eppendorf

The Pure Truth

Eppendorf Forensic DNA Grade according to ISO 18385

»Eppendorf Forensic DNA Grade, for results you can trust.«

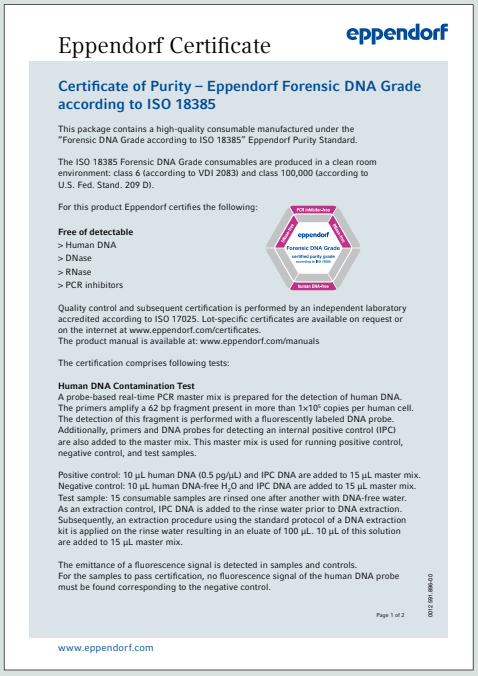
The prevention of contamination is one of the major challenges in forensic DNA analysis. In order to minimize the risk of contamination, forensic laboratories have established strict internal processes. Even more safety is expected from the implementation of the ISO 18385 standard.

This standard specifies the demands on manufacturers of products which will be used in forensic DNA laboratories. Eppendorf Forensic DNA Grade products are in compliance with the sophisticated requirements of this standard.

Eppendorf Certificate

Certified compliance with ISO 18385
Working in accordance with standards and regulations entails providing proof of compliance. Eppendorf consistently addresses these requirements and supports laboratories in maintaining seamless documentation:

All purity parameters which apply to the purity grade »Forensic DNA Grade« are listed in a quality certificate enclosed with each product. Eppendorf confirms compliance with these purity parameters for every production lot and provides lot specific certificates.



Eppendorf Certificate

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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 clean room environment: class 6 (according to VDI 2083) and class 100,000 (according to U.S. Fed. Stand. 209 D).

For this product Eppendorf certifies the following:

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

Quality control and subsequent certification is 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

The certification comprises 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 $1x10^5$ 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 H_2O 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.

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.

