

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	SID-00007
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> • Manufactured and sealed in class 2 safety cabinet • Bottled with qualified liquid handling workstation and dispenser tool • 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	05.04.2019
EXPIRY DATE	Apr 2020
CONCENTRATION	80 ng/ml
QUANTITY	400 ng
NOMINAL VOLUME	5 ml
MUTATION	p.T790M (COSM6240*, substitution, c.2369C>T, Exon 20) <small>* GRCh38 COSMIC v88</small>
ALLELIC FREQUENCY	1%
QUALITY	Quantity traceable to internationally certified reference material ¹
STORAGE CONDITIONS	+ 2 – 8 °C
MANUFACTURING AND QUALITY CONTROL SITES	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

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Managing Director: Björn Nowack

TEST METHOD AND
ACCEPTANCE CRITERIA

Quality Control	Test Method	Acceptance criteria
Fragmentation	Fragment Length Analysis ² Agilent High Sensitivity DNA Kit (Agilent Techn.)	peak size 167 bp ± 10% (151 bp – 181 bp)
Quantification	Spectrophotometry ssDNA [ng/μl] = (A260- A320)*38 ^{3,4}	18,0 – 22,0 ng/μl
Allelic Frequency	dPCR Analysis ⁵ using BioRad QX200™ System	AF 1% ±40% (0,6–1,4%)

RESULTS OF ANALYSIS

	Result	PASS/FAIL
Fragmentation	166 bp	Pass
Quantification	20,1 ng/μl	Pass
Allelic Frequency	1,02 %	Pass

COMMENTS/REMARKS

Not applicable

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

Mr. Björn Nowack

Date of batch release: 02. May 2019

Signature batch release:



² Measured after extraction

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

⁴ measured cfDNA conc. before spiking in

⁵ Measured after extraction