

BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	PIK3CA-11 mutations 12.5% AF cfDNA- PIK3CA E545A & C420R
DESCRIPTION	PIK3CA-11 mutations 12.5% AF cfDNA- PIK3CA E545A & C420R is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000099 (5)
BATCH NUMBER	00277
MANUFACTURING CONDITIONS	· Manufactured und sealed in class 2 safety cabinet · At room temperature · Produced according to DIN EN ISO 13485:2016
PACKAGE SIZE AND TYPE	· 2D barcoded tube with screw cap · Material: Polypropylen (PP)
DATE OF MANUFACTURE	18.02.2022
EXPIRY DATE	17.02.2024
TARGET CONCENTRATION	20 ng/μl (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 μl
MUTATION * GRCh38 COSMIC v91	PIK3CA p.E545A (COSM12458*, COSV55873209*, substitution, c.1634A>C, Exon 9) PIK3CA p.C420R (COSM757*, COSV55874020* substitution, c.1258T>C, Exon 7)
ALLELE FREQUENCY	12.5 %
QUALITY	DNA quantity metrologically traceable to internationally certified reference material (ERM_AD442K). 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 SITE	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

TEST METHOD AND ACCEPTANCE CRITERIA	Quality control	Test method		Acceptance criteria
	Fragmentation	Fragment length analysis Agilent D5000 ScreenTape System (Agilent Technologies)		Peak size 167 bp ± 15% (167 bp – 192 bp)
	Quantification	Total DNA measurement (ssDNA): Spectrophotometry**		Total DNA: not applicable
		dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)		dsDNA: 17.5 – 22.5 ng/µl
	**Protocol NK603 – Community Reference Laboratory for GM Food and Feed			
	Allele frequency	Allele frequency analysis ddPCR (BioRad QX200™)		AF 12.5% ± 20% (10.0–15.0%)
RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Fragmentation	179 bp		PASS
	Quantification	32.8 ng/µl (total DNA)		PASS
		22.04 ng/µl (dsDNA)		
	Allele frequency	Mutation	AF in %	PASS / FAIL
		PIK3CA E545A	12.81	PASS
PIK3CA C420R		12.68	PASS	

COMMENTS / REMARKS	Additional information: Measurement of copy number		
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ μ l	CN mut/ μ l
	PIK3CA E545A	5547	815
	PIK3CA C420R	2403	349
	wt: wildtype; mut: mutation		
	<i>The table above indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~20 ng. The value for the respective mutation results from the mean value of QC samples according to ISO 2859-1:2014-08 (CN values are rounded). CN concentration values per microliter (μl) 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>		

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

Björn Nowack, Managing Director

Date of batch release: 08.03.2022

Signature batch release: Björn Nowack

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PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	PIK3CA-11 mutations 12.5% AF cfDNA- PIK3CA E542K & Q546R
DESCRIPTION	PIK3CA-11 mutations 12.5% AF cfDNA- PIK3CA E542K & Q546R is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000099 (1)
BATCH NUMBER	00278
MANUFACTURING CONDITIONS	· Manufactured und sealed in class 2 safety cabinet · At room temperature · Produced according to DIN EN ISO 13485:2016
PACKAGE SIZE AND TYPE	· 2D barcoded tube with screw cap · Material: Polypropylen (PP)
DATE OF MANUFACTURE	18.02.2022
EXPIRY DATE	17.02.2024
TARGET CONCENTRATION	20 ng/µl (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 µl
MUTATION * GRCh38 COSMIC v91	PIK3CA p.E542K (COSM760*, COSV55873227*, substitution, c.1624G>A, Exon 9) PIK3CA p.Q546R (COSM12459*, COSV55876869* substitution, c.1637A>G, Exon 9)
ALLELE FREQUENCY	12.5 %
QUALITY	DNA quantity metrologically traceable to internationally certified reference material (ERM_AD442K). 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 SITE	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