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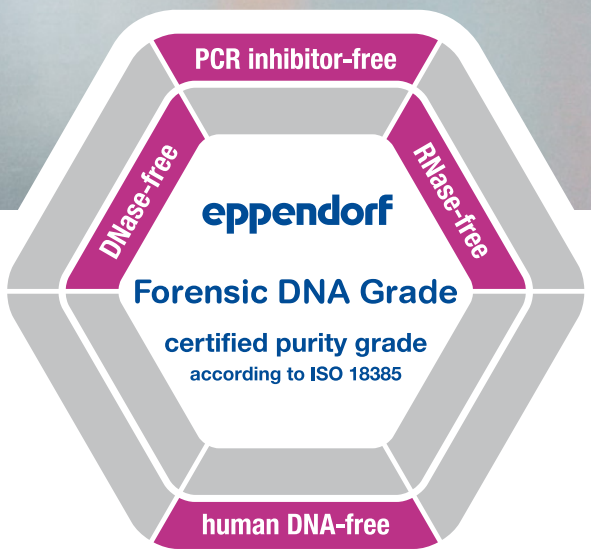
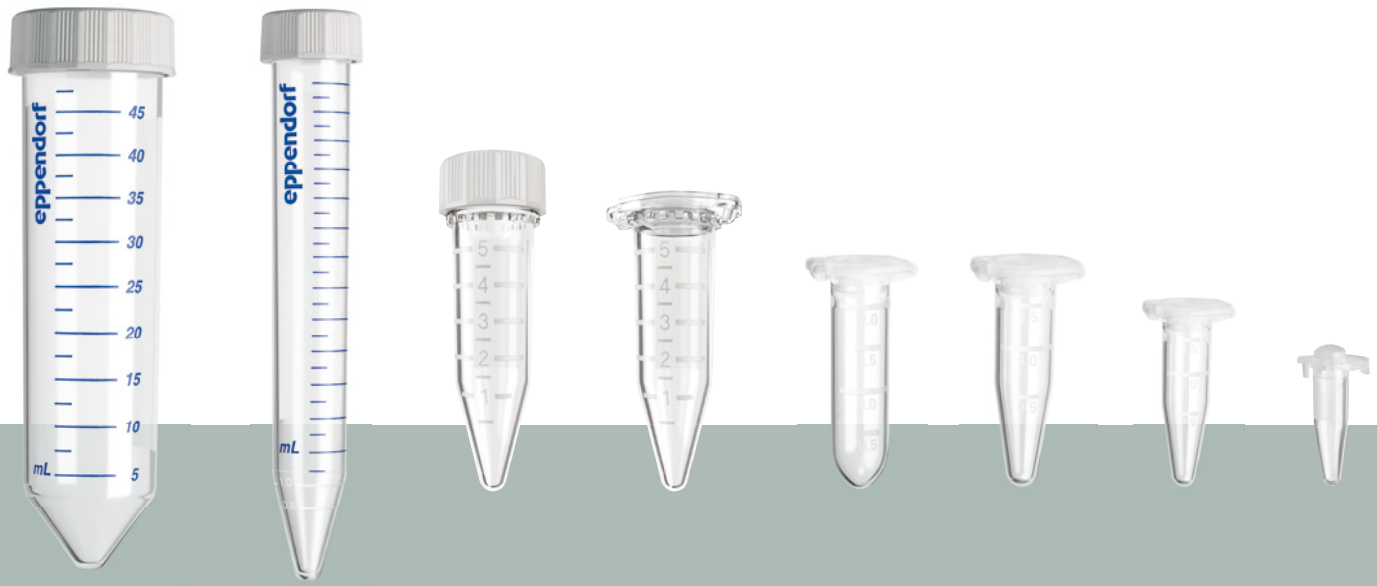
> Lot specific certificates available at:
www.eppendorf.com/certificates

