

BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	DPYD-Multiplex Set gDNA with 100%, 50% and 0% AF		
DESCRIPTION	DPYD-Multiplex Set gDNA with 100% AF, 50% AF and 0% AF in highly characterized human DNA from cell lines		
CATALOG NUMBER	SID-000110		
BATCH NUMBER	100% AF	50% AF	0% AF
	00335	00334	00333
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> · Manufactured und sealed in class 2 safety cabinet · At room temperature · 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) 		
ALLELE FREQUENCY	100% AF	50% AF	0% AF
DATE OF MANUFACTURE	16.03.2022	16.03.2022	16.03.2022
EXPIRY DATE	15.03.2024	15.03.2024	15.03.2024
CONCENTRATION	10 ng/µl (dsDNA)	10 ng/µl (dsDNA)	10 ng/µl (dsDNA)
QUANTITY	1000 µg (dsDNA)	1000 µg (dsDNA)	1000 µg (dsDNA)
NOMINAL VOLUME	100 µl	100 µl	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)		
QUALITY	DNA quantity metrological 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: 7.5 – 12.5 ng/μl		
	Allele Frequency		ddPCR Analysis* using BioRad QX200™ System	AF 100% (95.0 – 105.0%) AF 50% (45.0 – 55.0%) AF 0% (0.00 – 0.10%)		
*Measured after filling into product tube						
RESULTS OF ANALYSIS	Quality control	AF	Result		PASS / FAIL	
	Quality	100%	Bright band of high-molecular-weight gDNA ≥ 20 kb		PASS	
		50%				
		0%				
	Quantity	100%	10.4 ng/μl (dsDNA)		PASS	
		50%	10.2 ng/μl (dsDNA)			
		0%	11.04 ng/μl (dsDNA)			
	Allele Frequency	100%	AF	Mutation	AF in %	PASS
			DPYD rs56038477	99.9		
			DPYD rs56276561	99.7		
DPYD rs67376798			99.8			
DPYD rs75017182			99.8			
DPYD rs55886062			99.8			
DPYD rs3918290			99.9			
DPYD rs115232898			99.6			
DPYD rs72549309	99.2					

RESULTS OF ANALYSIS	Allele Frequency	AF	Mutation	AF in %	PASS / FAIL
		50%	DPYD rs56038477	47.0	PASS
	DPYD rs56276561	49.3			
	DPYD rs67376798	55.0			
	DPYD rs75017182	50.6			
	DPYD rs55886062	46.4			
	DPYD rs3918290	49.2			
	DPYD rs115232898	51.6			
	DPYD rs72549309	47.9			
	0%	DPYD rs56038477	0.0	PASS	
		DPYD rs56276561	0.0		
		DPYD rs67376798	0.0		
		DPYD rs75017182	0.0		
		DPYD rs55886062	0.0		
		DPYD rs3918290	0.0		
		DPYD rs115232898	0.0		
		DPYD rs72549309	0.0		
COMMENTS / REMARKS	not applicable				

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

Björn Nowack, Managing Director

Date of batch release: 31.03.2022

Signature batch release: Björn Nowack

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