

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

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Product Name	: PLATE,96 WELL,ASSAY BLOCK, 1ml,STANDARD,STERILE		
Catalog Number	: 3958	Manufacture Date	: 2024-11-22
Lot ID	: 32724000		
Expiration Date	: 2027-11-22		

Quality Management System - Complies with the current version of the EN ISO 13485 Standard.

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" and USP <85>, "Bacterial Endotoxins Test". The acceptance level for product is ≤ 0.05 EU/ml or ≤ 2 EU/device.

DNase/RNase Free - Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10^{-7} Kunitz units/uL for DNase and 10^{-9} Kunitz units/uL for RNase.

PCR Inhibition - Tested with real time Polymerase Chain Reaction and found no inhibition of real time PCR with a Ct comparison of ≤ 5 XCTPosCtrl-Ct.

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".

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

Sterilization - 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^{-6} .

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.



Anthony Sloan
Quality Manager