

Corning Incorporated - Life Sciences
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Refer to website for regional contact information.

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Product Name	: Plate 4 Well TC IVF MEA Tested		
Catalog Number	: 353654	Manufacture Date	: 2014-09-19
Lot ID	: 4250048		
Expiration Date	: 2018-08-28		

Quality Management System - Complies to the current version of the EN ISO 9001 Standard, the EN ISO 13485 Standard, the Medical Device Directive (MDD) 93/42/EEC as amended with 2007/47/EEC, and the FDA CFR 21 Part 820.

Cytotoxicity - Testing has been conducted to qualify all material resins per USP Class VI, "Requirements for plastic containers and closures", and shown to be non-cytotoxic. Product has been tested and shown to be non-cytotoxic per the requirements of ISO 10993-5, "Biological evaluation of medical devices - Tests for in vitro cytotoxicity".

Embryotoxicity - Each lot has been tested for embryotoxicity using the mouse 1-cell embryotoxicity assay. At least 75% of both test and control embryos must reach the hatched and/or expanded blastocyst stage in order for test product to be deemed non-embryotoxic and acceptable for product release.

Sterilization - Product has been sterilized and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137, "Sterilization of health care products - Radiation". Products meet a minimum Sterility Assurance Level (SAL) of 10^{-6} .

Non-Pyrogenic - Each lot has been tested and meets the criteria established in the current version of United States Pharmacopeia (USP) Chapter <85>, "Bacterial Endotoxins Test". The acceptance level for product is less than 0.1 EU/mL or 5 EU/device.

Tissue Culture - Each lot has been subjected to an actual performance test for growth with a mammalian cell line. Cells are plated to be confluent within 72 hours. A minimum of 90% confluency is required for lot acceptance.

Quality Control Testing - Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release.

- This product met Corning Incorporated - Life Sciences' high standards of quality at the time of batch/lot release.



Tara Rogers
Quality Manager