Bringing Precision to MDx

Release Date	30.03.2026
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BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	5-Gene-Multiplex 1 % AF cfDNA AKT1/BRAF/ERBB2/KRAS/PIK3CA
DESCRIPTION	5-Gene-Multiplex 1 % AF cfDNA AKT1/BRAF/ERBB2/KRAS/PIK3CA is highly characterized human DNA from cell line.
CATALOG NUMBER	SID-000093
BATCH NUMBER	**01062**
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	24.03.2026
EXPIRY DATE	23.03.2028
TARGET CONCENTRATION	20 ng/µl (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	20 µl
VARIANT	AKT1 p.E17K c.49G>A (ENSG00000142208, 14:104780214C>T (GRCh38.p14))
	BRAF p.V600E c.1799T>A (ENSG00000157764, 7:140753336A>T (GRCh38.p13))
	ERBB2 (HER2) p.E770_A771insAYVM (p.Y772_A775dup) c.2313_2324dup (ENSG00000141736, 17:39724742-39724743 (GRCh38 p14))
	KRAS p.G12D c.35G>A (ENSG00000133703, 12:25245350C>T (GRCh38 p14))
	KRAS p.Q61K c.181C>A (ENSG00000133703, 12:25227343G>T (GRCh38 p14))
	KRAS p.A146T c.436G>A (ENSG00000133703, 12:25225628C>T (GRCh38.p14))
	PIK3CA p.H1047R c.3140A>G (ENSG00000121879, 3:179234297A>G (GRCh38 p13))
	PIK3CA p.E545K c.1633G>A (ENSG00000121879, 3:179218303G>A (GRCh38.p14))
ALLELE FREQUENCY	1.00 %
QUALITY	DNA quantity metrologically traceable to internationally certified reference material (ERM_AD442K). 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) derived units of volume.
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
	Fragmentation	Fragment length analysis: Agilent D5000 ScreenTape System (Agilent Technologies)		Peak size: 167 bp ± 15 % (142 bp – 192 bp)
	Quantification	dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)		dsDNA: 20.0 ng/µl (17.5 – 22.5 ng/µl)
	Allele frequency	Allele frequency analysis: dPCR (QIAGEN® QIAcuity Four)		AF 1.00 % ± 40 % (0.60 – 1.40 %)
RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Fragmentation	167 bp		PASS
	Quantification	22.1 ng/µl (dsDNA)		PASS
	Allele frequency	Variant	AF in %	PASS / FAIL
		AKT1 E17K	0.99	PASS
		BRAF V600E	0.97	PASS
		ERBB2 E770_A771insAYVM (new: Y772_A775dup)	0.93	PASS
		KRAS G12D	0.85	PASS
		KRAS Q61K	0.88	PASS
		KRAS A146T	0.98	PASS
		PIK3CA H1047R	1.35	PASS
		PIK3CA E545K	1.26	PASS

COMMENTS / REMARKS	*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.

MEASUREMENT OF COPY NUMBER

Variant	CN wt/ng	CN mut/ng
AKT1 E17K	410.57	4.10
BRAF V600E	488.34	4.77
ERBB2 E770_A771insAYVM (new: Y772_A775dup)	379.03	3.56
KRAS G12D	544.36	4.66
KRAS Q61K	609.04	5.41
KRAS A146T	389.15	3.87
PIK3CA H1047R	422.76	5.80
PIK3CA E545K	465.42	5.96

wt: wildtype; mut: mutation

The table above indicates the values of the QC assays performed by SensID GmbH with a DNA input of 1 ng. The value for the respective mutation results from the mean value of QC samples based on ISO 2859-1:2014-08 (CN values are rounded). CN concentration values per nanogram (ng) are based on digital (dPCR) assay counts and dilution factors. The detection of the amount of CNs may vary depending on the assay used. Therefore, due to assay properties, there may be deviations in the observed number of copies and allele frequencies compared to the values given here.

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

Björn Nowack, Managing Director

Date of batch release: 30.03.2026

Signature batch release: Björn Nowack

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