



Standard Practice for Testing for Classical Pathway Complement Activation in Serum by Solid Materials¹

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1. Scope

1.1 This practice provides a protocol for rapid, *in vitro* functional screening for classical pathway complement activating properties of solid materials used in the fabrication of medical devices that will contact blood.

1.2 This practice is intended to evaluate the acute *in vitro* classical pathway complement activating properties of solid materials intended for use in contact with blood. For this practice, “serum” is synonymous with “complement.”

1.3 This practice consists of two procedural parts. Procedure A describes exposure of solid materials to a standard lot of human serum [HS], using 0.1 mL serum per 13×100 mm disposable glass test tube. Procedure B describes assaying the exposed serum for significant functional classical pathway complement depletion (decrease in amount of C4) as compared to control serum samples not exposed to the material. The endpoint in Procedure B is lysis of sheep red blood cells (RBC) coated with antibody (hemolysin).

1.4 This practice does not address the use of plasma as a source of complement.

1.5 This practice is one of several developed for the assessment of the biocompatibility of materials. Practice F748 may provide guidance for the selection of appropriate methods for testing materials for other aspects of biocompatibility. Practice F1984 provides guidance for testing solid materials for whole complement activation in human serum, but does not discriminate between the classical or alternative pathway of activation. Practice F2065 provides guidance for testing solid materials for alternative pathway complement activation in serum.

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

1.7 *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 *ASTM Standards:*²

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

F1984 Practice for Testing for Whole Complement Activation in Serum by Solid Materials

F2065 Practice for Testing for Alternative Pathway Complement Activation in Serum by Solid Materials

2.2 *Other Document:*

ISO 10993-4 Biological Evaluation of Medical Devices, Part 4: Selection of Tests for Interactions with Blood³

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *water*—distilled, endotoxin-free.

3.2 *Abbreviations:*

3.2.1 *Ab*—antibody (hemolysin)

3.2.2 *BBS*—barbital buffered saline

3.2.3 *BBS-G*—barbital buffered saline–gelatin

3.2.4 *BBS-GM (Ca Buffer)*—barbital buffered saline–gelatin metals

3.2.5 *C'*—complement

3.2.6 *C4*—the fourth component of complement

3.2.7 *C4(-)GPS*—C4-deficient guinea pig serum [serum from guinea pigs genetically incapable of producing C4]

3.2.8 *EDTA*—ethylenediaminetetraacetic acid, disodium salt, dihydrate

3.2.9 *HAGG*—heat aggregated gamma globulin

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 F04.16 on Biocompatibility Test Methods.

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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 Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.