

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 in Plasma
DESCRIPTION	5-Gene-Multiplex 5% AF cfDNA AKT1/BRAF/ERBB2/KRAS/PIK3CA in highly characterized human DNA from cell lines. Human proteins in common plasma concentrations, electrolytes, EDTA, cfDNA / ctDNA in common plasma concentrations.
CATALOG NUMBER	SID-000090
BATCH NUMBER	00139
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • Bottled with qualified liquid handling workstation • At room temperature
PACKAGE SIZE	<ul style="list-style-type: none"> • 2D barcoded tube with screw cap
PACKAGE TYPE	<ul style="list-style-type: none"> • Material: Polypropylen (PP)
DATE OF MANUFACTURE	09.12.2020
EXPIRY DATE	08.12.2022
TARGET CONCENTRATION	80 ng/ml (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	5 ml
MUTATION	AKT1 p.E17K (COSM33765*, COSV62571334*, substitution, c.49G>A, Exon 2) BRAF p.V600E (COSM476*, COSV56056643*, substitution, c.1799T>A, Exon 15) ERBB2 p.E770_A771insAYVM (new: p.Y772_A775dup) (COSM20959*, COSV54062409*, insertion, c.2313_2324dup, Exon 19) KRAS p.G12D (COSM521*, COSV55497369*, substitution, c.35G>A, Exon 1) KRAS p.Q61K (COSM549*, COSV55502066*, substitution, c.181C>A, Exon 2) KRAS p.A146T (COSM19404*, COSV55501778*, substitution, c.436G>A, Exon 3) PIK3CA p.H1047R (COSM775*, COSV55873195*, substitution, c.3140A>G, Exon 20) PIK3CA p.E545K (COSM763*, COSV55873239* substitution, c.1633G>A, Exon 9) * GRCh38 COSMIC v91
ALLELE FREQUENCY	5%
QUALITY	DNA quantity metrologically traceable to internationally certified reference material ¹

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

	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 AND QUALITY CONTROL SITES	SensID GmbH Schillingallee 68, 18057 Rostock, Germany		
TEST METHOD AND ACCEPTANCE CRITERIA	Quality Control	Test Method	Acceptance Criteria
	Fragmentation	Fragment Length Analysis ² Agilent High Sensitivity DNA Kit (Agilent Technologies)	peak size 167 bp ± 10% (151 bp – 181 bp)
	Quantification	dsDNA measurement: Qubit ² dsDNA BR Assay Kit (Invitrogen) dsDNA amount per ml plasma	80 ng/ml ± 10% (72-88 ng/ml)
	Allele Frequency	ddPCR Analysis ² using BioRad QX200™ System	AF 5% ±30% (3.5-6.5%)
RESULTS OF ANALYSIS		Result	PASS/FAIL
	Fragmentation	169 bp	PASS
	Quantity	80 ng/ml plasma	PASS
	Allele Frequency		
		Mutation	AF in %
AKT1 E17K		4.2	PASS
BRAF V600E		4.6	PASS
ERBB2 E770_A771insAYVM (new: Y772_A775dup)		4.1	PASS
KRAS G12D		4.8	PASS
KRAS Q61K		4.5	PASS
KRAS A146T		5.2	PASS
PIK3CA H1047R		4.6	PASS
PIK3CA E545K	4.6	PASS	

² Measured before filling in product tube
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COMMENTS/REMARKS

ADDITIONAL INFORMATION:

Copy numbers (CN) of the respective measurements

Mutation	CN wt ³ /ml	CN mut ⁴ /ml
AKT1 E17K	9811	434
BRAF V600E	8187	392
ERBB2 E770_A771insAYVM (new: Y772_A775dup)	14358	607
KRAS G12D	11985	603
KRAS Q61K	14273	676
KRAS A146T	16719	922
PIK3CA H1047R	17921	872
PIK3CA E545K	11578	561

Table 1 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 three measured replicates (CN values are rounded). CN concentration values per milliliter (ml) plasma 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.

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

Mr. Björn Nowack, Managing Director

Date of batch release: 16.12.2020

Signature batch release: Björn Nowack

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

³ Wild Type

⁴ Mutation