



Bioinert and Biocompatible

SilcoTek Coatings for the Medical and
BioPharma Industries

Unique Coatings, Unique Solutions

- Most surface innovation in the medical industry thus far has been aimed at *in vivo* devices for patients (hydrophilic coatings)
- However, *in vitro* diagnostics also face significant challenges:
 - Inaccurate diagnostic results caused by “sticking” of proteins, peptides, and more within the analytical system’s flow path
 - Frequent downtime to clean and maintain instrumentation
 - Corrosion or “rouging” from bleach, water for injection (WFI), and more
- SilcoTek’s patented CVD coatings are completely inert and highly non-stick to biological material while being robust against harsh chemicals and cleaning agents

Company Background

1987: CVD first used to coat chromatography columns

1988-2008: many new applications discovered

2009: SilcoTek spun-off from Restek

2013: SilcoTek builds 35,000 sqft facility

2019: SilcoTek expands to 70,000 sqft

2020: SilcoTek coats thousands of customer parts every day for many industries



SilcoTek's Most Popular Coatings



Functionalized amorphous silicon, oxygen, and carbon

Enhances corrosion resistance to most acids and bases

Resists sticking of polymers, liquids, and foulants

Typical thickness: 0.5-1.5 μ m



Functionalized amorphous silicon

Chemically inert – ideal for analyzing trace levels of gases

Prevalent in oil and gas applications for sulfur detection and analysis

Typical thickness: 0.2-0.8 μ m



Multi-layer amorphous silicon

Barrier coating that is highly resistant to acids

Ensures no contamination from base metal – preferred corrosion solution in semiconductor

Typical thickness: 1 μ m

How SilcoTek is Different

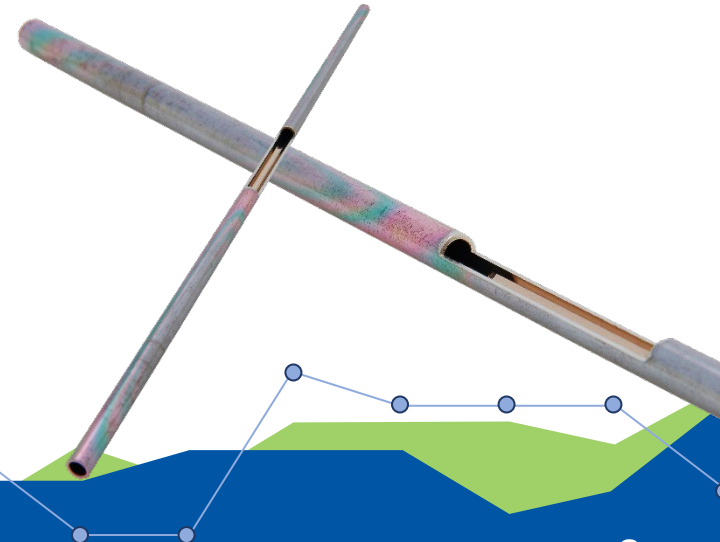
1. Chemical vapor deposition (CVD) coating process
 - Gas-phase process that coats 100% of part surfaces
 - Capable of coating sub-micron channels without clogging
 - Superior adhesion due to coating's molecular bond with the substrate
2. Game-changing coatings
 - Versatile high-performance surfaces that are specially engineered for medical applications
3. Decades of experience perfecting coating services for the special demands of analytical, diagnostic, and laboratory customers
 - SilcoTek does not make or sell products; we are dedicated to coating innovation and service expertise for customers both large and small
 - “Plus 1” customer service mantra

CVD Coating Process



Advantages of CVD Coatings

- Non-line-of-sight deposition; uniformly treats 3D, high aspect ratio part geometries
- Molecular adhesion to base substrate. Won't flake nor delaminate.
- Scalable, versatile, and highly reproducible



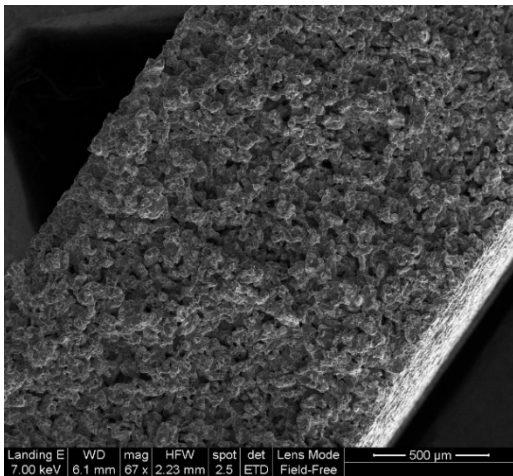
SilcoTek Capabilities

- We regularly apply CVD coatings to:
 - Tubing as small as 0.1mm ID
 - Narrow-bore needles and sample probes
 - Sub-micron filter media
 - Ancillary components throughout instrument flow path
 - Miniature and/or complex parts
 - Large vessels, tanks, and containers
 - Orders ranging from one-offs to thousands of parts per batch
 - Variety of materials – SS, aluminum, titanium, specialty alloys, glass, and more

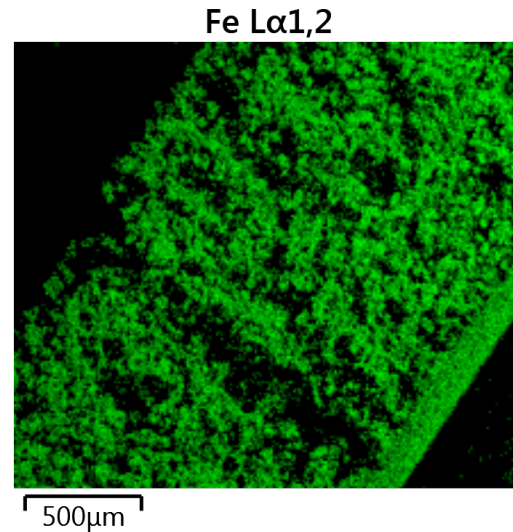


Example of non-line-of-sight coating:

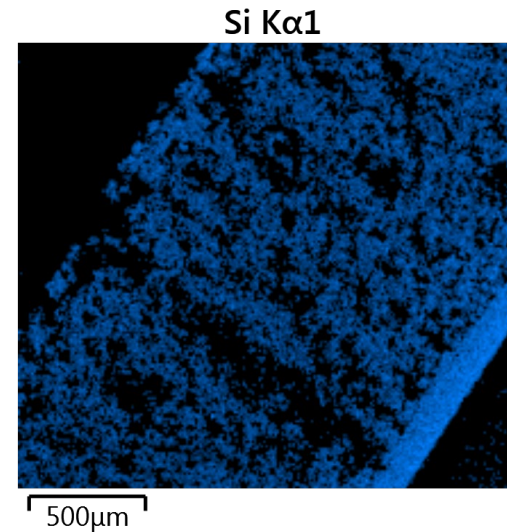
- Whole frit coated with Dursan, then broken in half...
- Cross section view of a the 2 μ m nominal pore size frit:



