

Corning Incorporated Life Sciences

Registered
ISO 9001:2008

Product Description

Catalog Number: 3832BC

Product Description: Corning® 1536-well, Corning® CellBIND® surface, black plate with clear flat bottom, mid web, low base, with lid, with barcode labels

Component Materials:

- Plate walls - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures. Black concentrate
- Plate bottom - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
- Lid - Virgin Polystyrene, meets *USP, Class VI* requirements for plastic containers and closures.
- Barcode Label - White Polypropylene base, acrylic adhesive

Special Feature:

Barcode Label (format 128) on A1 short side & A1 long side and H12 short side & H12 long side

Product Dimensions:

Length of Plate	-	5.030 in.	Width of Square Well @ Top	-	.070 in.
Width of Plate	-	3.365 in.	Width of Square Well @ Bottom	-	.059 in.
Depth of Well	-	.332 in.	Height with Lid	-	.050 in.
Tolerances of Dimensions	-	+/- .010 in.	Working Volume per well	-	5 µL to 15 µL

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)

Surface Characterization:

Surface is characterized to be hydrophilic and negatively charged, composed of ≥ 20% oxygen atoms. This surface composition has been optimized for cell attachment and growth.

Cell Attachment and Growth Characteristics:

The product has been tested for the attribute of cell attachment and growth utilizing an attachment-dependent mammalian cell line in a serum supplemented media.

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product complies with the latest revision of EMEA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicine products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

Optical Characteristics:

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

Performance Testing:

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

Visual Attributes:

Visual examination of the product.

Packaging:

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

Opacity:

Visual, using a fluorescent compound.

Cell Culture Treatment:

Wettability test using water to insure the presence of a hydrophilic surface.

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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: 3