Assessing Nanoparticle Migration from Commercial Food Contact Materials into Aqueous Food Simulants

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Regulatory Authority

1958 Amendment Food Drug and Cosmetic Act

- Defines “food additive”.
- Requires premarket approval of new uses of food additives.

1997 Food and Drug Administration Modernization Act (FDAMA)

- Established the Notification program for Food Contact Substances (FCS).
- Establishes proprietary use of FCS to the notifier.
- Guidance documents present nonbinding recommendations on assessing the safety of FCS.

Regulated in Title 21 of the US Code of Federal Regulations (21 CFR)

Interagency Agreement
FDA and CPSC/ FDA and NIST

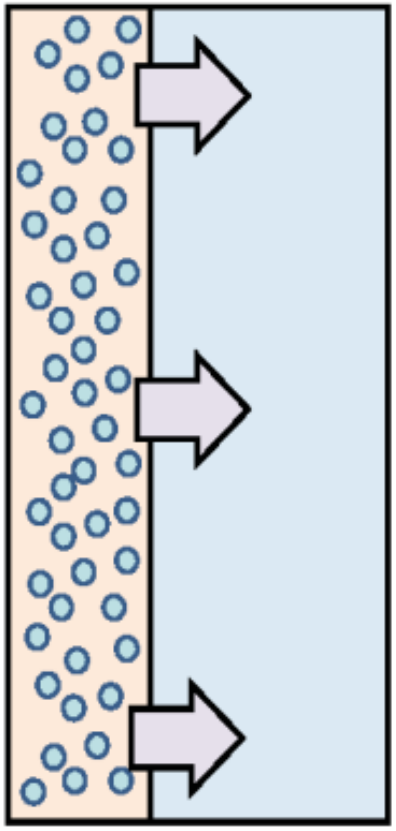
Certain products are also regulated by the Consumer Product Safety Commission

- CFSAN – Food Safety
- CPSC – Safety of design and life cycle

Objectives of the Interagency Agreements

- Identify commercially available food contact materials that may contain nanomaterials.
- Quantify potential for nanomaterial migration.
- Evaluate the applicability of current migration models and testing conditions.
- Evaluate the potential for nanomaterial release under stressful use conditions

Migration from Food Contact Materials (FCM)



Safety depends on:

1) Toxicity: are migrants harmful to health?

2) Exposure: can nanoparticles migrate into foods?

- Diffusion of nanoparticles through plastics
- Partitioning of nanoparticles into food matrix
- Post diffusion processes

Migration measurements under Condition of Use

Single Use

Repeat Use Room Temp.

Repeat Use High Temp.

Product Evaluation

Product Characterization

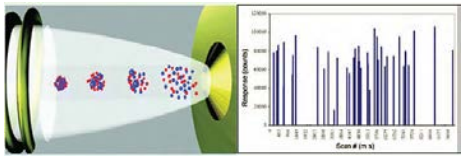
FTIR

ICP-MS

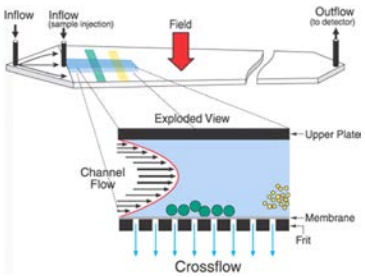
TEM/SEM

Migration/Simulant Characterization

ICP-MS

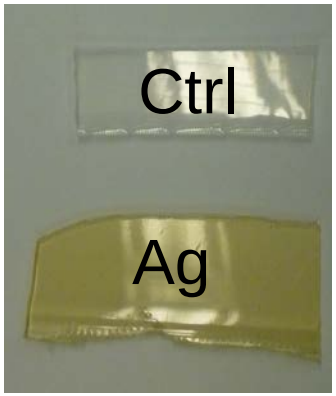


Field Flow



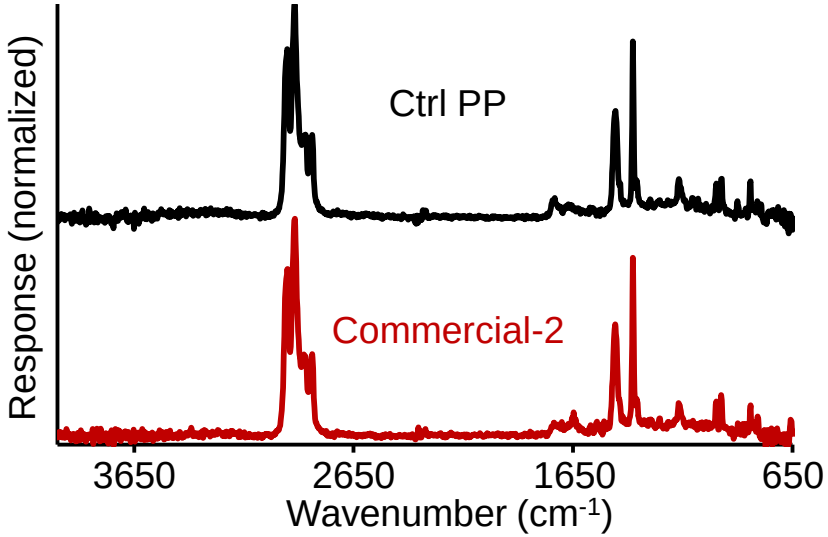
TEM/SEM

Polypropylene

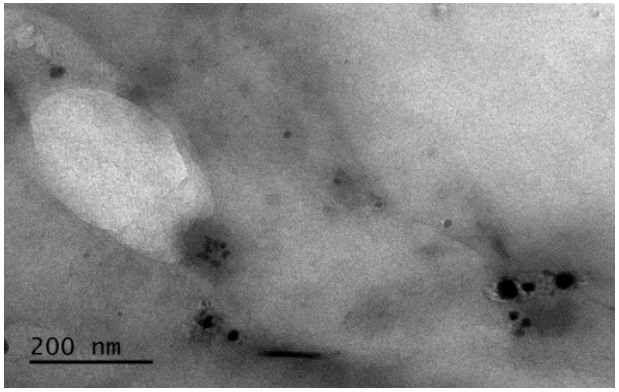


	Thickness	Density	Ag Conc.
Ctrl	1.71 mm	0.905 g/cm^3	< 0.5 ng Ag/g PP
Ag	1.79 mm	0.900 g/cm^3	29 μg Ag/g PP

