



Designation: F 813 – 83 (Reapproved 1996)^{ε1}

Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices¹

This standard is issued under the fixed designation F 813; 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.

^{ε1} NOTE—Footnote 4 was corrected editorially December 1996.

1. Scope

1.1 This practice covers a reference method of direct contact cell culture testing which may be used in evaluating the cytotoxic potential of materials for use in the construction of medical materials and devices.

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

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

1.4 Assessment of cytotoxicity is one of several tests employed in determining the biological response to a material, as recommended in Practice F 748.

1.5 The L-929 cell line was chosen because it has a significant history of use in assays of this type. This is not intended to imply that its use is preferred; only that the L-929 is an established cell line, well-characterized and readily available, that has demonstrated reproducible results in several laboratories.

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:

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices²

2.2 Other Documents:

The American Type Culture Collection (ATCC), Catalogue of Strains II³

¹ This practice is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.16 on Biocompatibility Test Methods.

Current edition approved April 29, 1983. Published June 1983.

² *Annual Book of ASTM Standards*, Vol 13.01.

³ American Type Culture Collection, 12031 Parklawn Drive, Rockville, MD 10852.

USP Negative Control Plastic Reference Standard⁴

3. Summary of Practice

3.1 Cell cultures are grown to a confluent monolayer in Petri dishes. The growth medium is aspirated and replenished to provide a resting, confluent cell layer. Test and control specimens are placed in direct contact with the cell layer to provide an accelerated assessment of the presence or absence of a cytotoxic effect from a given material or device.

4. Significance and Use

4.1 This practice is useful for assessing cytotoxic potential both when evaluating new materials or formulations for possible use in medical applications, and as part of a quality control program for established medical materials and medical devices.

4.2 This practice assumes that assessment of cytotoxicity potential provides one method for predicting the potential for cytotoxic or necrotic reactions to medical materials and devices during clinical applications to humans. In general, cell culture testing methods have shown good correlation with animal assays and are frequently more sensitive to toxic moieties.

4.3 This cell culture test method is suitable for adoption in specifications and standards for materials for use in the construction of medical devices that are intended to be implanted in the human body or placed in contact with tissue, tissue fluids, or blood on a long-term basis.

5. Apparatus

5.1 The following apparatus shall be used:

5.2 *Incubator*, to maintain $37 \pm 2^\circ\text{C}$ and 4 to 6 % CO_2 with greater than 90 % relative humidity.

5.3 *Tissue Culture Grade Petri Dishes*, that are sterile and 35 mm in diameter by 10 mm deep.

NOTE 1—Plastic dishes are recommended because they provide a flat surface that contributes to the formation of a uniform cell monolayer.

5.4 *Disposable, Sterile, Centrifuge Tubes*.

5.5 *Inverted Optical Microscope*, with magnifications of 40×, 100×, and 200×.

⁴ *U.S. Pharmacopeia*, Vol 23, Rand McNally, Taunton, MA, 1994, pp. 1652–1653. Use latest supplement to ensure current cumulative revisions are used.