

Development of a Cell Reference Standard for CD34+ Cell Enumeration

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Enumeration of CD34+ cells by flow cytometry is widely used as a clinical method to evaluate engraftment potential of peripheral blood stem cell collections and can also be used for optimizing the timing of apheresis collections. Standardizing the method and procedures for enumeration of the CD34+ cells is important to ensure consistency in the measurement of CD34+ cells in different clinical applications. USP Chapter <127> Flow Cytometric Enumeration of CD34+ Cells provides a standardized method for CD34+ cell enumeration based on the International Society of Hematotherapy and Graft Engineering (ISHAGE) protocol. The chapter describes a single platform, flow cytometric method, including specific gating instructions for enumeration of CD34+ cells. The USP CD34+ Cell Enumeration System Suitability Reference Standard is a freeze dried cell preparation used to assess the reagents and ensure the correct gating during data acquisition and analysis. Data from the multi-laboratory collaborative study for the development of this reference standard will be presented.