



Designation: F1830 – 19

Standard Practice for Collection and Preparation of Blood for Dynamic *in vitro* Evaluation of Hemolysis in Blood Pumps¹

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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

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. 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

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.

dynamic *in vitro* evaluation of blood pumps is essential, and this recommended practice will allow an acceptable comparison of test results among hemolysis tests involving similar testing methods.

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 drawn using a venipuncture technique should use a large bore needle appropriate for the donor species (e.g. 14 G or larger for bovines) into a blood collection container which contains a sufficient volume of anticoagulant, such as ACD-A (anticoagulant citrate dextrose solution A, see [Appendix X1](#)), CPDA-1 (citrate phosphate dextrose adenine anticoagulant solution, see [Appendix X2](#)) or heparin (see [Appendix X3](#)). The blood is obtained 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 and/or rhinorrhea, and whose hematological profile is in an acceptable 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 For blood transportation, the temperature can be maintained with ice packs within the range of 2 to 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 Prior to testing, refrigerated whole blood should be warmed in a suitable container to the appropriate temperature for blood pump testing (see Practice [F1841](#)) using a water bath (not to exceed 39 °C) or other appropriate method.

6.7 To remove any particulate matter, microthrombi, and aggregated platelets from the blood prior to priming of the test system, filtration through a plastic mesh or the use of a transfusion kit with a micro filter, 80 µm pore size or less, should be used.

6.8 Air bubbles should be eliminated from the *in vitro* blood pump test loop before starting the evaluation (see Practice [F1841](#)).

6.9 Generally, it is not recommended to use any whole blood having an initial free plasma hemoglobin concentration of more than 50 mg/dL.

6.10 Appropriate physiological blood parameters should be maintained prior to and throughout the testing (e.g., pH, glucose concentration).³ An antibiotic, such as gentamicin, may be used to stabilize blood parameters susceptible to bacterial contamination.³

7. Keywords

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

APPENDIXES

(Nonmandatory Information)

X1. ANTICOAGULANT CITRATE DEXTROSE SOLUTION A (ACD-A)

X1.1 The volume ratio of ACD-A solution to blood is approximately 1:5 to 1:8. For example, 150 mL ACD-A solution can be added to 850 mL of blood.

X1.2 Each 100 mL of ACD-A solution contains 2.45 g of

dextrose (monohydrate) USP, 2.2 g sodium citrate (dihydrate) USP, and 730 mg citric acid (anhydrous) USP. The pH of the solution may be adjusted with sodium hydroxide.