Bringing Precision to MDx

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BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	DPYD 19-Plex 50 % AF gDNA
DESCRIPTION	DPYD 19-Plex 50 % AF gDNA is highly characterized human DNA from cell line.
CATALOG NUMBER	SID-000176
BATCH NUMBER	**01106**
MANUFACTURING CONDITIONS	· Manufactured and 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	01.07.2026
EXPIRY DATE	30.06.2028
TARGET CONCENTRATION	10 ng/µl (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	40 µl
VARIANT	DPYD p.E412= c.1236G>A (ENSG00000188641, 1:97573863C>T (GRCh38.p14))
	DPYD c.483+18G>A (ENSG00000188641, chr1: g.97721492C>T (GRCh38.p14))
	DPYD p.D949V c.2846A>T (ENSG00000188641, 1:97082391T>A (GRCh38.p14))
	DPYD c.1129-5923C>G (ENSG00000188641, 1:97579893G>C (GRCh38.p14))
	DPYD p.I560S c.1679T>G (ENSG00000188641, 1:97515787A>C (GRCh38.p14))
	DPYD c.1905+1G>A (ENSG00000188641, 1:97450058C>T (GRCh38.p14))
	DPYD p.Y186C c.557A>G (ENSG00000188641, 1:97699474T>C (GRCh38.p14))
	DPYD p.F100fs c.299_302del (ENSG00000188641, 1:97740411_97740418del (GRCh38.p14))
	DPYD p.K290E c.868A>G (ENSG00000188641, 1:97595149T>C (GRCh38.p14))
	DPYD p.T760I c.2279C>T (ENSG00000188641, 1:97305279G>A (GRCh38.p14))
	DPYD p.R235W c.703C>T (ENSG00000188641, 1:97691776G>A (GRCh38.p14))
	DPYD p.F438L c.1314T>G (ENSG00000188641, 1:97573785A>C (GRCh38.p14))
	DPYD p.S492L c.1475C>T (ENSG00000188641, 1:97549609G>A (GRCh38.p14))
	DPYD p.R592W c.1774C>T (ENSG00000188641, 1:97450190G>A (GRCh38.p14))
	DPYD p.G880V c.2639G>T (ENSG00000188641, 1:97098616C>A (GRCh38.p14))
	DPYD p.R21* c.61C>T (ENSG00000188641, 1:97883353G>A (GRCh38.p14))
	DPYD p.R235Q c.704G>A (ENSG00000188641, 1:97691775C>T (GRCh38.p14))
	DPYD p.D342N c.1024G>A (ENSG00000188641, 1:97593322C>T (GRCh38.p14))
	DPYD p.L682IfsTer24 c.2043_2058del (ENSG00000188641, 1:97373561_97373577del (GRCh38.p14))
ALLELE FREQUENCY	50.0 %

CERTIFICATION	DIN EN ISO 13485:2016, Registration-No.: SX 1652079-1, TÜV Rheinland®		
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	Fragment length analysis: Agilent Tape Station Genomic DNA ScreenTape (Agilent Technologies)	Peak size: ≥ 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 %)
*Except DPYD c.703C>T and DPYD c.704G>A: AF 40.0 % (36.0 – 44.0 %)			

RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Quality	53,257 bp		PASS
	Quantification	12.0 ng/µl (dsDNA)		PASS
	Allele frequency	Variant	AF in %	PASS / FAIL
		DPYD c.1236G>A	49.7	PASS
		DPYD c.483+18G>A	49.9	PASS
		DPYD c.2846A>T	50.5	PASS
		DPYD c.1129-5923C>G	53.2	PASS
		DPYD c.1679T>G	50.8	PASS
		DPYD c.1905+1G>A	51.6	PASS
		DPYD c.557A>G	51.3	PASS
		DPYD c.299_302del	51.1	PASS
		DPYD c.868A>G	49.0	PASS
		DPYD c.2279C>T	47.2	PASS
		DPYD c.703C>T	40.4	PASS
		DPYD c.1314T>G	49.7	PASS
		DPYD c.1475C>T	49.0	PASS
		DPYD c.1774C>T	51.6	PASS
		DPYD c.2639G>T	49.1	PASS
		DPYD c.61C>T	50.2	PASS
		DPYD c.704G>A	40.4	PASS
		DPYD c.1024G>A	51.2	PASS
		DPYD c.2043_2058del	49.4	PASS

COMMENTS / REMARKS	The detection of the allele frequency may vary depending on the assay used. Therefore, due to assay properties, there may be deviations in the observed allele frequencies compared to the values given here. Furthermore, some DPYD variants included in the DPYD 19-Plex Set gDNA are located in close physical proximity. Depending on assay design and workflow (e.g., PCR or NGS), this may affect the detection and discrimination of individual variants.

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

Björn Nowack, Managing Director

Date of batch release: 08.07.2026

Signature batch release: Björn Nowack

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