Container 1



TEM Micrograph

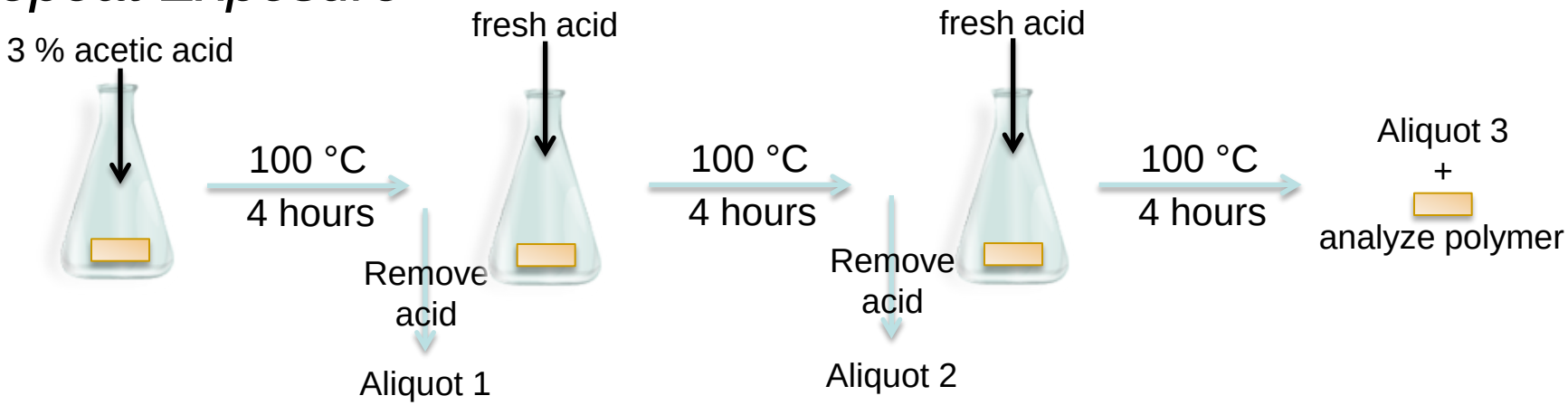


Plastic FCMs Evaluated

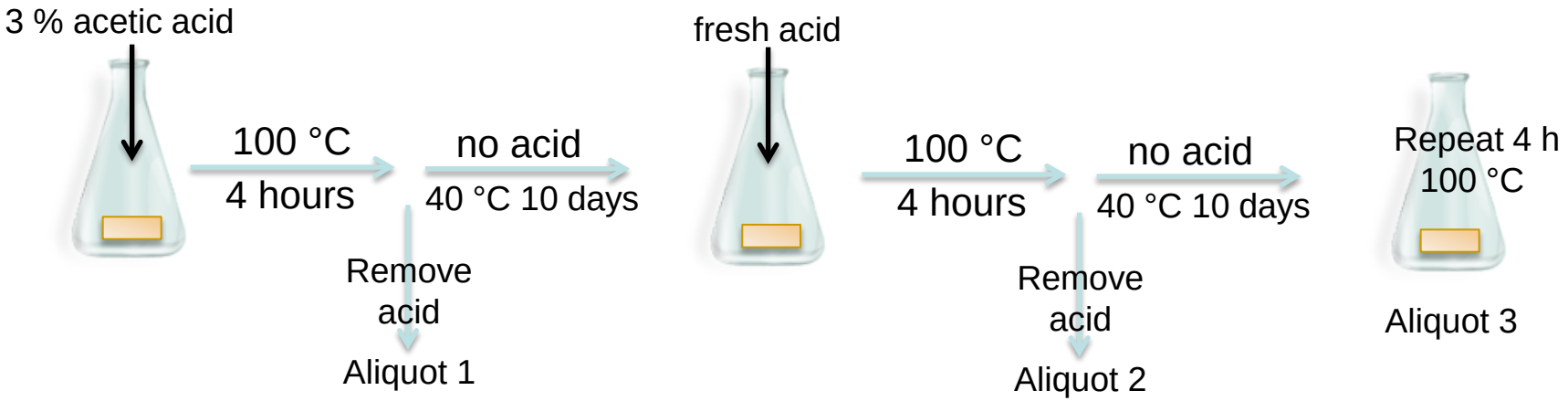
Sample	Thickness (mm)	Density (g/mL)	Nature of Polymer	Ag Conc ($\mu g\ g^{-1}$)	Ag Nanoparticles
Baby Bottle 1	1.67	0.909	PP	10^{-3}	No
Baby Bottle 2	1.20	>1	PES	1	No
Container 2	1.05	0.900	PP	9	No
Cutting Board	2.33	0.920	LDPE	7	Yes
Container 1	1.79	0.900	PP	29	Yes
Container 3	1.75	0.904	PP	25	Yes
Food Storage Bag	63	0.942	LDPE	36	Yes

