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Holographic characterization of protein aggregates¹ CHEN WANG, XIAO ZHONG, New York University, DAVID RUFFNER, Spheryx, Inc., ALEXAN-DRA STUTT, Packer Collegiate Institute, LAURA PHILIPS, Spheryx, Inc., MICHAEL WARD, DAVID GRIER, New York University — Holographic characterization directly measures the size distribution of subvisible protein aggregates in suspension and offers insights into their morphology. Based on holographic video microscopy, this analytical technique records and interprets holograms of individual aggregates in protein solutions as they flow down a microfluidic channel, without requiring labeling or other exceptional sample preparation. The hologram of an individual protein aggregate is analyzed in real time with the Lorenz-Mie theory of light scattering to measure that aggregates size and optical properties. Detecting, counting and characterizing subvisible aggregates proceeds fast enough for timeresolved studies, and lends itself to tracking trends in protein aggregation arising from changing environmental factors. No other analytical technique provides such a wealth of particle-resolved characterization data in situ. Holographic characterization promises accelerated development of therapeutic protein formulations, improved process control during manufacturing, and streamlined quality assurance during storage and at the point of use.

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