

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

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<b>Product Name</b> : Plate 384w 120ul TCBlkClr wlid 50cs	
<b>Catalog Number</b> : 353962	<b>Manufacture Date</b> : 2019-11-05
<b>Lot ID</b> : E19093U8	
<b>Expiration Date</b> : 2023-09-05	

**Quality Management System** - Complies with the current version of the ISO 9001 Standard.

**Non-Pyrogenic** - Validated per FDA guidelines on Pyrogen and Endotoxins testing. The acceptance level for product is  $\leq 0.03$  EU/ml.

**USP Class VI Testing** - All material resin is tested, qualified and shown to be non-toxic as established in the Standards USP Class VI Chapter<87>, "Biological reactivity Tests, in Vitro" and Chapter<88>, "Biological Reactivity Tests, in vivo".

**Tissue Culture** - Tested for the ability to promote cell attachment and proliferation of mammalian cells. The intra-plate CV  $\leq 10\%$  for acceptance.

**Human DNA Free** - Tested by PCR method and found to be free of detectable human DNA contamination. The assay detection limit is hDNA 5pg.

**DNase/RNase Free** - Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is  $1.3 \times 10^{-8}$  Kunitz units/ul for DNase and  $5.0 \times 10^{-11}$  Kunitz units/ul for RNase.

**Sterility** - 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  $10^{-3}$ .

**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.



ANDREW J (ANDY) FRANKS  
CMO Quality Manager