Eppendorf Certificate

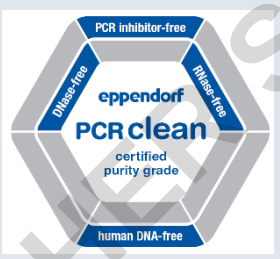
Certificate of Purity – PCR clean

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 x 10^{-7} Kunitz units
RNase	< 1.0 x 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.

Hamburg, June 2024

DOMINIQUE DUTSCHER SAS

Joana Tziolis
Product Life Cycle Manager
Division Consumables

Thomas Hengstmann
Head of Global Quality Operations

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ISO 9001 Certified | ISO 13485 Certified | ISO 14001 Certified

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Eppendorf Certificate

Certificate of Quality
Eppendorf Laboratory Consumables

STATEMENT ON BSE/TSE

As a leading manufacturer of biotech products, Eppendorf uses PP (polypropylene), PC (polycarbonate), PS (polystyrene), and PE (polyethylene) granulates specifically suited for laboratory applications and the manufacturing process of laboratory consumables. PP, PC, PS, and PE granulates may contain small amounts of materials derived from animals.

Eppendorf only works with granulate suppliers who guarantee that their animal components derive exclusively from countries without BSE (bovine spongiform encephalopathy) occurrences. Risk materials are not used. Thus, the requirements of the EU Regulation 1326/2001 and Commission Decision 2001/2/EC amending Decision 2000/418/EC regulating the use of materials presenting risks regarding transmissible spongiform encephalopathies (TSE) are fulfilled.

The granulate production includes – depending on the process – hydrolysis, esterification, or hydrogenation steps in different variations. The common features of these steps include processing conditions with temperatures above 235°C and pressures above 3,000 kPa with retention times up to several hours. The final product is obtained through fractionation, neutralization, and purification. The subsequent extrusion (for the production of granulate) takes place at minimum 200°C for several minutes.

Thus, the production chain of raw materials by far exceeds the stringent requirement of 200°C for 20 minutes (Annex VI, chapter III of EU Regulation 1774/2002, in EU Directives 2000/6/EC and 1999/82/EC, referring to Document EMEA/410/01-Final, latest version: Rev. 3 – 05.03.2011, and in the Report WHO/CDS/VPH/95.145). Any virus, bacterium, or substance causing immunological diseases (TSE, BSE, CJD) is destroyed.

Eppendorf states that the materials and laboratory consumables are to be considered safe with respect to BSE and TSE transmission when used in consumer applications.

This certificate applies to the following Eppendorf Laboratory Consumables:

Pipette tips	epT.I.P.S.®*1
	epT.I.P.S.® 384
	epT.I.P.S.® Long
	epT.I.P.S.® Motion
	ep Dualfilter T.I.P.S.®*1
	ep Dualfilter T.I.P.S.® 384
	ep Dualfilter T.I.P.S.® SealMax®*1
	GELoader®
	Microloader
	Eppendorf Serological Pipets

*1 applies also to the BioBased variants

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Positive displacement tips	Mastertip® Varitips® Combitips® advanced incl. adapters ViscoTip®
Eppendorf Tubes®	Eppendorf Tubes® 3810X/ Flex-Tube® Eppendorf Safe-Lock Tubes* Eppendorf DNA LoBind®/ Protein LoBind® Tubes, Eppendorf Tubes® 5 mL*, *1 incl. adapters Eppendorf Conical Tubes 15 mL*, *1, 50 mL*, *1, SnapTec® 50 Eppendorf Conical Tubes 25 mL*1 incl. adapters
Eppendorf Plates®	Eppendorf Microplates* Eppendorf Deepwell Plates* Eppendorf DNA LoBind®/ Protein LoBind® Plates Eppendorf Assay/Reader Microplates
PCR Consumables	Eppendorf twin.tec® PCR Plates*,*1 Eppendorf twin.tec® PCR Plates LoBind®*1 Eppendorf twin.tec® *microbiology* PCR Plates Eppendorf twin.tec® *real-time* PCR Plates PCR Tube Strips Fast PCR Tube Strips *real-time* PCR Tube Strips PCR Cap Strips PCR Tubes PCR Films & Foils
Cell Culture Consumables	Eppendorf Cell Culture Dishes Eppendorf Cell Culture Plates Eppendorf Cell Culture Flasks Eppendorf Cell Imaging Dishes Eppendorf Cell Imaging Plates CCCadvanced® Cell Imaging Slides & Coverglasses
Cuvettes	UVette® Vis Cuvette
Sample Handling Consumables	Wide-neck bottles

*applies also to the SafeCode variants *1applies also to the BioBased variants

Hamburg, February 2024

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ISO 9001 Certified
ISO 13485 Certified
ISO 14001 Certified

Eppendorf®, the Eppendorf Brand Design, epT.I.P.S.®, ep Dualfilter T.I.P.S.®, GELoader®, Mastertip®, Varitips®, CCCadvanced®, Combitips®, ViscoTip®, Eppendorf Tubes®, Flex-Tube®, Eppendorf twin.tec®, LoBind®, LoRetention®, SnapTec®, SealMax® and UVette® are registered trademarks of Eppendorf SE, Germany.
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Eppendorf Certificate

Certificate of Quality

Eppendorf PCR Consumables

The Eppendorf Quality Management System is certified according to ISO 9001, ISO 13485, and ISO 14001.

Environment and production process

Eppendorf twin.tec® PCR Plates*,*1, PCR Tubes, PCR Tube Strips, Fast PCR Tube Strips, *real-time* PCR Tube Strips and PCR Cap Strips (in the following: Eppendorf PCR Consumables) are produced in a controlled environment according to ISO class 8 of ISO 14644-1. The consistent reliable quality of Eppendorf products is ensured by monitored process control and checks from the raw material to the final packed product.

Material

Eppendorf PCR Consumables are made of virgin polypropylene of highest purity and quality. Material suppliers do not use or intentionally incorporate the following agents into the materials Eppendorf uses for the production of Eppendorf PCR Consumables:

- Slip agents (including oleamide, erucamide, stearamide)
- Biocides (including di(2-hydroxyethyl)methyl dodecyl ammonium salts (DiHEMDA))
- Plasticizers (including phthalates)
- Bisphenol A
- Latex
- Metallic dyes
- Mineral oil

Eppendorf confirms that Eppendorf PCR Consumables and packaging material comply to REACH regulation of the European Union EC No 1907/2006.

Purity

For the certification of absence of DNA, DNase, RNase, and PCR inhibitors please refer to the lot-specific certificate of the respective product. Lot-specific purity certificates can be downloaded on www.eppendorf.com/certificates.

* applies also to the SafeCode variants

*1 applies also to the BioBased variants

Hamburg, April 2024

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ISO 9001 Certified

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