Batch Certificate
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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
BATCH NUMBER	00043
MANUFACTURING CONDITIONS PACKAGE SIZE PACKAGE TYPE	• Manufactured and sealed in class 2 safety cabinet • At room temperature • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	13.03.2020
EXPIRY DATE	12.03.2022
CONCENTRATION	20 ng/µl (dsDNA)
QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 µl; (508 ng)
MUTATION	PIK3CA p.E542K (COSM760*, COSV55873227*, substitution, c.1624G>A, Exon 9) PIK3CA p.Q546R (COSM12459*, COSV55876869* substitution, c.1637A>G, Exon 9) * GRCh38 COSMIC v90
ALLELE FREQUENCY	12.5%
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
	Fragmentation	Fragment Length Analysis Agilent High Sensitivity DNA Kit (Agilent Technologies)	peak size 167 bp ± 10% (151 bp – 181 bp)
	Quantification	Total DNA measurement: Spectrophotometry ssDNA [ng/µl] = (A260-A320)*38[2,3] dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	Total DNA: n.a.[4] dsDNA: 17.5 – 22.5 ng/µl
	Allele Frequency	ddPCR Analysis using BioRad QX200™ System	AF 12.5% ±20% (10.0-15.0%)

RESULTS OF ANALYSIS

	Result	PASS/FAIL
Fragmentation	180 bp	PASS
Quantity	28.7 ng/µl (total DNA) 20.3 ng/µl (dsDNA)	PASS

Allele Frequency

Mutation	AF in %	PASS/FAIL
PIK3CA E542K	10.2	PASS
PIK3CA Q546R	10.1	PASS

COMMENTS/REMARKS

Additional information:

Copy numbers (CN) of the respective measurements

Mutation	CN wt[5]/µl	CN mut[6]/µl
PIK3CA E542K	5830	660
PIK3CA Q546R	6637	744

Table 1 indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~40 ng. The value for the respective mutation results from the mean value of five measured replicates (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.

[2] Protocol NK603 – Community Reference Laboratory for GM Food and Feed
[3] Measured before filling in product tube
[4] not applicable
[5] Wild Type
[6] Mutation

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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
BATCH NUMBER	00044
MANUFACTURING CONDITIONS PACKAGE SIZE PACKAGE TYPE	• Manufactured and sealed in class 2 safety cabinet • At room temperature • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	13.03.2020
EXPIRY DATE	12.03.2022
CONCENTRATION	20 ng/µl (dsDNA)
QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 µl; (473 ng)
MUTATION	PIK3CA p.E545D (COSM765*, COSV55874040*, substitution, c.1635G>T, Exon 9) PIK3CA p.H1047L (COSM776*, COSV55873401* substitution, c.3140A>T, Exon 20) * GRCh38 COSMIC v90
ALLELE FREQUENCY	12.5%
QUALITY	DNA quantity metrologically traceable to internationally certified reference material[7] 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

[7] ERM_AD442K

TEST METHOD AND ACCEPTANCE CRITERIA	Quality Control	Test Method	Acceptance criteria
	Fragmentation	Fragment Length Analysis Agilent High Sensitivity DNA Kit (Agilent Technologies)	peak size 167 bp ± 10% (151 bp – 181 bp)
	Quantification	Total DNA measurement: Spectrophotometry ssDNA [ng/µl] = (A260-A320)*38[8,9] dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	Total DNA: n.a.[10] dsDNA: 17.5 – 22.5 ng/µl
	Allele Frequency	ddPCR Analysis using BioRad QX200™ System	AF 12.5% ±20% (10.0-15.0%)

RESULTS OF ANALYSIS

	Result	PASS/FAIL
Fragmentation	179 bp	PASS
Quantity	27.0 ng/µl (total DNA) 18.9 ng/µl (dsDNA)	PASS

Allele Frequency

Mutation	AF in %	PASS/FAIL
PIK3CA E545D	13.2	PASS
PIK3CA H1047L	14.6	PASS

COMMENTS/REMARKS

Additional information:

Copy numbers (CN) of the respective measurements

Mutation	CN wt[11]/µl	CN mut[12]/µl
PIK3CA E545D	3371	511
PIK3CA H1047L	4111	704

Table 2 indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~40 ng. The value for the respective mutation results from the mean value of five measured replicates (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.