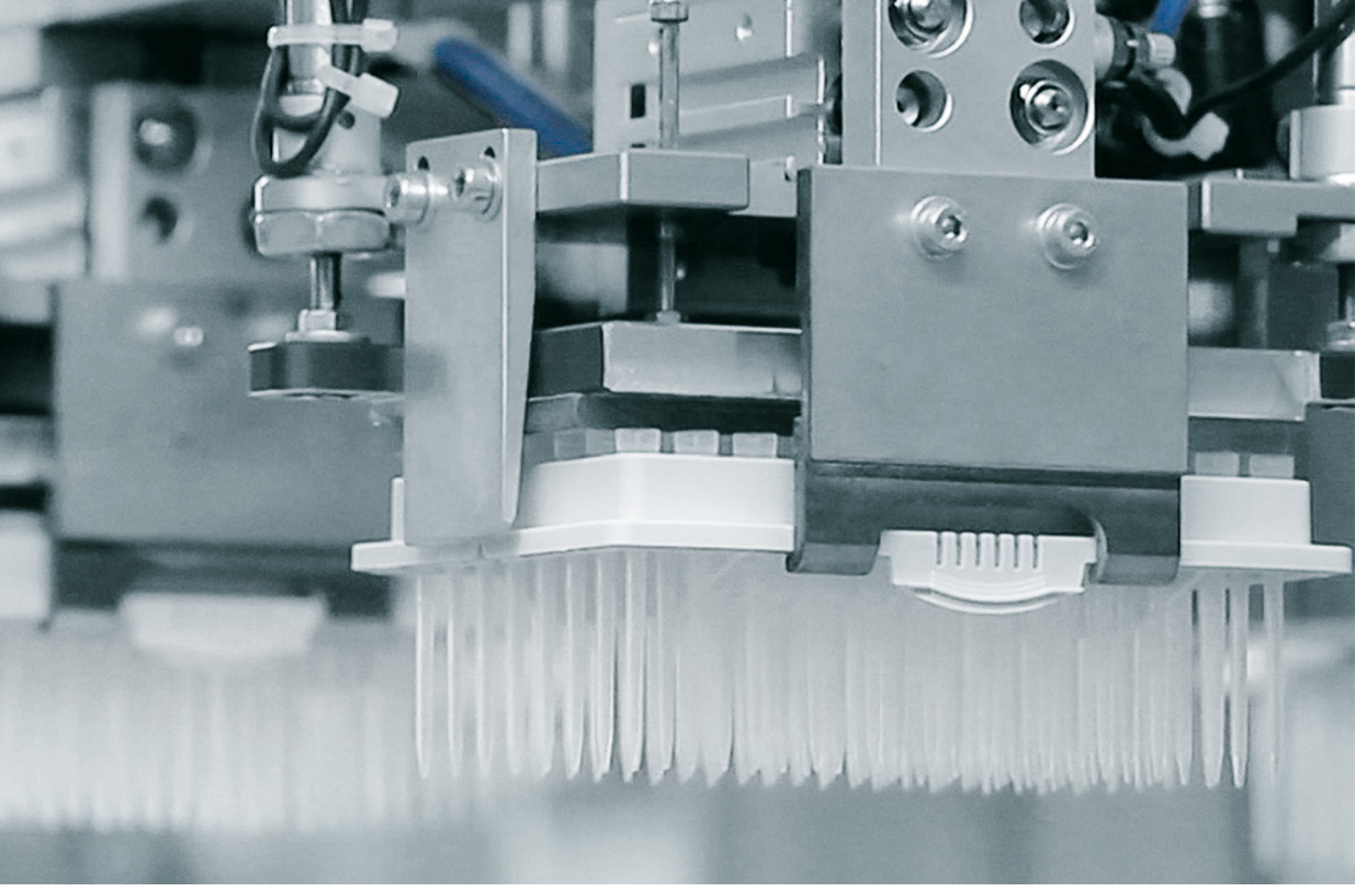


High quality manufacturing

The Forensic DNA Grade product line encompasses consumables for DNA extraction, sample processing and PCR setup as well as for sample storage. The high Eppendorf quality standards upheld during the manufacturing process represent an essential cornerstone by which the strict demands of the ISO 18385 standard are met, this includes:

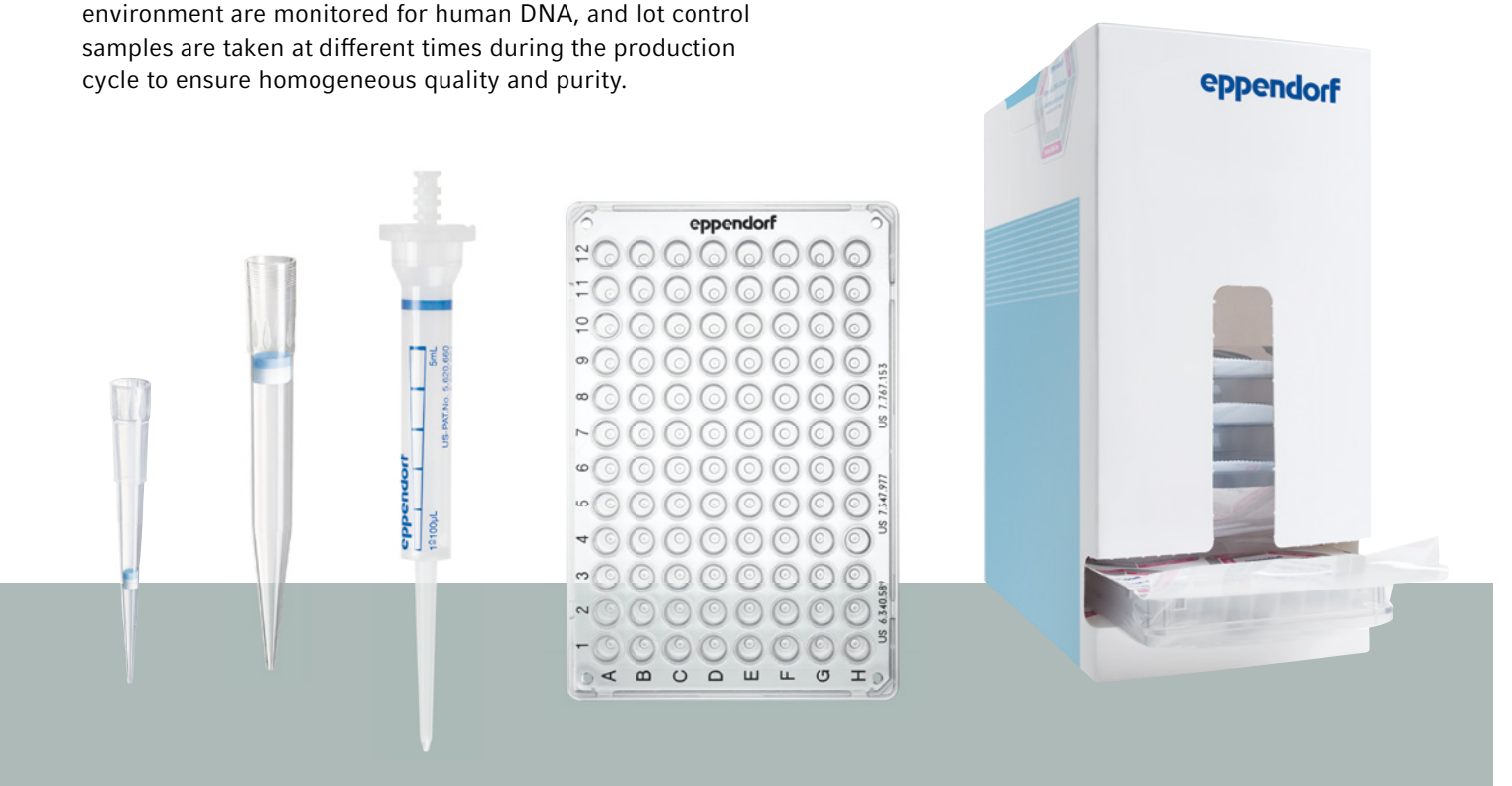
> A high degree of automation to minimize direct contact between staff and product
> Strict adherence to cleaning procedures and protocols minimize the risk of contamination
> Positive air pressure prevents intrusion of dust