Migration Conditions

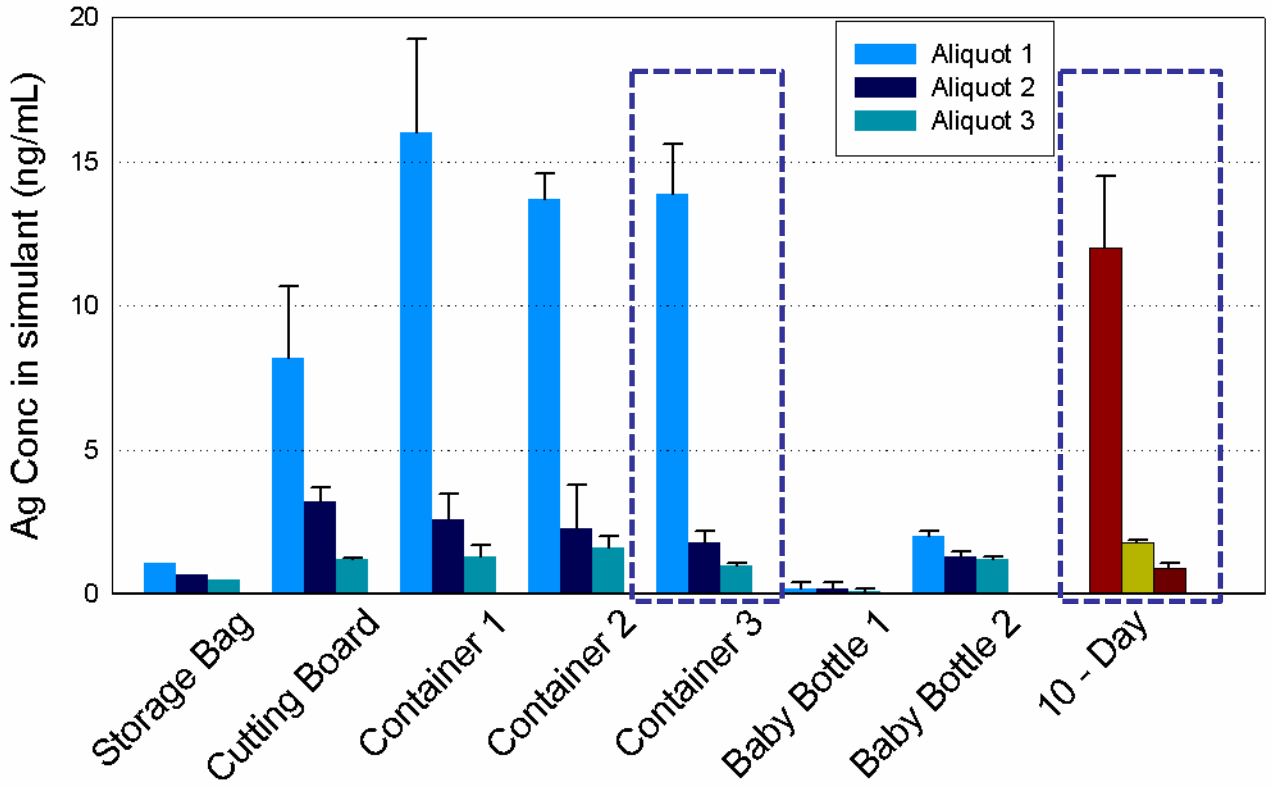
Repeat Exposure



10 Day Storage

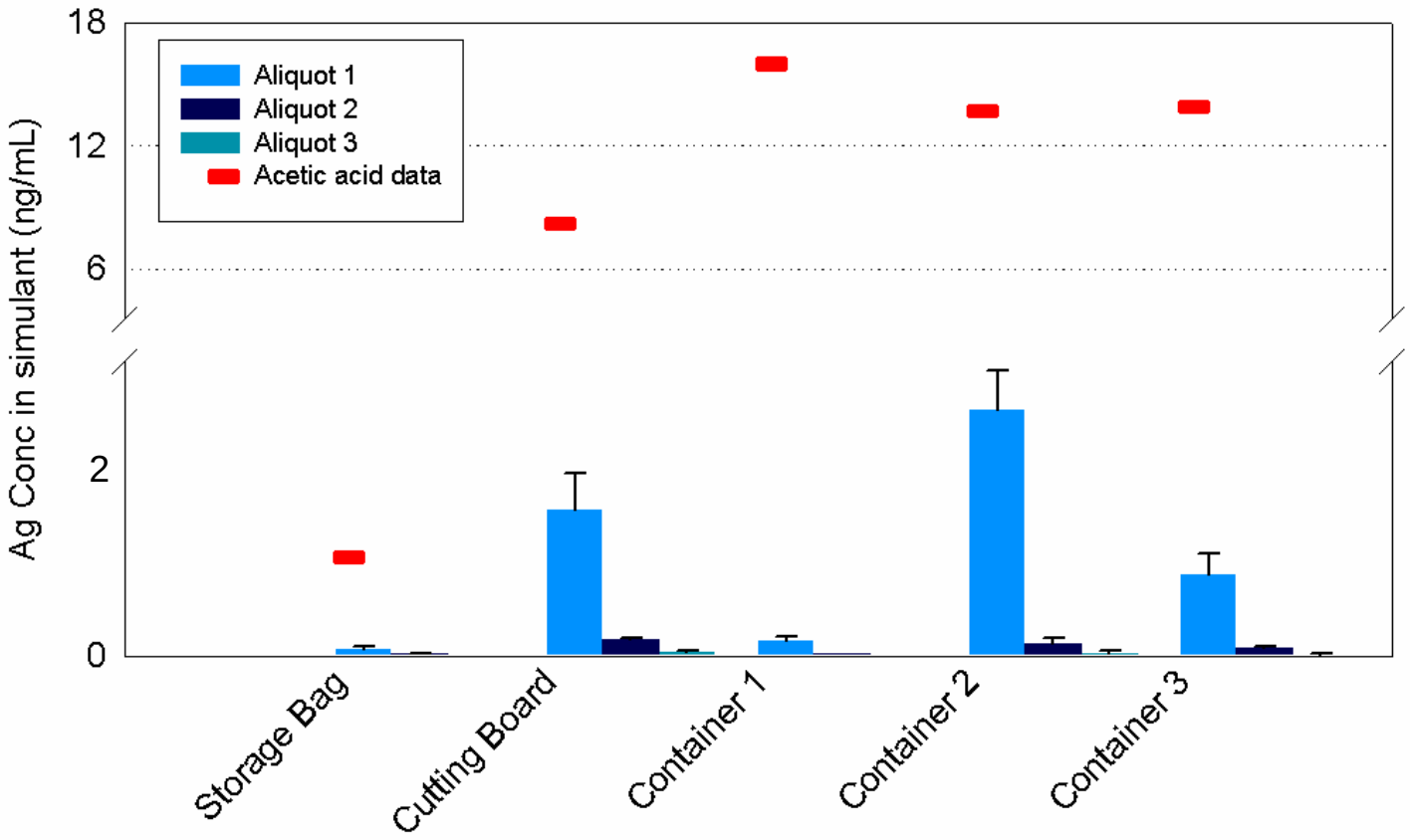


Migration into 3% acetic acid – Plastic FCMs



Addo Ntim et al. 2015 *Food Additives and Contaminants*.

Migration into water – Plastic FCMs

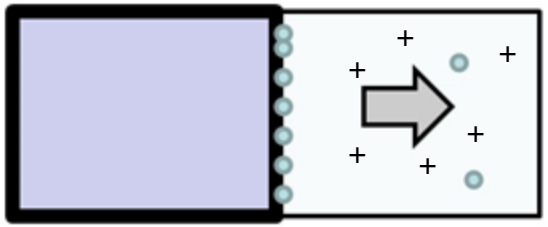


Addo Ntim et al. 2015 *Food Additives and Contaminants*.

