BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	PanCancer cfDNA Reference Standard		
DESCRIPTION	Platform-agnostic single-vial cancer multiplex control containing 80 variants in 33 genes (50 SNV, 11 Indels, 19 fusions) in highly characterized human DNA derived from tumor cell line.		
CATALOG NUMBER	SID-000178		
BATCH NUMBER	**01031**		
MANUFACTURING CONDITIONS	· Manufactured and sealed in class II biological safety cabinet · Manufactured according to DIN EN ISO 13485:2016		
PACKAGE SIZE AND TYPE	· 2D barcoded tube with screw cap · Material: Polypropylene (PP)		
DATE OF MANUFACTURE	17.02.2026		
EXPIRY DATE	16.02.2028		
TARGET CONCENTRATION	10 ng/µl		
TARGET QUANTITY	250 ng		
NOMINAL VOLUME	25 µl		
VARIANTS	see Appendix for all included Variants (from page 3 onward)		
ALLELE FREQUENCY	nominal 1.00 %		
FUSION PRESENCE	> 0 Copies/ng		
METROLOGICAL TRACEABILITY	Digital PCR (dPCR) is an SI-traceable method for copy number (CN) determination (see comments and remarks). The copy number values are metrologically traceable to the natural units count 1 and ratio 1 and to International System of Units (SI).		
CERTIFICATION	SensID's quality management system is certified according to 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
	Fragmentation	Fragment length analysis: Agilent D5000 ScreenTape System (Agilent Technologies)	Peak size 167 bp ± 15 % (142 bp – 192 bp)
	Quantification	dsDNA measurement: Qubit™ 1X dsDNA HS Assay-Kit (Invitrogen)	dsDNA: 10.0 ng/µl ± 25 % (7.5 – 12.5 ng/µl)
	Allele frequency	Allele frequency analysis: dPCR (QIAGEN® QIAcuity Four)	AF: 1.00 % (> 0.5 %)
	Fusion Presence	DNA-fusion analysis: dPCR (QIAGEN® QIAcuity Four)	Copies/ng: > 0 Copies/ng

TEST METHOD AND ACCEPTANCE CRITERIA	Quality control	Test method	Acceptance criteria
	NGS	Allele frequency and DNA-fusion analysis: TruSight™ Oncology 500 ctDNA v2 Assay* (Illumina)	NGS result represents the mean of three replicates of 20 ng input after library preparation; for information only, not used for batch release
	*Allele frequencies and supporting reads for fusions testing performed by an ISO/IEC 17025:2018 accredited third-party genetic sequencing provider.		
RESULTS OF ANALYSIS	Quality control	Result	PASS / FAIL
	Fragmentation	166 bp	PASS
	Quantification	9.6 ng/µl (dsDNA)	PASS
	The results obtained by dPCR are used for batch release. Information derived from NGS is supplementary and intended for informational purposes only. All assessed variants fulfill the acceptance criteria as described above. For individual values, see Appendix.		
COMMENTS / REMARKS	Additional endogenous alterations, including mutations and fusion events, are present in the tumor cell line.		
	Whale, Alexandra S., et al. "Assessment of digital PCR as a primary reference measurement procedure to support advances in precision medicine." Clinical chemistry 64.9 (2018): 1296-1307. Whale et al. (2018) validated dPCR as an SI-traceable reference measurement procedure based on enumeration and demonstrates how it can be applied for assignment of copy number concentration and fractional abundance values to DNA reference materials in an aqueous solution. High-accuracy measurements using dPCR will support the implementation and traceable standardization of molecular diagnostic procedures needed for advancements in precision medicine.		
Additional information	1. Tumor mutational burden (TMB, mut/Mb) observed by TSO500: 125.2 mut/Mb		
	2. List of genes with copy number variation including Fold change, see Appendix		

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

Björn Nowack, Managing Director

Date of batch release:	22.04.2026
Signature batch release:	Björn Nowack

This document has been created electronically and is valid without signature.

