

Eppendorf Certificate

General Certificate of Quality for epT.I.P.S.[®], Combitips[®] advanced, ViscoTip[®], Eppendorf Tubes[®]*,*¹, Eppendorf Plates[®], UVette[®]

STATEMENT ON NITROSAMINE

N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA) are classified as potential human carcinogens, that have been found in human medicinal products. Hence in accordance with Article 5(3) of Regulation (EC) No 726/2004 the EMEA published an Assessment report EMA/369136/2020 regarding the detection, management, and prevention of presence of N-nitrosamines in medicinal products for human use.

One possible root cause is that N-nitrosamine impurities can be carried over during the manufacturing process when using already contaminated equipment. Therefore, Eppendorf performed an additional risk evaluation with focus on N-nitrosamine potentially included in Eppendorf Consumables. As a result, Eppendorf confirms as manufacturer of Laboratory Consumables the following:

There is no risk of formation of nitrosamines during the manufacturing process:

- Eppendorf Consumables are made of virgin polypropylene, polyethylene, polycarbonate of highest purity and quality. Material suppliers do not use or intentionally incorporate Nitrosamine as specified in the absence of substances list.
- No reagents, solvents, or catalysts that could be a possible source of nitrosamines are used in the manufacturing process of Eppendorf Consumables.
- No packaging material/printing ink that could be a possible source of nitrosamines are used in the manufacturing process of Eppendorf Consumables.

There is no risk of contamination with nitrosamines during the cleaning process of product-contacting parts

- No cleaning agents based on quaternary ammonium salts are used for cleaning process equipment.

Hamburg, August 2022

* applies also to the SafeCode variants

*¹ applies also to the BioBased variants



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ISO 9001
Certified

ISO 13485
Certified

ISO 14001
Certified

Eppendorf®, Eppendorf Brand Design, epT.I.P.S.[®], Combitips[®] advanced, ViscoTip[®], Eppendorf Tubes[®], Eppendorf Plates[®], Biopur[®] and UVette[®], are registered trademarks of Eppendorf SE, Germany.
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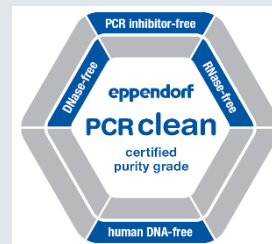
Certificate of Purity – PCR clean

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

The Eppendorf PCR clean consumables are produced in an ISO class 8 clean room environment according to 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^{-6} Kunitz units
RNase	< 1.0×10^{-9} Kunitz units
PCR inhibitors	less than 10 targets amplifiable

Quality control and subsequent certification is done by an independent laboratory. Lot-related certificates are available on request or on the internet at www.eppendorf.com/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 1×10^5 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 H₂O) plus a negative control (10 µL DNA-free H₂O).

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 agarose-gel electrophoresis. 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 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 10⁵ 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.

October, 2019

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ISO 13485
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ISO 14001
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www.eppendorf.com

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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*, 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 manufactured in a controlled ISO class 8 clean room environment according to 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)-methyldodecylammonium 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 amended by Commission Regulation EC No. 552/2009.

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.

January, 2020

* applies also to the SafeCode variants



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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), 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.®
epT.I.P.S.® 384
epT.I.P.S.® Long
epT.I.P.S.® LoRetention®
epT.I.P.S.® Motion
ep Dualfilter T.I.P.S.®
ep Dualfilter T.I.P.S.® 384
ep Dualfilter T.I.P.S.® SealMax®
ep Dualfilter T.I.P.S.® LoRetention®
GELoader®
Microloader
Eppendorf Serological Pipets

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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*
Eppendorf twin.tec® PCR Plates LoBind®
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, August 2022

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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 an ISO class 8 clean room environment according to 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 x 10 ⁻⁶ Kunitz units
RNase	< 1.0 x 10 ⁻⁹ Kunitz units
PCR inhibitors	less 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 www.eppendorf.com/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: www.Eppendorf.com/dna-exclusion

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: www.eppendorf.com/forensic-grade-registration

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 1×10⁵ 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 agarose-gelelectrophoresis. 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-gelelectrophoresis. 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 1×10^5 copies per human cell. This master mix is used for running control and test samples.

Control sample: 10 µL human DNA-free H₂O 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.

January, 2020

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