DPYD-Multiplex 50% AF gDNA, (SID-000135) – Instructions for use

For Research Use Only

SensID Bringing Precision to Molecular Diagnostics

Every diagnostic test as well as R&D needs references and controls. SensID GmbH manufactures High Quality Reference Materials / Controls for Molecular Diagnostics.
Our mission is to provide certified standards ready for your needs in the highest quality to ease your processes.

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Content

Product	Catalog No.
DPYD-Multiplex 50% AF gDNA	SID-000135

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

1. Control in workflow validations.
2. Validation and development of sequencing protocols (e.g. Whole Genome Sequencing (WGS), Amplicon Sequencing) and PCR protocols.
3. Analyze the performance of your NGS pipeline by comparing to freely available datasets.
4. Calibration and development of instruments and workflows in DNA processing (e.g. DNA fragmentation via acoustic shearing, enzymatic digestion or sonication).

Product Background

The SensID DPYD-Multiplex 50% AF gDNA Reference Material consists of various dihydropyrimidine dehydrogenase gene (DPYD) variants that are known to have an impact on 5-fluorouracil (5-FU) catalyzation. 5-FU is used for treatment of cancer. In patients with defective DPYD, 5-FU toxicity occurs with standard doses of 5-FU causing severe and life-threatening effects.
SensID DNA products are precisely quantitated using standard methods traceable to internationally certified reference material. The SensID DPYD-Multiplex 50% AF gDNA Reference Material consists of one vial with 50% mutant allele frequency. Well characterized human gDNA from proprietary cell line is used as wild-type background. For additional information see table 1 and 2.

Protocol: DPYD-Multiplex 50% AF gDNA

Important point before starting:

- It is recommended to centrifuge SID-000135 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!
- No further purification or DNA isolation steps needed.
- DNA purified from a proprietary cell line, present in TE- buffer (Tris-EDTA (10 mM Tris, 1 mM EDTA), pH 8.0).
- Product is ready-to-use.

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 DPYD-Multiplex 50% AF gDNA is tested against predetermined specifications to ensure consistent product quality.
DPYD-Multiplex 50% AF gDNA should appear as a clear liquid. Alterations in this appearance may indicate instability or deterioration of the product and vials should be discarded.

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 is capable of transmitting infectious agents. This product is formulated using a cell line, which is a proprietary, female B-lymphocytic cell line.

Equipment and Reagents to Be Supplied by User

- Pipets (adjustable)[1]
- Sterile pipet tips with filters

[1] Ensure that instruments have been checked and calibrated according to the manufacturer's recommendations.

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Table 1 General information about DPYD. Taken from https://www.ncbi.nlm.nih.gov/gene/1806.

Official Symbol	DPYD
Official Full Name	dihydropyrimidine dehydrogenase
Organism	Homo sapiens
Also known as	DHPDHASE; DHPDHase; DPD; DHP
Summary	The protein encoded by this gene is a pyrimidine catabolic enzyme and the initial and rate-limiting factor in the pathway of uracil and thymidine catabolism. Mutations in this gene result in dihydropyrimidine dehydrogenase deficiency, an error in pyrimidine metabolism associated with thymine-uraciluria and an increased risk of toxicity in cancer patients receiving 5-fluorouracil chemotherapy. Two transcript variants encoding different isoforms have been found for this gene. [provided by RefSeq, May 2009]

Table 2 Mutations present in the SensID DPYD-Multiplex 50% AF gDNA Reference material. HGVS = Human Genome Variation Society.

Gene	dbSNP	Type of mutation	HGVS Nomenclature	Localisation in Genome (GRCh38)	Amino acid change
DPYD	rs56038477	Substitution	1236G>A	1: 97573863 Exon 10	p.Glu412=
DPYD	rs56276561	Substitution	c.483+18G>A	1: 97721492 Exon 4	-
DPYD	rs67376798	Substitution	c.2846A>T	1: 97082391 Exon 21	p.Asp949Val (p.D949V)
DPYD	rs75017182	Substitution	c.1129–5923C>G	1: 97579893 Between Exon9&10	IVS10
DPYD	rs55886062	Substitution	c.1679T>G	1: 97515787 Exon 12	p.Ile560Ser (p.I560S) other names: DPYD*13
DPYD	rs3918290	Substitution	c.1905+1G>A	1: 97450058 Exon 13	IVS14, G-A, +1 other names: DPYD*2A
DPYD	rs115232898	Substitution	c.557A>G	1: 97699474 Exon 5	p.Tyr186Cys (p.Y186C)
DPYD	rs72549309	Deletion	c.295_298delTCAT	1: 97740411-97740414 Exon 3	p.Phe100fs (p.F100fs) other names: DPYD*7
DPYD	rs1801160	Substitution	c.2194G>A	1:97305364-97305364 Exon 18	p.Val732Ile other names: DPYD*6