Designation: F 2382 – 04

Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time (PTT)[1]

This standard is issued under the fixed designation F 2382; 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 test method covers the screening of cardiovascular device materials for their ability to induce blood coagulation. This assay should be part of the hemocompatibility evaluation for devices and materials contacting human blood.

1.2 All safety policies and practices shall be observed during the performance of this test method.

1.3 All plasma and any materials that had contact with plasma will be bagged in a biohazard bag, properly labeled with the contents, and disposed by appropriate means. The plasma should be handled at the Biosafety Level 2 as recommended in the Centers for Disease Control/National Institutes of Health Manual Biosafety in Microbiological Laboratories.

1.4 The normal pooled human plasma must have tested negative for Hepatitis B (HBV) or Human Immunodeficiency (HIV) viruses. The plasmas should be treated like any patient plasma using universal precautions. The plasma should be handled at the Biosafety Level 2 as recommended in the Centers for Disease Control/National Institutes of Health Manual Biosafety in Microbiological Laboratories.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ANSI Standard:*

ANSI/AAMI/ISO 10993-4 Biological Evaluation of Medical Devices—Part 4: Selection of Tests for Interactions with Blood[2]

2.2 *Other Document:*

Centers for Disease Control/National Institutes of Health Manual Biosafety in Microbiological Laboratories, 1999[3]

3. Terminology

3.1 *Definitions:*

3.1.1 *activator*—a medical material which demonstrates a shortened clotting time; an initiator of the intrinsic coagulation pathway.

3.1.2 *partial thromboplastin time (PTT) assay*—a modification of the Activated Partial Thromboplastin Time (APTT) assay; unlike the APTT test, the PTT assay uses reagent (rabbit brain cephalin) without activating substances (silica, kaolin, elagic acid.) The material being tested acts as the activator.

3.1.3 *read time*—the time during which data is collected to detect a clot.

3.1.4 *blank time*—a period at the beginning of an assay when no data is taken. This is done to eliminate interference from premixing reagents, bubbles, and so forth.

3.1.5 *equilibration time*—the time allowed for the plasma samples to warm to 37°C. The fibrometer can be set to zero if samples are pre-warmed to this temperature.

3.1.6 *duplicate flag*—the agreement between the results of duplicate samples in percent. For example, if set to “15,” the difference between the two channels must be less than or equal to 15 %. If the variance in clot times exceeds this percentage, an asterisk “*” will be printed by the average results on the report.

4. Significance and Use

4.1 The purpose of this test method is to determine the time citrated plasma exposed to medical materials takes to form a clot when exposed to a suspension of phospholipid particles and calcium chloride. In this test method, the test article is the activator. The PTT assay is a general screening test for medical material’s ability to activate the intrinsic coagulation pathway. Material samples that show a shortened PTT are activators of the intrinsic coagulation pathway.

4.2 In this test method, the test sample is the activator. Test samples that show a shortened PTT are activators of the

[1] This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.16 on Biocompatibility Test Methods.

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[2] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

[3] Available from National Institute of Health (NIH), 9000 Rockville Pike, Bethesda, MD 20892.