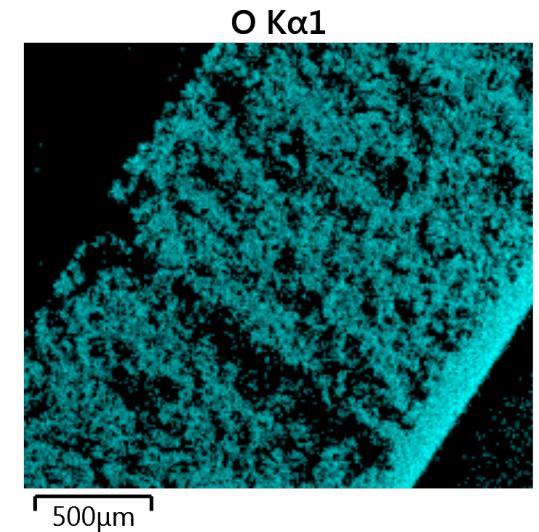
SEM micrograph



Iron EDS map

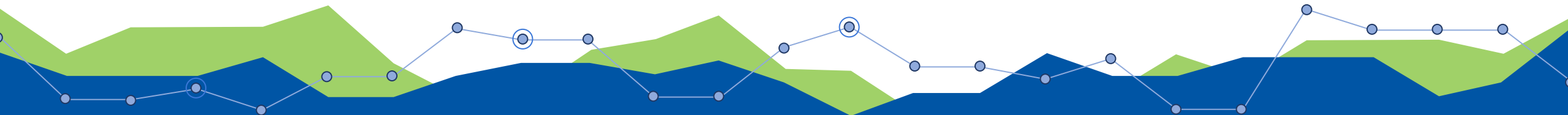


Silicon EDS map



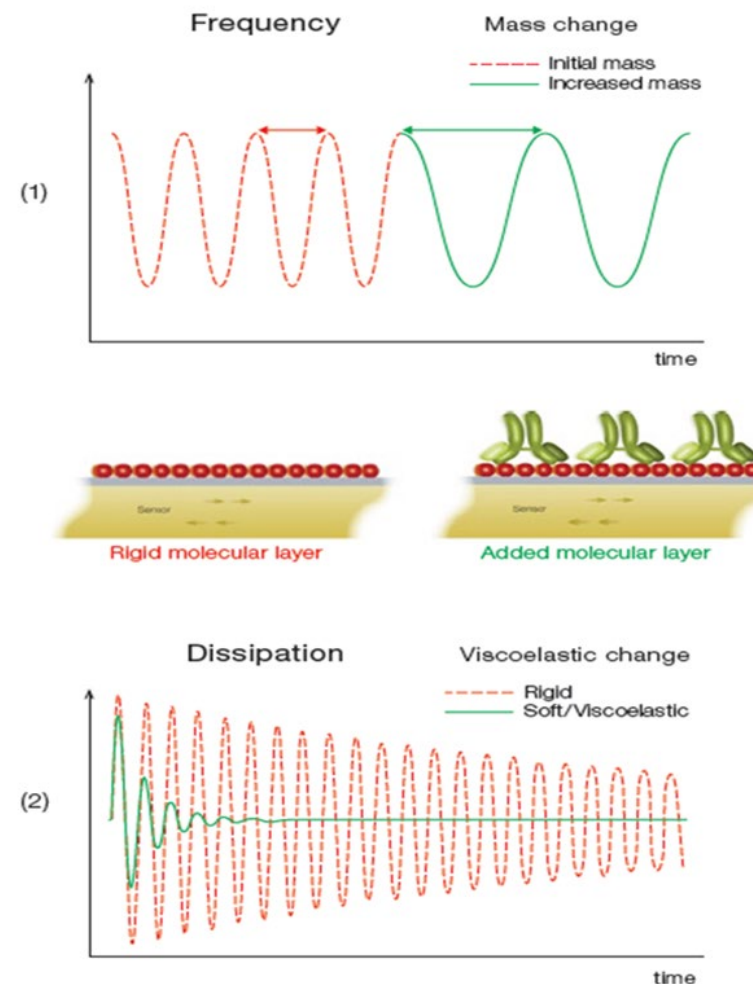
Oxygen EDS map

Coating Performance

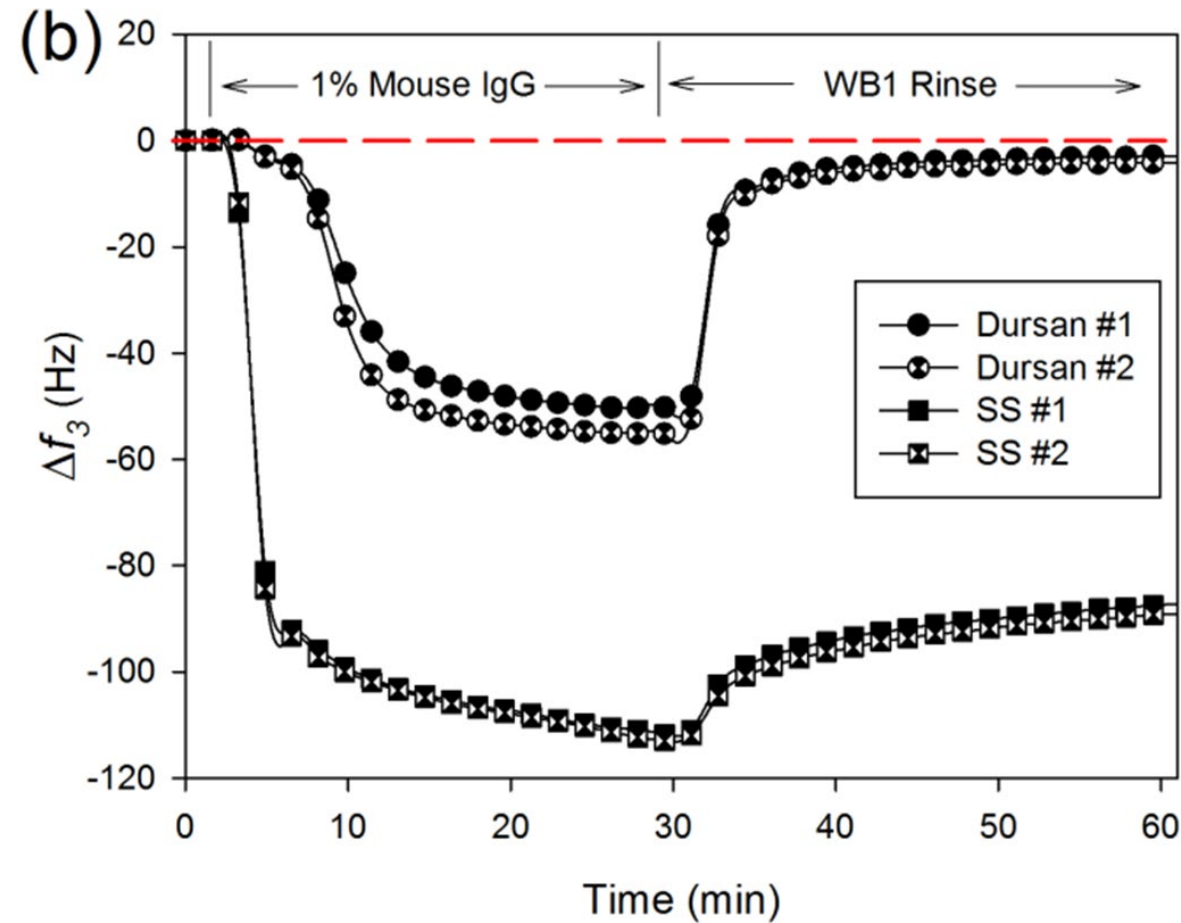


Bio-Inertness: Non-specific protein adsorption studies

- Collaborative study between Abbott Laboratories and SilcoTek on protein adsorption
- 316L SS QCM-D sensor was coated with Dursan and compared to uncoated and PTFE-coated (AF-1600)
- Protein solutions were flowed over the sensor and the frequency was monitored over time

