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Phase Separation in Solutions of Monoclonal Antibodies[1]
GEORGE BENEDEK[2], YING WANG, ALEKSEY LOMAKIN, Massachusetts Institute of Technology, RAMIL LATYPOV, Amgen, Inc — We report the observation of liquid-liquid phase separation (LLPS) in a solution of humanized monoclonal antibodies, IgG2, and the effects of human serum albumin, a major blood protein, on this phase separation. We find a significant reduction of phase separation temperature in the presence of albumin, and a preferential partitioning of the albumin into the antibody-rich phase. We provide a general thermodynamic analysis of the antibody-albumin mixture phase diagram and relate its features to the magnitude of the effective inter-protein interactions. Our analysis suggests that additives (HSA in this report), which have moderate attraction with antibody molecules, may be used to forestall undesirable protein condensation in antibody solutions. Our findings are relevant to understanding the stability of pharmaceutical solutions of antibodies and the mechanisms of cryoglobulinemia.

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