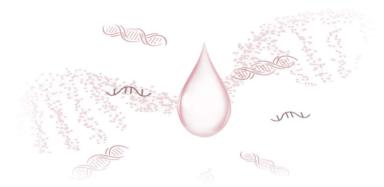
# **Product Data Sheet**



# **Product Summary**

#### **Product ID/Name**

CB-HMEC\_01
HMEC wt-cfDNA, mono-nuc (166), in Buffer

## **Product Description**

Highly characterized wildtype mono-nucleosomal (~166 bp) cfDNA for improved QC, preanalytical validation, and analytical validation in dPCR, NGS, and liquid biopsy applications.

Research Use Only (RUO)

# **Product Specifications**

## Allelic frequency:

This product is 100% wildtype, validation data for KRASG12D on digital PCR is available.

## **Product size:**

500 ng in total (20 ng/μL in 25 μL buffer)

#### **Formulation**

In buffer - Tris-EDTA (10 mM Tris, 1 mM EDTA), pH 8.0

## Transport and storage

2 - 8 °C

#### **Derived from**

HMEC-1 cells



# Improved biospecimen analogue

Experience an enhanced standard in wild-type cfDNA with our mono-nucleosomal cell-free DNA (cfDNA), derived from the supernatant of HMEC-1 cells to preserve natural degradation profiles. Unlike enzymatically or mechanically fragmented genomic DNA, this real cfDNA closely mimics native patient-derived cfDNA, offering superior performance in assay validation and quality control. With a natural fragmentation size of ~166 bp and authentic degradation patterns, this cfDNA provides the most biologically relevant background for liquid biopsy research, dPCR, and NGS-based assays. Unlike artificially digested DNA, it undergoes true cellular shedding and nuclease activity, ensuring realistic adsorption effects, PCR amplification efficiency, and VAF variability. Designed for precision, our wild-type cfDNA is the ultimate reference material for optimizing sensitivity, accuracy, and reproducibility in cfDNA-based diagnostics and liquid biopsy applications. Elevate your assay validation with cfDNA that truly reflects the real-world clinical sample experience.

# **Enhanced Characterization & Quality Control**

We ensure precise characterization and rigorous quality control of our cfDNA reference materials using multiple state-of-the-art methods for size determination, quantification, and confounder analysis.

## **Size Determination Using Multiple Platforms**

- Bioanalyzer High Sensitivity DNA Kit High-resolution sizing of cfDNA fragments.
- Agilent TapeStation cfDNA ScreenTape & 5000 bp ScreenTape for comprehensive profiling.
- Shallow Whole Genome Sequencing (sWGS) on Illumina In-depth analysis of fragment size distribution.

## **Quantification & Copy Number Calculation**

- Qubit dsDNA HS Assay Kit Reliable low-concentration DNA measurement.
- NanoDrop One Broad-range nucleic acid quantification.
- QIAcuity One dPCR Absolute DNA quantification with copy number precision.

## Confounder Analysis: Detection of Single-Stranded DNA (ssDNA)

 Unaccounted-for ssDNA can affect method validation and assay performance. We provide detailed data on ssDNA presence or absence, ensuring you have full transparency in your cfDNA reference materials. With enhanced characterization and stringent quality control, you get highly reproducible, well-defined cfDNA that supports assay optimization, quality control, and method validation with confidence.

liquid-biopsy.new-diagnostics.com Phone: +49 (0) 40288 67 0 Mail: info@ new-diagnostics.com Page **2** of **3** Release: 03.03.2025 Print date: 03.03.2025

#### **Ideal Use Cases**

This Research Use Only (RUO) product is designed to enhance quality control, accuracy, and precision in both preanalytical and analytical validation of cfDNA-based assays. Its naturally fragmented structure makes it an ideal reference material for a variety of applications, including:

- Internal Control for DNA Size Assessment Ensures accurate evaluation of cfDNA fragmentation, closely mimicking native cfDNA.
- Internal Control for DNA Quantification Provides a reliable reference for precise and reproducible DNA concentration measurements.
- Spike-In Control for cfDNA Extraction Efficiency When added to DNA-depleted plasma, it helps assess extraction efficiency under real-world conditions.
- Background DNA for Variant Allele Frequency (VAF) Validation Serves as an ideal wild-type background for mixing with mutant DNA, enabling accurate VAF optimization and assay validation.

By replicating endogenous cfDNA properties, this product ensures more realistic assay performance in liquid biopsy, dPCR, and NGS applications.

## On-Demand Customization – Tailored to Your Needs

Our flexible production process enables the rapid creation of bespoke reference materials, ensuring you get precisely what you need—when you need it. Whether you are optimizing assay performance or conducting specialized research, we offer customizable cfDNA solutions with short turnaround times.

Tell us your specific requirements, and we will assess feasibility and provide a prompt response. Examples of available customizations include:

- Alternative modal sizes for the mono-nucleosomal population (e.g., 157 bp, 167 bp, 177 bp).
- Higher DNA concentrations for enhanced assay performance.
- Controlled ssDNA content available with or without ssDNA, depending on your needs.

Need something unique? Let's collaborate to create the perfect cfDNA reference material for your application.