



Certificate of Quality

KATALOGUE NUMBER:

LOT NUMBER:

Single Tray Tip Pre-Sterilized 10 – 10 000 µl

All tips manufactured by ULPLAST

This certifies that this product is manufactured with the highest quality and purity criteria. The product is certified to be DNase, RNase and endotoxin free. The product is tested by an independent laboratory.

Endotoxins

Analysis and test method used:

Sample preparation was carried out according to FDA guidelines for medical devices by extracting the pipette tips cut into pieces for 1 hour at 37 °C with an optimised volume of pyrogen-free water. Endotoxins in the extractions were detected with LAL gel clot method according to Ph. Eur.5, 2.6.14, Method A, which is based on clotting of the Limulus amoebocyte lysate in the presence of bacterial endotoxins. Validated test result for Endotoxin-free pipette tips is < 0.03 IU/ml (EU/ml).

RNase

Analysis and test method used:

The tips were pipetted up and down in an optimised volume of pure water using maximal pipette tip capacity. RNase activity in the extraction was measured with fluorometric assay by detecting degradation of labeled RNase substrate. RNase-free pipette tips show no evidence of RNase activity in the assay with the detection level of $< 3,125 \cdot 10^{-9}$ U/µl when RNase A was used as a standard.

DNase

Analysis and test method used:

The tips were pipetted up and down in an optimised volume of pure water using maximal pipette tip capacity. DNase activity in the extraction was measured with fluorometric assay by detecting degradation of labeled DNase substrate. DNase-free pipette tips show no evidence of DNase activity in the assay with the detection level of $< 6,25 \cdot 10^{-5}$ U/µl when DNase I was used as a standard.



Approved By:

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