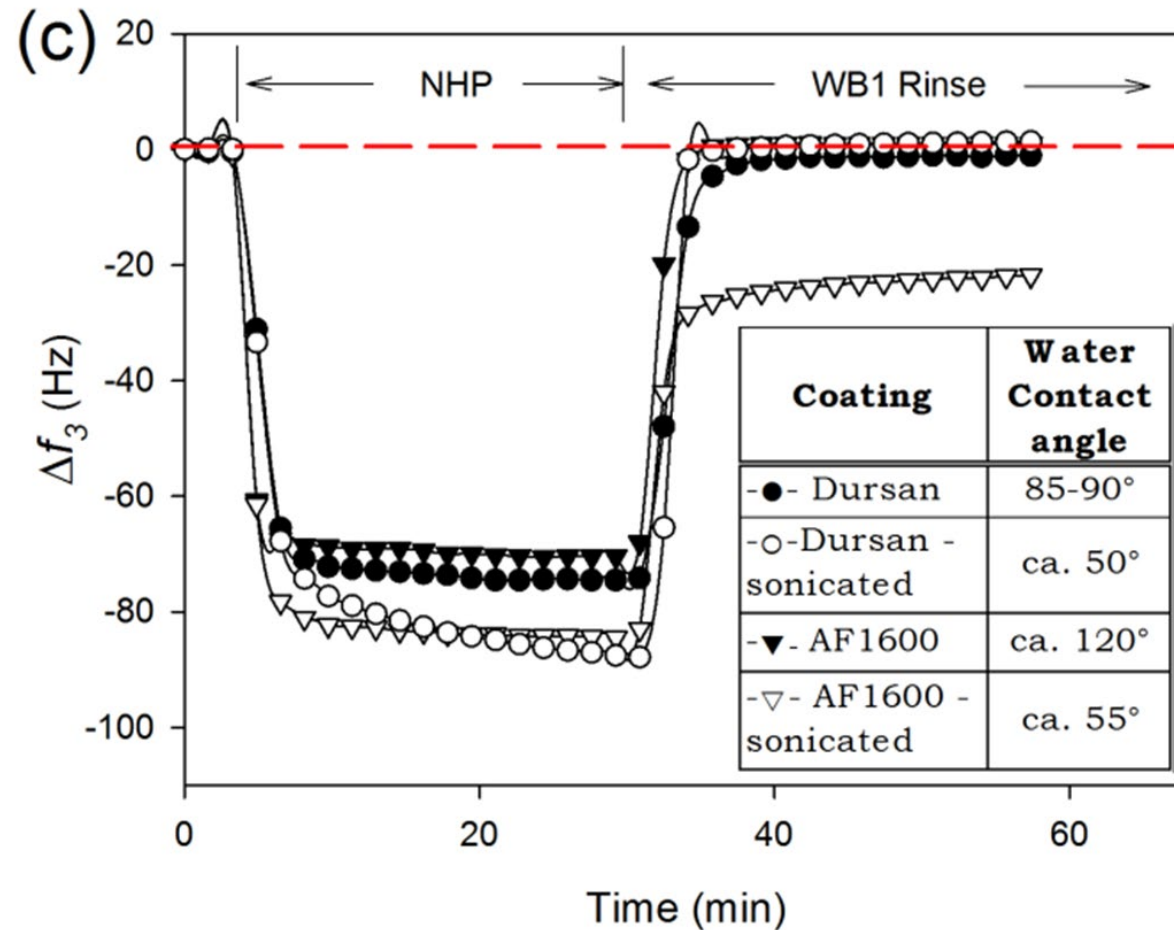


Easy Release of Immunoglobulins



Vaidya, S.V.; Yuan, M.; Narvaez, A.R.; Daghfal, D.; Mattzela, J.; Smith, D. Appl. Surf. Sci. 2016, 364, 896-908.

Outperforms fluoropolymer coatings

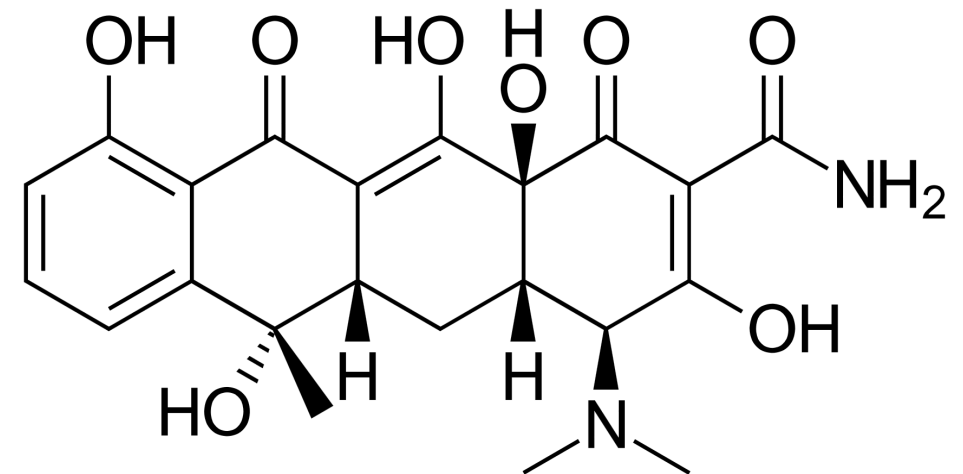


The Elsie Bischof story



Tetracycline

- Tetracycline is an antibiotic, commonly used for acne and skin infections, that is often quantified via liquid chromatography
- The molecule has numerous chelating groups that bind readily to metal sites
- Dursan makes steel HPLC analytical columns inert toward metal-loving molecules like tetracycline, thus improving accuracy

