Certificate of Conformity

PIPETMAN® DIAMOND Filter Tips
Contaminant Free Certified

This package contains a high-quality consumable manufactured in a controlled environment following ISO 14644-1. This lot is certified by validation of the manufacturing process following the requirements defined in ISO 18385.

The products are free of the following contaminants:

- Human DNA
- Bacterial DNA
- RNA
- ATP
- DNase
- RNase
- PCR inhibitors
- Endotoxins
- Protein

This lot of tips has been Gamma irradiated for sterilization. The protocol analysis for validation of the sterilization process to ensure a Sterility Assurance Level (SAL) of 10^{-6} has been carried out following ISO 11137-2 for establishing the sterilization dosage.

Quality control and subsequent certification is done by independent, accredited laboratories (NF EN ISO/CEI 17025 - COFRAC).

FORENSIC GRADE ISO 18385

Product certified ISO 18385
Company certified ISO 9001 and ISO 13485

ISO 9001 BUREAU VERITAS Certification

ISO 13485 BUREAU VERITAS Certification

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The certification comprises the following tests:

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.

Human DNA detection < 2 pg
Preparation of sample with sterile and pyrogen free water. Extraction of DNA with a commercial kit. An aliquot of liquid extract is exposed to PCR reaction reagents containing primers (to amplify the β-actin housekeeping gene). A range of human DNA (2, 5, 10, 20 and 50 pg) is also amplified and used as positive control. Amplicons are obtained after cycles of amplification, analyzed by electrophoresis on a 2% agarose gel into TBE 0,5X buffer. No DNA have to be detected in the sample.

Bacterial DNA < 2 pg
Preparation of sample with sterile and pyrogen free water. Extraction of DNA with a commercial kit. An aliquot of liquid extract is exposed to PCR reaction reagents containing primer (to amplify RNA 16s gene).
A range of bacterial DNA (2, 5, 10, 20 and 50 pg) is also amplified and used as positive control. Amplicons are obtained after cycles of amplification, analyzed by electrophoresis on a 2% agarose gel into TBE 0,5X buffer. No DNA have to be detected in the sample.

RNA detection < 1 pg
Preparation of sample with sterile and pyrogen free water. Extraction, purification and RNA concentration are performing with a kit, and RNA converted to cDNA with an other kit, procedure recommended by the manufacturer. The cDNA is exposed to PCR reaction reagents containing primers (to amplify the β-actin housekeeping gene). A range of human RNA (1, 2, 4, 8 and 16 pg) is also amplified and used as positive control. Amplicons are obtained after cycles of amplification, analyzed by electrophoresis on a 2% agarose gel into TBE 0,5X buffer. No RNA have to be detected in the sample.

Endotoxin Detection < 0,005 EU/mL
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 < 0.005 EU/mL sensitivity. European Pharmacopoeia section 2.6.14 methodology for bacterial endotoxin testing.

DNase detection < 12,5 pg
Preparation of sample with sterile and pyrogen free water. 10 µL of liquid extract are incubated 2 hours at 37°C with variable concentrations of 1Kb plus DNA ladder (0, 10, 50 and 100 ng). Positive controls (0, 10, 50 and 100 ng of DNA + DNase I: 12,5 pg) and negative controls (0, 10, 50 and 100 ng of DNA) are incubated in the same conditions. Samples are analyzed by electrophoresis (2% agarose gel into TBE 0,5X buffer). The intensity of samples signals is compared with negative and positive controls. The degradation of DNA indicates the presence of DNase in the liquid extract. No degradation have to be observed, the intensity of negative control and the sample have to be identically.

RNase detection < 0,25 ng
Preparation of sample with sterile and pyrogen free water. 10 µL of liquid extract are incubated 10' at room temperature (20-25°C) with 350 ng of RNA (0,1 – 2Kb RNA ladder). Positive control (350 ng of RNA + 0,25 ng of RNase A) and negative control (350 ng of RNA) are incubated in the same conditions. Samples are analyzed by electrophoresis (2% agarose gel into TBE 0,5X buffer). The intensity of samples signals is compared with negative and positive controls. The degradation of RNA indicates the presence of RNase in the liquid extract. No degradation have to be observed, the intensity of negative control and the sample have to be identically.

ATP detection < 1.10^{-18} mol/L
Preparation of sample with sterile and ATP free water. Evaluation of ATP by luminescence (enzymatic reaction of luciferase - commercial kit). The intensity of the samples signals is compared with a negative control (DNase-RNase free water) and with ATP standards curve. The intensity of samples signals is compared with negative and positive controls curve. No ATP have to be detected.

Protein detection < 2 µg/mL
Preparation of sample with sterile and pyrogen free water. 150 µL of liquid extract are tested for the detection of proteins by absorption measurements (commercial kit). Positive control is a standard range supply by the kit, the negative control is sterile and pyrogen free water. Analysis are performed by absorbance reading at the plate reader. The intensity of samples signals is compared with negative and positive controls curve.
No protein have to be detected.

Inhibitors of PCR detection
Preparation of sample with sterile and pyrogen free water. Add of 50 pg of control genomic DNA for each sample. Amplification by PCR. Positive control is 50 ng of genomic DNA and an inhibitor standard (e.g. ethanol 0.25%, 0.50%, 1%, 2%, 5%), negative control is sterile and pyrogen free water. A DNA fragment with the same size of amplicon have to be detected.