

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 highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000094
BATCH NUMBER	00068
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • 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	27.05.2020
EXPIRY DATE	26.05.2022
CONCENTRATION	20 ng/μl (dsDNA)
QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 μl; (490 ng)
MUTATION	<p>AKT1 p.E17K (COSM33765*, COSV62571334*, substitution, c.49G>A, Exon 2)</p> <p>BRAF p.V600E (COSM476*, COSV56056643*, substitution, c.1799T>A, Exon 15)</p> <p>ERBB2 p.E770_A771insAYVM (new: p.Y772_A775dup) (COSM20959*, COSV54062409*, insertion, c.2313_2324dup, Exon 19)</p> <p>KRAS p.G12D (COSM521*, COSV55497369*, substitution, c.35G>A, Exon 1)</p> <p>KRAS p.Q61K (COSM549*, COSV55502066*, substitution, c.181C>A, Exon 2)</p> <p>KRAS p.A146T (COSM19404*, COSV55501778*, substitution, c.436G>A, Exon 3)</p> <p>PIK3CA p.H1047R (COSM775*, COSV55873195*, substitution, c.3140A>G, Exon 20)</p> <p>PIK3CA p.E545K (COSM763*, COSV55873239* substitution, c.1633G>A, Exon 9)</p> <p><small>* GRCh38 COSMIC v91</small></p>
ALLELE FREQUENCY	5.0%
QUALITY	<p>DNA quantity metrologically traceable to internationally certified reference material¹</p> <p>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.</p>
STORAGE CONDITIONS	+ 2 - 8 °C
MANUFACTURING AND QUALITY CONTROL SITES	<p>SensID GmbH</p> <p>Schillingallee 68, 18057 Rostock, Germany</p>

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

TEST METHOD AND ACCEPTANCE CRITERIA	Quality Control	Test Method	Acceptance criteria
	Fragmentation	Fragment Length Analysis 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: Qubit dsDNA BR Assay Kit (Invitrogen)	Total DNA: n.a. ⁴ dsDNA: 17.5 – 22.5 ng/μl
	Allele Frequency	ddPCR Analysis using BioRad QX200™ System	AF 5% ±30% (3.5-6.5%)

RESULTS OF ANALYSIS																													
	Result	PASS/FAIL																											
Fragmentation	167 bp	PASS																											
Quantity	29.3 ng/μl (total DNA) 19.6 ng/μl (dsDNA)	PASS																											
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² Protocol NK603 – Community Reference Laboratory for GM Food and Feed

³ Measured before filling in product tube

⁴ not applicable

COMMENTS/REMARKS

ADDITIONAL INFORMATION:

Copy numbers (CN) of the respective measurements

Mutation	CN wt ⁵ /μl	CN mut ⁶ /μl
AKT1 E17K	2329	118
BRAF V600E	1766	97
PIK3CA H1047R	4368	197
PIK3CA E545K	2743	153
ERBB2 E770_A771insAYVM (new: Y772_A775dup)	3501	167
KRAS G12D	2939	164
KRAS Q61K	3610	191
KRAS A146T	4166	219

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 five 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. 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: 04.06.2020

Signature batch release: Björn Nowack

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

⁵ Wild Type
⁶ Mutation