

Batch Certificate For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-T790M 1% AF cfDNA
DESCRIPTION	EGFR- T790M 1% AF cfDNA is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000013
BATCH NUMBER	00076
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	22.07.2020
EXPIRY DATE	21.07.2022
CONCENTRATION	20 ng/μl (dsDNA)
QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	23 μl; (432 ng)
MUTATION	p.T790M (COSM6240*, COSV51765492*, substitution, c.2369C>T, Exon 20) <small>* GRCh38 COSMIC v91</small>
ALLELE FREQUENCY	1.0%
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
MANUFACTURING AND QUALITY CONTROL SITES	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

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 1.0% ±40% (0.6–1.4%)

RESULTS OF ANALYSIS	Result		PASS/FAIL						
	Fragmentation	176 bp		PASS					
Quantity	35.5 ng/μl (total DNA)		n.a. ⁴						
	18.8 ng/μl (dsDNA)		PASS						
Allele Frequency	<table border="1"> <thead> <tr> <th>Mutation</th> <th>AF in %</th> <th>PASS/FAIL</th> </tr> </thead> <tbody> <tr> <td>EGFR T790M</td> <td>0.7</td> <td>PASS</td> </tr> </tbody> </table>			Mutation	AF in %	PASS/FAIL	EGFR T790M	0.7	PASS
	Mutation	AF in %	PASS/FAIL						
EGFR T790M	0.7	PASS							

COMMENTS/REMARKS						
Additional information: Copy numbers (CN) of the respective measurements <table border="1"> <thead> <tr> <th>Mutation</th> <th>CN wt⁵/μl</th> <th>CN mut⁶/μl</th> </tr> </thead> <tbody> <tr> <td>EGFR T790M</td> <td>4090</td> <td>28</td> </tr> </tbody> </table> <p><i>Table 1 indicates the values of the QC assays performed by SensID GmbH with a 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. Therefore, due to assay properties, there may be deviations in the observed number of copies and allele frequencies compared to the values given here.</i></p>	Mutation	CN wt ⁵ /μl	CN mut ⁶ /μl	EGFR T790M	4090	28
Mutation	CN wt ⁵ /μl	CN mut ⁶ /μl				
EGFR T790M	4090	28				

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

³ Measured before filling in product tube

⁴ not applicable

⁵ Wild Type

⁶ Mutation



Bringing Precision to MD_x

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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.

Phone: +49 (0) 381 377 182 01

Net: www.sens-id.com
SensID GmbH, Schillingallee 68, 18057 Rostock, Germany

Mail: support@sens-id.com

VAT No: DE305142405, district court: Rostock HRB 14621
CEO: Björn Nowack