Migration Processes

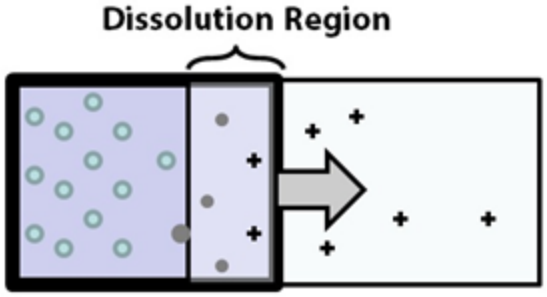
DESORPTION: Weak bonding to surface

- Agitation
- Surfactants / detergents
- pH
- Temperature



DISSOLUTION: Ions released into product

- pH
- Ionic strength
- Size and shape
- Concentration



Did not detect any particle migration.

Slide adapted from Andrew Whelton University of South Alabama

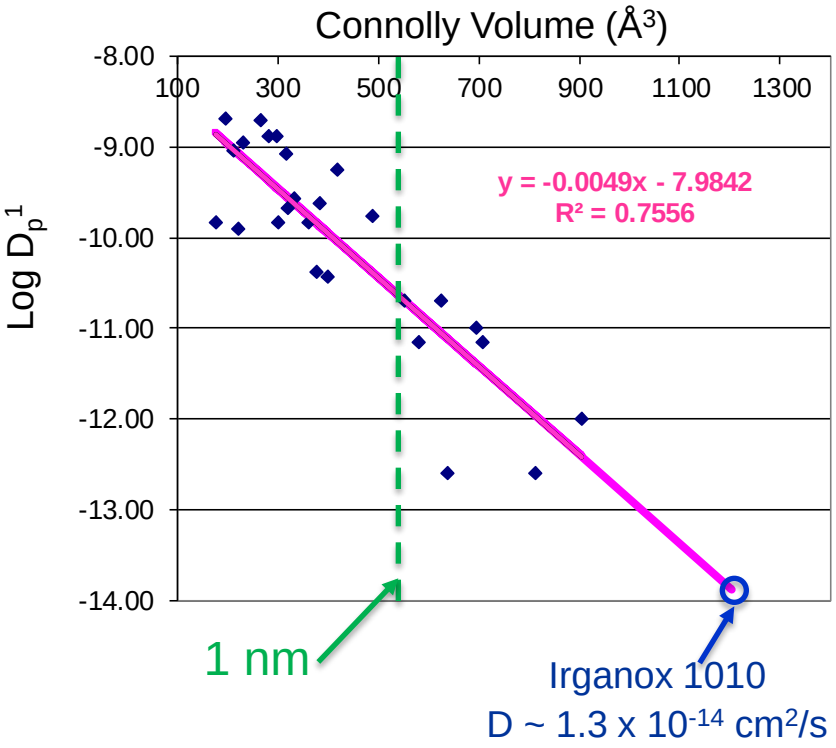
Migration Estimation/Theory

Physicochemical view[2]

Polymer	Diffusion Coefficient ($cm^2\ s^{-1}$)	
	25 °C	4 °C
LDPE	6.6×10^{-23}	3.2×10^{-23}
PP	1.1×10^{-23}	1.3×10^{-23}

Assume a nanoparticle with 5 nm radius.

Extrapolation



2 nm sphere

Connolly Volume ~ 4200 Å^3

$D \sim 3 \times 10^{-29}\ cm^2\ s^{-1}$

[2]Diffusion Coefficients: A. Simon et al. J Food Nutr. Res. 47 105-113 (2008)

[1]Diffusion Data: A. Reynier et al. Food Addit. Contam.16: 137-152 (1999)

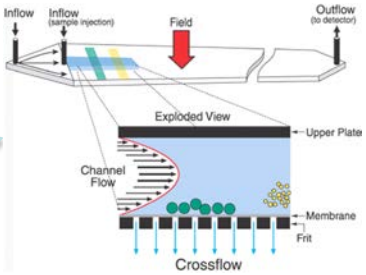
Effects of Choice of Food Simulant

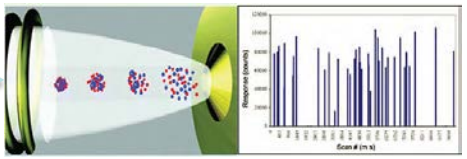
AgNP Dispersion in food simulant before incubation