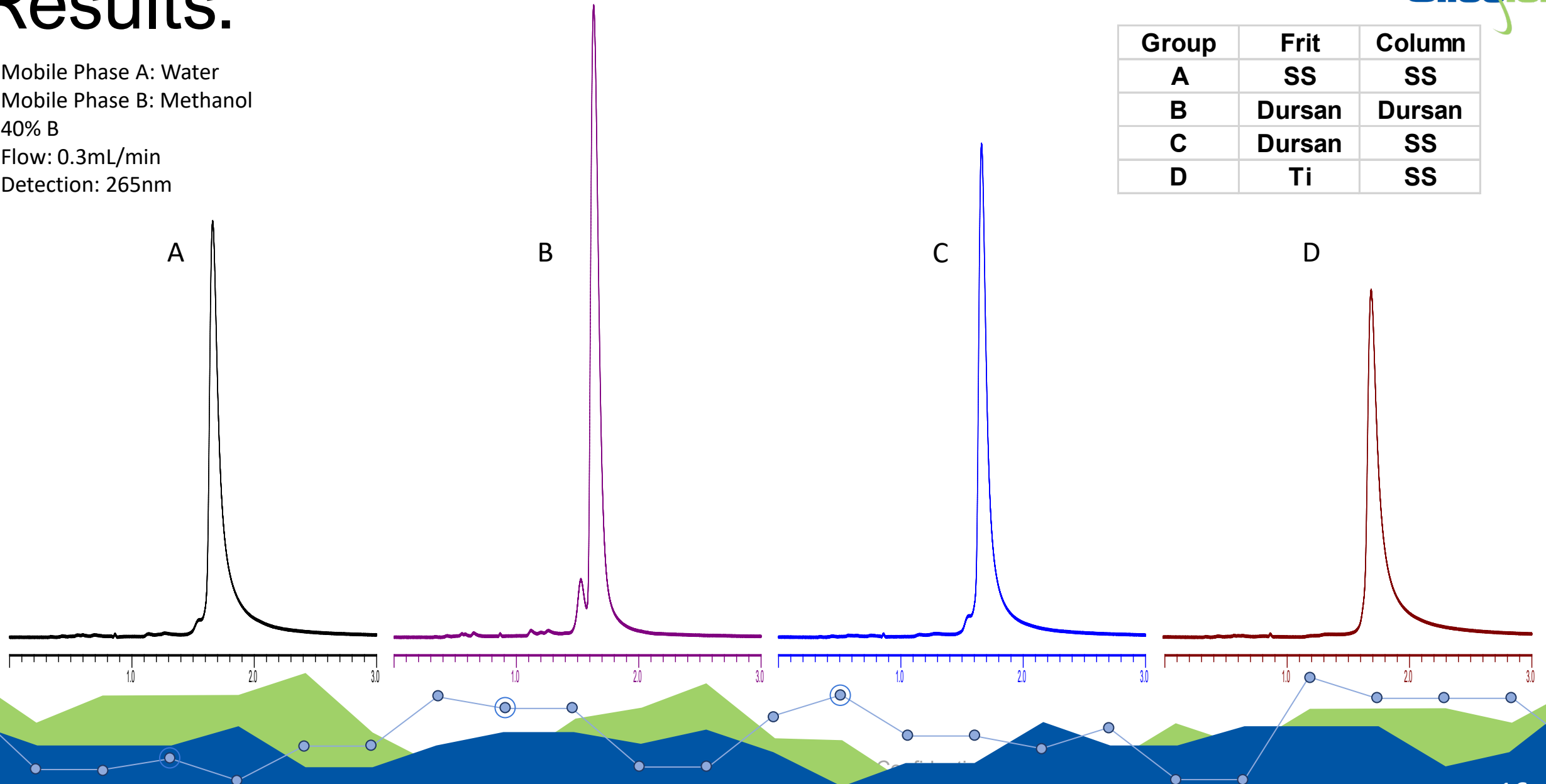


Molecular structure of tetracycline

Results:

Mobile Phase A: Water
Mobile Phase B: Methanol
40% B
Flow: 0.3mL/min
Detection: 265nm

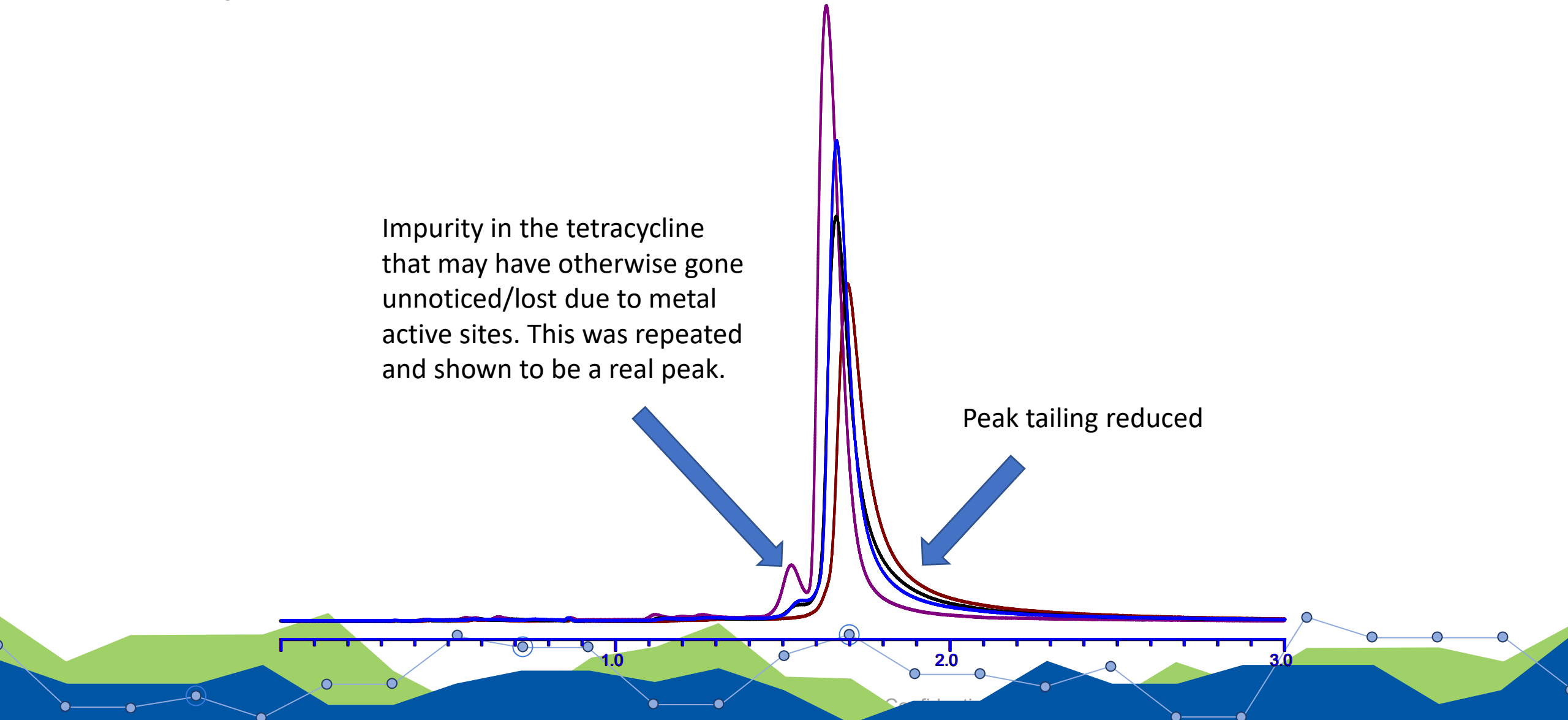
Group	Frit	Column
A	SS	SS
B	Dursan	Dursan
C	Dursan	SS
D	Ti	SS



Overlay of all 4 columns:

