

Batch Certificate

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	5-Gene-Multiplex 5% AF cfDNA in Plasma
DESCRIPTION	AKT1/BRAF/ERBB2/KRAS/PIK3CA
CATALOG NUMBER	SID-000090
BATCH NUMBER	00024
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 AND TYPE	<ul style="list-style-type: none"> • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	12.11.2019
EXPIRY DATE	11.11.2021
CONCENTRATION	80 ng/ml (ds DNA)
QUANTITY	400 ng (ds DNA)
NOMINAL VOLUME	18.4 µl in 5 ml plasma
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* / COSM404915*, COSV54062409*, insertion, c.2313_2324dup/ c.2310_2311ins12, 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 v90</small>
ALLELIC FREQUENCY	5%
QUALITY	DNA quantity metrologically traceable to internationally certified reference material ¹ 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

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

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	Total DNA measurement: Spectrophotometry ssDNA [ng/μl] = (A260-A320)*38 ^{2,3} dsDNA measurement ² : Qubit dsDNA BR Assay Kit (Invitrogen)	ssDNA: n.a. ⁴ dsDNA: n.a. ⁴	
	Allelic Frequency	dPCR Analysis ² using BioRad QX200™ System	AF 5% ±30% (3.5-6.5%)	
RESULTS OF ANALYSIS		Result	PASS/FAIL	
	Fragmentation	179 bp	PASS	
	Quantity	31.6 ng/μl (total DNA) 21.9 ng/μl (dsDNA)		
	Allelic Frequency	Mutation	AF in %	PASS
		AKT1 E17K	5.4	
BRAF V600E		5.4		
ERBB2 E770_A771insAYVM (Y772_A775dup)		4.9		
KRAS G12D		5.4		
KRAS Q61K		5.9		
KRAS A146T		6.4		
PIK3CA H1047R		5.5		
PIK3CA E545K	6.5			
COMMENTS/REMARKS	Additional information: Copy numbers (CN) of the respective measurements <i>Table 1 indicates the values of the QC assays performed by SensID GmbH with an DNA input of ~40 ng. The value for the respective mutation results from the mean value of three measured replicates (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.</i>			

² Measured before spiking in

³ Protocol NK603 – Community Reference Laboratory for GM Food and Feed

⁴ not applicable

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VAT No: DE305142405, district court: Rostock HRB 14621

CEO: Björn Nowack

Therefore, due to assay properties, there may be deviations in the observed number of copies and allele frequencies compared to the values given here.

Mutation	CN wt⁵/μl	CN mut⁶/μl
AKT1 E17K	2340	135
BRAF V600E	2128	123
ERBB2 E770_A771insAYVM (Y772_A775dup)	3437	179
KRAS G12D	2805	161
KRAS Q61K	3332	211
KRAS A146T	3997	271
PIK3CA H1047R	4189	246
PIK3CA E545K	2836	198

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

Mr. Björn Nowack, Managing Director

Date of batch release: 12.11.2019

Signature batch release: Björn Nowack

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

⁵ Wild Type

⁶ Mutation

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