



Case study

Equivalent mAb aggregation rates

The MSD has been used to perform freeze-thaw cycles with the equivalent stresses to the manufacturing equipment, to mimic the large-scale process. For example, the samples frozen in the MSD showed a substantial increase in higher molecular weight species (HMWS) and subvisible particles $\geq 1 \mu\text{m}$ per mL (SVPs), with freeze-thaw cycles, while vials frozen and thawed under the same conditions of the manufacturing equipment cannot mimic the large scale process (no aggregation was found) (Fig. 5).

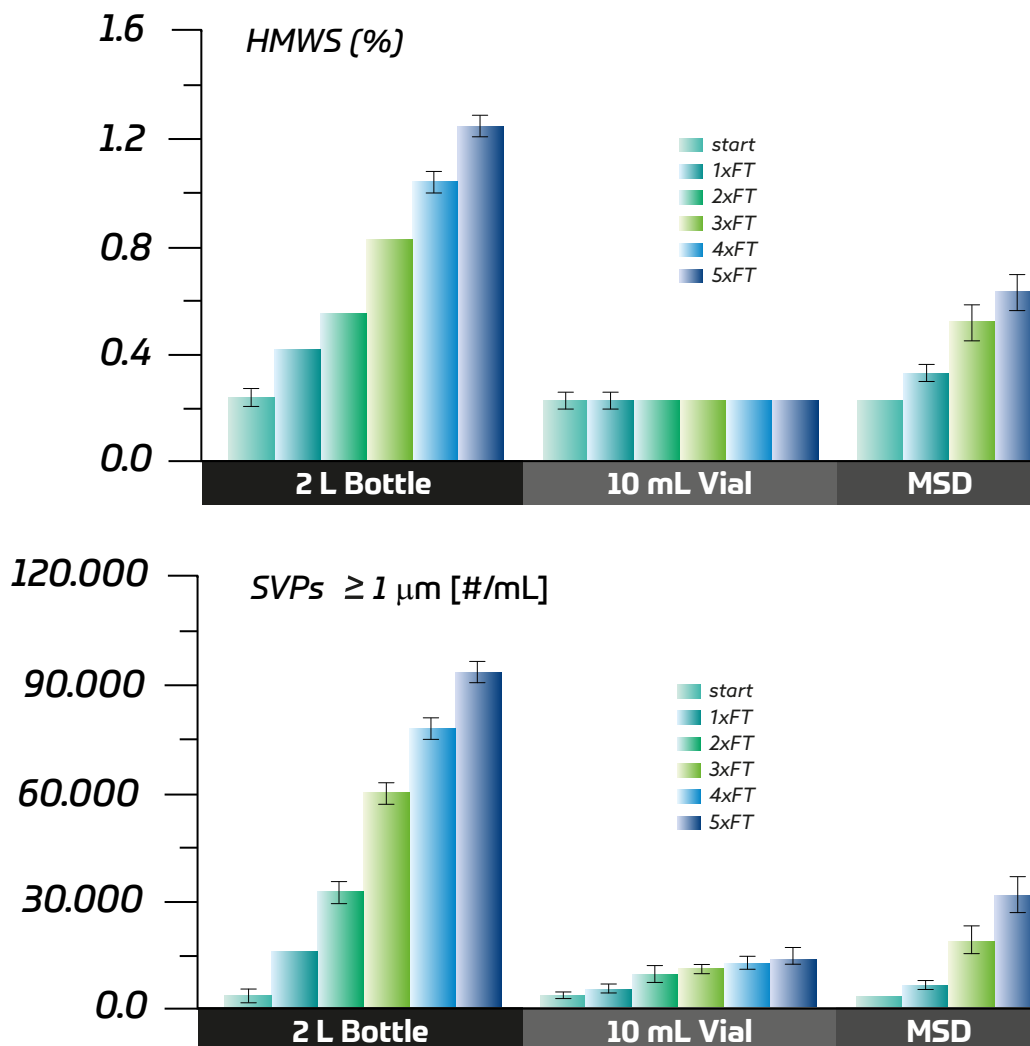


Fig. 5 - Comparison of mAb aggregation after freeze-thaw cycles (FT) in the large-scale 2 L bottle (0.4 °C/min.), 10 mL vials (0.4 °C/min.), and using the MSD. This study was carried for a 1 mg/mL mAb2 solution in 25 mM adipic acid buffer at pH 5.2.

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