Certificate of Analysis

TTQ12140
IT-101578

96 well Tissue Culture Plates

Catalog Number: PC396-0100
Batch Number: 2020001
Expiry Date: 2023-02

Sterilization

Product labeled as sterile is irradiated and dosimetrically released upon ISO11137 recommended practices in effect at the time of validation. Sterilization records are reviewed and signed off by qualified personnel for product release. GeneDireX, Inc. products labeled sterile meet a minimum requirement of 10^{-6} SAL (Sterility Assurance Level).

Tissue Culture Treated

Products labeled tissue culture treated are taken some samples random from total Lot as representative sample for actual performance test for growth with Hep-g2 (human Hepatic carcinoma cells). Cells are plated to be confluent within 72 hours. Not less than 90% covering is required for lot acceptance.

Non-Pyrogenic

Products labeled non-pyrogenic have been validated per FDA guidelines on LAL (Limulus Amebocyte Lysate) testing for medical devices and Company guidelines. The acceptance level for product is less than 0.5 EU/mL.

DNase & RNase Free

This product has been tested and is free of any detectable DNase / RNase contamination, and free of heavy metal detection.

Cytotoxicity

Testing is conducted to qualify all material resins using USP and ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.

Quality Control Testing

Products are Inspected and controlled through whole production processing in accordance with current applicable product specifications and QC SOP. Inspection records are reviewed and signed off by qualified personnel for product release.