

BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	DPYD-Multiplex 100% AF gDNA
DESCRIPTION	DPYD-Multiplex 100% AF gDNA is highly characterized human DNA from cell line.
CATALOG NUMBER	SID-000136
BATCH NUMBER	00494
MANUFACTURING CONDITIONS	· Manufactured und sealed in class 2 safety cabinet · Manufactured according to DIN EN ISO 13485:2016
PACKAGE SIZE AND TYPE	· 2D barcoded tube with screw cap · Material: Polypropylen (PP)
DATE OF MANUFACTURE	17.05.2023
EXPIRY DATE	16.05.2025
TARGET CONCENTRATION	10 ng/µl (dsDNA)
TARGET QUANTITY	1000 ng (dsDNA)
NOMINAL VOLUME	100 µl
MUTATION	DPYD rs56038477 (p.Glu412=, 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, 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 5)
	DPYD rs72549309 (F100fs, DPYD*7, c.295_298delTCAT, Exon 3)
DPYD rs1801160 (p.Val732Ile, DPYD*6, c.2194G>A, Exon 18)	
ALLELE FREQUENCY	100.0%
QUALITY	DNA quantity metrologically traceable to internationally certified reference material (ERM_AD442K).
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 BR Assay Kit (Invitrogen)		dsDNA: 10.0 ng/μl 7.5 – 12.5 ng/μl
	Allele frequency	Allele frequency analysis: ddPCR (BioRad QX200™)		AF 100.0% (95.0 – 105.0%)
RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Quality	Bright band of high-molecular-weight gDNA ≥ 20 kb		PASS
	Quantification	11.2 ng/μl (dsDNA)		PASS
	Allele frequency	Mutation	AF in %	PASS / FAIL
		DPYD rs56038477	99.3	PASS
		DPYD rs56276561	99.3	PASS
		DPYD rs67376798	99.3	PASS
		DPYD rs75017182	99.4	PASS
		DPYD rs55886062	99.3	PASS
		DPYD rs3918290	99.7	PASS
DPYD rs115232898		99.6	PASS	
DPYD rs72549309	99.7	PASS		
DPYD rs1801160	99.7	PASS		
COMMENTS / REMARKS	not applicable			

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

Björn Nowack, Managing Director

Date of batch release: 26.05.2023

Signature batch release: Björn Nowack

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