Process controls
In order to guarantee consistently clean conditions, the production area is closely monitored. An effective quality control system fulfills the requirements of the standards and certifications with which the manufacturing site complies, e.g. ISO 13485. Moreover, controls have been established in accordance with the specific needs of Forensic DNA Grade consumables. For example, the surfaces in the production environment are monitored for human DNA, and lot control samples are taken at different times during the production cycle to ensure homogeneous quality and purity.

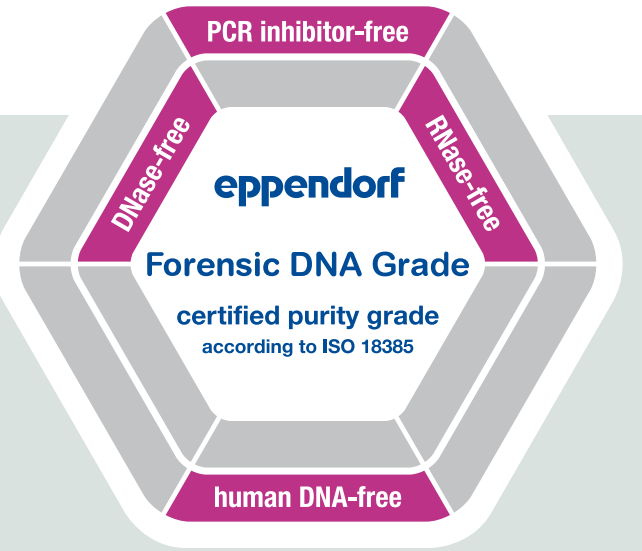
Restricted access
Access to the production area of the Forensic DNA Grade consumables is severely restricted and controlled. Intensive training measures for staff are as mandatory as strict adherence to specific clothing regulations.



Packaging matters
A comprehensive approach considers not only factors relevant to production and application, but also aspects related to the handling of a product in the lab. This of course includes packaging. With regard to products used in a forensic DNA laboratory, the packaging should support relevant product features, such as contamination- and error-free handling. Therefore, special attention has been directed towards the packaging of Eppendorf Forensic DNA Grade products:

> Clearly marked labels are not only attached to the folding box but also to each individual product bag, which ensures unambiguous identification during use.
> Product-specific adjustment of the packaging size: depending on the product, the Eppendorf Forensic DNA Grade consumables are either packaged individually or in workflow-oriented numbers of items per bag.
> If not all consumables are used within one work process, re-sealable bags allow contamination-free storage.