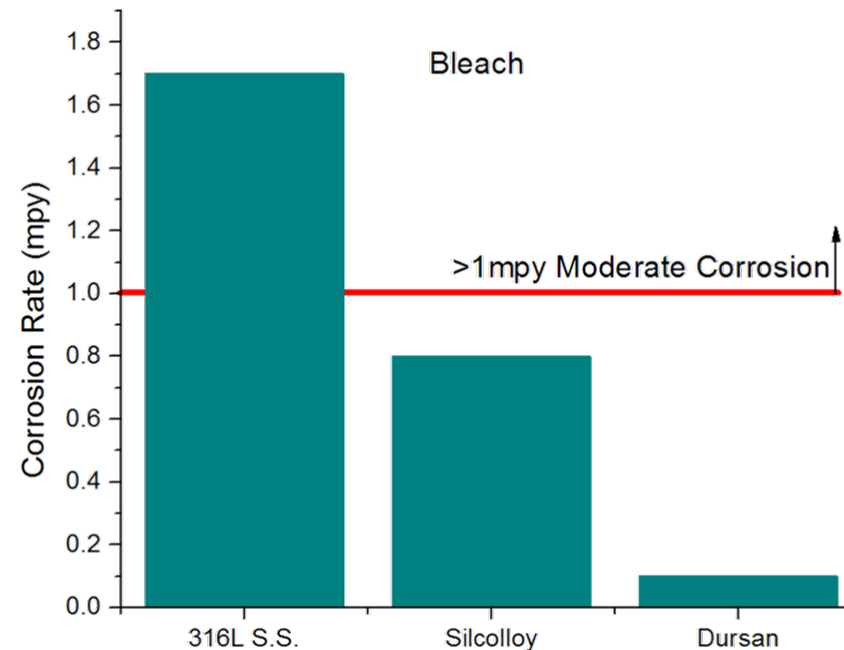
Impurity in the tetracycline that may have otherwise gone unnoticed/lost due to metal active sites. This was repeated and shown to be a real peak.

Peak tailing reduced



Corrosion resistance in Bleach (NaClO)

- ASTM G31 Guidelines
- 15% NaClO Exposure
- 72 hrs at Room Temperature

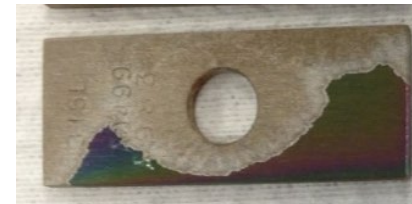
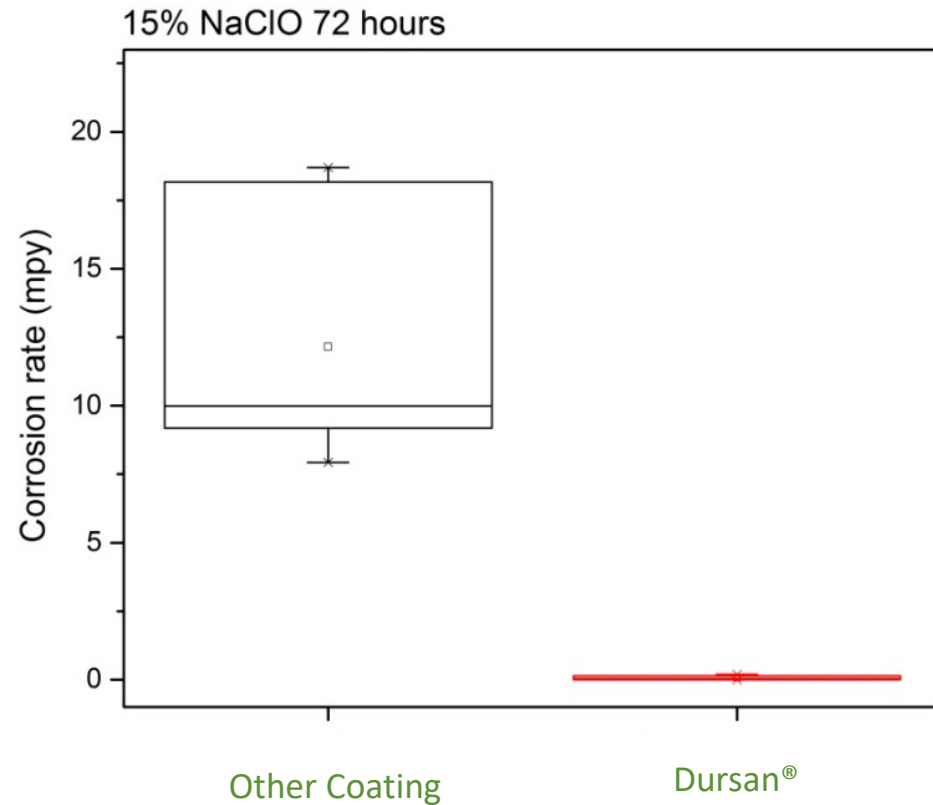


Bleach is very aggressive to stainless steel and other surface treatments, but Dursan provides stable protection.

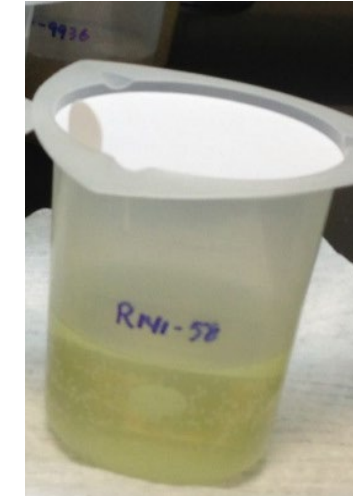
This is especially useful in biomedical and pharma applications where bleach is commonly used.

Bleach Corrosion (continued)

