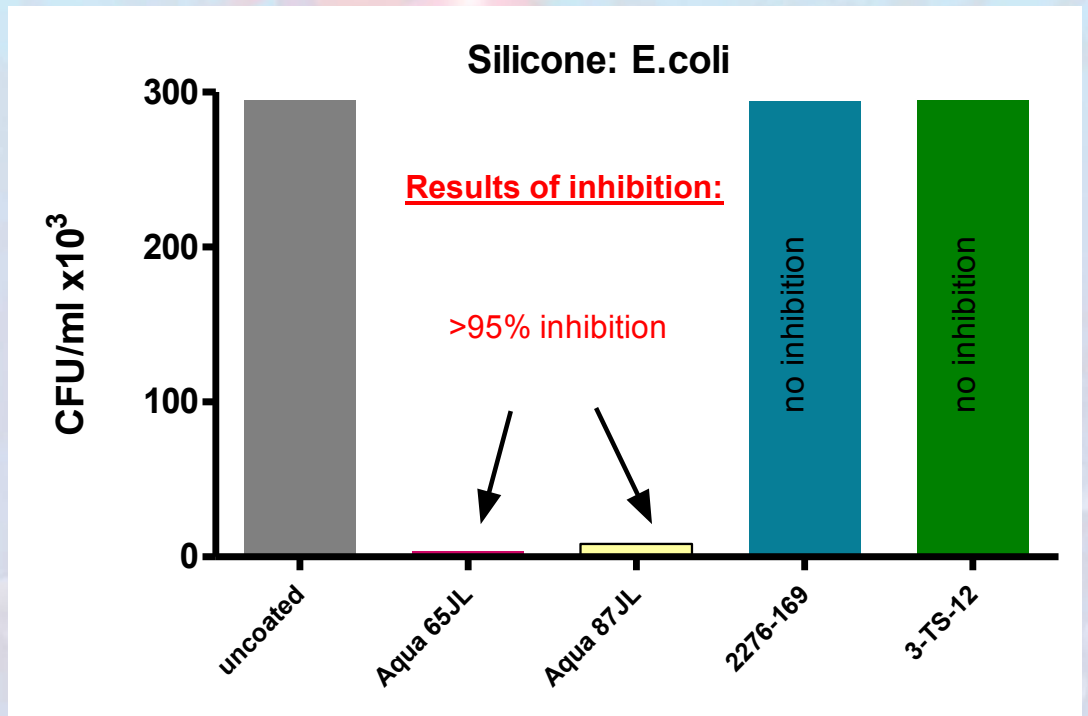
For yeast

- **Mix 10 μ l of this broth and 70 μ l MEB, then spread onto MEB agar plate**
- **Count colonies after incubation at 25°C for 48-72 hours.**

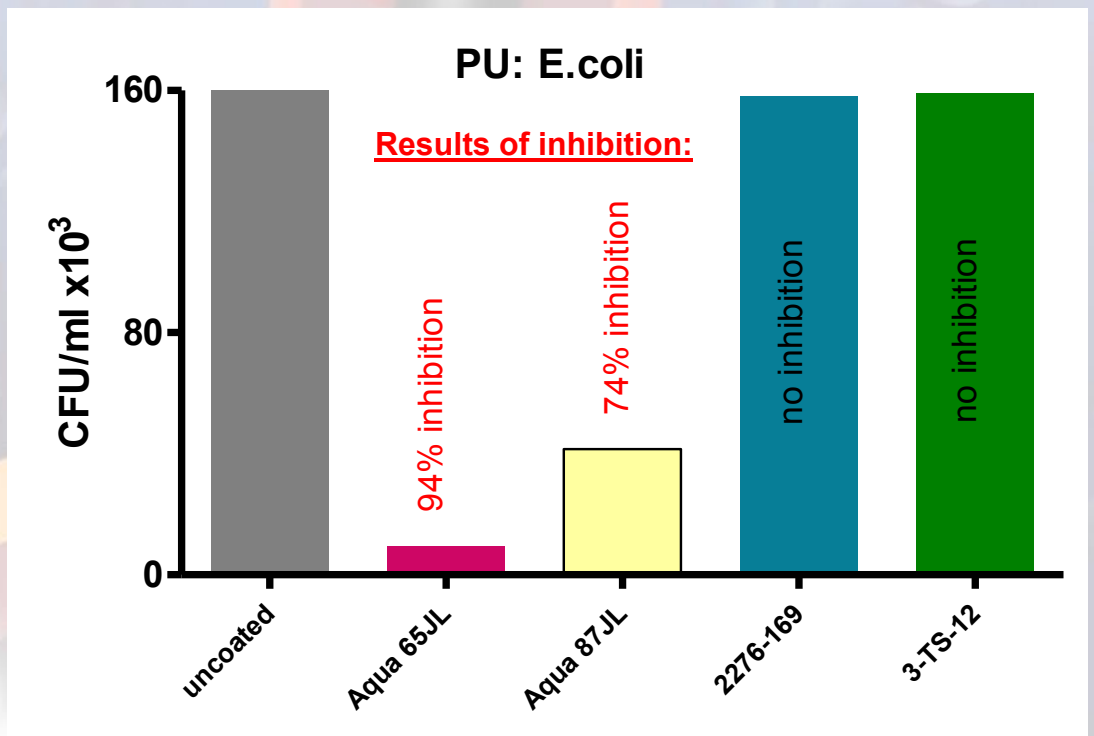
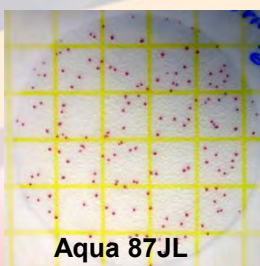
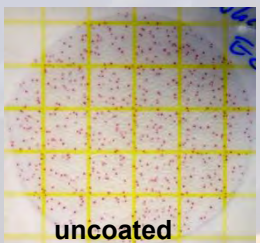
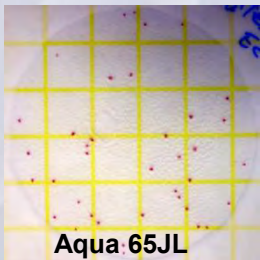
Test For Antimicrobial Activity Against E. coli (Gram negative)



