

75T flask VENT

Catalog Number: PC275-0100

Batch Number: 2020001

Expiry Date: 2023-03-31

Materials:

Virgin Polystyrene, meets USP, Class VI requirements for plastic containers.

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).

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.

Cell Attachment and Growth Characteristics:

The product has been tested for the attribute of Cell Attachment and Growth utilizing an attachment dependent mammalian cell line in a serum supplemented media, Attachment and Growth Performance.

RNase/DNase Free:

Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination.

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:

Test:	Results
Visual Attributes:	Pass
Hydrophilic Test	Pass
Leak Test:	Pass