



Certificate of Analysis

Product: DeNoody® Tips

Lot Number: 102024

Manufacturer Code: 0655

Expiration Date: 2027-03

Sterilization:

Product gamma radiated at a minimum to meet Sterility Assurance Level (SAL) 10^{-6} monitored by review of dosimetry report for dose range and quarterly dose audit testing.

Toxicity Testing (1-Cell MEA):

The percent of embryos developing to the blastocyst stage were assessed at 96 hours. The MEA is considered acceptable if 80% or more of the embryos exposed to the product reach the blastocyst stage.

Control	95%
Product	95%

Endotoxin Testing:

Testing is performed using the Limulus Ambocyte Lysate (LAL) test with units per device less than 20 to be considered acceptable.

Results:

<0.00500 Endotoxin Units (EU) per device.