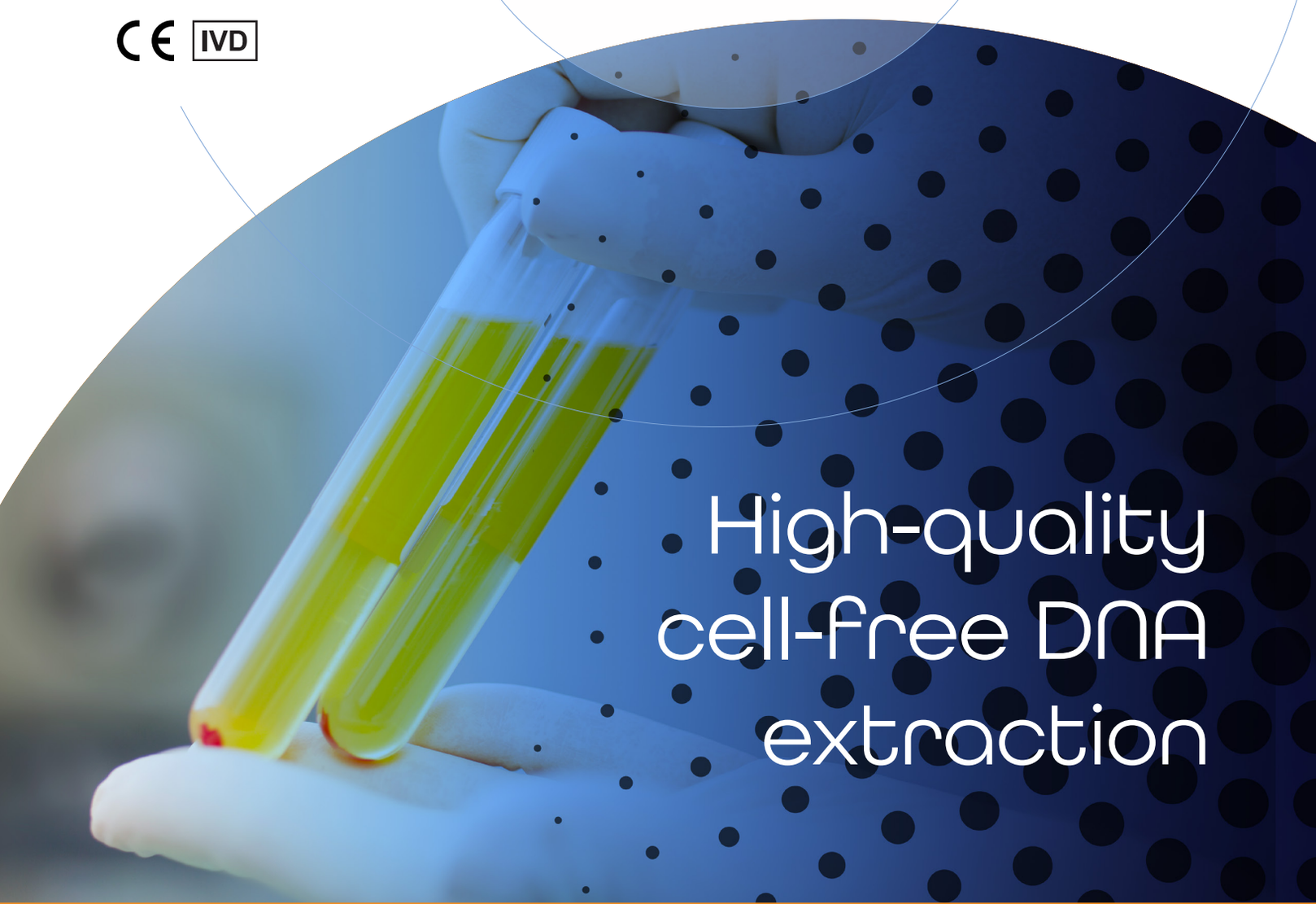
Clean NA

# Clean Cell Free DNA kit

## For In Vitro Diagnostic Use

CE IVD



# Unlock the potential of your diagnostic cfDNA workflow

**Cell-free DNA (cfDNA) has experienced a remarkable rise in interest as a diagnostic and research tool in medicine. Over the last years, cfDNA had a major impact on prenatal diagnostics by enabling non-invasive prenatal testing (NIPT). Furthermore, it is rapidly evolving into the new diagnostic standard for oncology, transplant medicine, and cardiovascular diseases. Our CE-IVD marked Clean Cell Free DNA Kit helps laboratories with the first step of the diagnostic process: extracting the cfDNA from human plasma.**

Our kit extracts cfDNA fragments from 1 mL human plasma in a three-step procedure that is easy to automate. The unique lysis buffer releases the DNA from proteins and vesicles and the optimised buffer combination enriches DNA fragments ranging from 120 to 400 base pairs. Combined with the CE-IVD marking, this makes the Clean Cell Free DNA Kit the ideal start to reliable and reproducible qPCR results in molecular diagnostics.

