

**Corning Incorporated
Life Sciences**

Registered
ISO 9001:2008

Product Description

Catalog Number: 4520

Product Description: Corning® Spheroid Microplate, 96-well, black clear round bottom, ultra low attachment, with Lid

Component Materials:

- Plate walls - Medium Impact Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures. Black concentrate.
- Plate bottom - Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
- Lid - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
- Surface - Proprietary hydrogel.

Product Dimensions:

- | | | | | | |
|--------------------------|---|------------------|------------------------|---|-----------|
| Length of Plate | - | 5.034 in. | Diameter @ top of well | - | 0.270 in. |
| Width of Plate | - | 3.365 in. | Well bottom radius | - | 0.100 in. |
| Depth of Well | - | .492 in. | Well bottom elevation | - | 0.073 in. |
| Tolerances of Dimensions | - | +/- .010 in. | Height with Lid | - | 0.650 in. |
| Working Volume per well | - | 0.075 to 0.30 mL | | | |

Sterilization:

This lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization*.
Sterility Assurance Level: SAL 10⁻³

Pyrogens:

The product has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72:2002/ (R)2010 *Bacterial Endotoxins - Test methodologies, routine monitoring, and alternative to batch testing*. *Results: ≤ 0.1 EU/mL (≤ 4EU/device)*

Optical Characteristics:

The product is made of opaque black polystyrene walls to minimize well-to-well crosstalk and background fluorescence. The bottom is made of clear thin polystyrene to permit direct microscopic viewing.

Surface Characterization:

Surface is characterized to be hydrophilic and neutrally charged, composed of a covalently bound hydrogel layer that is biologically inert and non-degradable. This surface composition has been optimized for cell attachment inhibition.

Cell Spheroid Growth Characteristics:

This product has been tested for the attribute of cell spheroid growth using a tumor cell line in serum supplemented media. Cell spheroid formation must be observed in ≥ 95% of the wells in a plate

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product is manufactured with animal free materials.

Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Cell Spheroid Formation:

Verification of cell spheroid formation.

Visual Attributes:

Visual and microscopic examination of the product.

Packaging:

Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.

Lot Number Designation:

8 Digit Lot Number: First 3 digits - Julian date, start of manufacturing; Next 2 digits - Year of manufacture; Last 3 digits - Batch identification.

Rev No: 2