

BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	DPYD-Multiplex 50 % AF gDNA		
DESCRIPTION	DPYD-Multiplex 50 % AF gDNA is highly characterized human DNA from cell line.		
CATALOG NUMBER	SID-000135		
BATCH NUMBER	00834		
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> · Manufactured and sealed in class 2 safety cabinet · Manufactured according to DIN EN ISO 13485:2016 		
PACKAGE SIZE AND TYPE	<ul style="list-style-type: none"> · 2D barcoded tube with screw cap · Material: Polypropylen (PP) 		
DATE OF MANUFACTURE	10.12.2024		
EXPIRY DATE	09.12.2026		
TARGET CONCENTRATION	10 ng/μl (dsDNA)		
TARGET QUANTITY	400 ng (dsDNA)		
NOMINAL VOLUME	40 μl		
MUTATION <small>¹⁾ The haplotype previously designated as "HapB3" is a decreased function allele, currently defined by two variants, linkage disequilibrium</small>	DPYD rs56038477 (p.Glu412=/p.E412=, HapB3 ¹⁾ , c.1236G>A, Exon 10)		
	DPYD rs56276561 (c.483+18G>A, Exon 4)		
	DPYD rs67376798 (p.D949V, c.2846A>T, Exon 21)		
	DPYD rs75017182 (IVS10, HapB3 ¹⁾ , c.1129-5923C>G, Exon 9-10)		
	DPYD rs55886062 (p.I560S, DPYD*13, c.1679T>G, Exon 12)		
	DPYD rs3918290 (IVS14, DPYD*2A, c.1905+1G>A, Exon 13)		
	DPYD rs115232898 (p.Y186C, c.557A>G, Exon 6)		
	DPYD rs72549309 (F100fs, DPYD*7, c.299_302delTCAT, Exon 4)		
	DPYD rs146356975 (p.K290E, c.868A>G, Exon 9)		
	DPYD rs112766203 (p.T760I, c.2279C>T, Exon 18)		
ALLELE FREQUENCY	50.0 %		
STORAGE CONDITIONS	+ 2-8 °C		
MANUFACTURING SITE	SensID GmbH Schillingallee 68, 18057 Rostock, Germany		
TEST METHOD AND ACCEPTANCE CRITERIA	Quality control	Test method	Acceptance criteria
	Quality	Agarose gel electrophoresis: 1 % Gel with fluorescent DNA stain in 1 % TAE buffer	Bright band of high-molecular-weight gDNA ≥ 20 kb
	Quantification	dsDNA measurement: Qubit dsDNA HS Assay Kit (Invitrogen)	dsDNA: 10.0 ng/μl 7.5 – 12.5 ng/μl
	Allele frequency	Allele frequency analysis: dPCR (QIAGEN® QIAcuity Four)	AF 50.0 % (45.0 – 55.0 %)

RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Quality	Bright band of high-molecular-weight gDNA ≥ 20 kb		PASS
	Quantification	10.8 ng/μl (dsDNA)		PASS
	Allele frequency	Mutation	AF in %	PASS / FAIL
		DPYD rs56038477	46.5	PASS
		DPYD rs56276561	47.1	PASS
		DPYD rs67376798	47.1	PASS
		DPYD rs75017182	48.6	PASS
		DPYD rs55886062	46.2	PASS
		DPYD rs3918290	50.6	PASS
DPYD rs115232898		49.3	PASS	
DPYD rs72549309		47.4	PASS	
DPYD rs146356975	50.6	PASS		
DPYD rs112766203	46.5	PASS		
COMMENTS / REMARKS	Mutations based on AMP & EMA recommendation			

Name and position/title of person authorising the batch release:

Björn Nowack, Managing Director

Date of batch release: 06.01.2025

Signature batch release: Björn Nowack

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