

Relationships between visual inspection detectability and liquid extraction measurement of particulate matter in bioprocess containers



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In this poster, best practices for visual inspection and for the liquid extraction and measurement of particulate matter inside single-use bioprocessing equipment are described. The relationships between visual detectability and container plastic film and container complexity are compared to results obtained from the liquid extraction (destructive testing) and count/sizing/identification of particulate matter present inside the containers.

Visual Inspection of Bioprocess Containers



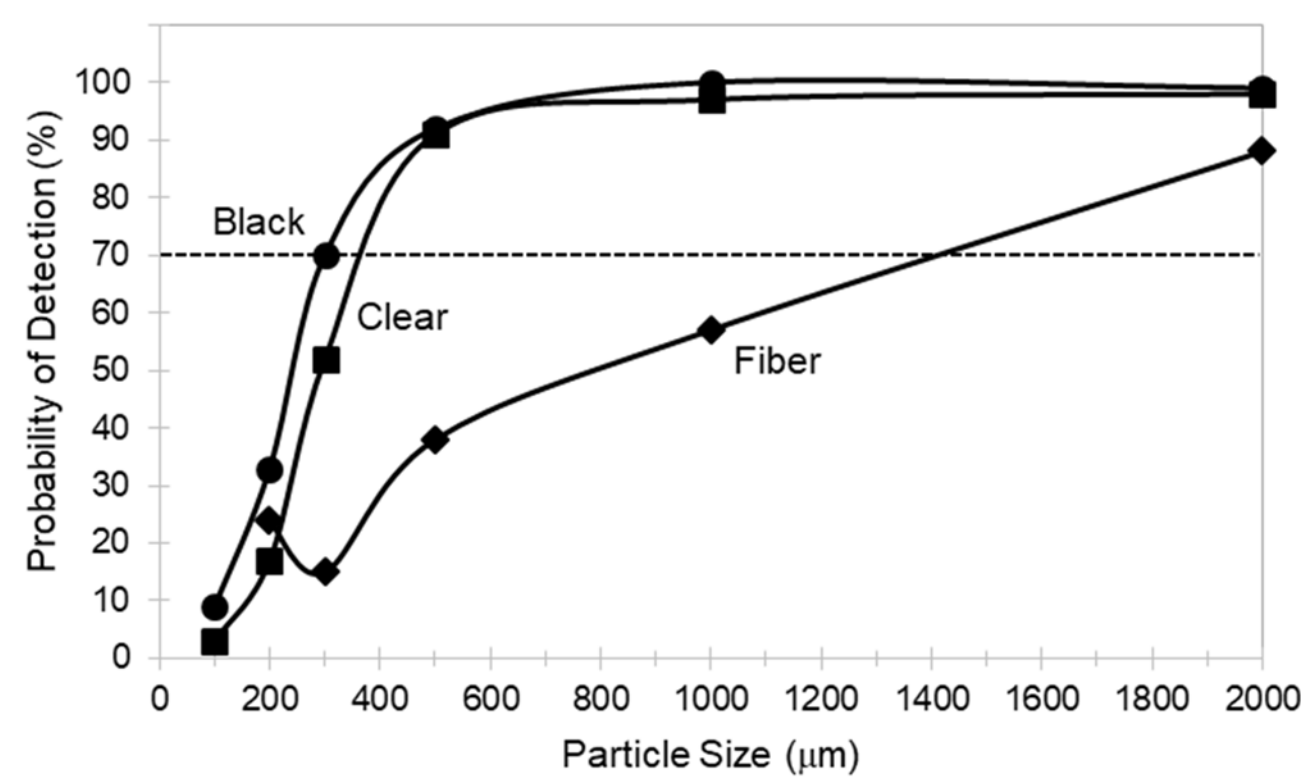
Light table (transmission) at 1900 lux, 35 second inspection time
See Wormuth et al, PDA Journal 2021 Vol 75 page 332
[ASTM Standard under development: E55 WK87243](#)