100 °C

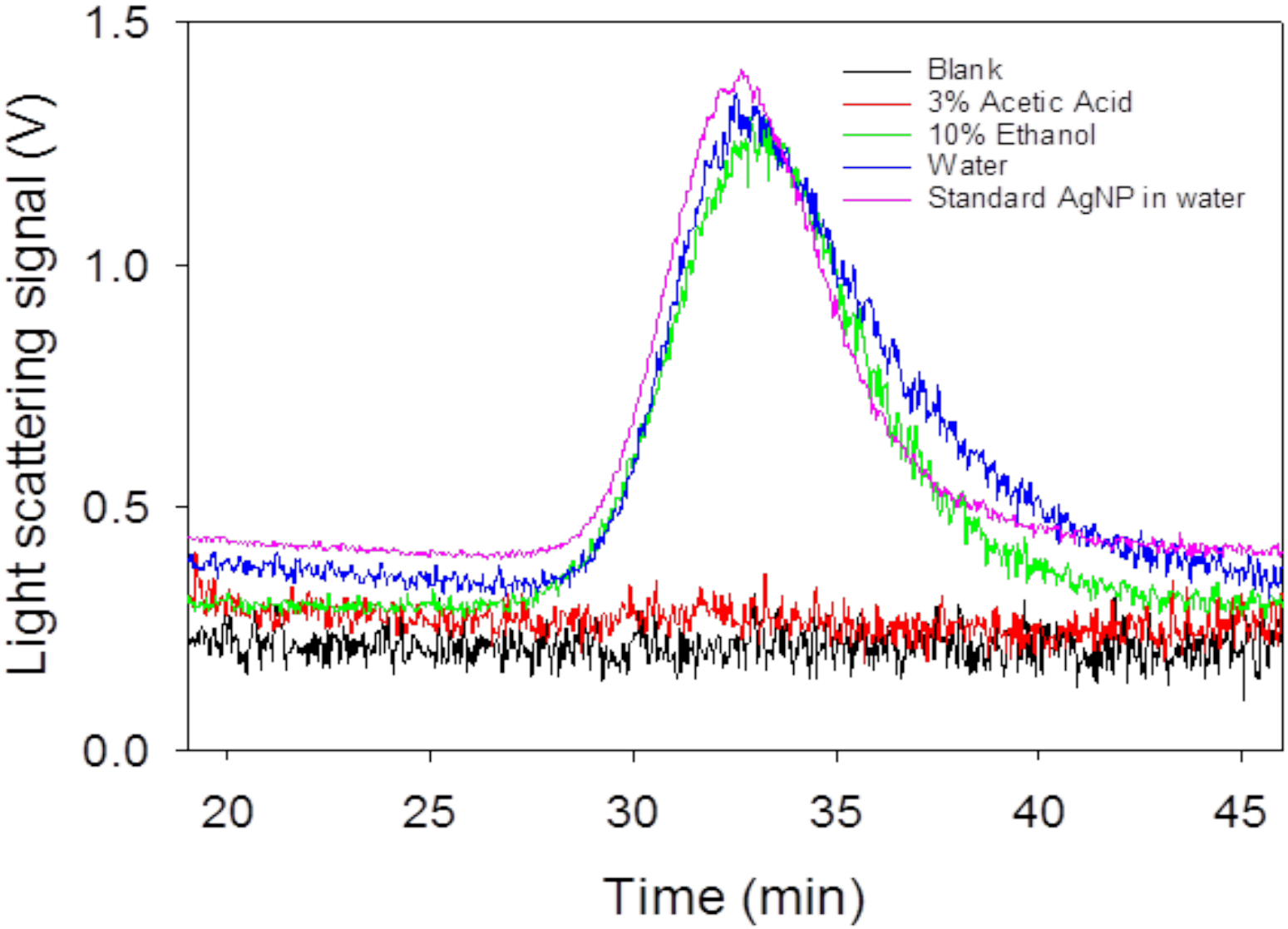
4 hours

AgNP Dispersion in food simulant after incubation

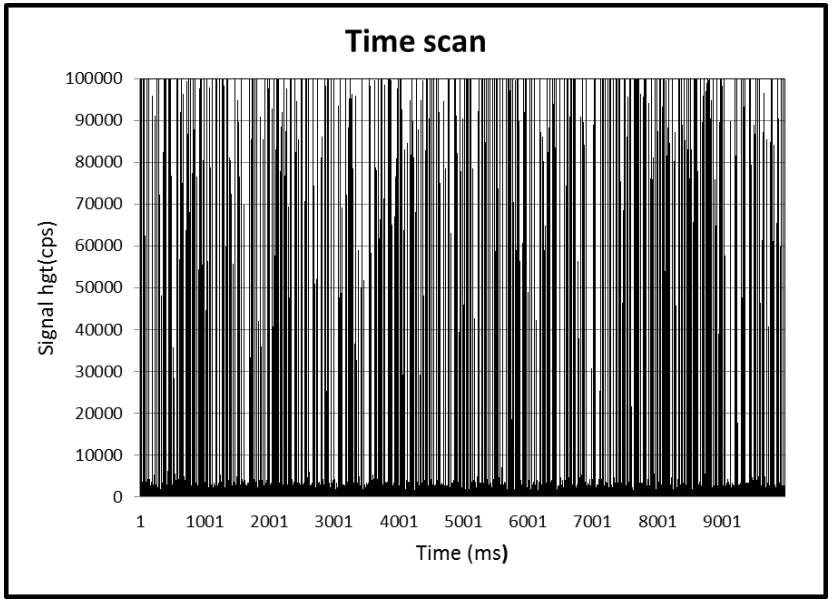


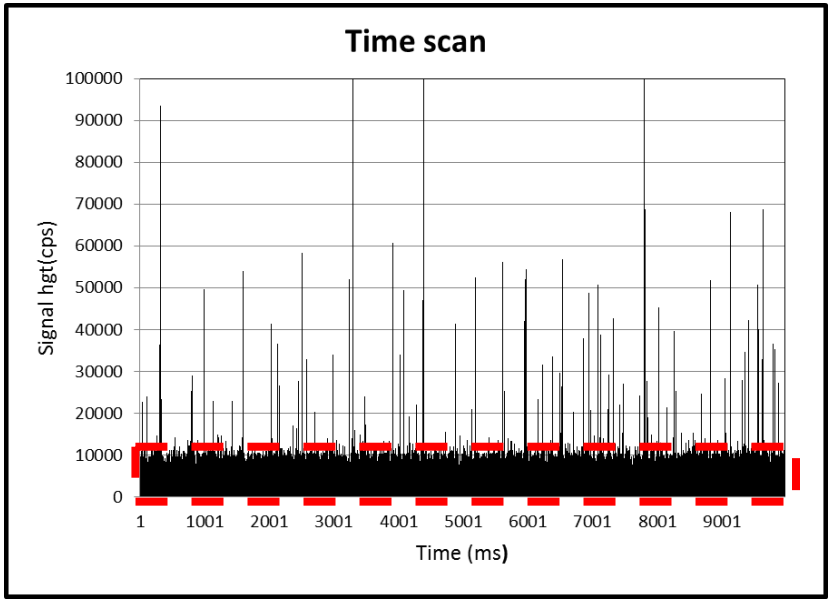


Field Flow Fractionantion Data

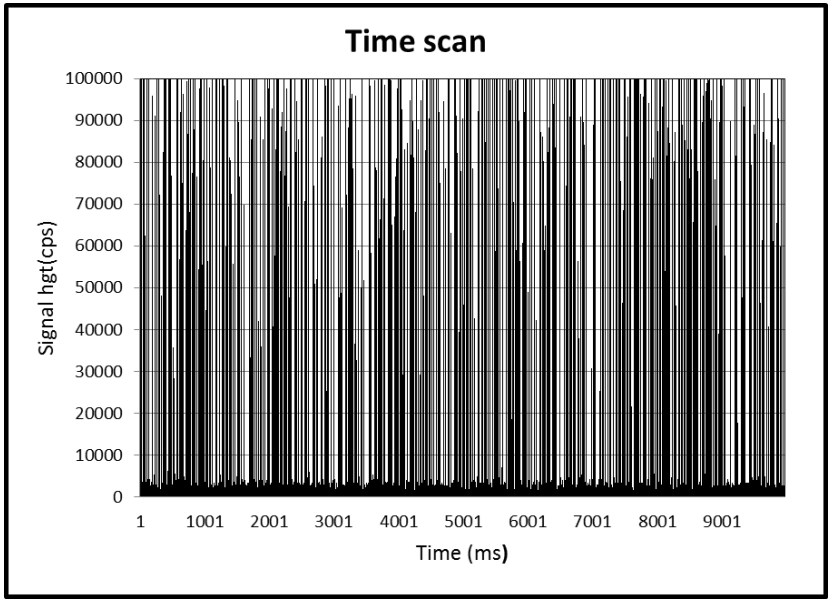


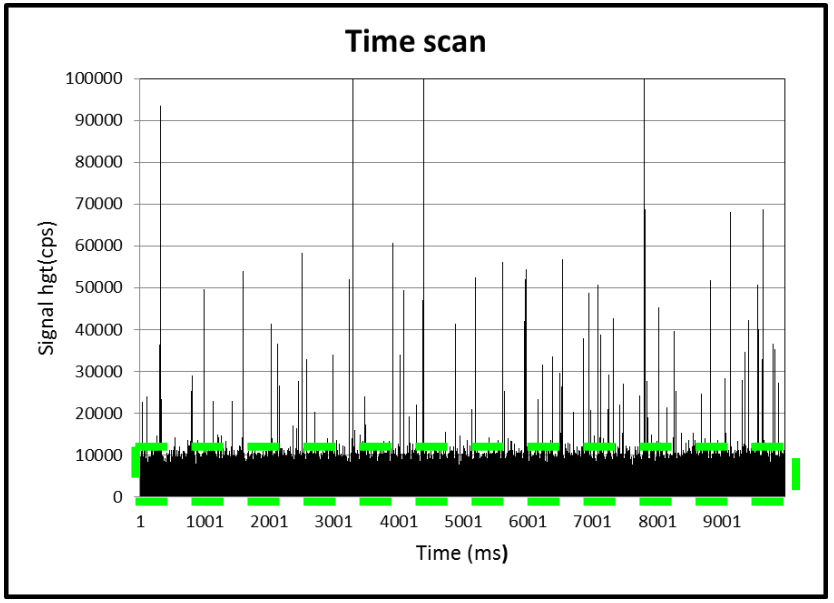
Single Particle ICP-MS Data

