Eppendorf Certificate

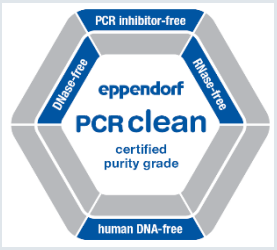
Certificate of Purity – PCR clean

This package contains a high-quality consumable manufactured under the PCR clean Eppendorf Purity Standard.

The Eppendorf PCR clean 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



[*] Filtertips are additionally sterile & free of pyrogens, UVettes are free of protein.

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

Human DNA	< 2 pg
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 done by an independent laboratory. Lot-related certificates are available on request or on the Internet at http://www.eppendorf.com/lot-certificates.

The certification comprises the following tests:

Human DNA Contamination Test

A PCR master mix is prepared using the QuantiTect® SYBR® Green PCR Kit (QIAGEN®) and primer for the detection of human DNA. The primers amplify a 294 bp fragment present in more than $1x10^5$ copies per human cell. The master mix (20 µL) is added to 5 positive control vessels containing known amounts of human DNA (32, 16, 8, 4 and 2 pg in 5 µL H_2O) plus a negative control (10 µL DNA-free H_2O).

15 samples are rinsed one after another with DNA-free water. 10 µL of this solution are added to 20 µL master mix. PCR is done for 30 cycles.

The emittance of SYBR Green-induced fluorescence is detected in samples and controls. For the samples to pass certification, no fluorescence must be found.

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DNase Test

15 samples are rinsed one after another with DNA-free water. 17 µL of these solutions 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. 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 these solutions 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 vessels 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 the QuantiTect SYBR Green PCR Kit (QIAGEN®), primer for the detection of human DNA and 16 pg human DNA. The primers amplify a 294 bp fragment present in more than 10^5 copies per human cell.

15 samples are rinsed one after another with DNA-free water. 10 µL of this solution are added to 15 µL master mix plus 16 pg human DNA. PCR is done for 30 cycles.

The emittance of SYBR Green-induced fluorescence is detected in samples and controls. For the samples to pass certification, the CT values of the samples are compared with the positive control (containing 16 pg human DNA). The difference of the CT value between the samples and the control must be in range of +/- 2 cycles.

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Joana Tziolis
Product Life Cycle Manager
Division Consumables

Thomas Hengstmann
Head of Global Quality Operations

Your local distributor: www.eppendorf.com/contact
Eppendorf SE · Barkhausenweg 1 · 22339 Hamburg · Germany
E-mail: eppendorf@eppendorf.com

ISO 9001 Certified | ISO 13485 Certified | ISO 14001 Certified