Bleach Corrosion



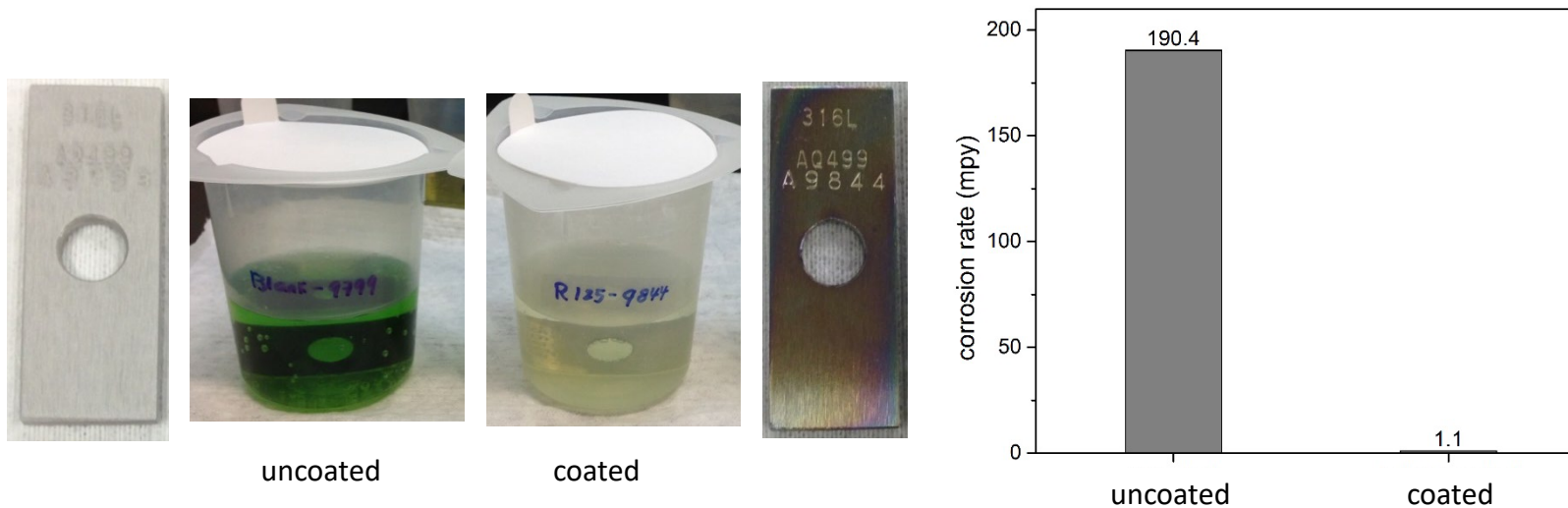
Other Coating



Dursan®

Corrosion resistance in Hydrochloric Acid

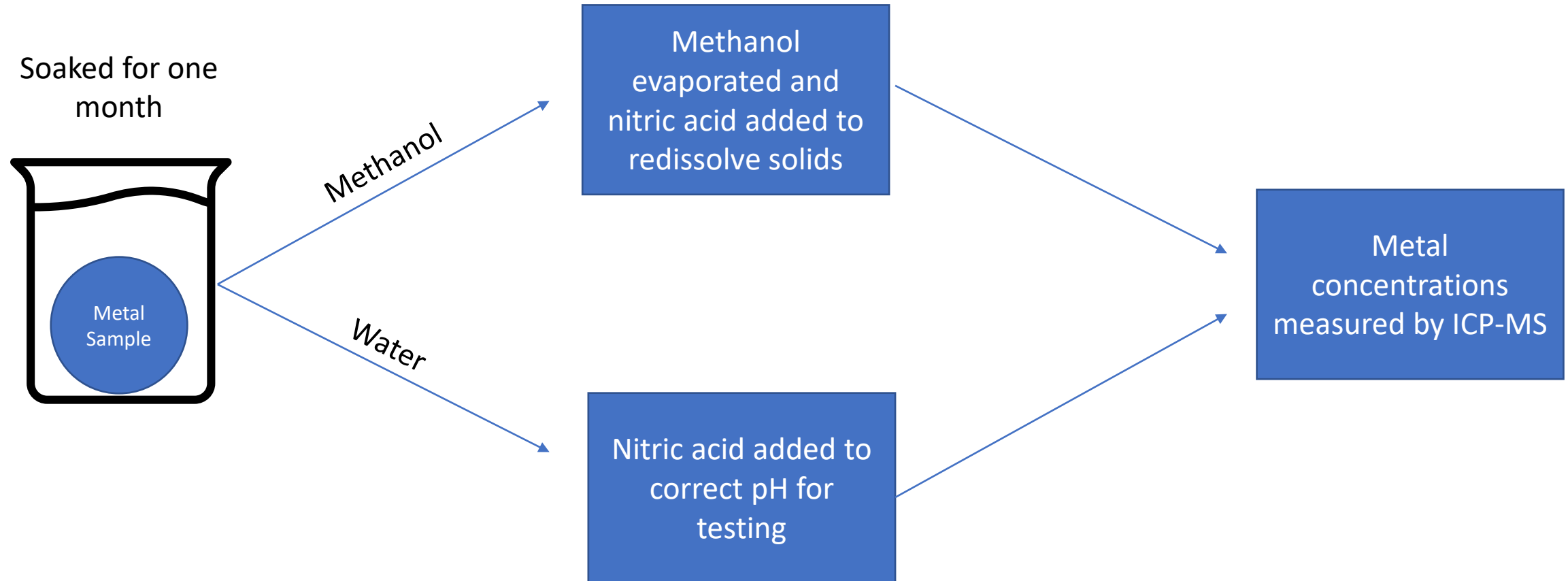
- ASTM G31 guidelines
- 20% (6M) HCl room temperature immersion 24 hours
- Over 170x improvement with coating



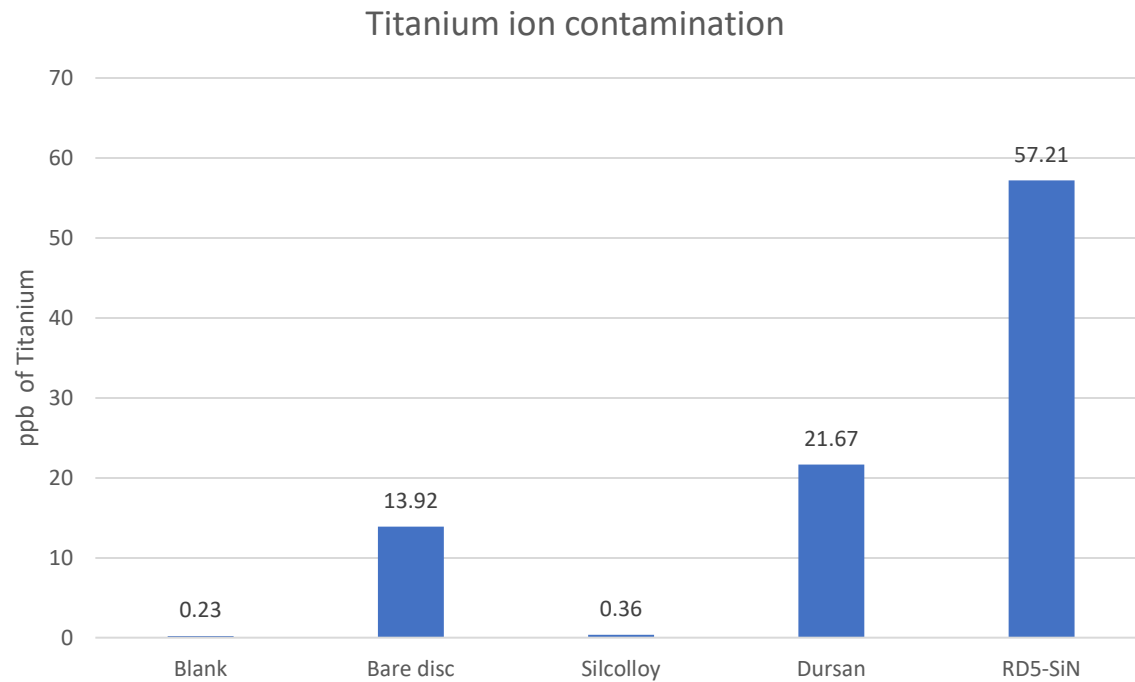
Prevent leaching of metal ions

- A major problem in most applications requiring high purity is the leaching of metal ions out of SS and other metallic system components into the process/sample stream
- This leads to contamination issues to surrounding environment or downstream
- Next, we show how even Hastelloy®, an exotic super-corrosion resistant alloy, suffers from metal ion contamination whereas SilcoTek-coated surfaces do not

