

Batch Certificate For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	Ashkenazim Son FFPE Reference Standard
DESCRIPTION	Human FFPE Reference Standard (curl)
CATALOG NUMBER	SID-000100
BATCH NUMBER	00060
MANUFACTURING CONDITIONS	<ul style="list-style-type: none"> • Manufactured and sealed according to internal quality standards related to EN ISO 13485 • 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	12.03.2020
EXPIRY DATE	11.03.2022
FORMAT	10 µm section / 1 curl
MUTATION	PIK3CA p.H1047R (COSM775*, COSV55873195*, substitution, c.3140A>G, Exon 20) PIK3CA p.E542K (COSM760*, COSV55873227* substitution, c.1624G>A, Exon 9) <small>* GRCh38 COSMIC v91</small>
ALLELIC FREQUENCY	0.00 %
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
Phone: +49 (0) 381 377 182 01

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 0.00 % (0.00-0.10 %)

RESULTS OF ANALYSIS	Result		PASS/FAIL
Cell Density	Visual: > 60 %		PASS
Quality	Bright band of high-molecular-weight gDNA ≥ 20 kb		PASS
Quantity	1106.8 ng (dsDNA) 1540.0 ng (RNA)		PASS
Allelic Frequency	Mutation	AF in %	PASS
	PIK3CA H1047R	0.08	
	PIK3CA E542K	0.08	

COMMENTS/REMARKS									
<p>Additional information:</p> <p>Theoretical DNA yield from 1 curl under the assumption of a diploid chromosome set:</p> <p>2,865 ng (dsDNA)</p> <p>Copy numbers (CN) of the respective measurements</p> <p><i>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.</i></p> <table border="1"> <thead> <tr> <th>Mutation</th> <th>CN wt³/ ng extracted DNA</th> <th>CN mut⁴/ ng extracted DNA</th> </tr> </thead> <tbody> <tr> <td>PIK3CA E542K</td> <td>593</td> <td>0.5</td> </tr> <tr> <td>PIK3CA H1047R</td> <td>594</td> <td>0.5</td> </tr> </tbody> </table>	Mutation	CN wt ³ / ng extracted DNA	CN mut ⁴ / ng extracted DNA	PIK3CA E542K	593	0.5	PIK3CA H1047R	594	0.5
Mutation	CN wt ³ / ng extracted DNA	CN mut ⁴ / ng extracted DNA							
PIK3CA E542K	593	0.5							
PIK3CA H1047R	594	0.5							

² Measured after extraction with Qiagen AllPrep DNA/RNA FFPE Kit

³ Wild Type

⁴ Mutation



Bringing Precision to MD_x

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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

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

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