Forensic DNA Grade



Monitored purity
Eppendorf consumables exemplify highest quality and performance. The product line sealed with the new purity grade »Eppendorf Forensic DNA Grade« rigorously adopted this approach. The test parameters and sensitivity levels correspond to the requirements of the ISO 18385 standard and are subject to strict controls.

All tests performed to verify the certified purity parameters are carried out by an independent external testing laboratory which is accredited in accordance with ISO 17025 – the same accreditation standard which is applied to forensic laboratories.

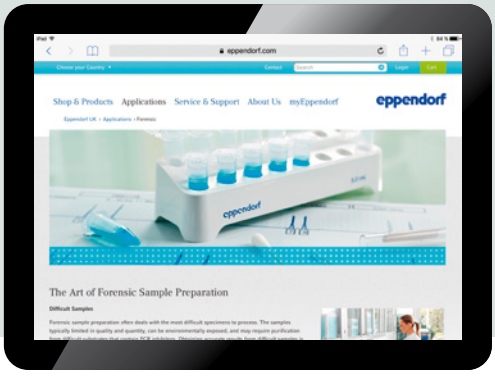
> Additional information available at:
www.eppendorf/purity

Ordering information

Description	International Order No.	North America Order No.
Safe-Lock Tubes 0.5 mL, 500 pcs., 10 bags of 50 tubes each	0030 123.603	0030123603
Safe-Lock Tubes 1.5 mL, 500 pcs., 10 bags of 50 tubes each	0030 123.611	0030123611
Safe-Lock Tubes 2.0 mL, 500 pcs., 10 bags of 50 tubes each	0030 123.620	0030123620
Eppendorf Tubes® 5.0 mL with screw cap, 200 pcs, 4 bags of 50 each	0030 122.402	0030122402
Eppendorf Tubes® 5.0 mL, 200 pcs, 4 bags of 50 each	0030 119.606	0030119606
Eppendorf Conical Tubes 15 mL, colorless, 100 pcs., individually packed tubes	0030 122.259	0030122259
Eppendorf Conical Tubes 50 mL, 48 pcs., individually packed tubes	0030 122.267	0030122267
ep Dualfilter T.I.P.S.® 0.1–10 µL, 960 Tips, 10 racks of 96 tips each	0030 077.768	0030077768
ep Dualfilter T.I.P.S.® 2–20 µL, 960 Tips, 10 racks of 96 tips each	0030 077.776	0030077776
ep Dualfilter T.I.P.S.® 2–200 µL, 960 Tips, 10 racks of 96 tips each	0030 077.784	0030077784
ep Dualfilter T.I.P.S.® 50–1,000 µL, 960 Tips, 10 racks of 96 tips each	0030 077.792	0030077792
Combitips advanced® 1.0 mL, 100 pcs., individually packed tips	0030 089.855	0030089855
Combitips advanced® 2.5 mL, 100 pcs., individually packed tips	0030 089.863	0030089863
Combitips advanced® 5.0 mL, 100 pcs., individually packed tips	0030 089.871	0030089871
PCR Tubes 0.2 mL, 500 pcs., 10 bags of 50 tubes each	0030 124.707	0030124707
Eppendorf twin.tec® PCR Plate 96, semi-skirted, 10 pcs., individually packed plates	0030 129.610	0030129610
Eppendorf twin.tec® PCR Plate 96, skirted, 10 pcs., individually packed plates	0030 129.601	0030129601
Eppendorf twin.tec® PCR Plate 384, 10 pcs., individually packed plates	0030 129.628	0030129628
Eppendorf twin.tec® real-time PCR Plate 96, semi-skirted, 10 pcs., individually packed plates	0030 129.644	0030129644
Eppendorf twin.tec® real-time PCR Plate 96, skirted, 10 pcs., individually packed plates	0030 129.636	0030129636

From preparation to storage
Find more information on workflow-oriented premium solutions for forensic science applications.

> www.eppendorf.com/forensics



Your local distributor: www.eppendorf.com/contact
Eppendorf AG · 22331 Hamburg · Germany
eppendorf@eppendorf.com · www.eppendorf.com

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