## Benefits:

- **For use in diagnostic procedures (CE-IVD)**
- **Easy automation**
- **Fit for downstream (q)PCR**

## Application

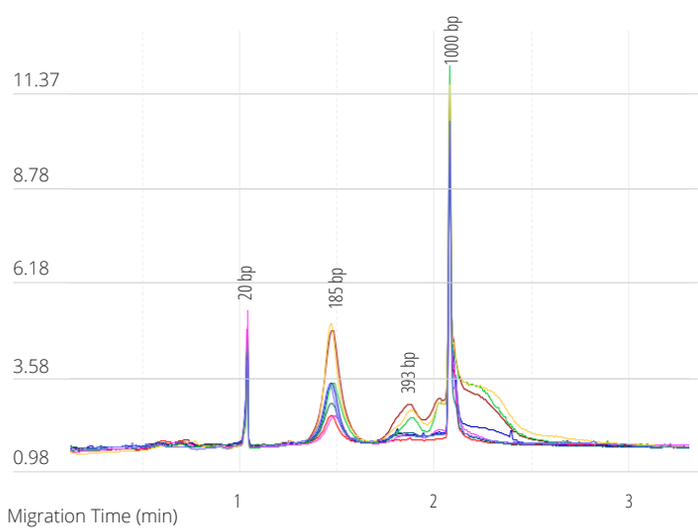
The cfDNA extracted by the Clean Cell Free DNA Kit can be used for downstream detection procedures based on (q)PCR. Cancer diagnostics, prenatal screening, organ transplantation, post-trauma monitoring and cardiovascular diagnostics are some of the main fields where cfDNA is applied.

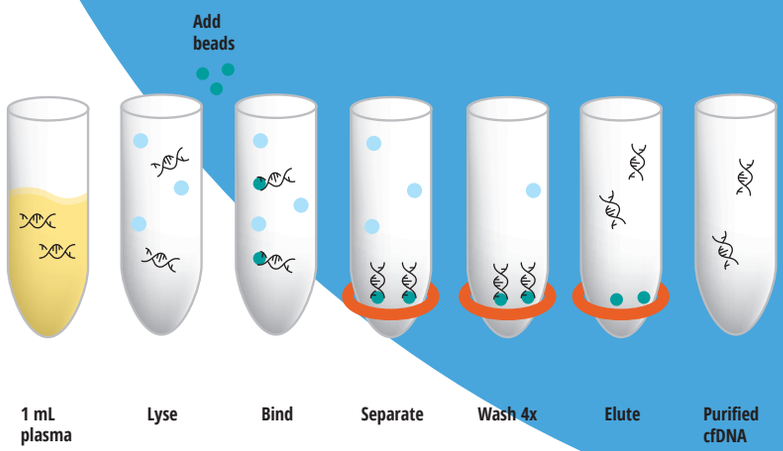
## Proof of principle

We extracted cfDNA from 8 different human plasma samples of 1 mL using the Clean Cell Free DNA Kit. The samples were collected in blood collection tubes containing either EDTA or sodium citrate as anticoagulant. Because the plasma samples were from different patients, the quantity of cfDNA may vary. The extraction was performed on the Dynamic Devices' Lynx liquid handling instrument and the samples were analysed on the BiOptic Qsep100 bio-fragment analyzer. Figure 1 shows a high peak around the length of 185 base pairs, indicating that our Clean Cell Free DNA Kit captures small DNA fragments of the size of cfDNA. (Faas *et al.*, 2012) [1]

**FIGURE 1.**

**Electropherogram of 8 different human plasma samples after extraction with the Clean Cell Free DNA Kit.**






# Workflow

Initially, the uniquely formulated lysis buffer is added to the plasma sample to release the cfDNA from proteins and vesicles, while DNases and RNases are inactivated. After binding of the cfDNA to the added magnetic beads, the cfDNA-magnetic bead complex can be separated from the lysate by using a magnetic separation device. A series of quick wash steps remove trace contaminants and the purified cfDNA can be eluted from the magnetic beads using the Elution Buffer.

