Batch Certificate
For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL	
NAME OF PRODUCT	PIK3CA-E542K 100%AF FFPE Reference Standard
DESCRIPTION	Human FFPE Reference Standard (curl)
CATALOG NUMBER	SID-000101
BATCH NUMBER	00061
MANUFACTURING CONDITIONS	• Manufactured and sealed according to internal quality standards related to EN ISO 13485 • At room temperature
PACKAGE SIZE AND TYPE	• 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	14.04.2020
EXPIRY DATE	13.04.2022
FORMAT	10 µm section / 1 curl
MUTATION	PIK3CA p.E542K (COSM760*, COSV55873227*, substitution, c.1624G>A, Exon 9) * GRCh38 COSMIC v91
ALLELIC FREQUENCY	100.0 %
QUALITY	DNA quantity metrologically traceable to internationally certified reference material[1] 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.
STORAGE CONDITIONS	+ 2-8 °C
MANUFACTURING AND QUALITY CONTROL SITES	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

[1] ERM_AD442K

TEST METHOD AND ACCEPTANCE CRITERIA

Quality Control	Test Method	Acceptance criteria
Cell Density	Visual	> 60 %
Quality	Agarose gel electrophoresis[2] 1% Gel with fluorescent DNA stain in 1 % TAE buffer	Bright band of high-molecular-weight gDNA ≥ 20 kb
Quantification	dsDNA measurement[2]: Qubit dsDNA BR Assay Kit (Invitrogen) RNA measurement[2]: Qubit RNA BR Assay Kit (Invitrogen)	dsDNA: > 400 ng RNA: > 400 ng
Allelic Frequency	ddPCR Analysis[2] using BioRad QX200™ System	AF 100.0 % (95.0 – 105.0 %)

RESULTS OF ANALYSIS

	Result	PASS/FAIL
Cell Density	Visual: > 60 %	PASS
Quality	Bright band of high-molecular-weight gDNA ≥ 20 kb	PASS
Quantity	1449.0 ng (dsDNA) 1968.0 ng (RNA)	PASS
Allelic Frequency	Mutation: PIK3CA p.E542K; AF in %: 100.0	PASS

COMMENTS/REMARKS

Additional information:

Theoretical DNA yield from 1 curl under the assumption of a diploid chromosome set:

4,107 ng (dsDNA)

Copy numbers (CN) of the respective measurements

Table 1 indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~10 ng. The value for the respective mutation results from the mean value of five measured replicates (CN values are rounded). CN values per nanogram extracted DNA, 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.

Mutation	**CN wt[3]/ ng extracted DNA**	**CN mut[4]/ ng extracted DNA**
PIK3CA E542K	0	494

[2] Measured after extraction with Qiagen AllPrep DNA/RNA FFPE Kit
[3] Wild Type
[4] Mutation

Name and position/title of Person authorising the batch release:
Mr. Björn Nowack, Managing Director

Date of batch release:	09.06.2020
Signature batch release:	Björn Nowack

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