Eppendorf Certificate

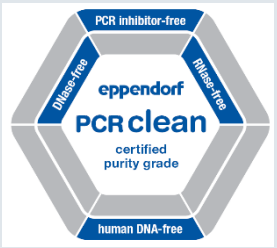
Certificate of Purity – PCR clean

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

The Eppendorf PCR clean consumables are produced in 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 x 10^{-6} Kunitz units
RNase	< 1.0 x 10^{-9} Kunitz units
PCR inibitors	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 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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Eppendorf Certificate

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-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 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-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 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.

October, 2019

0012557.051-08

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Dr. Birgit Schreiber
Vice President Quality Management &
Regulatory Affairs

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ISO 9001 Certified | ISO 13485 Certified | ISO 14001 Certified

Eppendorf Certificate

Certificate of Quality

Eppendorf Plates® – Typical values for trace metals

The values in the table indicate typical values of trace metal concentrations obtained by incubating Eppendorf Plates with concentrated nitric acid for 1 hour (see Materials and Methods).

As the indicated values were determined in a one-time measurement they cannot be guaranteed for every lot of Eppendorf Plates. Rather they give an idea to what extent trace elements can be eluted from Eppendorf Plates.

	Trace metal release [ng/µl]								
	Al	Cd	Cr	Cu	Hg	Mn	Ni	Pb	Zn
Eppendorf Microplates									
96/F	0.029	<0.00002	0.00064	0.0022	<0.001	0.00054	0.00036	0.00059	0.008
96/U	0.028	<0.00002	0.00062	0.0021	<0.001	0.00052	0.00035	0.00058	0.008
96/V	0.028	<0.00002	0.00063	0.0022	<0.001	0.00053	0.00036	0.00059	0.008
384/F	0.048	0.00003	0.00108	0.0037	<0.001	0.00090	0.00061	0.00100	0.014
384/V	0.047	0.00003	0.00105	0.0036	<0.001	0.00088	0.00059	0.00098	0.013
Eppendorf Deepwell Plates									
384/200 µl	0.049000	0.000030	0.001100	0.003800	<0.001	0.000920	0.000620	0.001020	0.014000
96/500 µl	0.027591	0.000017	0.000619	0.002140	<0.001	0.000518	0.000349	0.000574	0.007883
96/1000 µl	0.027297	0.000017	0.000613	0.002117	<0.001	0.000513	0.000345	0.000568	0.007799
96/2000 µl	0.021787	0.000013	0.000489	0.001690	<0.001	0.000409	0.000276	0.000454	0.006225
Protein LoBind® Plates									
384/200 µl	0.008000	<0.00002	0.000110	0.000400	<0.001	0.000140	0.000070	0.000160	0.013000
384/V-PP	0.007668	<0.00002	0.000105	0.000383	<0.001	0.000134	0.000067	0.000153	0.012461
96/500 µl	0.004505	<0.00002	0.000062	0.000225	<0.001	0.000079	0.000039	0.000090	0.007320
96/1000 µl	0.004457	<0.00002	0.000061	0.000223	<0.001	0.000078	0.000039	0.000089	0.007242
DNA LoBind® Plates									
384/200 µl	0.015000	0.000030	0.000130	0.000700	<0.001	0.000042	0.000070	0.000100	0.007000
384/V-PP	0,014378	0,000029	0,000125	0,000671	<0,001	0,000403	0,000067	0,000096	0,006710
96/500 µl	0.008446	0.000017	0.000073	0.000394	<0.001	0.000236	0.000039	0.000056	0.003942
96/1000 µl	0.008356	0.000017	0.000720	0.000390	<0.001	0.000234	0.000039	0.000056	0.003900
96/V-PP	0.008648	<0.00002	0.000075	0.000404	<0.001	0.000242	<0.00005	0.000058	0.004036

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Eppendorf Certificate

	Trace metal release [ng/µl]								
	Al	Cd	Cr	Cu	Hg	Mn	Ni	Pb	Zn
Eppendorf twin.tec® PCR Plates									
384	0.000379	<0.00002	<0.00005	<0.00010	<0.001	0.000123	<0.00005	<0.00005	<0.0010
384 *microbiology*	0.002000	<0.00002	<0.00005	<0.00010	<0.001	0.000123	<0.00005	<0.00005	<0.0010
96 semi-skirted	0.001300	<0.00002	<0.00005	<0.00010	<0.001	0.000070	<0.00005	<0.00005	<0.0010
96 skirted	0.001420	<0.00002	<0.00005	<0.00010	<0.001	0.000076	<0.00005	<0.00005	<0.0010
96 unskirted 150 µl	0.001420	<0.00002	<0.00005	<0.00010	<0.001	0.000076	<0.00005	<0.00005	<0.0010
96 unskirted 250 µl	0.001300	<0.00002	<0.00005	<0.00010	<0.001	0.000070	<0.00005	<0.00005	<0.0010
Eppendorf twin.tec® PCR Plates LoBind®									
96 semi-skirted	0.003300	<0.00002	<0.00005	<0.00002	<0.00005	<0.00010	<0.001	<0.00005	<0.00005
96 skirted	0.003605	<0.00002	<0.00005	<0.00002	<0.00005	<0.00010	<0.001	<0.00005	<0.00005

Materials and Methods

Eppendorf Plates were filled with their nominal volume using concentrated nitric acid (65 %) and incubated for 1 hour at room temperature (20 ˚C). The eluate was then analyzed by inductively coupled plasma mass spectrometry (ICP-MS). The trace metal concentrations are expressed in ng/µL. The values represent an average of three individually analyzed samples. All values labeled with "<" indicate concentrations below the detection limit of the ICP-MS method. The trace metal release of the remaining Eppendorf Plates were calculated from their surface/volume ratio.

No metal release was observed after 5-10 times rinsing with concentrated nitric acid or after rinsing with 10 % acetic acid or water. All analyses were performed by an independent laboratory accredited according to ISO/IEC 17025:2018-03.

Hamburg, November 2020

0015 033.508-02

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Monika Schneider
Head of Global Quality Management &
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ISO 9001 Certified | ISO 13485 Certified | ISO 14001 Certified

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*, 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.

* applies also to the SafeCode variants

January, 2020

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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

Eppendorf Certificate

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

Joana Tziolis
Product Life Cycle Manager
Division Consumables

Monika Schneider
Vice President Global Quality Management & Regulatory Affairs

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ISO 9001 Certified | ISO 13485 Certified | ISO 14001 Certified

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 inibitors	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 1×10^5 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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Eppendorf Certificate

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 $1x10^5$ 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.

January, 2020

0012591896-02

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