cfDNA in Plasma for Metagenomics (SID-000152) – Instructions for use

For Research Use Only

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Every diagnostic test as well as R&D needs references and controls. SensID GmbH manufactures High Quality Reference Materials / Controls for Molecular Diagnostics.
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Content

Product	Catalog No.
cfDNA in Plasma for Metagenomics	SID-000152

Symbols

REF	Catalog number
LOT	Lot number
	Use by
	Legal manufacturer
	Not for reuse
	Temperature limitations

Storage

The product should be stored at 2 °C to 8 °C upon arrival. DO NOT FREEZE. The product is stable until the expiration date when stored under these conditions.

Intended Use

The product contains a precisely defined allele frequency as indicated on the corresponding certificate in a 1-fold concentrated human-tech plasma matrix. The product was designed for use in **liquid biopsy** with the **intended application:**

1. DNA extraction control (e.g. instrument qualification)
2. As a comparative probe for validation and control of processes using Metagenomics and its workflow verification / validation.
3. Analyze the performance of a NGS pipeline (including capture-based assays) by comparing to freely available datasets.

Plasma (human-tech) is human recreated DNA free plasma. It contains all relevant components of human plasma after a blood draw and plasma separation:

1. Human serum proteins in common plasma concentrations
2. Electrolytes
3. EDTA

EDTA concentration in all plasma products complies with the recommendations of ICSH (International Council Society of Haematology) and the CLSI (Clinical and Laboratory Standards Institute) for EDTA in blood collection tubes.

Protocol: cfDNA in Plasma for Metagenomics

Important point before starting:

- It is recommended to centrifuge SID-000152 briefly to avoid liquid holding back in the lid of the vial!
- To avoid contaminations in the vial work in clean environment (e.g. laminar flow hood)
- Mix by pipetting up and down 10 times to obtain a homogeneous suspension. Do not vortex!
- DNA isolation from plasma required.
- The purified DNA is present in Plasma (human-tech) at a fragment size of 167 bp ±15 %.
- While the presence of copy numbers of synthetic pathogen-derived sequences is monitored during manufacturing using ddPCR assay there may be differences in copy numbers due to assay characteristics.

Technical Assistance

Our Technical Service Assistance is staffed by experienced scientists with extensive practical and theoretical expertise with our products. If you have any questions or experience any difficulties regarding the particular product or SensID GmbH products in general, please do not hesitate to contact us.
SensID GmbH customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to other scientists as well as to the researchers at SensID GmbH. We therefore encourage you to contact us if you have any suggestions about product performance or new applications and techniques.
For technical assistance and more information, please see our Website www.sens-id.com or call one of the SensID GmbH Technical Service Assistance.

Product Use limitations

Attention should be paid to expiration dates and storage conditions printed on the box and labels of all components. Do not use expired or incorrectly stored components. Check primary packaging before first opening. Do not use products from damaged primary packaging.

Quality Control

In accordance with SensID's Quality Management System, each lot of cfDNA in Plasma for Metagenomics is tested against predetermined specifications to ensure consistent product quality.
The product should appear as a clear to pale yellow liquid. Alterations in this appearance may indicate instability or deterioration of the product and vials should be discarded. The product contains a precisely defined copy number of synthetic pathogen-derived sequences on the corresponding certificate in a 1-fold concentrated human-tech plasma matrix.

Warnings and precautions

When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). These are available online in convenient and compact PDF format at www.sens-id.com, where you can find, view, and print the SDS for each SensID GmbH products, kit component and other products.
Avoid contamination of the product when opening and closing the vial.
CAUTION: Handle as though it can transmit infectious agents. This product is formulated using a proprietary cell line, which is a B-lymphocytic, female cell line.

Equipment and Reagents to be supplied by User

- Pipets (adjustable)
- Sterile pipet tips with filters

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