TEST METHOD AND ACCEPTANCE CRITERIA	Quality control	Test method		Acceptance criteria
	Fragmentation	Fragment length analysis Agilent D5000 ScreenTape System (Agilent Technologies)		Peak size 167 bp ± 15% (167 bp – 192 bp)
	Quantification	Total DNA measurement (ssDNA): Spectrophotometry**		Total DNA: not applicable
		dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)		dsDNA: 17.5 – 22.5 ng/µl
	**Protocol NK603 – Community Reference Laboratory for GM Food and Feed			
	Allele frequency	Allele frequency analysis ddPCR (BioRad QX200™)		AF 12.5% ± 20% (10.0–15.0%)
RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Fragmentation	179.4 bp		PASS
	Quantification	33.2 ng/µl (total DNA)		PASS
		21 ng/µl (dsDNA)		
	Allele frequency	Mutation	AF in %	PASS / FAIL
		PIK3CA E542K	11.95	PASS
PIK3CA Q546R		12.06	PASS	

COMMENTS / REMARKS	Additional information: Measurement of copy number		
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ μ l	CN mut/ μ l
	PIK3CA E542K	5801	787
	PIK3CA Q546R	6147	843
	wt: wildtype; mut: mutation		
	<i>The table above indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~20 ng. The value for the respective mutation results from the mean value of QC samples according to ISO 2859-1:2014-08 (CN values are rounded). CN concentration values per microliter (μl) 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>		

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

Björn Nowack, Managing Director

Date of batch release: 08.03.2022

Signature batch release: Björn Nowack

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PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	PIK3CA-11 mutations 12.5% AF cfDNA- PIK3CA E545D & H1047L
DESCRIPTION	PIK3CA-11 mutations 12.5% AF cfDNA- PIK3CA E545D & H1047L is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000099 (2)
BATCH NUMBER	00279
MANUFACTURING CONDITIONS	· Manufactured und sealed in class 2 safety cabinet · At room temperature · Produced according to DIN EN ISO 13485:2016
PACKAGE SIZE AND TYPE	· 2D barcoded tube with screw cap · Material: Polypropylen (PP)
DATE OF MANUFACTURE	18.02.2022
EXPIRY DATE	17.02.2024
TARGET CONCENTRATION	20 ng/μl (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 μl
MUTATION * GRCh38 COSMIC v91	PIK3CA p.E545D (COSM765*, COSV55874040*, substitution, c.1635G>T, Exon 9) PIK3CA p.H1047L (COSM776*, COSV55873401* substitution, c.3140A>T, Exon 20)
ALLELE FREQUENCY	12.5 %
QUALITY	DNA quantity metrologically traceable to internationally certified reference material (ERM_AD442K). 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 SITE	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

TEST METHOD AND ACCEPTANCE CRITERIA	Quality control	Test method		Acceptance criteria
	Fragmentation	Fragment length analysis Agilent D5000 ScreenTape System (Agilent Technologies)		Peak size 167 bp ± 15% (167 bp – 192 bp)
	Quantification	Total DNA measurement (ssDNA): Spectrophotometry**		Total DNA: not applicable
		dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)		dsDNA: 17.5 – 22.5 ng/μl
	**Protocol NK603 – Community Reference Laboratory for GM Food and Feed			
	Allele frequency	Allele frequency analysis ddPCR (BioRad QX200™)		AF 12.5% ± 20% (10.0–15.0%)
RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Fragmentation	177 bp		PASS
	Quantification	29.7 ng/μl (total DNA)		PASS
		20.66 ng/μl (dsDNA)		
	Allele frequency	Mutation	AF in %	PASS / FAIL
		PIK3CA E545D	13.02	PASS
PIK3CA H1047L		13.06	PASS	

COMMENTS / REMARKS	Additional information: Measurement of copy number		
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ μ l	CN mut/ μ l
	PIK3CA E545D	3359	503
	PIK3CA H1047L	4523	639
	wt: wildtype; mut: mutation		
	<i>The table above indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~20 ng. The value for the respective mutation results from the mean value of QC samples according to ISO 2859-1:2014-08 (CN values are rounded). CN concentration values per microliter (μl) 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>		

