

Corning Incorporated - Life Sciences  
6507 South 400 West  
Salt Lake City UT 84107 USA  
www.corning.com/lifesciences  
Refer to website for regional contact information.

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<b>Product Name</b>	: PLT,96W,ASSAY BLOCK,2ml,STANDARD FOOTPRINT,STERILE		
<b>Catalog Number</b>	: 3960	<b>Manufacture Date</b>	: 2025-01-02
<b>Lot ID</b>	: 00225000		
<b>Expiration Date</b>	: 2028-01-02		

**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  $\leq 0.05$  EU/ml or  $\leq 2$  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  $\leq 5$  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