

Batch Certificate For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	DPYD-Multiplex Set gDNA 0% AF
DESCRIPTION	DPYD-Multiplex Set gDNA 0% AF is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000110
BATCH NUMBER	00101
MANUFACTURING CONDITIONS PACKAGE SIZE PACKAGE TYPE	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • At room temperature • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	29.09.2020
EXPIRY DATE	28.09.2022
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)
ALLELE FREQUENCY	0.0%
QUALITY	DNA quantity metrologically traceable to internationally certified reference material ¹
STORAGE CONDITIONS	+ 2 - 8 °C
MANUFACTURING AND QUALITY CONTROL SITES	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

¹ERM_AD442K
Phone: +49 (0) 381 377 182 01

TEST METHOD AND ACCEPTANCE CRITERIA	Quality Control	Test Method	Acceptance criteria
	Quality	Agarose gel electrophoresis ² 1% Gel with fluorescent DNA stain in 1 % TAE buffer	Bright band of high-molecular-weight gDNA ≥ 20 kb
	Quantification	dsDNA measurement ² : Qubit dsDNA BR Assay Kit (Invitrogen)	dsDNA: 7.5 – 12.5 ng/μl
	Allele Frequency	ddPCR Analysis ² using BioRad QX200™ System	AF 0% (0.00 – 0.10%)

RESULTS OF ANALYSIS	Result		PASS/FAIL																											
	Quality	Bright band of high-molecular-weight gDNA ≥ 20 kb		PASS																										
Quantity	9.2 ng/μl (dsDNA)		PASS																											
Allele Frequency	<table border="1"> <thead> <tr> <th>Mutation</th> <th>AF in %</th> <th>PASS/FAIL</th> </tr> </thead> <tbody> <tr> <td>DPYD rs56038477 (c.1236G>A)</td> <td>0.00</td> <td>PASS</td> </tr> <tr> <td>DPYD rs56276561 (c.483+18G>A)</td> <td>0.03</td> <td>PASS</td> </tr> <tr> <td>DPYD rs67376798 (c.2846A>T)</td> <td>0.03</td> <td>PASS</td> </tr> <tr> <td>DPYD rs75017182 (c.1129–5923C>G)</td> <td>0.00</td> <td>PASS</td> </tr> <tr> <td>DPYD rs55886062 (c.1679T>G)</td> <td>0.00</td> <td>PASS</td> </tr> <tr> <td>DPYD rs3918290 (c.1905+1G>A)</td> <td>0.00</td> <td>PASS</td> </tr> <tr> <td>DPYD rs115232898 (c.557A>G)</td> <td>0.00</td> <td>PASS</td> </tr> <tr> <td>DPYD rs72549309 (c.295_298delTCAT)</td> <td>0.00</td> <td>PASS</td> </tr> </tbody> </table>			Mutation	AF in %	PASS/FAIL	DPYD rs56038477 (c.1236G>A)	0.00	PASS	DPYD rs56276561 (c.483+18G>A)	0.03	PASS	DPYD rs67376798 (c.2846A>T)	0.03	PASS	DPYD rs75017182 (c.1129–5923C>G)	0.00	PASS	DPYD rs55886062 (c.1679T>G)	0.00	PASS	DPYD rs3918290 (c.1905+1G>A)	0.00	PASS	DPYD rs115232898 (c.557A>G)	0.00	PASS	DPYD rs72549309 (c.295_298delTCAT)	0.00	PASS
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COMMENTS/REMARKS	Additional information: Not applicable																													

² Measured after filling into product tube



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

Mr. Björn Nowack, Managing Director

Date of batch release: 08.10.2020

Signature batch release: Björn Nowack

This document was created electronically and is valid without a signature.

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VAT No: DE305142405, district court: Rostock HRB 14621
CEO: Björn Nowack

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PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	DPYD-Multiplex Set gDNA 50% AF
DESCRIPTION	DPYD-Multiplex Set gDNA 50% AF is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000110
BATCH NUMBER	00102
MANUFACTURING CONDITIONS PACKAGE SIZE PACKAGE TYPE	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • At room temperature • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	06.10.2020
EXPIRY DATE	05.10.2022
TARGET CONCENTRATION	10 ng/μl (dsDNA)
TARGET QUANTITY	1000 ng (dsDNA)
NOMINAL VOLUME MUTATION	100 μl 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)
ALLELE FREQUENCY	50.0%
QUALITY	DNA quantity metrologically traceable to internationally certified reference material ¹
STORAGE CONDITIONS	+ 2 - 8 °C
MANUFACTURING AND QUALITY CONTROL SITES	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

¹ERM_AD442K
Phone: +49 (0) 381 377 182 01

TEST METHOD AND ACCEPTANCE CRITERIA	Quality Control	Test Method	Acceptance criteria
	Quality	Agarose gel electrophoresis ² 1% Gel with fluorescent DNA stain in 1 % TAE buffer	Bright band of high-molecular-weight gDNA ≥ 20 kb
	Quantification	dsDNA measurement ² : Qubit dsDNA BR Assay Kit (Invitrogen)	dsDNA: 7.5 – 12.5 ng/μl
	Allele Frequency	ddPCR Analysis ² using BioRad QX200™ System	AF 50% (45.0 – 55.0%)

RESULTS OF ANALYSIS	Result		PASS/FAIL																											
	Quality	Bright band of high-molecular-weight gDNA ≥ 20 kb		PASS																										
Quantity	11.7 ng/μl (dsDNA)		PASS																											
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COMMENTS/REMARKS	Additional information: Not applicable																													

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Mr. Björn Nowack, Managing Director

Date of batch release: 08.10.2020

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CEO: Björn Nowack

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PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	DPYD-Multiplex Set gDNA 100% AF
DESCRIPTION	DPYD-Multiplex Set gDNA 100% AF is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000110
BATCH NUMBER	00097
MANUFACTURING CONDITIONS PACKAGE SIZE PACKAGE TYPE	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • At room temperature • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	21.09.2020
EXPIRY DATE	20.09.2022
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)
ALLELE FREQUENCY	100.0%
QUALITY	DNA quantity metrologically traceable to internationally certified reference material ¹
STORAGE CONDITIONS	+ 2 - 8 °C
MANUFACTURING AND QUALITY CONTROL SITES	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

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	Quality	Agarose gel electrophoresis ² 1% Gel with fluorescent DNA stain in 1 % TAE buffer	Bright band of high-molecular-weight gDNA ≥ 20 kb
	Quantification	dsDNA measurement ² : Qubit dsDNA BR Assay Kit (Invitrogen)	dsDNA: 7.5 – 12.5 ng/μl
	Allele Frequency	ddPCR Analysis ² using BioRad QX200™ System	AF 100% (95.0 – 105.0%)

RESULTS OF ANALYSIS	Result	PASS/FAIL																											
Quality	Bright band of high-molecular-weight gDNA ≥ 20 kb	PASS																											
Quantity	11.9 ng/μl (dsDNA)	PASS																											
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