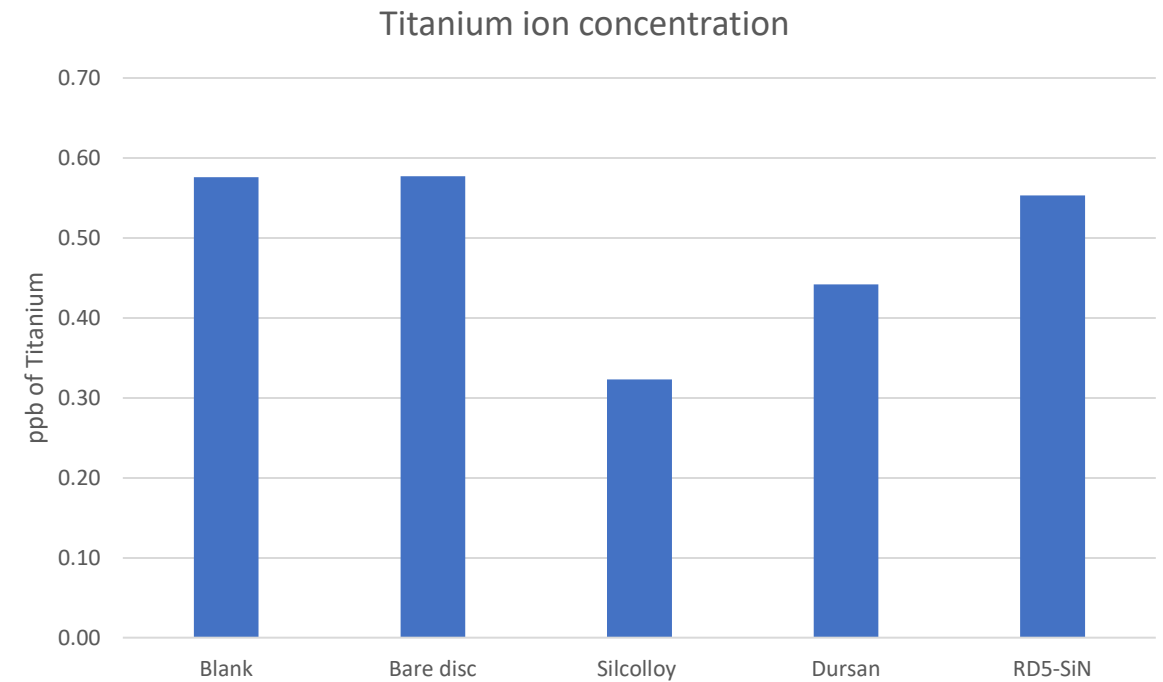
Experimental setup



Results of titanium sintered discs



Methanol

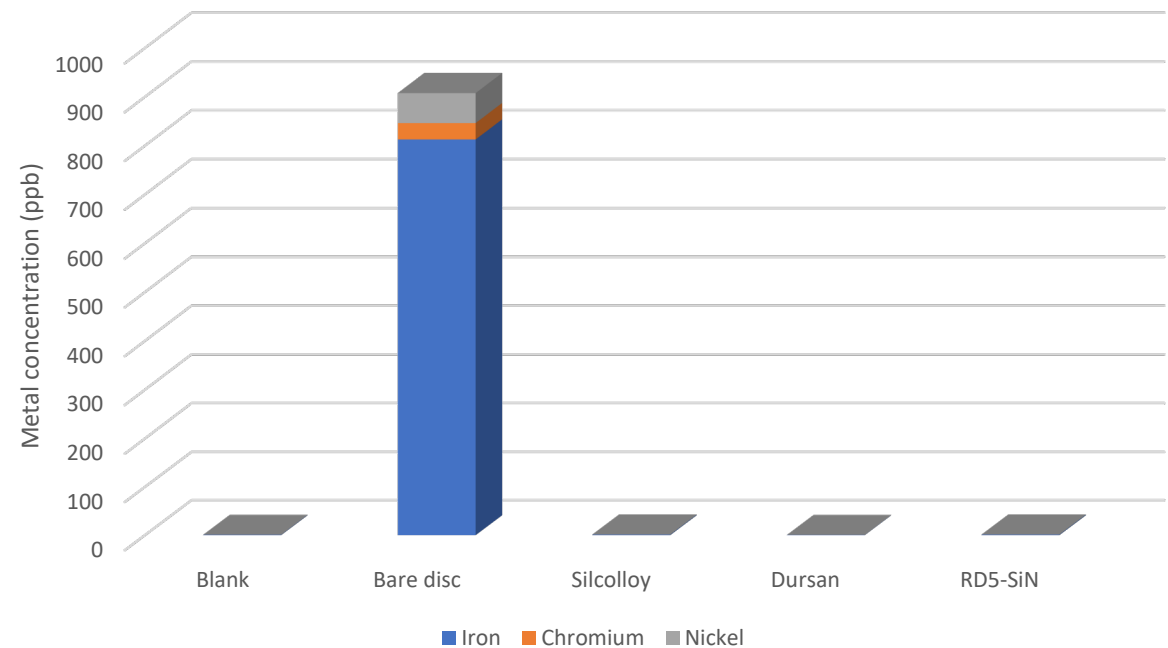


Water

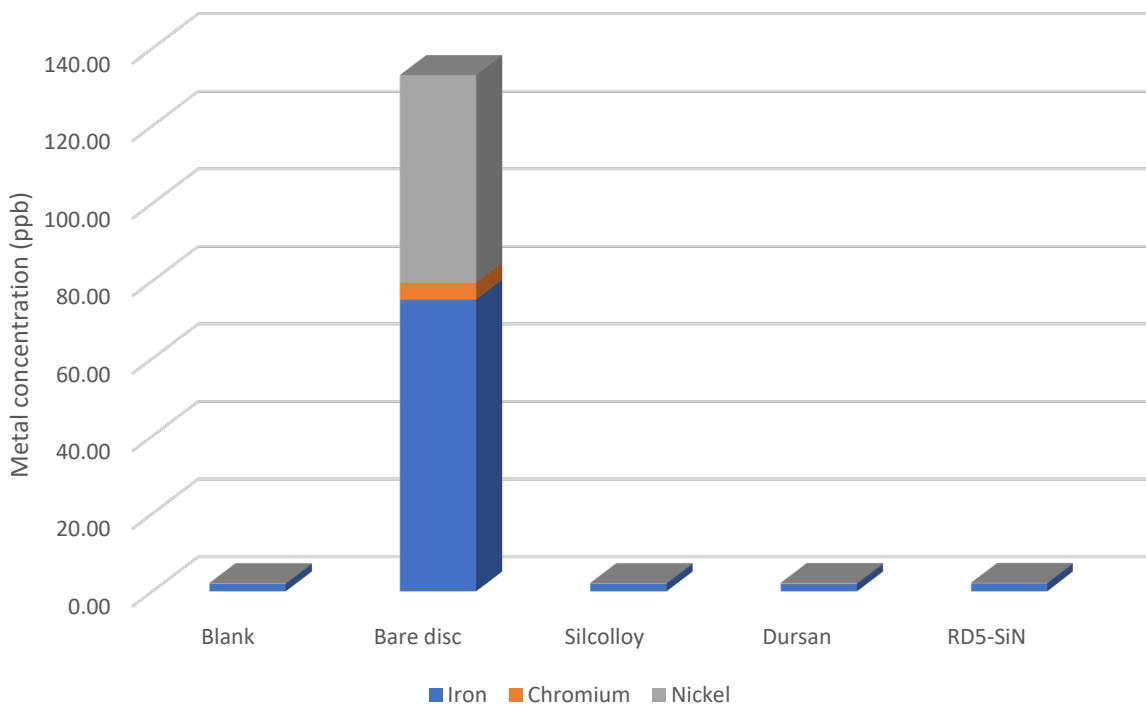
Results of 316L Stainless Steel sintered discs



