

Batch Certificate For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-T790M 1% AF cfDNA in Plasma
DESCRIPTION	Human proteins in common plasma concentrations, electrolytes, EDTA, cfDNA / ctDNA in common plasma concentrations
CATALOG NUMBER	SID-000012
BATCH NUMBER	00077
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • Bottled with qualified Dispenser • 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	21.07.2021
CONCENTRATION	80 ng/ml (dsDNA)
QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	23.0 µl in 5 ml plasma (518 ng)
MUTATION	p.T790M (COSM6240*, COSV51765492*, substitution, c.2369C>T, Exon 20) <small>* GRCh38 COSMIC v91</small>
ALLELE FREQUENCY	1.0%
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	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						
TEST METHOD AND 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						
	Allele Frequency	ddPCR Analysis ² using BioRad QX200™ System	AF 1.0% ±40% (0.6–1.4%)						
	RESULTS OF ANALYSIS								
		Result	PASS/FAIL						
	Fragmentation	171 bp	PASS						
	Quantity	35.7 ng/μl (total DNA) 22.5 ng/μl (dsDNA)	n.a. ⁴						
	Allele Frequency	<table border="1"> <thead> <tr> <th>Mutation</th> <th>AF in %</th> </tr> </thead> <tbody> <tr> <td>T790M</td> <td>0.6</td> </tr> </tbody> </table>	Mutation	AF in %	T790M	0.6	PASS		
Mutation	AF in %								
T790M	0.6								
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 milliliter (ml), 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> <table border="1"> <thead> <tr> <th>Mutation</th> <th>CN wt⁵/ml</th> <th>CN mut⁶/ml</th> </tr> </thead> <tbody> <tr> <td>EGFR T790M</td> <td>18147</td> <td>110</td> </tr> </tbody> </table>			Mutation	CN wt ⁵ /ml	CN mut ⁶ /ml	EGFR T790M	18147	110
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EGFR T790M	18147	110							

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.

² Measured before spiking in

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

⁴ not applicable

⁵ Wild Type

⁶ Mutation