

Batch Certificate For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-Multiplex 0.1% AF cfDNA
DESCRIPTION	EGFR-Multiplex 0.1% AF cfDNA is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000015
BATCH NUMBER	00082
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • 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	22.07.2020
EXPIRY DATE	21.07.2022
CONCENTRATION	20 ng/μl (dsDNA)
QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 μl; (540 ng)
MUTATION	<p>p.G719S (COSM6252*, COSV51767289*, substitution, c.2155G>A, Exon 18)</p> <p>p.E746_A750delELREA (COSM6225*, COSV51765066*, deletion, c.2236_2250del15, Exon 19)</p> <p>p.S752_I759delSPKANKEI (COSM6256*, COSV51774879*, deletion, c.2254_2277del24, Exon 19)</p> <p>p.S768I (COSM6241*, COSV51768106* substitution, c.2303G>T, Exon 20)</p> <p>p.V769_D770insASV (new: p.A767_V769dup) (COSM20884*, COSV51850427* Insertion, c.2303_2304insTGTGGCCAG, Exon 20)</p> <p>p.T790M (COSM6240*, COSV51765492*, substitution, c.2369C>T, Exon 20)</p> <p>p.L858R (COSM6224*, COSV51765161*, substitution, c.2573T>G, Exon 21)</p> <p>p.L861Q (COSM6213*, COSV51766344*, substitution, c.2582T>A, Exon 21)</p> <p><small>* GRCh38 COSMIC v91</small></p>
ALLELE FREQUENCY	0.1%
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

¹ ERM_AD442K
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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 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 dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	Total DNA: n.a. ³ dsDNA: 17.5 – 22.5 ng/μl
	Allele Frequency	ddPCR Analysis using BioRad QX200™ System	AF 0.1% ±60% (0.04-0.16%)

RESULTS OF ANALYSIS	Result		PASS/FAIL
	Fragmentation	178 bp	PASS
	Quantity	33.0 ng/μl (total DNA) 21.6 ng/μl (dsDNA)	PASS
	Allele Frequency	Mutation	AF in %
EGFR L858R		0.06	PASS
EGFR L861Q		0.15	PASS
EGFR S768I		0.06	PASS
EGFR E746_A750delELREA		0.08	PASS
EGFR T790M		0.05	PASS
EGFR G719S		0.12	PASS
EGFR V769_D770insASV		0.06	PASS
EGFR S752_I759delSPANKEI		0.08	PASS

² Protocol NK603 – Community Reference Laboratory for GM Food and Feed

³ not applicable

COMMENTS/REMARKS

ADDITIONAL INFORMATION:

Copy numbers (CN) of the respective measurements

Mutation	CN wt ⁴ /μl	CN mut ⁵ /μl
EGFR L858R	3519	2
EGFR L861Q	4791	7
EGFR S768I	3267	2
EGFR E746_A750delELREA	3788	3
EGFR T790M	3666	2
EGFR G719S	4204	5
EGFR V769_D770insASV	3414	2
EGFR S752_I759delSPANKEI	2477	2

Table 1 indicates the values of the QC assays performed by SensID GmbH with an DNA input of ~130 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. 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

Date of batch release: 28.07.2020

Signature batch release: Björn Nowack

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

⁴ Wild Type

⁵ Mutation