

## Batch Certificate

### For Research Use Only

#### PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	EGFR-Multiplex 0.1% AF cfDNA
DESCRIPTION	EGFR-Multiplex 0.1% AF cfDNA is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000015
BATCH NUMBER	SID-00009
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</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	29.04.2019
EXPIRY DATE	28.04.2021
CONCENTRATION	20 ng/μl (total DNA)
QUANTITY	400 ng (total DNA)
NOMINAL VOLUME	25.3 μl
MUTATION	<p>p.G719S (COSM6252*, COSV51767289*, substitution, c.2155G&gt;A, Exon 18)</p> <p>p.E746_A750delELREA (COSM6225*, COSV51765066*, deletion, c.2236_2250del15, Exon 19)</p> <p>p.S752_I759delSPKANKEI (COSM6256*, COSV51774879*, deletion, c.2254_2277del24, Exon 19)</p> <p>p.S768I (COSM6241*, COSV51768106* substitution, c.2303G&gt;T, Exon 20)</p> <p>p.V769_D770insASV (COSM20884*, COSV51850427* Insertion, c.2303_2304insTGTGGCCAG, Exon 20)</p> <p>p.T790M (COSM6240*, COSV51765492*, substitution, c.2369C&gt;T, Exon 20)</p> <p>p.L858R (COSM6224*, COSV51765161*, substitution, c.2573T&gt;G, Exon 21)</p> <p>p.L861Q (COSM6213*, COSV51766344*, substitution, c.2582T&gt;A, Exon 21)</p> <p><small>* GRCh38 COSMIC v90</small></p>
ALLELE FREQUENCY	0.1%
QUALITY	Quantity traceable to internationally certified reference material <sup>1</sup>
STORAGE CONDITIONS	+ 2-8 °C

<sup>1</sup>ERM\_AD442K  
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**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 Agilent High Sensitivity DNA Kit (Agilent Techn.)	peak size 167 bp ± 10% (151 bp – 181 bp)
Quantification	Total DNA measurement: Spectrophotometry ssDNA [ng/μl] = (A260-A320)*38 <sup>2</sup> dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	12 – 28 ng/μl ----- n.a.
Allele Frequency	dPCR Analysis using BioRad QX200™ System	AF 0.1% ±60% (0.04–0.16%)

**RESULTS OF ANALYSIS**

	Result	PASS/FAIL
Fragmentation	157 bp	PASS
Quantity	12.54 ng/μl (total DNA) 9.52 ng/μl (dsDNA)	PASS
Allele Frequency	<b>Mutation</b>	<b>AF in %</b>
	L858R	0.13
	L861Q	0.05
	S768I	0.14
	E746_A750delELREA	0.08
	T790M	0.12
	G719S	0.13
	V769_D770insASV	0.09
S752_I759delSPANKEI	0.08	
		PASS

**COMMENTS/REMARKS**

Not applicable

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

**Mr. Björn Nowack**

Date of batch release: 06.05.2019

 Signature batch release: **Björn Nowack**
<sup>2</sup> Protocol NK603 – Community Reference Laboratory for GM Food and Feed

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Bringing Precision to MD<sub>x</sub>

Released document 01 Oct 2018

Version 01

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