APPENDIX TO BATCH CERTIFICATE

For Research Use Only

RESULTS OF ANALYSIS - VARIANTS - dPCR (QIAGEN® QIAcuity Four) and NGS (TSO500 ctDNA v2)

Variant	AF dPCR [%]	AF NGS [%]
AKT1 p.E17K c.49G>A (ENSG00000142208, chr14: g.104780214C>T (GRCh38.p14))	0.94	0.62
AR p.H875Y c.2623C>T (ENSG00000169083, chrX: g.67723701C>T (GRCh38.p14))	1.16	1.55
AR p.L702H c.2105T>A (ENSG00000169083, chrX: g.67711621T>A (GRCh38.p14))	0.61	2.34
AR p.W742L c.2225G>T (ENSG00000169083, chrX: g.67717529G>T (GRCh38.p14))	1.03	1.91
ATM p.R337C c.1009C>T (ENSG00000149311, chr11: g.108247071C>T (GRCh38.p14))	1.23	1.38
ATM p.R3008C c.9022C>T (ENSG00000149311, chr11: g.108365359C>T (GRCh38.p14))	1.19	1.90
BRAF p.G469A (II) c.1406G>C (ENSG00000157764, chr7: g.140781602C>G (GRCh38.p14))	1.59	1.37
BRAF p.V600E c.1799T>A (ENSG00000157764, chr7: g.140753336A>T (GRCh38.p13))	1.03	0.77
BRCA1 p.C61G c.181T>G (ENSG00000012048, chr17: g.43106487A>C (GRCh38.p13))	1.10	0.93
BRCA1 p.K654Sfs*47 c.1961del (ENSG00000012048, chr17: g.43093577del (GRCh38))	1.93	1.58
BRCA2 p.Ser1722fs/p.S1722Yfs*4 c.5164_5165del (ENSG00000139618, chr13: g.32339519_32339520del (GRCh38.p14))	1.05	1.20
BRCA2 p.R2645Nfs*3 c.7934delG (ENSG00000139618, chr13: g.32362651del (GRCh38.p13))	1.22	1.05
CDK12 p.W719* c.2157G>A (ENSG00000167258, chr17: g.39492799C>T (GRCh38.p14))	0.93	1.08
CDK12 p.E928_L929insYTKI c.2784_2785insTACACAAAGATA (ENSG00000167258, chr17: g.39515746_39515747ins (GRCh38.p14))	0.94	0.80
CHEK2 p.E321K c.961G>A (ENSG00000167258, chr22: g.28699885C>T (GRCh38.p14))	1.41	1.48
CHEK2 p.K373E c.1117A>G (ENSG00000183765, chr22: g.28695852T>C (GRCh38.p14))	2.42	4.16
CHEK2 p.R117G c.349A>G (ENSG00000183765, chr22: g.28725338T>C (GRCh38.p14))	1.25	1.19
EGFR p.E746_A750del c.2235_2249del (ENSG00000146648, chr7: g.55174772-55174786del (GRCh38))	0.71	0.66
EGFR p.L858R c.2573T>G (ENSG00000146648, chr7: g.55191822T>G (GRCh38))	1.43	0.94
EGFR p.T790M c.2369C>T (ENSG00000146648, chr7: g.55181378C>T (GRCh38))	1.11	1.28
ERBB2 (HER2) p.R678Q c.2033G>A (ENSG00000141736, chr17: g.39723405G>A (GRCh38.p14))	1.43	1.23
ERBB2 (HER2) p.L755S c.2264T>C (ENSG00000141736, chr17: g.39723967T>C (GRCh38.p14))	0.88	0.85
ERBB2 (HER2) p.S310F c.929C>T (ENSG00000141736, chr17: g.39711955C>T (GRCh38.p14))	0.90	0.95
ERBB2 (HER2) p.E770_A771insAYVM/p.Y772_A775dup c.2313_2324dup (ENSG00000141736, chr17: g.39724728-39724729ins (GRCh38.p14))	0.97	0.97