Liquid Extraction of Bioprocess Containers

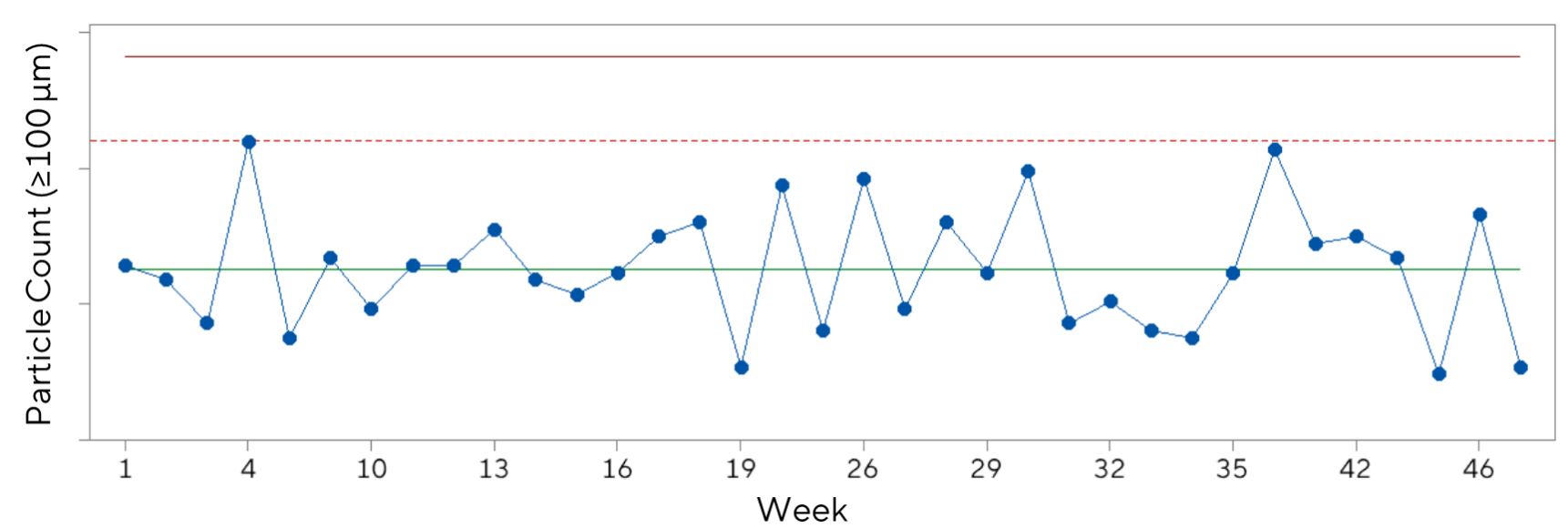


Extraction with water and measurement via automated membrane microscopy
See Wormuth et al, PDA Journal 2024 Vol 78 page 90
[Relevant ASTM Standards E3230, E3411, E3425, E3466, E3468](#)