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

Björn Nowack, Managing Director

Date of batch release: 08.03.2022

Signature batch release: Björn Nowack

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PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	PIK3CA-11 mutations 12.5% AF cfDNA- PIK3CA E545G & H1047R
DESCRIPTION	PIK3CA-11 mutations 12.5% AF cfDNA- PIK3CA E545G & H1047R is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000099 (3)
BATCH NUMBER	00280
MANUFACTURING CONDITIONS	· Manufactured und sealed in class 2 safety cabinet · At room temperature · Produced according to DIN EN ISO 13485:2016
PACKAGE SIZE AND TYPE	· 2D barcoded tube with screw cap · Material: Polypropylen (PP)
DATE OF MANUFACTURE	18.02.2022
EXPIRY DATE	17.02.2024
TARGET CONCENTRATION	20 ng/μl (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 μl
MUTATION * GRCh38 COSMIC v91	PIK3CA p.E545G (COSM764*, COSV55873220*, substitution, c.1634A>G, Exon 9) PIK3CA p.H1047R (COSM775*, COSV55873195* substitution, c.3140A>G, Exon 20)
ALLELE FREQUENCY	12.5 %
QUALITY	DNA quantity metrologically traceable to internationally certified reference material (ERM_AD442K). 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 SITE	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

TEST METHOD AND ACCEPTANCE CRITERIA	Quality control	Test method		Acceptance criteria
	Fragmentation	Fragment length analysis Agilent D5000 ScreenTape System (Agilent Technologies)		Peak size 167 bp ± 15% (167 bp – 192 bp)
	Quantification	Total DNA measurement (ssDNA): Spectrophotometry**		Total DNA: not applicable
		dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)		dsDNA: 17.5 – 22.5 ng/µl
	**Protocol NK603 – Community Reference Laboratory for GM Food and Feed			
	Allele frequency	Allele frequency analysis ddPCR (BioRad QX200™)		AF 12.5% ± 20% (10.0–15.0%)
RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Fragmentation	180 bp		PASS
	Quantification	32.8 ng/µl (total DNA)		PASS
		22.28 ng/µl (dsDNA)		
	Allele frequency	Mutation	AF in %	PASS / FAIL
		PIK3CA E545G	12.43	PASS
PIK3CA H1047R		12.43	PASS	

COMMENTS / REMARKS	Additional information: Measurement of copy number		
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ μ l	CN mut/ μ l
	PIK3CA E545G	4673	663
	PIK3CA H1047R	4326	614
	wt: wildtype; mut: mutation		
	<i>The table above indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~20 ng. The value for the respective mutation results from the mean value of QC samples according to ISO 2859-1:2014-08 (CN values are rounded). CN concentration values per microliter (μl) 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>		

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

Björn Nowack, Managing Director

Date of batch release: 08.03.2022

Signature batch release: Björn Nowack

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PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	PIK3CA-11 mutations 12.5% AF cfDNA- PIK3CA E545K & H1047Y
DESCRIPTION	PIK3CA-11 mutations 12.5% AF cfDNA- PIK3CA E545K & H1047Y is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000099 (4)
BATCH NUMBER	00281
MANUFACTURING CONDITIONS	· Manufactured und sealed in class 2 safety cabinet · At room temperature · Produced according to DIN EN ISO 13485:2016
PACKAGE SIZE AND TYPE	· 2D barcoded tube with screw cap · Material: Polypropylen (PP)
DATE OF MANUFACTURE	18.02.2022
EXPIRY DATE	17.02.2024
TARGET CONCENTRATION	20 ng/μl (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	24 μl
MUTATION * GRCh38 COSMIC v91	PIK3CA p.E545K (COSM763*, COSV55873239*, substitution, c.1633G>A, Exon 9) PIK3CA p.H1047Y (COSM774*, COSV55876499* substitution, c.3139C>T, Exon 20)
ALLELE FREQUENCY	12.5 %
QUALITY	DNA quantity metrologically traceable to internationally certified reference material (ERM_AD442K). 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 SITE	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

