

OPTIMIZED PROCESS FOR REGULATORY T CELL ACTIVATION AND EXPANSION USING DYNABEADS™ TREG CD3/CD28 FOR CLINICAL APPLICATIONS

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Key Words: Dynabeads™, Treg immunotherapies

CD4⁺CD25⁺ Tregs are a suppressive subset of CD4⁺ T helper cells important for the regulation of immune responses. Tregs are proven highly effective in preventing graft versus host disease (GVHD) and autoimmunity in murine models. The relative frequency of Tregs in peripheral blood is approximately 1-2% of total lymphocytes implicating the necessity of ex vivo expansion of Tregs prior to adoptive transfer for most clinical applications. The Dynabeads™ CD3/CD28 CTS™ has been developed for ex vivo isolation, activation, and expansion of human T cells for use in various immunotherapies. To address the specific needs for Treg expansion, we have generated a new product, Dynabeads™ Treg CD3/CD28, designed to provide optimal activation and expansion of Tregs. We have compared the functionality of Dynabeads™ Treg CD3/CD28 with other existing technologies (competitors and Dynabeads™ CD3/CD28 CTS™) regarding expansion of CD4⁺CD25⁺CD127^{low} flow sorted **Tregs and magnetically isolated Tregs**. Our studies demonstrate superior fold expansion of functional Tregs with the Dynabeads™ Treg CD3/CD28. **We show several hundred fold expansion of Treg cells in 14 days culture and with maintenance of high FOXP3 expression and suppressive activity.** This optimized Dynabeads™ Treg CD3/CD28 support consistent and scalable Treg manufacturing for immunotherapies, supplementing our Cell Therapy System (CTS™) portfolio.

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