In another experiment, we extracted DNA from 13 human plasma samples of 1 mL by using the Clean Cell Free DNA Kit and a kit from Company Q. Both extractions were performed manually. After extraction, we performed a qPCR on the human albumin gene and a DNA concentration measurement with the DeNovix DS-11 FX. Figure 2 shows a lower average Ct-value for the samples extracted with the Clean Cell Free DNA Kit. Figure 3 shows a higher average DNA yield for the samples extracted with the Clean Cell Free DNA Kit.

**FIGURE 2.**

**Albumin directed TaqMan® qPCR performed with Sensifast Lo-Rox after extracting DNA from human plasma with the Clean Cell Free DNA Kit and Company Q.**

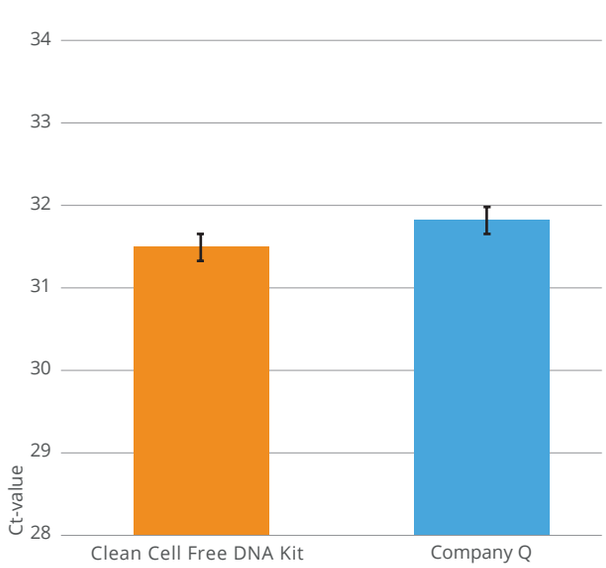
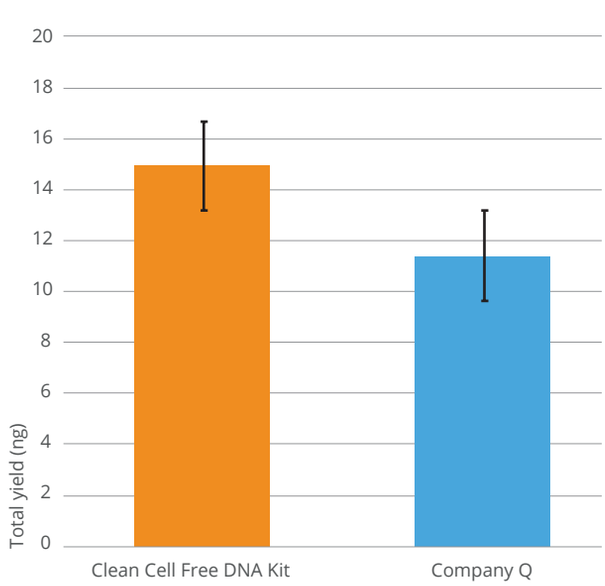



**FIGURE 3.**

**Yield after extracting DNA from 1 mL human plasma with the Clean Cell Free DNA Kit and Company Q, measured with the DeNovix DS-11 FX.**




[1] Faas BH, de Ligt J, Janssen I, Eggink AJ, Wijnberger LD, van Vugt JM, Vissers L, Geurts van Kessel A. Non-invasive prenatal diagnosis of fetal aneuploidies using massively parallel sequencing-by-ligation and evidence that cell-free fetal DNA in the maternal plasma originates from cytotrophoblastic cells. Expert Opin Biol Ther. 2012 Jun;12 Suppl 1:S19-26. doi: 10.1517/14712598.2012.670632. Epub 2012 Apr 16. PMID: 22500971.

# About CleanNA

CleanNA is a Dutch manufacturer of magnetic bead-based nucleic acid extraction kits. We produce our reagents according to our EN-ISO 13485 certified quality management system. Our kits are easy to automate on general liquid handling systems. CleanNA's product portfolio includes kits for extraction from a range of sample types, both for research and diagnostic procedures.

ISO 13485 BUREAU VERITAS Certification

Our quality management system is certified to EN-ISO 13485 by Bureau Veritas



## Contact

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| Product | Preps | Part Number |
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