[8] Protocol NK603 – Community Reference Laboratory for GM Food and Feed
[9] Measured before filling in product tube
[10] not applicable
[11] Wild Type
[12] Mutation

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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
BATCH NUMBER	00045
MANUFACTURING CONDITIONS PACKAGE SIZE PACKAGE TYPE	• Manufactured and sealed in class 2 safety cabinet • At room temperature • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	13.03.2020
EXPIRY DATE	12.03.2022
CONCENTRATION	20 ng/µl (dsDNA)
QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 µl; (450 ng)
MUTATION	PIK3CA p.E545G (COSM764*, COSV55873220*, substitution, c.1634A>G, Exon 9) PIK3CA p.H1047R (COSM775*, COSV55873195* substitution, c.3140A>G, Exon 20) * GRCh38 COSMIC v90
ALLELE FREQUENCY	12.5%
QUALITY	DNA quantity metrologically traceable to internationally certified reference material[13] 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

[13] ERM_AD442K

TEST METHOD AND ACCEPTANCE CRITERIA	Quality Control	Test Method	Acceptance criteria
	Fragmentation	Fragment Length Analysis Agilent High Sensitivity DNA Kit (Agilent Technologies)	peak size 167 bp ± 10% (151 bp – 181 bp)
	Quantification	Total DNA measurement: Spectrophotometry ssDNA [ng/µl] = (A260-A320)*38[14],[15] dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	Total DNA: n.a.[16] dsDNA: 17.5 – 22.5 ng/µl
	Allele Frequency	ddPCR Analysis using BioRad QX200™ System	AF 12.5% ±20% (10.0-15.0%)

RESULTS OF ANALYSIS

	Result	PASS/FAIL
Fragmentation	179 bp	PASS
Quantity	23.9 ng/µl (total DNA) 18.0 ng/µl (dsDNA)	PASS

Allele Frequency

Mutation	AF in %	PASS/FAIL
PIK3CA E545G	12.1	PASS
PIK3CA H1047R	12.9	PASS

COMMENTS/REMARKS

Additional information:

Copy numbers (CN) of the respective measurements

Mutation	CN wt[17]/µl	CN mut[18]/µl
PIK3CA E545G	4271	587
PIK3CA H1047R	3805	565

Table 3 indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~40 ng. The value for the respective mutation results from the mean value of five measured replicates (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.

[14] Protocol NK603 – Community Reference Laboratory for GM Food and Feed
[15] Measured before filling in product tube
[16] not applicable
[17] Wild Type
[18] Mutation

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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
BATCH NUMBER	00046
MANUFACTURING CONDITIONS PACKAGE SIZE PACKAGE TYPE	• Manufactured and sealed in class 2 safety cabinet • At room temperature • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	13.03.2020
EXPIRY DATE	12.03.2022
CONCENTRATION	20 ng/µl (dsDNA)
QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 µl; (485 ng)
MUTATION	PIK3CA p.E545K (COSM763*, COSV55873239*, substitution, c.1633G>A, Exon 9) PIK3CA p.H1047Y (COSM774*, COSV55876499* substitution, c.3139C>T, Exon 20) * GRCh38 COSMIC v90
ALLELE FREQUENCY	12.5%
QUALITY	DNA quantity metrologically traceable to internationally certified reference material[19] 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

[19] ERM_AD442K

TEST METHOD AND ACCEPTANCE CRITERIA	Quality Control	Test Method	Acceptance criteria
	Fragmentation	Fragment Length Analysis Agilent High Sensitivity DNA Kit (Agilent Technologies)	peak size 167 bp ± 10% (151 bp – 181 bp)
	Quantification	Total DNA measurement: Spectrophotometry ssDNA [ng/µl] = (A260-A320)*38[20,21] dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	Total DNA: n.a.[22] dsDNA: 17.5 – 22.5 ng/µl
	Allele Frequency	ddPCR Analysis using BioRad QX200™ System	AF 12.5% ±20% (10.0-15.0%)

RESULTS OF ANALYSIS

	Result	PASS/FAIL
Fragmentation	180 bp	PASS
Quantity	29.5 ng/µl (total DNA) 19.4 ng/µl (dsDNA)	PASS

Allele Frequency

Mutation	AF in %	PASS/FAIL
PIK3CA E545K	12.2	PASS
PIK3CA H1047Y	11.0	PASS

COMMENTS/REMARKS

Additional information:

Copy numbers (CN) of the respective measurements

Mutation	CN wt[23]/µl	CN mut[24]/µl
PIK3CA E545K	2938	409
PIK3CA H1047Y	4187	520

Table 4 indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~40 ng. The value for the respective mutation results from the mean value of five measured replicates (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.