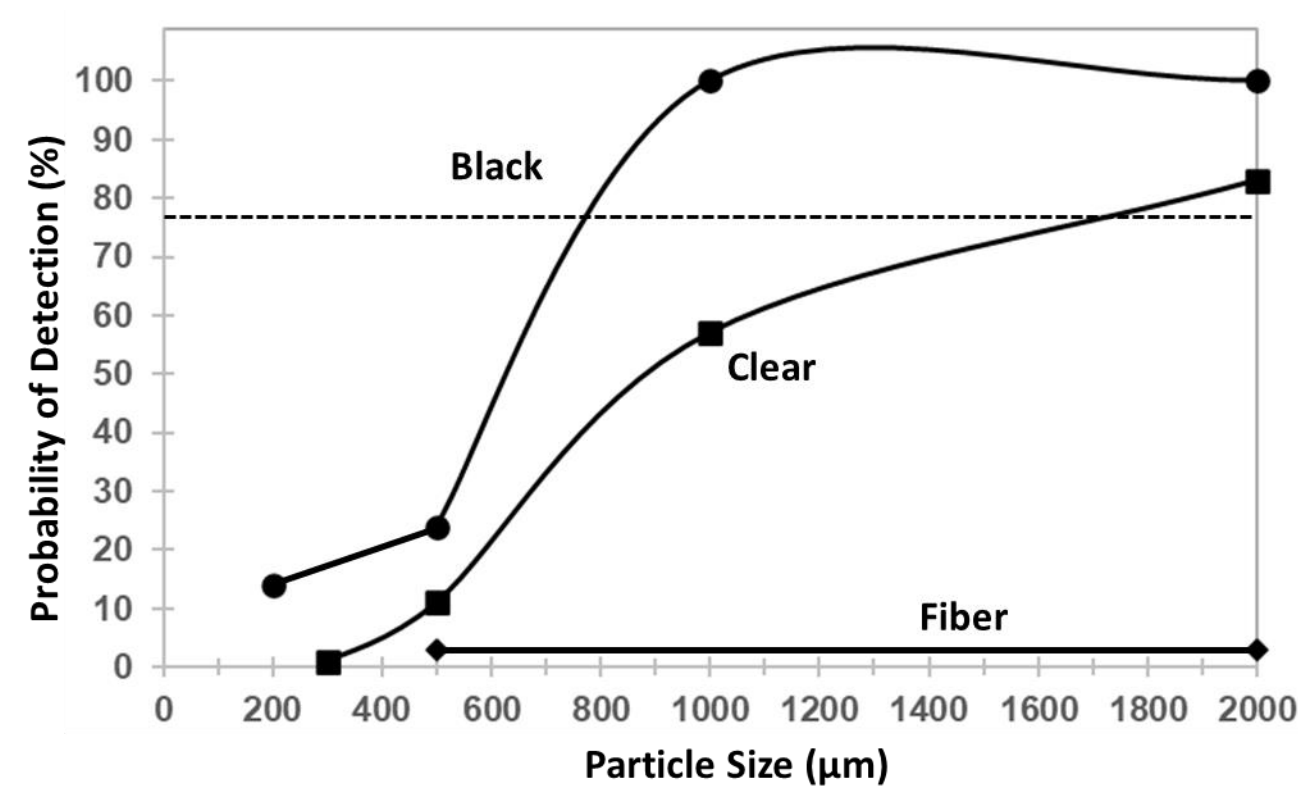
Average PoD for containers 5 mL to 50 L (plastic film #1)



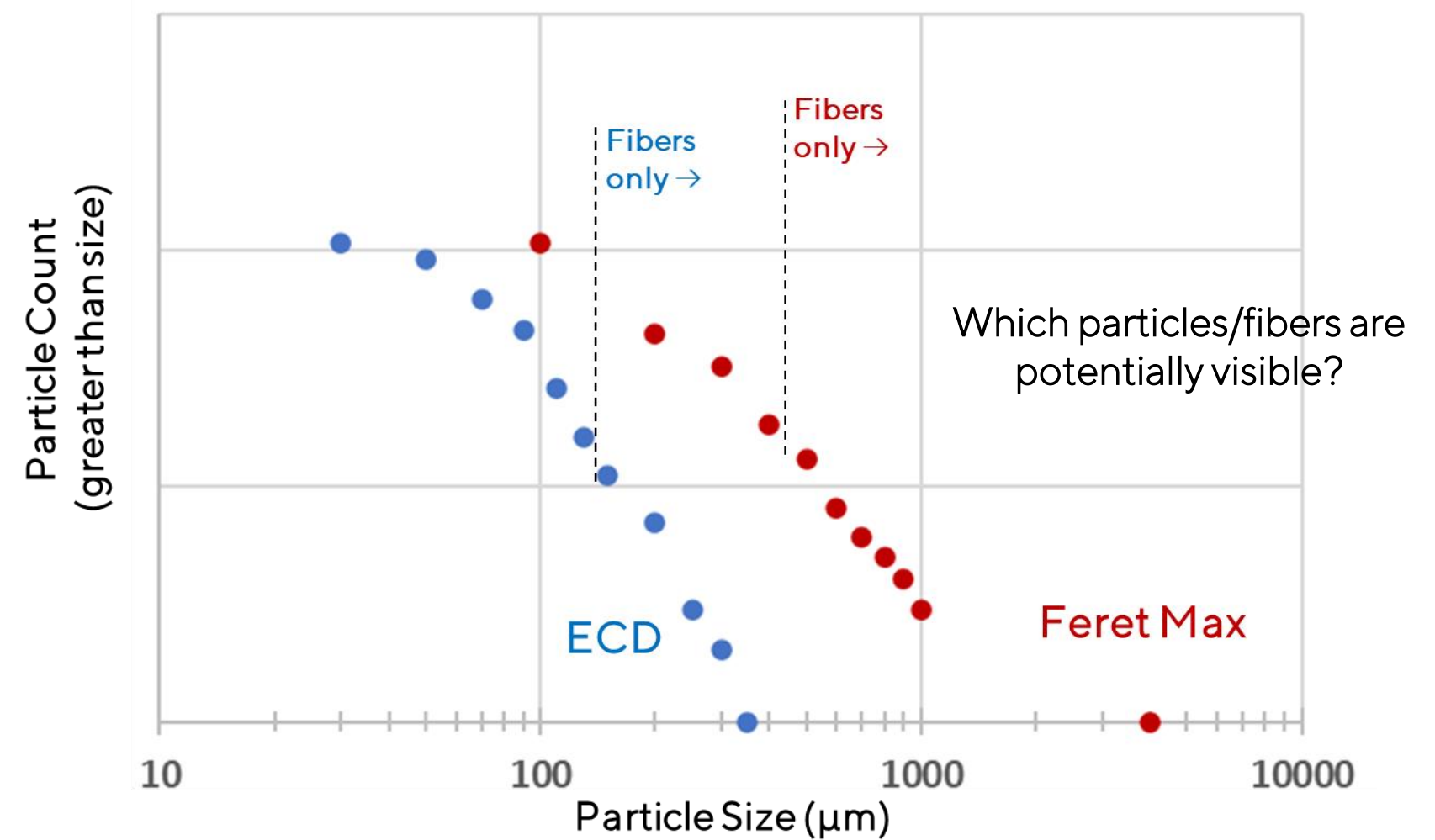
Particle count ($\geq 100 \mu\text{m}$) trend: Liquid extraction of containers