Silicone: Dow Corning, medical grade (primer: JL-35)

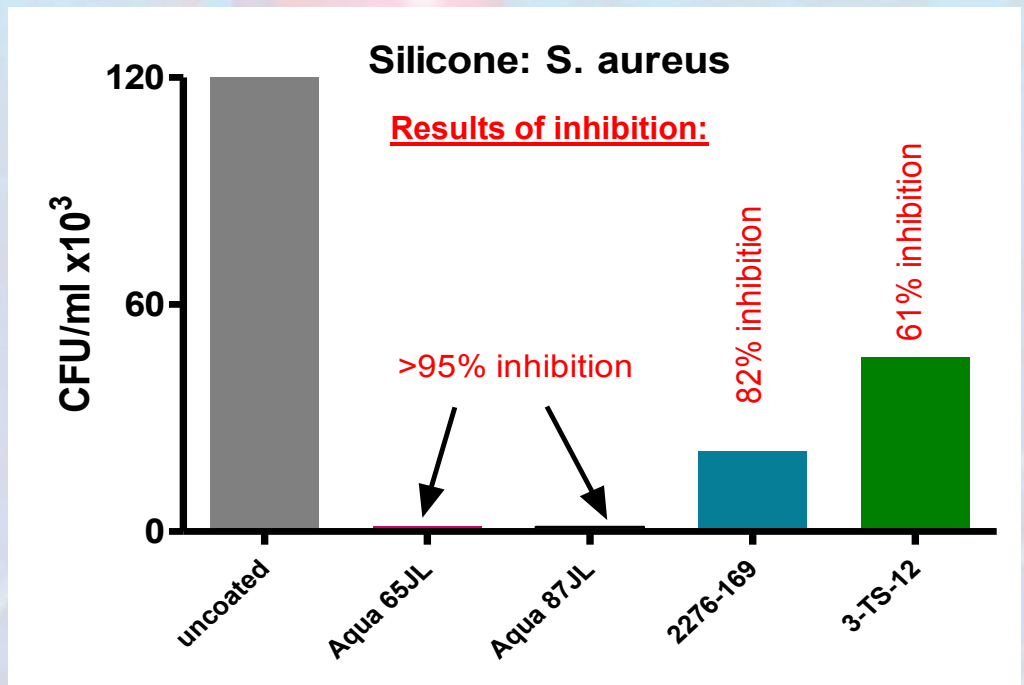
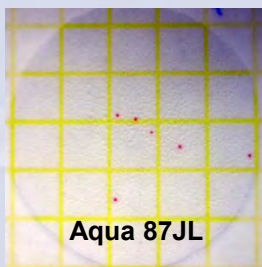
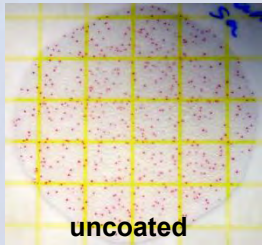
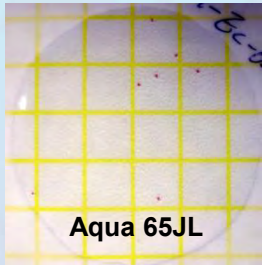


