

Batch Certificate

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-T790M 1% AF cfDNA		
DESCRIPTION	SensID cfDNA (human) is highly characterized human DNA from cell lines.		
CATALOG NUMBER	SID-000013		
BATCH NUMBER	00008		
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	04.04.2021		
CONCENTRATION	20 ng/μl		
QUANTITY	400 ng		
NOMINAL VOLUME	20.0 μl		
MUTATION	p.T790M (COSM6240*, COSV51765492*, substitution, c.2369C>T, Exon 20)		
ALLELE 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		
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%

¹ ERM_AD442K

² Measured after spiking in

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CEO: Björn Nowack

			(151 bp – 181 bp)
Quantification	Spectrophotometry ^{3,4} ssDNA [ng/μl] = (A260-A320)*38		17.0 – 23.0 ng/μl
Allele Frequency	dPCR Analysis ⁵ using BioRad QX200™ System		AF 1% ±40% (0.6-1.4%)
RESULTS OF ANALYSIS			
		Result	PASS/FAIL
	Fragmentation	158	Pass
	Quantification	17.24 ng/μl	Pass
	Allele Frequency	1.03 %	Pass
COMMENTS/REMARKS		Not applicable	

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

Mr. Björn Nowack

Date of batch release: 02.05.2019

Signature batch release: Björn Nowack

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

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

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