

Batch Certificate For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	5-Gene-Multiplex 0.1% AF cfDNA AKT1/BRAF/ERBB2/KRAS/PIK3CA in Plasma
DESCRIPTION	5-Gene-Multiplex 0.1% 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-000088
BATCH NUMBER	00141
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) <small>* GRCh38 COSMIC v91</small>
ALLELE FREQUENCY	0.1%
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 0.1% ±60% (0.04–0.16%)																										
RESULTS OF ANALYSIS		Result	PASS/FAIL																										
	Fragmentation	177 bp	PASS																										
	Quantity	80 ng/ml plasma	PASS																										
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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	8649	11
BRAF V600E	7524	7
ERBB2 E770_A771insAYVM (new: Y772_A775dup)	12722	11
KRAS G12D	10512	11
KRAS Q61K	12223	11
KRAS A146T	13519	11
PIK3CA H1047R	15743	22
PIK3CA E545K	10287	7

Table 1 indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~100 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