[20] Protocol NK603 – Community Reference Laboratory for GM Food and Feed
[21] Measured before filling in product tube
[22] not applicable
[23] Wild Type
[24] Mutation

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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
BATCH NUMBER	00047
MANUFACTURING CONDITIONS PACKAGE SIZE PACKAGE TYPE	• Manufactured and sealed in class 2 safety cabinet • At room temperature • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	13.03.2020
EXPIRY DATE	12.03.2022
CONCENTRATION	20 ng/µl (dsDNA)
QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 µl; (523 ng)
MUTATION	PIK3CA p.Q546E (COSM6147*, COSV55882350* substitution, c.1636C>G, Exon 9) * GRCh38 COSMIC v90
ALLELE FREQUENCY	12.5%
QUALITY	DNA quantity metrologically traceable to internationally certified reference material[25] 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

[25] ERM_AD442K

TEST METHOD AND ACCEPTANCE CRITERIA	Quality Control	Test Method	Acceptance criteria
	Fragmentation	Fragment Length Analysis Agilent High Sensitivity DNA Kit (Agilent Technologies)	peak size 167 bp ± 10% (151 bp – 181 bp)
	Quantification	Total DNA measurement: Spectrophotometry ssDNA [ng/µl] = (A260-A320)*38[26,27] dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	Total DNA: n.a.[28] dsDNA: 17.5 – 22.5 ng/µl
	Allele Frequency	ddPCR Analysis using BioRad QX200™ System	AF 12.5% ±20% (10.0-15.0%)

RESULTS OF ANALYSIS

	Result	PASS/FAIL
Fragmentation	180 bp	PASS
Quantity	29.9 ng/µl (total DNA) 20.9 ng/µl (dsDNA)	PASS

Allele Frequency

Mutation	AF in %	PASS/FAIL
PIK3CA Q546E	12.8	PASS

COMMENTS/REMARKS

Additional information:

Copy numbers (CN) of the respective measurements

Mutation	CN wt[29]/µl	CN mut[30]/µl
PIK3CA Q546E	5585	821

Table 5 indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~40 ng. The value for the respective mutation results from the mean value of five measured replicates (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.

[26] Protocol NK603 – Community Reference Laboratory for GM Food and Feed
[27] Measured before filling in product tube
[28] not applicable
[29] Wild Type
[30] Mutation

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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
BATCH NUMBER	00049
MANUFACTURING CONDITIONS PACKAGE SIZE PACKAGE TYPE	• Manufactured and sealed in class 2 safety cabinet • At room temperature • 2D barcoded tube with screw cap • Material: Polypropylen (PP)
DATE OF MANUFACTURE	23.03.2020
EXPIRY DATE	22.03.2022
CONCENTRATION	20 ng/µl (dsDNA)
QUANTITY	400 ng (dsDNA)
NOMINAL VOLUME	25 µl; (540 ng)
MUTATION	PIK3CA p.E545A (COSM12458*, COSV55873209*, substitution, c.1634A>C, Exon 9) PIK3CA p.C420R (COSM757*, COSV55874020* substitution, c.1258T>C, Exon 7) * GRCh38 COSMIC v90
ALLELE FREQUENCY	12.5%
QUALITY	DNA quantity metrologically traceable to internationally certified reference material[31] 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

[31] ERM_AD442K

TEST METHOD AND ACCEPTANCE CRITERIA	Quality Control	Test Method	Acceptance criteria
	Fragmentation	Fragment Length Analysis Agilent High Sensitivity DNA Kit (Agilent Technologies)	peak size 167 bp ± 10% (151 bp – 181 bp)
	Quantification	Total DNA measurement: Spectrophotometry ssDNA [ng/µl] = (A260-A320)*38[32,33] dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	Total DNA: n.a.[34] dsDNA: 17.5 – 22.5 ng/µl
	Allele Frequency	ddPCR Analysis using BioRad QX200™ System	AF 12.5% ±20% (10.0-15.0%)

RESULTS OF ANALYSIS

	Result	PASS/FAIL
Fragmentation	178 bp	PASS
Quantity	33.6 ng/µl (total DNA) 21.6 ng/µl (dsDNA)	PASS

Allele Frequency

Mutation	AF in %	PASS/FAIL
PIK3CA E545A[35]	11.9	PASS
PIK3CA C420R	14.1	PASS

COMMENTS/REMARKS

Additional information:

Copy numbers (CN) of the respective measurements

Mutation	CN wt[36]/µl	CN mut[37]/µl
PIK3CA E545A	5711	771
PIK3CA C420R	2316	381

Table 6 indicates the values of the QC assays performed by SensID GmbH with a DNA input of ~40 ng. The value for the respective mutation results from the mean value of five measured replicates (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.

[32] Protocol NK603 – Community Reference Laboratory for GM Food and Feed
[33] Measured before filling in product tube
[34] not applicable
[35] A BLAST sequence analysis shows 98% homology of PIK3CA E545A mutation sequence to genome locus Homo sapiens chromosome 22, GRCh38.p13. Therefore, a higher false positive rate is expected and measured, most likely due to a cross reaction of gene probe to genome locus Homo sapiens chromosome 22, GRCh38.p13. Cross reaction AF / false positive rate is substracted from AF for PIK3CA E545A mutation given in this CoA.
[36] Wild Type
[37] Mutation

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

Date of batch release:	24.03.2020
Signature batch release:	Björn Nowack

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