Variant	AF dPCR [%]	AF NGS [%]
ESR1 p.E380Q c.1138G>C (ENSG00000091831, chr6: g.152011697G>C (GRCh38.p13))	1.01	1.22
ESR1 p.S463P c.1387T>C (ENSG00000091831, chr6: g.152094402T>C (GRCh38.p13))	0.81	0.99
ESR1 p.V422del c.1265_1267del (ENSG00000091831, chr6: g.152061020_152061022del (GRCh38.p13))	0.66	1.08
ESR1 p.D538G c.1613A>G (ENSG00000091831, chr6: g.152098791A>G (GRCh38.p13))	0.76	1.06
FGFR3 p.Y373C c.1118A>G (ENSG00000068078, chr4: g.1804372A>G (GRCh38.p13))	1.21	1.05
FGFR3 p.S249C c.746C>G (ENSG00000068078, chr4: g.1801841C>G (GRCh38.p14))	1.71	1.53
IDH1 p.R132H c.395G>A (ENSG00000138413, chr2: g.208248388C>T (GRCh38.p13))	1.15	0.69
IDH2 p.R140Q c.419G>A (ENSG00000182054, chr15: g.90088702C>T (GRCh38.p14))	1.48	1.08
KIT p.A502_Y503dup c.1504_1509dup (ENSG00000157404, chr4: g.54726019-54726020 (GRCh38.p13))	1.26	1.93
KIT p.D816V c.2447A>T (ENSG00000157404, chr4: g.54733155A>T (GRCh38.p13))	0.99	1.54
KRAS p.Q61H c.183A>C (ENSG00000133703, chr12: g.25227341T>G (GRCh38.p14))	1.30	2.04
KRAS p.G12C c.34G>T (ENSG00000133703, chr12: g.25245351C>A (GRCh38.p14))	0.98	1.72
MET c.3082+1G>T (ENSG00000105976, chr7: g.116771990G>T (GRCh38))	1.46	2.41
NRAS p.Q61R c.182A>G (ENSG00000213281, chr1: g.114713908T>C (GRCh38.p14))	1.78	2.03
NTRK1 p.G595R c.1783G>A (ENSG00000198400, chr1: g.156876550G>A (GRCh38.p14))	1.24	0.93
PALB2 p.W1038* c.3113G>A (ENSG00000083093, chr16: g.23621362C>T (GRCh38.p14))	1.26	1.36
PALB2 p.M296* c.886del (ENSG00000083093, chr16: g.23635666Tdel (GRCh38.p14))	1.94	3.34
PDGFRA p.D842V c.2525A>T (ENSG00000134853, chr4: g.54285926A>T (GRCh38.p14))	0.98	0.85
PDGFRA p.N659K c.1977C>G (ENSG00000134853, chr4: g.54277981C>G (GRCh38.p14))	0.73	0.95
PIK3CA p.C420R c.1258T>C (ENSG00000121879, chr3: g.179210192T>C (GRCh38.p14))	1.21	1.16
PIK3CA p.E545K c.1633G>A (ENSG00000121879, chr3: g.179218303G>A (GRCh38.p14))	0.66	0.90
PIK3CA p.H1047R c.3140A>G (ENSG00000121879, chr3: g.179234297A>G (GRCh38.p13))	1.76	2.18
POLD1 p.D402N c.1204G>A (ENSG00000062822, chr19: g.50403559G>A (GRCh38.p14))	1.25	1.27
POLD1 p.E318K c.952G>A (ENSG00000062822, chr19: g.50402723G>A (GRCh38.p14))	1.03	0.78
POLD1 p.S478N c.1433G>A (ENSG00000062822, chr19: g.50406456G>A (GRCh38.p14))	1.09	0.91
POLE p.F367S c.1100T>C (ENSG00000177084, chr12: g.132675741A>G (GRCh38.p14))	0.83	0.71

Variant	AF dPCR [%]	AF NGS [%]
POLE p.V411L c.1231G>T (ENSG00000177084, chr12: g.132673703C>A (GRCh38.p14))	0.87	0.67
POLE p.P286R c.857C>G (ENSG00000177084, chr12: g.132676598G>C (GRCh38.p14))	1.08	1.10
PTEN p.R130Q c.389G>A (ENSG00000171862, chr10: g.87933148G>A (GRCh38.p14))	1.33	3.78
PTEN p.E73Dfs*25 c.219_222del (ENSG00000171862, chr10: g.87931055_87931058del (GRCh38 p13))	1.44	n.d.
PTEN p.T319* c.955_958del (ENSG00000171862, chr10: g:87961047_87961050del (GRCh38.p14))	1.15	n.d.
RAD51C p.R258H c.773G>A (ENSG00000108384, chr17: g:58709926G>A (GRCh38.p14))	1.47	1.22
STK11 p.F354L c.1062C>G (ENSG00000118046, chr19: g.1223126C>G (GRCh38.p14))	1.21	0.95
STK11 p.Q37* c.109C>T (ENSG00000118046, chr19: g.1207022C>T (GRCh38.p14))	1.39	1.10
STK11 p.P281Rfs*6 c.842del (ENSG00000118046, chr19: g.1221320del (GRCh38.p14))	1.52	0.79
TP53 p.R175H c.524G>A (ENSG00000143549, chr17: g.7675088C>T (GRCh38.p13))	3.09	2.64
TP53 p.R273H c.818G>A (ENSG00000143549, chr17: g.7673802C>T (GRCh38.p14))	1.38	1.01

RESULTS OF ANALYSIS - FUSIONS - dPCR (QIAGEN® QIAcuity Four) and NGS (TSO500 ctDNA v2)