Polyurethane with 20% BaSO₄ (E.coli)

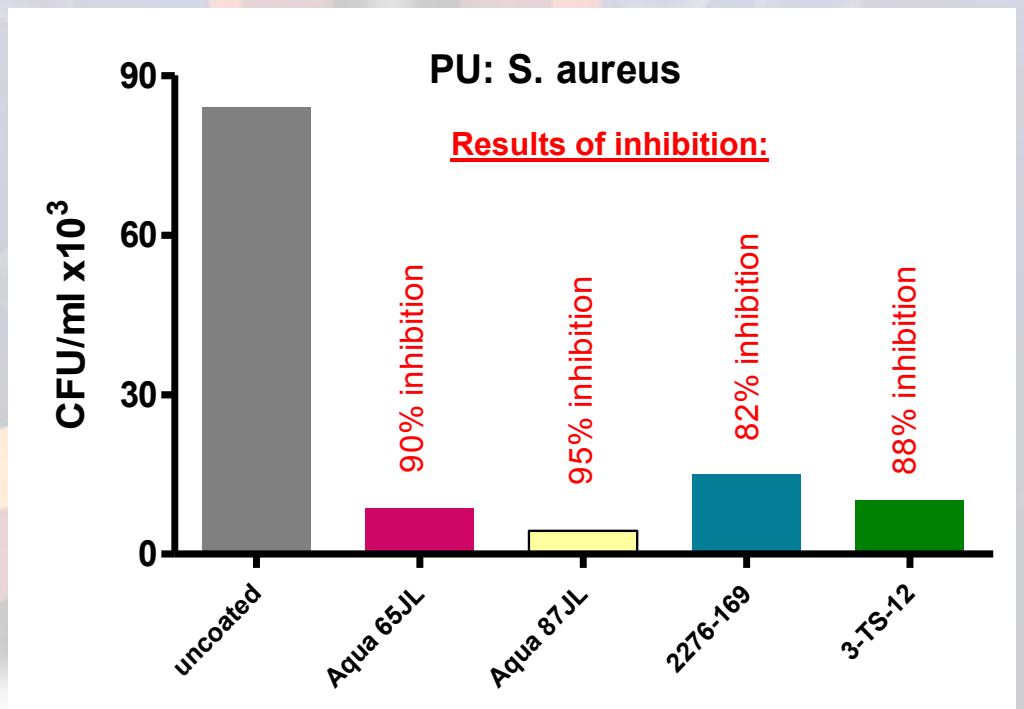
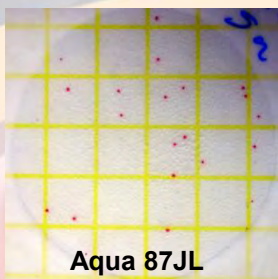
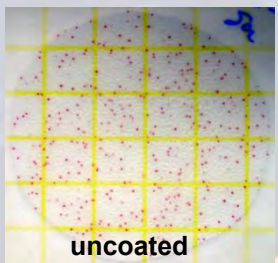
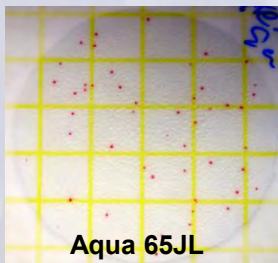


Test For Antimicrobial Activity Against *S. aureus* (Gram positive)

Silicone: Dow Corning, medical grade (primer: JL-35)

