Corning Incorporated Life Sciences

Registered ISO 9001:2008 **Product Description**

Catalog Number:		4596						
Product Description:		Corning ® 384-well, black with clear bottom plate, low flange, fibronectin coated, with lid						
Component Materials	:							
Plate walls	-	Medium Impact 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.						
Fibronectin	-	Human Plasma						
Product Dimensions:								
Length of Plate	-	5.030 in.	Width of Square Well@ Top	-	.143 in.			
Width of Plate	-	3.365 in.	Width of Square Well @ Bottom	-	.111 in.			
Depth of Well	-	.455 in.	Height with lid	-	.660 in.			
Tolerances of Dimension Dimensions	ons -	+/010 in.	Working volume per well	-	20 μL to 75 μL			

Non-Pyrogenic - Tested and met the criteria established in the current version of ANSI/AAMI ST 72, "Bacterial Endotoxins – Test methodologies, routine monitoring, and alternatives to batch testing". The acceptance level for product is ≤ 0.5 EU/mL or ≤ 20 EU/device.

Tissue Culture - Tested for the attribute of cell attachment and growth utilizing an attachment-dependent mammalian cell line. A minimum of 2 times the growth as compared to a non-coated control plate is required for acceptance.

Bioburden - Tested for Bioburden contamination. Contamination of < .52% of the wells is required for acceptance.

Optical Characteristics - 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.

Fibronectin Testing - Fibronectin used for coating is purified from human donor plasma. Tested negative for HBsAg, HIV-1, HIV-2 and HCV antibodies.

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. Key inspections and inline tests are listed below:

Visual Inspection	-	Pass		
Packaging Inspection	-	Pass		
Cell Attachment & Growth	Treatme	ent Verification	-	Pass

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

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: 1