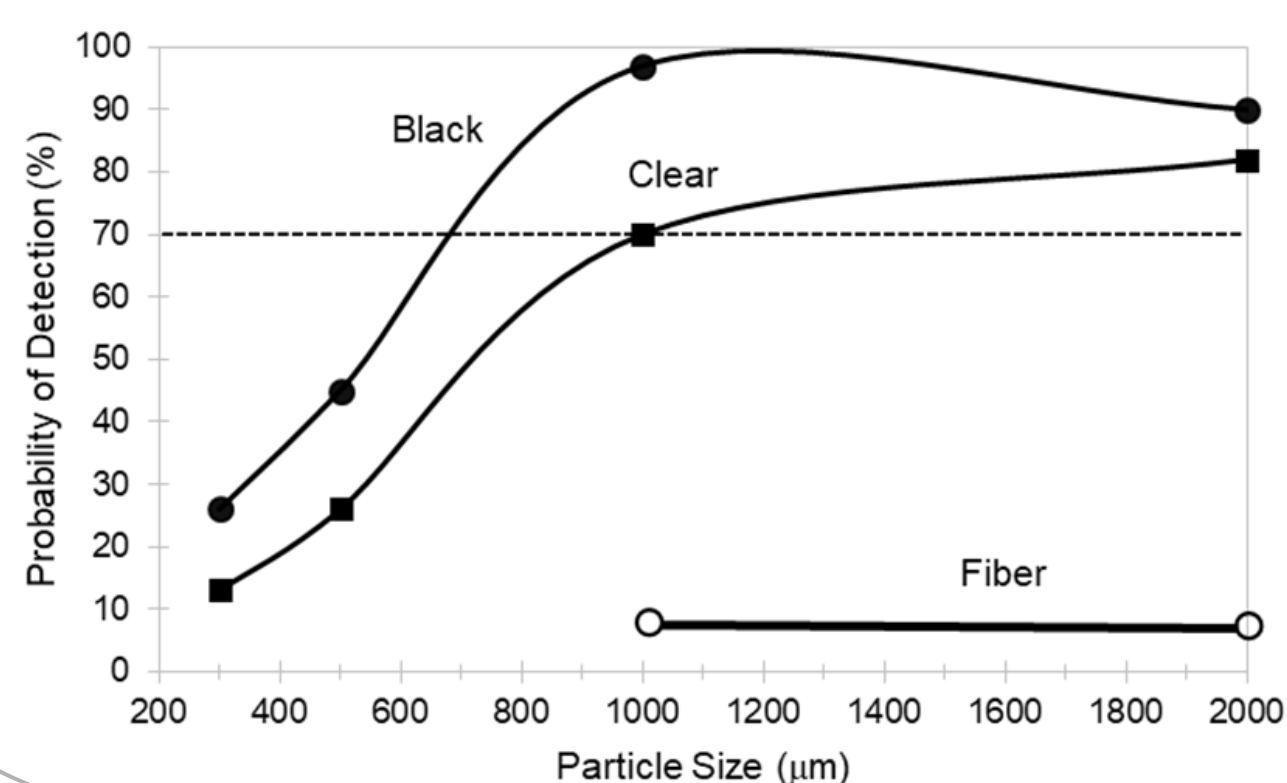
Average PoD for containers 1 L to 20 L (plastic film #2)



