Eppendorf Certificate

Certificate of Purity – Eppendorf Forensic DNA Grade according to ISO 18385

This package contains a high-quality consumable manufactured under the "Forensic DNA Grade according to ISO 18385" Eppendorf Purity Standard.
The ISO 18385 Forensic DNA Grade consumables are produced in a controlled environment according to ISO class 8 of ISO 14644-1. For this product Eppendorf certifies the following:

Free of detectable
- > Human DNA
- > DNase
- > RNase
- > PCR inhibitors

These parameters are continuously monitored by an independent certified laboratory. Eppendorf guarantees the conformity within the following limits:

Human DNA	< 0.5 pg/µL
DNase	< 1.0×10^{-7} Kunitz units
RNase	< 1.0×10^{-9} Kunitz units
PCR inhibitors	fewer than 10 targets amplifiable

Quality control and subsequent certification are performed by an independent laboratory accredited according to ISO 17025. Lot-specific certificates are available on request or on the Internet at https://www.eppendorf.com/lot-certificates/.
The product manual is available at: www.eppendorf.com/manuals

To support forensic laboratories in solving potential DNA contamination, a request form for checking the Eppendorf DNA Exclusion Database is available at: https://www.eppendorf.com/discover/staff-exclusion-request-form/

A procedure is in place to notify customers who purchased and registered products from a released production lot which has subsequently been found to have failed relevant product or quality specifications: https://www.eppendorf.com/discover/registration-of-forensic-dna-grade/

The certification comprises the following tests:

Human DNA Contamination Test

A probe-based real-time PCR master mix is prepared for the detection of human DNA. The primers amplify a 62 bp fragment present in more than 1×10^5 copies per human cell. The detection of this fragment is performed with a fluorescently labeled DNA probe. Additionally, primers and DNA probes for detecting an internal positive control (IPC) are also added to the master mix. This master mix is used for running positive control, negative control, and test samples.

Positive control: 10 µL human DNA (0.5 pg/µL) and IPC DNA are added to 15 µL master mix.
Negative control: 10 µL human DNA-free H2O and IPC DNA are added to 15 µL master mix.
Test sample: 15 consumable samples are rinsed one after another with DNA-free water.
As an extraction control, IPC DNA is added to the rinse water prior to DNA extraction.
Subsequently, an extraction procedure using the standard protocol of a DNA extraction kit is applied on the rinse water resulting in an eluate of 100 µL. 10 µL of this solution are added to 15 µL master mix.

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The emittance of a fluorescence signal is detected in samples and controls. For the samples to pass certification, no fluorescence signal of the human DNA probe must be found corresponding to the negative control.

DNase Test

15 samples are rinsed one after another with DNA-free water. 17 µL of this solution are mixed with 3 µL DNase buffer containing 100 bp DNA ladder in a DNase-free tube. A positive control is spiked with DNase, a negative control contains DNA-free water. All tubes are incubated for 24 h at 37 °C. The DNA is analyzed by fluorescence measurement. DNase contamination is indicated by degradation of the DNA ladder. For samples to pass certification, the relative intensities of the DNA pattern of the samples must correspond to the negative control.

RNase Test

15 samples are rinsed one after another with RNA-free water. 17 µL of this solution are mixed with 3 µL RNase buffer containing 100 bp RNA ladder in a RNase-free tube. A positive control is spiked with RNase, a negative control contains RNA-free water. All tubes are incubated for 24 h at 37 °C. The RNA is analyzed by agarose gel electrophoresis. RNase contamination is indicated by degradation of the RNA ladder. For samples to pass certification, the relative intensities of the RNA pattern of the samples must correspond to the negative control.

PCR Inhibitor Test

A PCR master mix is prepared using a commercially available real-time PCR Kit, primers for amplifying human DNA, fluorescently labeled DNA probes for detecting the human DNA target, and human DNA (0.64 pg/µL final concentration in master mix). The primers amplify a 62 bp fragment present in more than $1x10^5$ copies per human cell. This master mix is used for running control and test samples.

Control sample: 10 µL human DNA-free H_2O are added to 15 µL master mix.
Test sample: 15 consumable samples are rinsed one after another with human DNA-free water. 10 µL of this solution are added to 15 µL master mix.

The fluorescence signals and Ct values are detected in test and control samples. For the test samples to pass certification, the difference of the Ct values between test and control samples must be within the range of ±2 cycles.

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ISO 9001 Certified | ISO 13485 Certified | ISO 14001 Certified