

Certificate of Sterilization-Inspection for DNA, DNase, RNase and Endotoxins

Gilson Sterilized Diamond® Tips

The manufacturing and sterilization processes Gilson follows are certified to produce sterilized Diamond® Tips **free of detectable DNA, DNase, RNase and Endotoxins**. An independent accredited laboratory [NF EN ISO/CEI 17025 (COFRAC)] periodically audits these parameters.

Certificate of Sterilization

The manufacturing lot of tips listed below has been Gamma irradiated. The Bioburden analysis is carried out quarterly on a sample of tips drawn from current production in order to ensure a SAL of 10^{-6} (ISO 11137).

Bio-molecule detection protocols

For all tests, disposable tips are rinsed with sterile DNase-RNase free water called « liquid extract ». Negative controls, positive and extract controls are made to validate all steps of the different assays.

DNA detection < 5pg

Six products are rinsed 20 times with sterile DNase-RNase free water. Then, liquid extract (10 µL) is exposed to PCR reaction reagents containing specific primers of human DNA. Amplicons are obtained after 35 cycles of amplification, and are analysed by electrophoresis on a 1% agarose gel containing ethidium bromide. Positive controls (6 known amounts of genomic human DNA: 50ng, 10ng, 500pg, 50pg, 10pg and 5pg) and a negative control (10 µL of DNase-RNase free water) are included in the assay.

Endotoxin Detection

Gilson sterilized Diamond Tips certified non-pyrogenic have been tested for bacterial endotoxins. Samples selected at random were tested and validated using the LAL kinetic chromogenic method D with < 0.05EU/mL sensitivity. *European Pharmacopoeia section 2.6.14 methodology for bacterial endotoxin testing.*

DNase detection < 31.25 10⁻⁶ Kunits Units

Six products are rinsed 20 times with sterile DNase-RNase free water. 10 µL of liquid extract are incubated 10 minutes at room temperature (20-21°C) with variable concentrations of DNA ladder (10ng, 50ng and 100ng). Positive controls (10ng, 50ng and 100ng of DNA ladder) are incubated, in the same conditions, with 31.25 10⁻⁶ Kunits Units of DNase I. Positive and negative controls (10 µL of DNase-RNase free water) are included in each test. Samples are analysed by electrophoresis (1% agarose gel containing ethidium bromide). The intensity of samples' signals is compared with negative and positive controls. The degradation of DNA ladder indicates the presence of DNase in the liquid extract.

RNase detection < 35 10⁻⁶ Kunits Units

Six products are rinsed 20 times with sterile DNase-RNase free water. 10 µL of liquid extract are incubated 10 minutes at 25°C with 350ng of RNA ladder. Positive control (350ng of RNA ladder) are incubated, in the same conditions, with 35 10⁻⁶ Kunits Units of RNase. Positive and negative controls (10 µL of DNase-RNase free water) are included in each test.

Samples are analysed by electrophoresis (1.5% agarose gel ethidium bromide). The intensity of samples' signals is compared with negative and positive controls. The degradation of RNA ladder indicates the presence of RNase in the liquid extract.

Product Designation: DF200ST	Catalog Number: F161100	Lot Number: KEB5/01674	⌚ : 05/2012
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