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Standard Practice for Selection of Blood for *in vitro* Evaluation of Blood Pumps[1]

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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, and so forth) (see Practice F1841).

1.2.2 Pulsatile blood pumps (pneumatically driven, electromechanically driven, and so forth).

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.

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

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 *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 F1841).

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.

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[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.

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 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.

6.2 The blood should be refrigerated between 2 to 8°C temperature. For blood transportation, the temperature should be also within the range of 2 to 8°C.

6.3 Refrigerated blood should be warmed to the physiological temperature, using a water bath of 37 ± 1°C or other appropriate methods.

6.4 During warming of the blood, close attention should be given to micro air bubbles, and these air bubbles should be eliminated through the sampling port of the blood bag before starting the *in vitro* evaluation.

6.5 To accomplish the removal of particulate matter, microthrombus, and aggregated platelets during priming of the test circuit, a transfusion kit with a micro filter, 80 μm pore size or less, should be used. As a quality control measure, any blood having free plasma hemoglobin of more than 20 mg/dL should not be used for the test. The inclusion of total blood hemoglobin and hematocrit data are recommended in addition to blood source screening. Proper physiological blood parameters should be maintained prior to and during testing (for example, pH, base excess, glucose concentration).[3]

7. Keywords

7.1 blood trauma; condition of test blood; index of hemolysis; source of blood donor

APPENDIXES

(Nonmandatory Information)

X1. CITRATE PHOSPHATE DEXTROSE ADENINE (CPDA1) SOLUTION USP

X1.1 63 mL CPDA1 solution USP is added for collection of 450 mL blood.

X1.2 Each 63 mL of CPDA1 contains 2 g of dextrose (monohydrate) USP, 1.66 g sodium citrate(dihydrate) USP, 188 mg citric acid (anhydrous) USP, 140 mg monobasic sodium phosphate (monohydrate) USP and 17.3 mg adenine USP. The pH of the solution may be adjusted with sodium hydroxide.

X2. HEPARIN

X2.1 500 mL of blood containing 2000 to 3000 USP units of heparin is utilized.

X3. RATIONALE

X3.1 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.