

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	00702
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> · Manufactured and sealed in class 2 safety cabinet · 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	28.05.2024
EXPIRY DATE	27.05.2026
TARGET CONCENTRATION	20 ng/μl (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	20 μl
MUTATION * GRCh38 COSMIC v97	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	1.00%
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 ± 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: ddPCR (BioRad QX200™)		AF 1.00% ± 40% (0.60 – 1.40%)
RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Fragmentation	166 bp		PASS
	Quantification	20.5 ng/μl (dsDNA)		PASS
	Allele frequency	Mutation	AF in %	PASS / FAIL
		AKT1 E17K	1.22	PASS
		BRAF V600E	1.01	PASS
		ERBB2 E770_A771insAYVM (new: Y772_A775dup)	0.98	PASS
		KRAS G12D	0.93	PASS
		KRAS Q61K	1.16	PASS
		KRAS A146T	1.06	PASS
PIK3CA H1047R		1.07	PASS	
PIK3CA E545K	0.90	PASS		
COMMENTS / REMARKS	Additional information: Measurement of copy number			
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ng	CN mut/ng	
	AKT1 E17K	181.76	2.24	
	BRAF V600E	162.63	1.66	
	ERBB2 E770_A771insAYVM (new: Y772_A775dup)	292.15	2.89	
	KRAS G12D	433.11	4.08	
	KRAS Q61K	276.78	3.26	
	KRAS A146T	319.46	3.43	
	PIK3CA H1047R	339.95	3.67	
	PIK3CA E545K	353.60	3.22	
	wt: wildtype; mut: mutation <i>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 according to ISO 2859-1:2014-08 (CN values are rounded). CN concentration values per nanogram (ng) 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: 04.06.2024

Signature batch release: Björn Nowack

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