

## 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	SID-00008		
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> <li>• Manufactured and sealed in class 2 safety cabinet</li> <li>• Bottled with qualified liquid handling workstation and dispenser tool</li> <li>• At room temperature</li> </ul>		
PACKAGE SIZE AND TYPE	<ul style="list-style-type: none"> <li>• 2D barcoded tube with screw cap</li> <li>• Material: Polypropylen (PP)</li> </ul>		
DATE OF MANUFACTURE	05.04.2019		
EXPIRY DATE	Apr 2020		
CONCENTRATION	20 ng/μl		
QUANTITY	400 ng		
NOMINAL VOLUME	20,0 μl		
MUTATION	p.T790M (COSM6240*, substitution, c.2369C>T, Exon 20)		
ALLELIC FREQUENCY	1%		
QUALITY	Quantity traceable to internationally certified reference material <sup>1</sup>		
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 <sup>2</sup> Agilent High Sensitivity DNA Kit (Agilent Techn.)	peak size 167 bp ± 10% (151 bp – 181 bp)

<sup>1</sup>ERM\_AD442K

<sup>2</sup> Measured after spiking in

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VAT No: DE305142405, district court: Stralsund HRB 20227

CEO: Björn Nowack

	Quantification	Spectrophotometry <sup>3,4</sup> ssDNA [ng/μl] = (A260-A320)*38	17,0 – 23,0 ng/μl
	Allelic Frequency	dPCR Analysis <sup>5</sup> using BioRad QX200™ System	AF 1% ±40% (0,6-1,4%)
<b>RESULTS OF ANALYSIS</b>			
		<b>Result</b>	<b>PASS/FAIL</b>
	Fragmentation	158	Pass
	Quantification	17,24 ng/μl	Pass
	Allelic Frequency	1,03 %	Pass
<b>COMMENTS/REMARKS</b>		Not applicable	

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

Mr. Björn Nowack

Date of batch release:

Signature batch release:

<sup>3</sup> Protocol NK603 – Community Reference Laboratory for GM Food and Feed

<sup>4</sup> Measured after spiking in

<sup>5</sup> Measured after spiking in

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