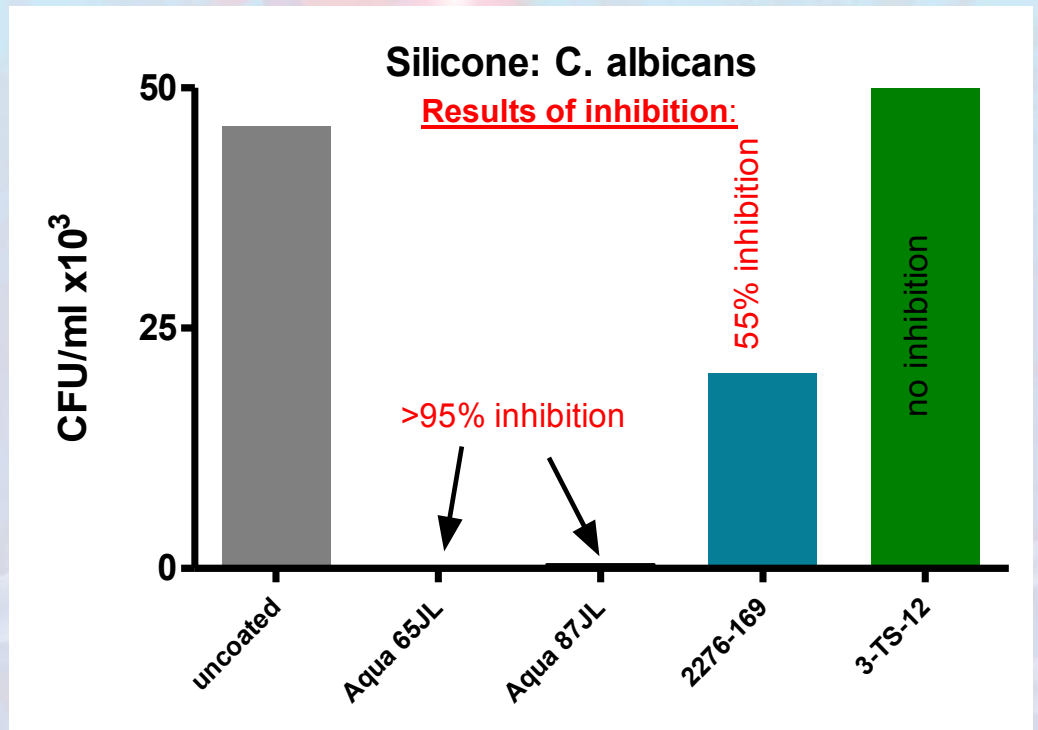


Polyurethane with 20% BaSO₄ (*S. aureus*)

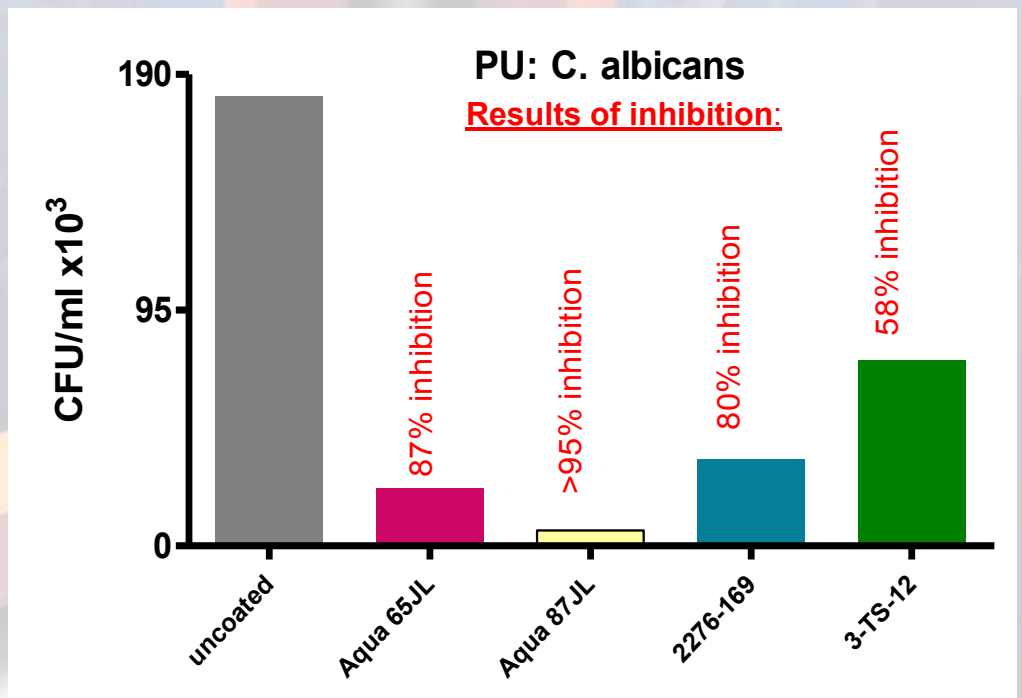
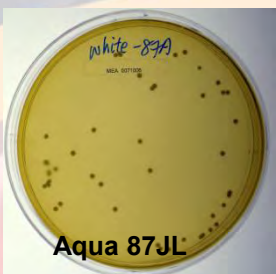
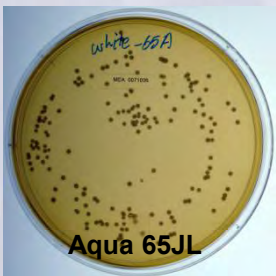


Test For Antimicrobial Activity Against *C. albicans* (Yeast)

Silicone: Dow Corning, medical grade (primer: JL-35)



Polyurethane with 20% BaSO₄ (*C. albicans*)





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Please note that this report contains results from Hydromer's in-house testing departments. It is the responsibility of our clients to seek FDA Approval for this coating system on their devices.

Hydromer is very interested in entering into cost sharing programs to assist in compiling additional product performance data.

Please contact us
For sample coatings and additional information

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