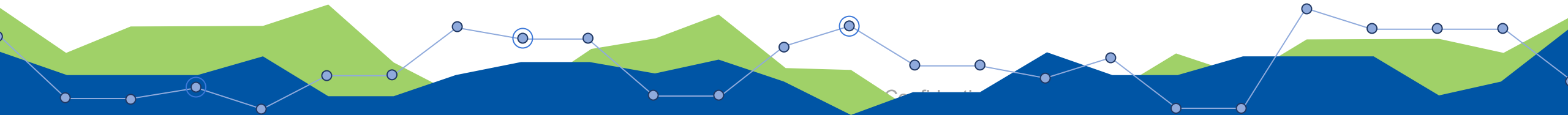
Stainless Steel metal ion contamination



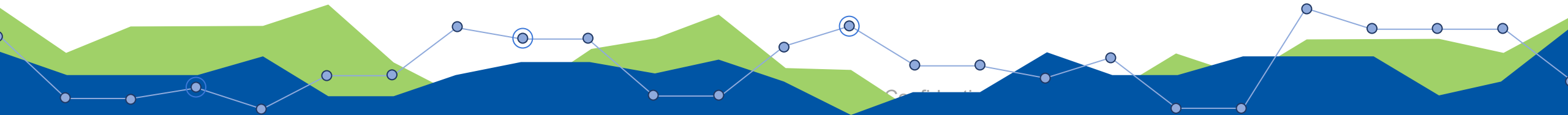
Stainless steel metal ion contamination



Methanol

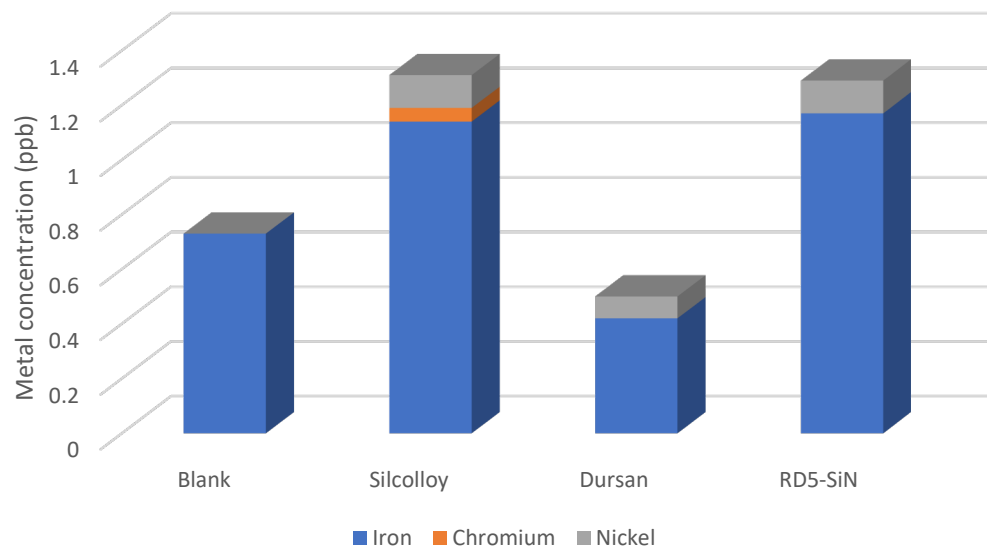


Water

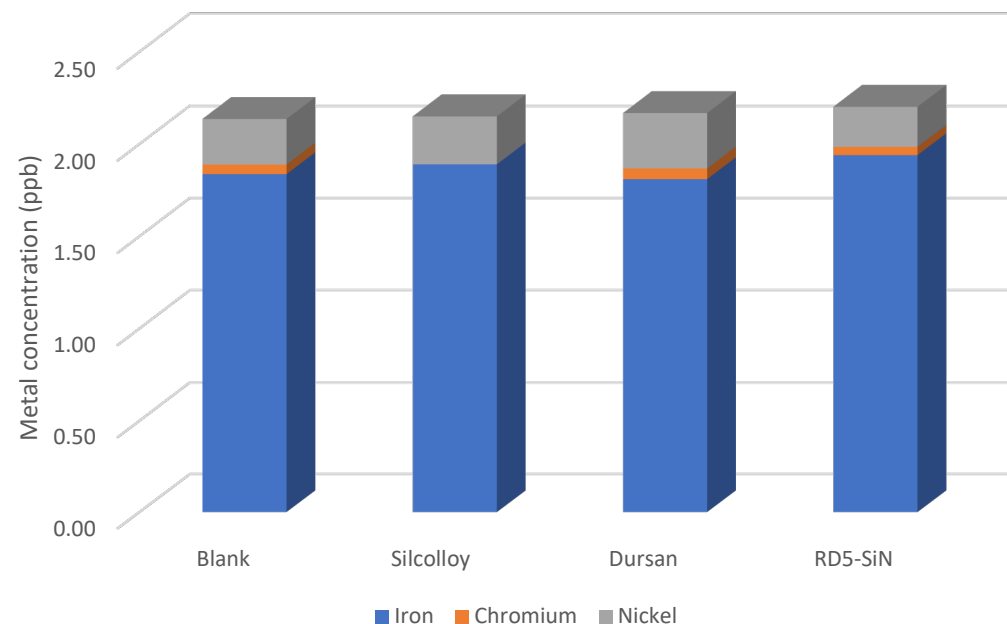


“Bare disc” removed to compare to blank

Stainless steel metal ion contamination

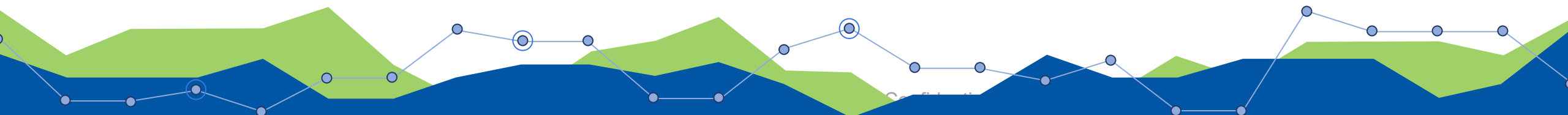


Stainless steel metal ion contamination



Methanol

Water



Dursan Coating Certifications

- USP Class VI Certification
 - Dursan has been fully tested and certified to meet USP Class VI standards for biocompatibility.
- NSF (National Sanitation Foundation) Certification
 - Dursan is compliant with NSF/ANSI 51 and all applicable requirements, meaning it is safe for food contact and meets the FDA's requirements for compliance.

What does “Bio Inertness” mean?

- Unlike bare metal surfaces – even highly polished ones – SilcoTek’s coatings minimize or eliminate reactivity with biochemical species
- Untreated metals can cause false positive/negative results and reduce the sensitivity of the analytical system
- Stainless steel will suffer from micro-scale corrosion or ion leaching, eventually causing failures and/or contamination
- SilcoTek’s bioinert coatings provide a stable, robust surface for your existing componentry to improve performance, service lifetime, and purity

Questions?