Designation: F 1830 – 97

Standard Practice for Selection of Blood for In Vitro Evaluation of Blood Pumps[1]

This standard is issued under the fixed designation F 1830; 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 blood that will be used for in vitro performance assessments of blood pumps. These assessments include the hemolytic properties of the devices.

1.2 This practice covers the utilization of blood for the in vitro evaluation of the following devices:

1.2.1 Continuous flow rotary blood pumps (roller pumps, centrifugal pumps, axial flow pumps, etc.) (see Practice F 1841).

1.2.2 Pulsatile blood pumps (pneumatically driven, electromechanically driven, etc.).

1.3 The source of blood utilized for in vitro evaluation of blood trauma (that is, hemolysis caused by the blood pumps, due to the pump design, construction, and materials used) substantially influences the results of the performance of these devices. Thus, a standardized blood source is required.

2. Referenced Documents

2.1 *ASTM Standards:*

F 1841 Practice for Assessment of Hemolysis in Continuous Flow Blood Pumps[2]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *continuous flow pump*—a blood pump that produces continuous blood flow due to its rotary motion.

3.1.2 *hemolysis*—one of the parameters of blood damage caused by a blood pump. This can be observed by a change in the plasma color and can be measured as an increase of free plasma hemoglobin concentration.

3.1.3 *pulsatile pump*—a blood pump that produces blood flow to mimic a natural heart.

4. Summary of Practice

4.1 For the experimental evaluation of blood pump designs and materials, an in vitro hemolysis test is recommended using fresh bovine or porcine blood. The donor animals should have normal body temperature, no physical signs of disease, including diarrhea and rhinorrhea, and an acceptable normal range of hematological profiles. The blood from a slaughterhouse should not be used because it may be contaminated with other body fluids, unless obtained by controlled venipuncture. However, for the preclinical studies, fresh human blood is recommended for use (see Practice F 1841).

4.2 For the in vitro hemolysis test, fresh bovine or porcine blood is used within 48 h, including the time for transport. Fresh human blood should be used within 24 h after blood harvesting. The collected blood should be refrigerated at 2 to 8°C.

5. Significance and Use

5.1 The test results are substantially affected by donor species and age, the method of harvesting, the period of storage, the biochemical state of the blood, and the hemoglobin and hematocrit level of blood.[3,4] Therefore, standardization of proper blood usage for in vitro evaluation of blood pumps is essential, and this recommended practice will allow a universal comparison of test results.

5.2 Drawing several units of blood from healthy cattle does not affect them or their health. Therefore, bovine blood is strongly suggested for usage in experimental evaluation of blood damage. Mixing two donor sources of blood should be avoided in hemolysis tests because the mixture may induce added hemolysis or a change in red cell resistance against trauma.

6. Collection and Preparation of Blood

6.1 Blood will be drawn using a venipuncture technique through a large bore needle (14 G or larger) into a blood bag which contains anticoagulants such as citrate phosphate dextrose adenine (CPDA-1) anticoagulant solution (see Appendix X1) or heparin sulfate (see Appendix X2). The blood is obtained from human volunteers, cattle or pigs having normal body temperature, no physical signs of disease, including diarrhea, rhinorrhea, and whose hematological profiles are in an acceptable range. No negative pressure in excess of 100

[1] This practice is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.30 on Cardiovascular Standards.

Current edition approved Nov. 10, 1997. Published June 1998.

[2] *Annual Book of ASTM Standards*, Vol 13.01.

[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.