Designation: ~~F1830 – 97 (Reapproved 2017)~~ F1830 – 19

Standard Practice for ~~Selection~~ 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 ~~assessments~~assessment of ~~blood pumps. These assessments include the hemolytic properties of the devices.~~hemolysis in blood pumps intended for clinical use.

1.2 This practice covers the ~~utilization of~~ 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 ~~rotary~~ blood pumps (roller pumps, centrifugal pumps, axial flow pumps, ~~and so forth) (see Practice~~ etc.).~~F1841).~~

1.2.2 Pulsatile and intermittent flow blood pumps (pneumatically driven, ~~electromechanically driven, and so forth).~~electromechanically driven, with an artificial pulse, etc.).

1.3 The source and preparation of whole blood utilized for the dynamic *in vitro* evaluation of ~~blood trauma (that is, hemolysis~~ red blood cell (erythrocyte) trauma caused by ~~the blood pumps, due to the pump design, construction, and materials used) substantially influences the results of the~~ blood pumps can substantially influence the hemolysis performance of these devices. Thus, ~~a~~ standardized ~~blood source is~~ 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~~F1841 Practice for Assessment of Hemolysis in Continuous Flow Blood Pumps (Withdrawn 0)[3]~~

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 ~~*continuous flow*~~ *blood pump*—a ~~blood pump that produces continuous blood flow due to its rotary motion.~~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. This can be observed by a change in the plasma color and can be measured as an increase of free plasma hemoglobin concentration.~~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.

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

[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.

4. Summary of Practice

4.1 For the experimental evaluation of ~~blood pump designs and materials, an~~ hemolysis caused by pump designs, materials, and operational conditions (see Practice F1841), dynamic *in vitro* hemolysis ~~test is~~tests are recommended using fresh ~~bovine~~animal or ~~porcine~~human blood. The blood donor ~~animals~~ should have ~~normal~~ an afebrile body temperature, no physical signs or symptoms of disease, including diarrhea ~~and~~and/or 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~~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 ~~F1841).~~studies, the practicality of obtaining sufficient quantities of cross-matched donor blood needs to be considered.[3]

~~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* *In vitro* hemolysis test results ~~are~~ for blood pumps may be substantially affected by donor ~~species and~~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 ~~blood usage for~~ whole blood collection and preparation for the dynamic *in vitro* evaluation of blood pumps is essential, and this recommended practice will allow ~~a universal~~an acceptable comparison of test ~~results.~~ results among hemolysis tests involving similar testing methods.

~~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 Bovine, porcine, ovine, and human blood have been used as the primary sources of blood for the *in vitro* dynamic assessment of blood pumps. Drawing several units of whole blood from healthy large animals (e.g. bovine, porcine, ovine) does not affect their health. Therefore, large animal blood is strongly suggested for use in the experimental evaluation of hemolysis in blood pumps. Pooling blood from several donors of a single species is not preferred practice because the mixture may induce added hemolysis, change red cell resistance against trauma, activate platelets, or induce thrombogenesis.

6.2 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.

6.3 Blood ~~will be~~ drawn using a venipuncture technique ~~through~~ should use a large bore needle ~~(14 G or larger)~~ appropriate for the donor species (e.g. 14 G or larger for bovines) into a blood ~~bag~~ collection container which contains ~~anticoagulants~~ a sufficient volume of anticoagulant, such as ~~citrate~~ ACD-A (anticoagulant citrate dextrose solution A, see Appendix X1), CPDA-1 (citrate phosphate dextrose adenine ~~(CPDA-1)~~ anticoagulant ~~solution (see~~solution, see Appendix ~~X1~~X2) or heparin ~~sulfate~~ (see Appendix ~~X2~~X3). The blood is obtained ~~from human volunteers, cattle, or pigs having normal~~either from a large animal (e.g. bovine, porcine, ovine) or human volunteer having afebrile body temperature, no physical signs or symptoms of disease, including ~~diarrhea,~~ diarrhea and/or rhinorrhea, and whose hematological ~~profiles are~~profile is in an acceptable ~~range. No negative pressure in excess of 100 mmHg should be applied during the drawing of the blood. Blood will be collected until the blood bag is full to obtain a total of 450 ± 45 mL of blood and with anticoagulants. A larger bag can also be used.~~normal range (e.g. RBC, WBC, and platelet counts, hematocrit, total hemoglobin concentration). To minimize damage to the blood, a vacuum in excess of -100 mmHg should not be applied during the drawing of the blood.

6.4 ~~The blood should be refrigerated between 2 to 8°C temperature.~~ For blood transportation, the temperature ~~should be also~~ can be maintained with ice packs within the range of 2 to ~~8°C.~~8 °C. If stored, the whole blood can be refrigerated in the range of 2 to 8 °C.

6.5 For *in vitro* dynamic hemolysis testing, blood is generally used within 48 hours of blood draw, including the time for transport. Best consistency may be expected when blood is used within 24 hours; older blood may only provide reliable comparison in paired studies.

6.6 ~~Refrigerated~~ Prior to testing, refrigerated whole blood should be warmed ~~to the physiological temperature,~~ in a suitable container to the appropriate temperature for blood pump testing (see Practice F1841) using a water bath ~~of 37 ± 1°C~~(not to exceed 39 °C) or other appropriate ~~methods.~~method.

[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.