



Standard Guide for Autologous Platelet-Rich Plasma for Use in Tissue Engineering and Cell Therapy¹

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1. Scope

1.1 This guide defines terminology and identifies key fundamental properties of autologous platelet-rich plasma (PRP) and PRP-derived platelet gels intended to be used for tissue engineered medical products (TEMPS) or for cell therapy applications. This guide provides a common nomenclature and basis for describing notable properties and processing parameters for PRP and platelet gels that may have utility for manufacturers, researchers, and clinicians. Further discussion is also provided on certain aspects of PRP processing techniques, characterization, and quality assurance and how those considerations may impact key properties. The PRP characteristics outlined in this guide were selected based on a review of contemporary scientific and clinical literature but do not necessarily represent a comprehensive inventory; other significant unidentified properties may exist or be revealed by future scientific evaluation. This guide provides general recommendations for how to identify and cite relevant characteristics of PRP, based on broad utility; however, users of this standard should consult referenced documents for further information on the relative import or significance of any particular PRP characteristic in a particular context.

1.2 The scope of this guide is confined to aspects of PRP and platelet gels derived and processed from autologous human peripheral blood. Platelet-rich plasma, as defined within the scope of this standard, may include leukocytes.

1.3 The scope of this document is limited to guidance for PRP and platelet gels that are intended to be used for TEMPS or for cell therapy applications. Processing of PRP, other platelet concentrates or other blood components for direct intravenous transfusion is outside the scope of this guide. Apheresis platelets and other platelet concentrates utilized in transfusion medicine are outside the scope of this document. Production of PRP or platelet gels for diagnostic or research applications unrelated to PRP intended for TEMPS or cell

therapy is also outside the scope of this guide. Fibrin gels devoid of platelets are also excluded from discussion within this document.

1.4 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

F1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices (Withdrawn 2012)³

F2149 Test Method for Automated Analyses of Cells—the Electrical Sensing Zone Method of Enumerating and Sizing Single Cell Suspensions

F2312 Terminology Relating to Tissue Engineered Medical Products

2.2 ISO Standards:⁴

ISO 5725–1 Accuracy (trueness and precision) of Measurement Methods and Results—Part 1: General Principles and Definitions—Technical Corrigendum 1

ISO 5725–2:1994 Accuracy (trueness and precision) of Measurement Methods and Results—Part 2: Basic Method for the Determination of Repeatability and Reproducibility of a Standard Measurement Method—Technical Corrigendum 1

3. Terminology

3.1 Definitions:

3.1.1 *autologous*, *adj*—cells, tissues, and organs in which the donor and recipient is the same individual. Synonyms: autogenous, autograft, or autotransfusion, a self-to-self graft.

F2312

¹ This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.43 on Cells and Tissue Engineered Constructs for TEMPS.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ The last approved version of this historical standard is referenced on www.astm.org.

⁴ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.