



Standard Practice for Assessment of Tissue and Cell Compatibility of Orofacial Prosthetic Materials and Devices¹

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1. Scope

1.1 This practice describes a procedure to assess the cytotoxic potential of materials for use in the construction of medical materials and devices using human excised donor (HED) tissues and their derived primary cells taken from the orofacial region.

1.2 This practice may be used either directly to evaluate materials or as a reference against which other cytotoxicity methods may be compared.

1.3 This practice is one of a series of reference methods for assessment of cytotoxic potential, employing different techniques.

1.4 Assessment of cytotoxicity is one of several procedures employed in determining the biological response to a material, as recommended in Practice [F748](#).

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

1.6 *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

[D883 Terminology Relating to Plastics](#)

[F604 Specification for Silicone Elastomers Used in Medical Applications](#) (Withdrawn 2001)³

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 The last approved version of this historical standard is referenced on www.astm.org.

[F703 Specification for Implantable Breast Prostheses](#)

[F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices](#)

[F813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices](#)

3. Terminology

3.1 Nomenclature relating to the physical, mechanical, and chemical characteristics of plastics shall be in accordance with Terminology [D883](#).

3.2 The nomenclature and glossary of terms related to tissue culturing shall conform to that of the Tissue Culture Association ([1](#)).⁴

3.3 For other definitions used in this practice, see [Annex A1](#).

4. Summary of Practice

4.1 Primary human orofacial tissue or cells and established human cell lines are cultured in Medium A3 or any medium supporting primary cell growth with homologous processed human serum or serum components in cell culture flasks or appropriate containers. The following series of cultures is set up:

4.1.1 Test material placed in contact with the cell layer.

NOTE 1—One or more replicates of [4.1.1](#) may be necessary.

4.1.2 Primary control wherein no material contacts the cell layer.

4.1.3 Positive control wherein the cell layer is contacted by a material eliciting a known cytotoxic response, such as a toxic chemical published in the Toxic Substances List ([2](#)).

4.1.4 Negative control wherein the cell layer is contacted by polystyrene used in tissue culture labware.

4.2 The test culture shall be observed daily for growth and signs of toxicity. The test shall be terminated upon the attainment of confluency.

NOTE 2—For an established cell line cultured with Holmes alpha growth factor (AGF), confluency is usually achieved in slightly more than 5 days.

NOTE 3—For first passage cells from human excised donor (HED)

⁴ The boldface numbers in parentheses refer to the list of references at the end of this practice.