



Standard Practice for Assessment of White Blood Cell Morphology After Contact with Materials¹

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1. Scope

1.1 This practice provides a protocol for the assessment of the effect of materials used in the fabrication of medical devices, that will contact blood, on the morphology of white blood cells.

1.2 This practice is intended to evaluate the acute *in vitro* effects of materials intended for use in contact with blood.

1.3 This practice uses direct contact of the material with blood, and extracts of the material are not used.

1.4 This practice is one of several developed for the assessment of the biocompatibility of materials. Practice F 748 provides general guidance for the selection of appropriate methods for testing materials for a specific application.

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.*

1.6 *Identification of a supplier of materials or reagents is for the convenience of the user and does not imply single source. Appropriate materials and reagents may be obtained from many commercial supply houses.*

2. Referenced Documents

2.1 ASTM Standards:

F 619 Practice For Extraction Of Medical Plastics²

F 748 Practice For Selecting Generic Biological Test Methods For Materials And Devices²

F 756 Practice for Assessment of Hemolytic Properties of Materials²

3. Terminology

3.1 Definitions:

3.1.1 *control material, n*—a material such as low density polyethylene (LDPE) which is expected to have minimal effect on the morphology of white blood cells.

3.1.2 *nuclear damage, n*—for the white blood cell morphology test, this term is used to describe the nucleus of a white blood cell appears to be condensed, fragmented or lysed; for the White Blood Cell Morphology Test. This includes nuclear damage that might be classified as karyolysis, karyorrhexis, pyknosis, or simply necrosis.

3.1.3 *positive control material, n*—a material such as latex (gloves, dental dam, or tubing) or TSV, tin-stabilized vinyl (slab), which is expected to have an adverse effect on the morphology of white blood cells.

3.2 Abbreviations:

3.2.1 *B*—basophil

3.2.2 *BR*—broken or lysed

3.2.3 *E*—eosinophil

3.2.4 *INDNM*—indistinct nuclear membrane: a degenerative change of the nucleus; for the White Blood Cell Morphology Test, this term is used to describe a nuclear membrane that is rough, ragged, or torn

3.2.5 *L*—lymphocyte

3.2.6 *M*—monocyte

3.2.7 *N*—neutrophil

3.2.8 *UNID*—unidentified

4. Summary of Practice

4.1 Test and control material specimens are exposed to contact with canine blood under defined static conditions and the effect on blood cell morphology is determined. The use of human blood is permissible if the laboratory is knowledgeable of precautions needed to handle human blood. If a source of blood other than canine or human is used, consideration should be given to the differences in hematologic values and morphology differences between that species and humans.

5. Significance and Use

5.1 The presence of material in contact with the blood may cause damage to white blood cells resulting in changes in function of these cells or changes in properties of the blood.

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 *Annual Book of ASTM Standards*, Vol 13.01.