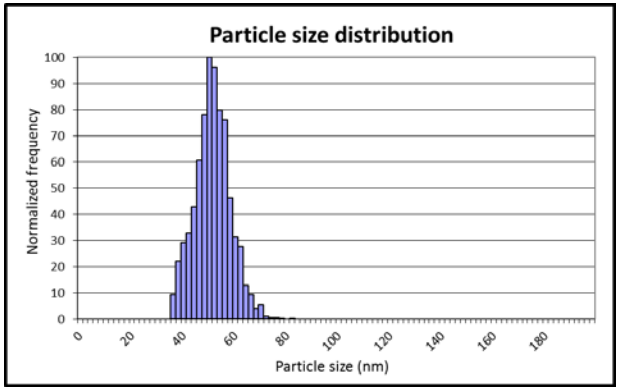




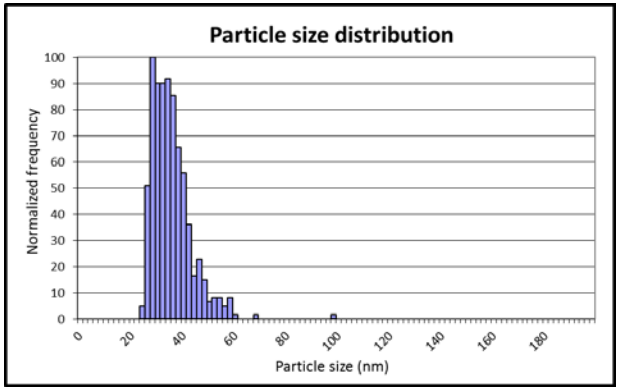
Single Particle ICP-MS Data





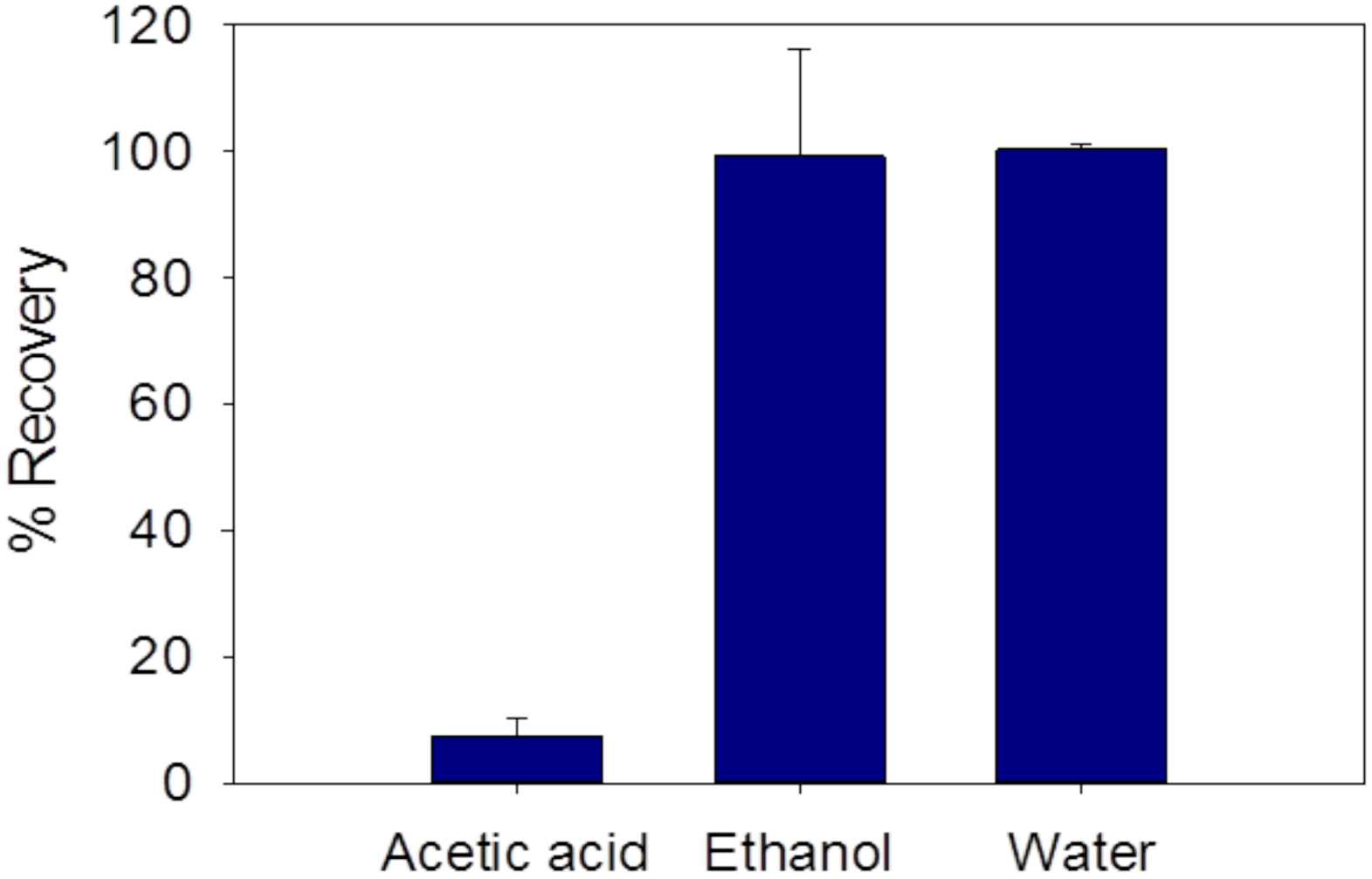


Particle diameter – 56 nm

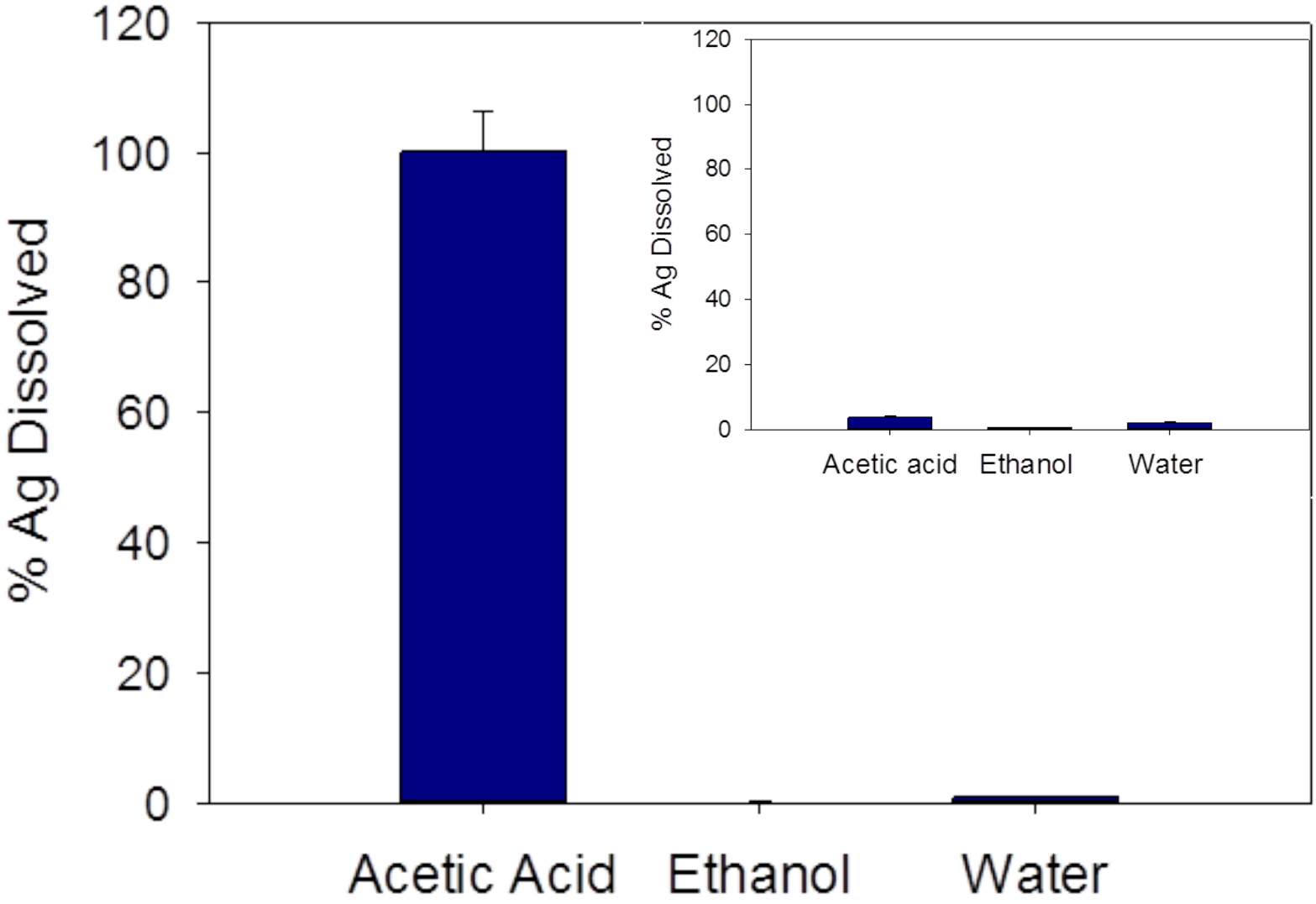


Particle diameter – 33 nm
Ionic Ag conc – 37 ng/L

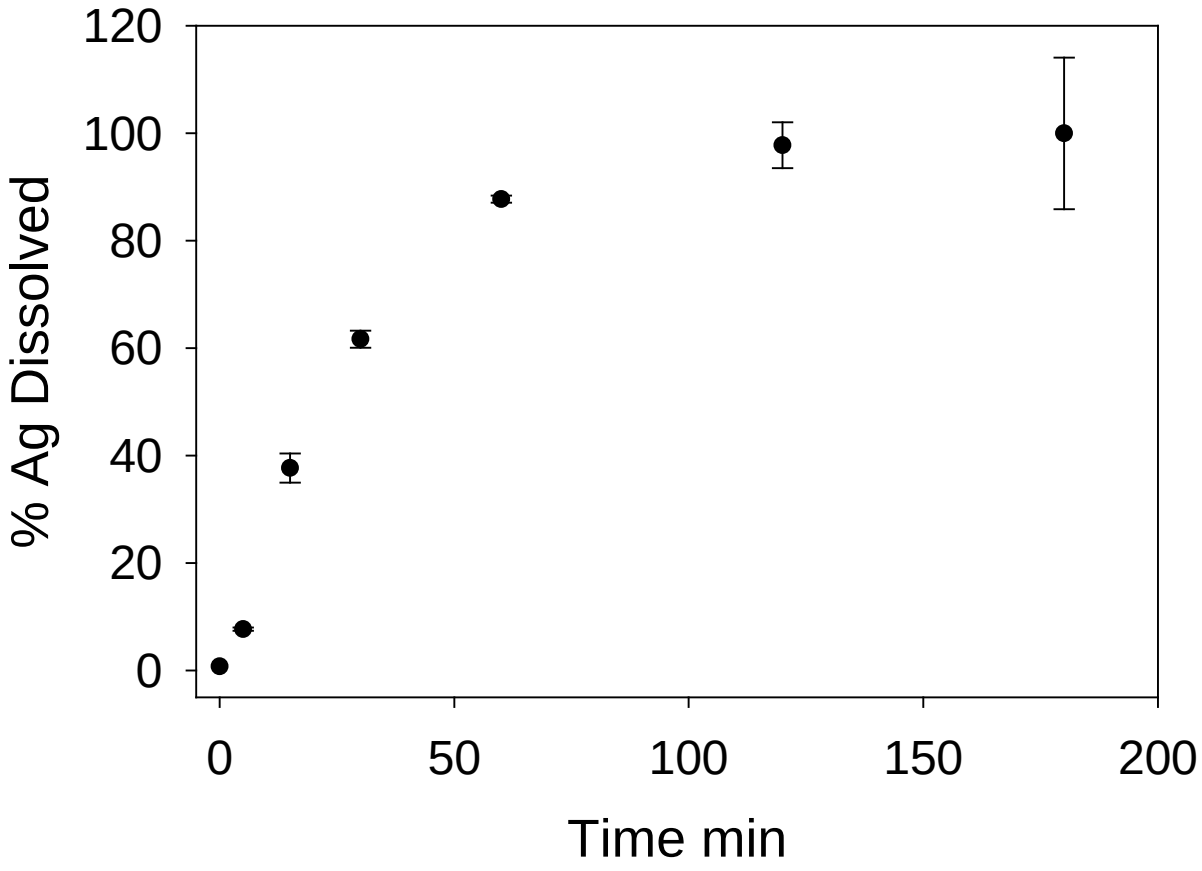
Single Particle ICP-MS Data