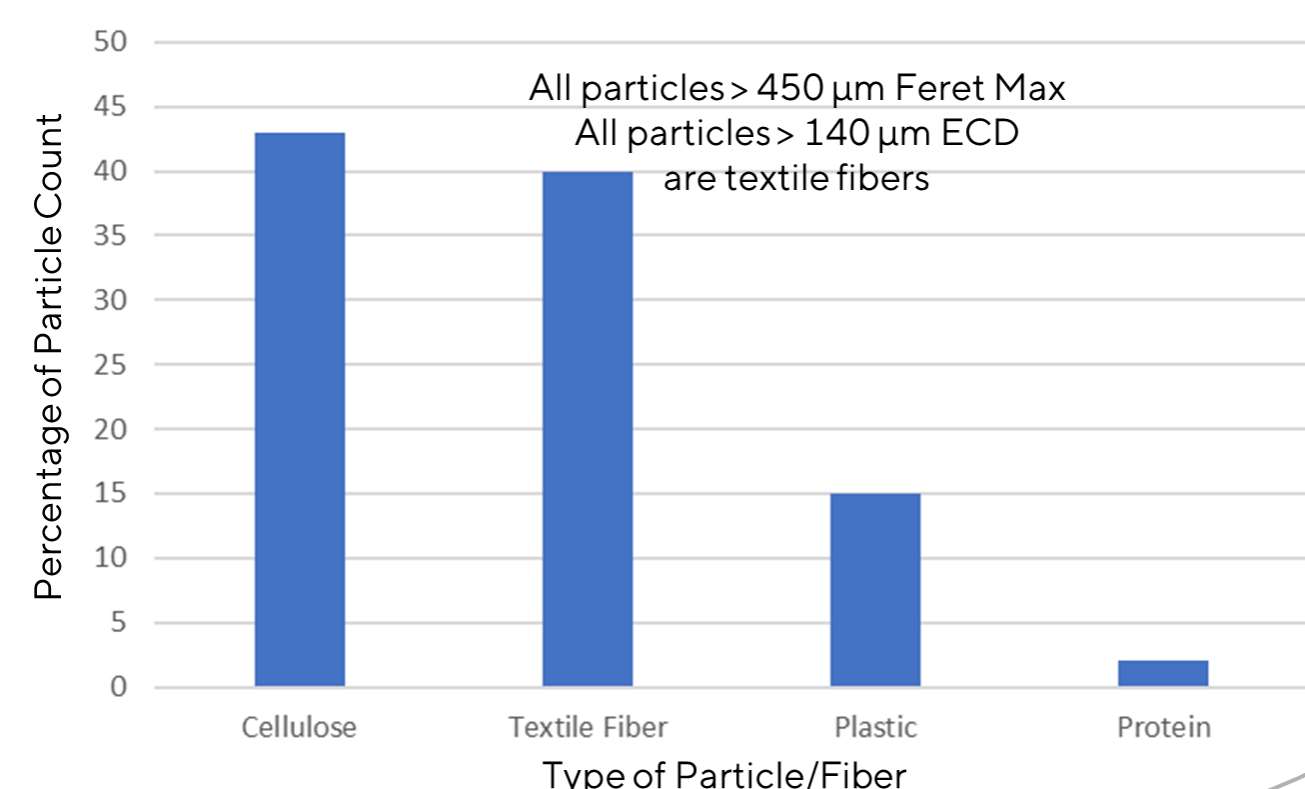
Particle size distribution: Liquid extraction of containers



Average PoD for containers plus tubing lines (plastic film #1)



Types of particles: Liquid extraction of containers



Conclusions

Detecting and controlling the risks from particulate matter present inside single-use bioprocess containers applied in biopharmaceutical manufacturing requires an understanding of the limitations in probability of detection in a visual inspection, along with the relationships to the particle sizes and types found upon liquid extraction (destructive testing).