Fusion	CN Fusion dPCR [CN/ng]	Fusion Supporting Reads (NGS)
EML4::ALK (ENST00000318522.10, ENST00000389048.8, exons 6, 20, fusion points 2:42264731, 2:29223528 (GRCh38.p14))	1.32	14
EML4::ALK (ENST00000318522.10, ENST00000389048.8, exons 20, 20, fusion points 2:42325554, 2:29223528 (GRCh38.p14))	1.84	40
EML4::ALK (ENST00000318522.10, ENST00000389048.8, exons 13, 20, fusion points 2:42295516, 2:29223528 (GRCh38.p13))	1.86	34
CD74::ROS1 (ENST00000009530.13, ENST00000368508.7, exons 6, 34, fusion points 5:150404680, 6:117324415 (GRCh38.p13))	3.89	29
CD74::ROS1 (ENST00000009530.13, ENST00000368508.7, exons 6, 32, fusion points 5:150404680, 6:117329446 (GRCh38))	5.60	44
ETV6::NTRK3 (ENST00000396373.9, ENST00000629765.3, exons 5, 15, fusion points 12:11869969, 15:87940753 (GRCh38.p14))	7.51	75
FGFR3::BAIAP2L1 (ENST00000440486.2, ENST00000005260.9, exons 17, 2, fusion points 4:1806934, 7:98362432 (GRCh38.p14))	1.14	15
FGFR3::TACC3 (ENST00000440486.2, ENST00000313288.4, exons 17, 11, fusion points 4:1806934, 4:1739702 (GRCh38.p13))	1.09	12
LMNA::NTRK1 (ENST00000368300.9, ENST00000524377.7, exons 2, 10, fusion points 1:156130773, 1:156874571 (GRCh38.p14))	2.82	13

Fusion	CN Fusion dPCR [CN/ng]	Fusion Supporting Reads (NGS)
NACC2::NTRK2 (ENST00000277554.4, ENST00000277120.8, exons 4, 11, fusion points 9:136013864, 9:84744973 (GRCh38.p14))	5.22	10
NPM1::ALK (ENST00000296930.10, ENST00000389048.8, exons 4, 20, fusion points 5:171391799, 2:29223528 (GRCh38.p14))	2.82	31
QKI::NTRK2 (ENST00000361752.8, ENST00000277120.8, exons 6, 14, fusion points 6:163563719, 9:84867243 (GRCh38.p14))	2.73	28
CCDC6::RET (ENST00000263102.7, ENST00000355710.8, exons 1, 12, fusion points 10:59906122, 10:43116584 (GRCh38.p14))	5.77	37
KIF5B::RET (ENST00000302418.5, ENST00000355710.8, exons 15, 12, fusion points 10:32028428, 10:43116584 (GRCh38.p14))	11.04	78
NCOA4::RET (ENST00000578454.5, ENST00000355710.8, exons 8, 12, fusion points 10:46012883, 10:43116584 (GRCh38.p14))	11.51	60
EZR::ROS1 (ENST00000367075.4, ENST00000368508.7, exons 10, 34, fusion points 6:158770764, 6:117324415 (GRCh38))	3.24	15
SLC34A2::ROS1 (ENST00000382051.8, ENST00000368508.7, exons 4, 34, fusion points 4:25664330, 6:117329446 (GRCh38.p14))	5.90	n.d.
TPM3::NTRK1 (ENST00000368533.8, ENST00000392302.7, exons 7, 10, fusion points 1:154170400, 1:156874571 (GRCh38.p13))	4.62	16
TRIM24::NTRK2 (ENST00000343526.9, ENST00000277120.8, exons 12, 14, fusion points 7:138573642, 9:84867243 (GRCh38.p14))	3.81	16

ADDITIONAL INFORMATION - LIST OF COPY NUMBER VARIATIONS - NGS (TSO500 ctDNA v2)

Gene	Fold Change	Gene	Fold Change
ALK	0.75	FGF10	0.75
AR	0.34	FGF14	0.67
BRAF	1.55	FGF19	1.77
BRCA2	2.01	FGF23	1.37
CCND1	1.85	FGFR1	0.74
CCND3	1.27	FGFR2	1.55
CCNE1	1.38	FGFR3	0.65
CDK6	1.61	JAK2	1.37
CHEK1	0.74	KRAS	1.69
CHEK2	2.68	MET	2.08
FGF1	1.41	MYC	2.25
FGF2	1.52	MYCN	0.50
FGF3	1.50	NRG1	0.69
FGF4	1.63	PDGFRB	1.34
FGF6	1.27	PIK3CB	1.93
FGF7	0.50	PTEN	0.65
FGF8	0.69	RET	2.17