

BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	5-Gene-Multiplex 5% AF cfDNA AKT1/BRAF/ERBB2/KRAS/PIK3CA
DESCRIPTION	5-Gene-Multiplex 5% AF cfDNA AKT1/BRAF/ERBB2/KRAS/PIK3CA is a highly characterized human DNA from cell line
CATALOG NUMBER	SID-000094
BATCH NUMBER	00142
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)
DATE OF MANUFACTURE	16.12.2020
EXPIRY DATE	15.12.2021
TARGET CONCENTRATION	20 ng/μl (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 μl
MUTATION * GRCh38 COSMIC v91	AKT1 p.E17K (COSV62571334*, substitution, c.49G>A, Exon 2) BRAF p.V600E (COSV56056643*, substitution, c.1799T>A, Exon 15) ERBB2 p.E770_A771insAYVM (new: p.Y772_A775dup) (COSV54062409*, insertion, c.2313_2324dup, Exon 19) KRAS p.G12D (COSV55497369*, substitution, c.35G>A, Exon 1) KRAS p.Q61K (COSV55502066*, substitution, c.181C>A, Exon 2) KRAS p.A146T (COSV55501778*, substitution, c.436G>A, Exon 3) PIK3CA p.H1047R (COSV55873195*, substitution, c.3140A>G, Exon 20) PIK3CA p.E545K (COSV55873239* substitution, c.1633G>A, Exon 9)
ALLELE FREQUENCY	5.0 %
QUALITY	DNA quantity metrologically traceable to internationally certified reference material (ERM_AD442K). The copy number values are metrologically traceable to the natural units count 1 and ratio 1 and International System of Units (SI) derived units of volume.
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 ± 10% (151 bp – 181 bp)
	Quantification	Total DNA measurement (ssDNA): Spectrophotometry** dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	Total DNA: not applicable dsDNA: 17.5 – 22.5 ng/μl
	Allele frequency	Allele frequency analysis ddPCR (BioRad QX200™)	AF 5% ± 30% (3.5–6.5%)

**Protocol NK603 – Community Reference Laboratory for GM Food and Feed; Measured before filling in product tube

RESULTS OF ANALYSIS	Quality control	Result	PASS / FAIL	
	Fragmentation	176 bp	PASS	
	Quantification	39.9 ng/μl (total DNA)	PASS	
		19.7 ng/μl (dsDNA)		
	Allele frequency	Mutation	AF in %	PASS / FAIL
		AKT1 E17K	5.00	PASS
		BRAF V600E	5.10	PASS
		ERBB2 E770_A771insAYVM (new: Y772_A775dup)	4.50	PASS
		KRAS G12D	4.20	PASS
		KRAS Q61K	5.20	PASS
KRAS A146T		4.90	PASS	
PIK3CA H1047R		4.60	PASS	
PIK3CA E545K	4.40	PASS		

COMMENTS / REMARKS	Additional information: Measurement of copy number		
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ μ l	CN mut/ μ l
	AKT1 E17K	1991	105
	BRAF V600E	2045	109
	ERBB2 E770_A771insAYVM (new: Y772_A775dup)	3220	150
	KRAS G12D	2882	127
	KRAS Q61K	3384	187
	KRAS A146T	3896	199
	PIK3CA H1047R	4230	204
	PIK3CA E545K	3195	147
	wt: wildtype; mut: mutation <i>The table above indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~20 ng. The value for the respective mutation results from the mean value of QC samples according to ISO 2859-1:2014-08 (CN values are rounded). CN concentration values per microliter (μl) are based on droplet digital (ddPCR) assay counts dilution factors, and droplet volume measurements. 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.</i>		

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

Björn Nowack, Managing Director

Date of batch release: 18.12.2020

Signature batch release: Björn Nowack

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