Designation: F1830 – 19

Standard Practice for Collection and Preparation of Blood for Dynamic *in vitro* Evaluation of Hemolysis in Blood Pumps[1]

This standard is issued under the fixed designation F1830; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This practice covers whole blood that will be used for the *in vitro* performance assessment of hemolysis in blood pumps intended for clinical use.

1.2 This practice covers the recommended standard collection, preparation, handling, storage, and utilization of whole blood for the *in vitro* evaluation (see Practice F1841) of the following devices:

1.2.1 Continuous flow blood pumps (roller pumps, centrifugal pumps, axial flow pumps, etc.).

1.2.2 Pulsatile and intermittent flow blood pumps (pneumatically driven, electro-mechanically driven, with an artificial pulse, etc.).

1.3 The source and preparation of whole blood utilized for the dynamic *in vitro* evaluation of red blood cell (erythrocyte) trauma caused by blood pumps can substantially influence the hemolysis performance of these devices. Thus, standardized whole blood collection and preparation methods are required.

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F1841 Practice for Assessment of Hemolysis in Continuous Flow Blood Pumps

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *blood pump*—a device that replaces or supplements the function of the human heart to circulate blood by producing continuous or time-varying blood flow.

3.1.2 *hemolysis*—one of the parameters of blood damage caused by a blood pump, characterized by the liberation of hemoglobin from damaged erythrocytes into the plasma. Hemolysis can occur from mechanical, thermal, or chemical sources in medical devices.

4. Summary of Practice

4.1 For the experimental evaluation of hemolysis caused by pump designs, materials, and operational conditions (see Practice F1841), dynamic *in vitro* hemolysis tests are recommended using fresh animal or human blood. The blood donor should have an afebrile body temperature, no physical signs or symptoms of disease, including diarrhea and/or rhinorrhea, and an acceptable normal range of hematological parameters (e.g. RBC, WBC, and platelet counts, hematocrit, total hemoglobin concentration). If animal blood is obtained from an abattoir, it is preferable that it be collected by controlled venipuncture to minimize the risk of contamination with debris or fluids other than blood. While human blood would be the most relevant for performing preclinical device studies, the practicality of obtaining sufficient quantities of cross-matched donor blood needs to be considered.[3]

5. Significance and Use

5.1 *In vitro* hemolysis test results for blood pumps may be substantially affected by donor species, sex, age, fasting, the method of harvesting, the anticoagulant properties, the period of storage, the biochemical state of the blood, and the hemoglobin and hematocrit level of blood.[3,4] Therefore, standardization of proper whole blood collection and preparation for the

[1] This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.30 on Cardiovascular Standards.

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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] Mueller NM, et al. *In Vitro* Hematological Testing of Rotary Blood Pumps: Remarks on Standardization and Data Interpretation. *Artif Organs*, 17 (2), 1993, pp. 103–110.

[4] Mizuguchi K, et al. Does Hematocrit Affect *In Vitro* Hemolysis Test Results?: Preliminary Studies with NASA Axial Flow Pump. *Artif Organs* 18 (9), 1994, pp. 650–656.