

**Corning Incorporated
Life Sciences**

Registered
ISO 9001:2008

Product Description

Catalog Number: 4573

Product Description: Corning® 1536-well, Corning® CellBIND® surface, solid white plate, flat bottom, without lid, with barcode labels

Component Materials:

- Plate - Cyclic Olefin Co-polymer, meets *USP, Class VI* requirements for plastic containers and closures. White cyclic olefin co-polymer concentrate
- Barcode Label: - White polypropylene base, acrylic adhesive

Product Dimensions:

- | | | | | | |
|-------------------------------------|---|------------------------|----------------------------|---|--------------|
| Length of Plate | - | 5.030 in. | Width of Square Well @ Top | - | .067 in. |
| Tolerances of Dimensions for Length | - | + .010 in. / -.015 in. | Width of Plate | - | 3.365 in. |
| Width of Square Well @ Bottom | - | 0.60 in. | Depth of Well | - | .195 in. |
| Height without Lid | - | .409 in. | Tolerances of Dimensions | - | +/- .010 in. |
| Working Volume | - | 8µL | Maximum well volume | - | 13µL |

Special Feature:

Barcode Label (format 128) on A1 longside and H12 longside

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.

Optical Characteristics:

The product is made of opaque white cyclic olefin co-polymer walls to minimize well to well crosstalk and background fluorescence and /or luminescence.

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.

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.
- 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: 2

DOMINIQUE DUTSCHER SAS