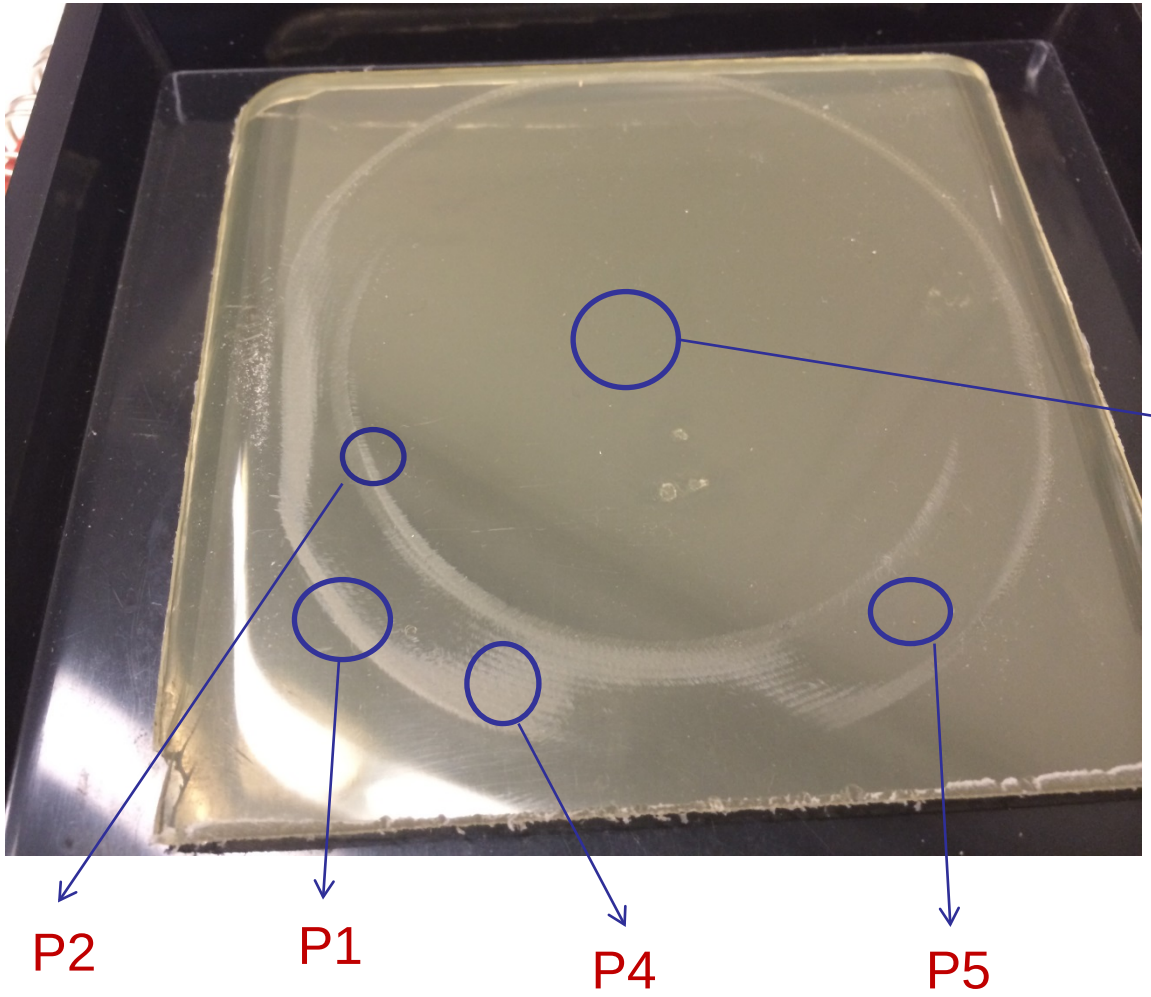
Ultrafiltration Data



Time-Resolved Ultrafiltration Data



Container 1



Abrasion parameters

- Speed: 60 rpm
- Force: 1000g
- # of abrasion cycles: 100

Sample – not flat – abrasion is not uniform

Conclusions

- Commercial FCMs contained low concentrations (ppm) of silver.
- Small amounts of silver detected in simulant after migration representing about 0.1% of silver in FCM.
- No particle migration detected.
- Migration profile characteristic of oxidative desorption of Ag+ from particle surface in contact with simulant.
- Choice of simulant influences particle stability.

Acknowledgements

U.S Food and Drug Administration

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