TEST METHOD AND ACCEPTANCE CRITERIA	Quality control	Test method		Acceptance criteria
	Fragmentation	Fragment length analysis Agilent D5000 ScreenTape System (Agilent Technologies)		Peak size 167 bp ± 15% (167 bp – 192 bp)
	Quantification	Total DNA measurement (ssDNA): Spectrophotometry**		Total DNA: not applicable
		dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)		dsDNA: 17.5 – 22.5 ng/µl
	**Protocol NK603 – Community Reference Laboratory for GM Food and Feed			
	Allele frequency	Allele frequency analysis ddPCR (BioRad QX200™)		AF 12.5% ± 20% (10.0–15.0%)
RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Fragmentation	174 bp		PASS
	Quantification	31.2 ng/µl (total DNA)		PASS
		21.54 ng/µl (dsDNA)		
	Allele frequency	Mutation	AF in %	PASS / FAIL
		PIK3CA E545K	12.57	PASS
PIK3CA H1047Y		13.30	PASS	

COMMENTS / REMARKS	Additional information: Measurement of copy number		
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ μ l	CN mut/ μ l
	PIK3CA E545K	2887	415
	PIK3CA H1047Y	4050	619
	wt: wildtype; mut: mutation		
	<i>The table above indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~20 ng. The value for the respective mutation results from the mean value of QC samples according to ISO 2859-1:2014-08 (CN values are rounded). CN concentration values per microliter (μl) 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>		

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

Björn Nowack, Managing Director

Date of batch release: 08.03.2022

Signature batch release: Björn Nowack

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PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	PIK3CA-11 mutations 12.5% AF cfDNA- PIK3CA Q546E
DESCRIPTION	PIK3CA-11 mutations 12.5% AF cfDNA- PIK3CA Q546E is highly characterized human DNA from cell lines.
CATALOG NUMBER	SID-000099 (6)
BATCH NUMBER	00282
MANUFACTURING CONDITIONS	· Manufactured und sealed in class 2 safety cabinet · At room temperature · Produced according to DIN EN ISO 13485:2016
PACKAGE SIZE AND TYPE	· 2D barcoded tube with screw cap · Material: Polypropylen (PP)
DATE OF MANUFACTURE	18.02.2022
EXPIRY DATE	17.02.2024
TARGET CONCENTRATION	20 ng/μl (dsDNA)
TARGET QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 μl
MUTATION * GRCh38 COSMIC v91	PIK3CA p.Q546E (COSM6147*, COSV55882350* substitution, c.1636C>G, Exon 9)
ALLELE FREQUENCY	12.5 %
QUALITY	DNA quantity metrologically traceable to internationally certified reference material (ERM_AD442K). 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 SITE	SensID GmbH Schillingallee 68, 18057 Rostock, Germany

TEST METHOD AND ACCEPTANCE CRITERIA	Quality control	Test method		Acceptance criteria
	Fragmentation	Fragment length analysis Agilent D5000 ScreenTape System (Agilent Technologies)		Peak size 167 bp ± 15% (167 bp – 192 bp)
	Quantification	Total DNA measurement (ssDNA): Spectrophotometry**		Total DNA: not applicable
		dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)		dsDNA: 17.5 – 22.5 ng/μl
	**Protocol NK603 – Community Reference Laboratory for GM Food and Feed			
	Allele frequency	Allele frequency analysis ddPCR (BioRad QX200™)		AF 12.5% ± 20% (10.0–15.0%)
RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL
	Fragmentation	180 bp		PASS
	Quantification	32.8 ng/μl (total DNA)		PASS
		21.56 ng/μl (dsDNA)		
	Allele frequency	Mutation	AF in %	PASS / FAIL
PIK3CA Q546E		12.85	PASS	

COMMENTS / REMARKS	Additional information: Measurement of copy number		
MEASUREMENT OF COPY NUMBER	Mutation	CN wt/ μ l	CN mut/ μ l
	PIK3CA Q546E	5413	798
	wt: wildtype; mut: mutation		
	<i>The table above indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~20 ng. The value for the respective mutation results from the mean value of QC samples according to ISO 2859-1:2014-08 (CN values are rounded). CN concentration values per microliter (μl) 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>		

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

Björn Nowack, Managing Director

Date of batch release: 08.03.2022

Signature batch release: Björn Nowack

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