

For Research Use Only

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

• Manufactured and sealed in class 2 safety cabinet

CONDITIONS • At room temperature

PACKAGE SIZE

• 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 material¹

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 -

+2 - +8 °C

MANUFACTURING AND

SensID GmbH

QUALITY CONTROL

Schillingallee 68, 18057 Rostock, Germany

SITES

¹ ERM_AD442K

Acceptance

TEST METHOD AND

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TEST METHOD AND	additty continui					
ACCEPTANCE CRITERIA					criterio	ı
	-	Fragment Len	gth Analysis		peak si	ize 167 bp ±
	Fragmentation	Agilent High Sensitivity DNA Kit			10%	
		(Agilent Technologies)			(151 bp - 181 bp)	
	Quantification	Total DNA me Spectrophoto ssDNA [ng/μl]	metry	*382,3	Total D	·NA:
		dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)			dsDNA: 17.5 – 22.5 ng/μl	
	Allala Fasanca a su	ddPCR Analysis			AF 12.5% ±20%	
	Allele Frequency	using BioRad QX200™ System			(10.0-15.0%)	
RESULTS OF ANALYSIS						
NESOLIS OF ANALISIS		Result				PASS/FAII
	Fragmentation	180 bp				PASS
	Quantity	28.7 ng/µl (total DNA) 20.3 ng/µl (dsDNA)			PASS	
	Allele	Mutation PIK3CA E54		AF in % 10.2		ASS/FAIL PASS
	Frequency	PIK3CA Q546R 10.1				PASS
COMMENTS/REMARKS	Additional inform		espective n	neasure	 ement	s
	Mutat	ion	CN wt⁵/μl		N mut	ⁱ /μl
	PIK3CA E542K		5830		660	
	PIK3CA Q546R		6637		744	

Test Method

Quality Control

Table 1 indic	cates 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 re	eplicates (CN values are rounded). CN concentration values per microliter (μl),
are based o	on droplet digital (ddPCR) assay counts dilution factors, and droplet volume
measureme	nts. The detection of the amount of CNs may vary depending on the assay used.
Therefore, a	lue to assay properties, there may be deviations in the observed number of
copies and a	ıllele frequencies compared to the values given here.

4not applicable 5 Wild Type 6 Mutation

² Protocol NK603 – Community Reference Laboratory for GM Food and Feed

³Measured before filling in product tube



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PRODUCT INFORMATION AND Q	QUALITY CONTROL
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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

• Manufactured and sealed in class 2 safety cabinet

CONDITIONS • At room temperature

PACKAGE SIZE • 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 $25 \mu l; (473 \text{ ng})$

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 material7

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 -

+2 - +8 °C

MANUFACTURING AND

SensID GmbH

QUALITY CONTROL

Schillingallee 68, 18057 Rostock, Germany

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⁷ ERM_AD442K

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ACCEPTANCE CRITERIA				criterio	a
		Fragment Length Ar	peak size 167 bp ±		
	Fragmentation	Agilent High Sensitiv	10%		
		(Agilent Technologie	es)	(151 bp - 181 bp)	
		Total DNA measurer	mont:	Total DNA:	
		Spectrophotometry		n.a. ¹⁰	
	Quantification	ssDNA [ng/µl] = (A26			
		dsDNA measuremen	nt: Qubit	dsDNA	
		dsDNA BR Assay Kit	(Invitrogen)	17.5 – 22.5 ng/μl	
	Allele Frequency	ddPCR Analysis		AF 12.5% ±20%	
	Allele Frequency	using BioRad QX200™ System		(10.0-15.0%)	
DESCRIPTO OF ANALYSIS	T				
RESULTS OF ANALYSIS		Result			PASS/FAIL
	Fragmentation	179 bp			PASS
		179 bp 27.0 ng/µl (total	DNA)		PASS
	Fragmentation Quantity	·			PASS PASS
		27.0 ng/µl (total			
	Quantity	27.0 ng/µl (total 18.9 ng/µl (dsDN/ Mutation	Δ) AF in 5	% PA	PASS ASS/FAIL
	Quantity Allele	27.0 ng/µl (total 18.9 ng/µl (dsDNA Mutation PIK3CA E545D	AF in 5	% PA	PASS ASS/FAIL PASS
	Quantity	27.0 ng/µl (total 18.9 ng/µl (dsDN/ Mutation	Δ) AF in 5	% PA	PASS ASS/FAIL
COMMENTS/REMARKS	Quantity Allele	27.0 ng/µl (total 18.9 ng/µl (dsDN/ Mutation PIK3CA E545D PIK3CA H1047L	AF in 5	% PA	PASS ASS/FAIL PASS
COMMENTS/REMARKS	Quantity Allele Frequency Additional inform	27.0 ng/µl (total 18.9 ng/µl (dsDN/ Mutation PIK3CA E545D PIK3CA H1047L	AF in 5 13.2 14.6		PASS ASS/FAIL PASS PASS
COMMENTS/REMARKS	Allele Frequency Additional inform Copy numbers	27.0 ng/µl (total 18.9 ng/µl (dsDN/ Mutation PIK3CA E545D PIK3CA H1047L nation: (CN) of the respec	AF in 9 13.2 14.6 ctive measu	rement	PASS ASS/FAIL PASS PASS
COMMENTS/REMARKS	Allele Frequency Additional inform Copy numbers	27.0 ng/µl (total 18.9 ng/µl (dsDN/ Mutation PIK3CA E545D PIK3CA H1047L nation: (CN) of the respec	AF in 9 13.2 14.6 ctive measu	rement	PASS ASS/FAIL PASS PASS PASS

Test Method

Quality Control

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

⁹Measured before filling in product tube

¹⁰not applicable 11 Wild Type 12 Mutation



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PRODUCT	INFORMATION	AND QUALITY	CONTROL
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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

• Manufactured and sealed in class 2 safety cabinet

CONDITIONS • At room temperature

PACKAGE SIZE • 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 material¹³

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 | SensID GmbH

QUALITY CONTROL Schillingallee 68, 18057 Rostock, Germany

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Acceptance

TEST METHOD AND

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ACCEPTANCE CRITERIA				criterio	а	
	Fragment Length Analysis			peak s	size 167 bp ±	
	Fragmentation	Agilent High S	ensitivity DNA Kit	10%	10%	
		(Agilent Techn	ologies)	(151 bp	(151 bp - 181 bp)	
	Quantification	Total DNA measurement: Spectrophotometry ssDNA [ng/µl] = (A260-A320)*38 ¹⁴ , ¹⁵		Total [n.a. ¹⁶	DNA:	
		dsDNA measu dsDNA BR Ass	rement: Qubit ay Kit (Invitrogen)		dsDNA: 17.5 – 22.5 ng/μl	
	Allala Fraguenay	ddPCR Analys	is	AF 12.5	% ±20%	
	Allele Frequency	using BioRad	Rad QX200™ System		(10.0-15.0%)	
		1		I		
RESULTS OF ANALYSIS		l B				
		Result			PASS/FAIL	
	Fragmentation	179 bp			PASS/FAIL PASS	
	Fragmentation Quantity					
		179 bp 23.9 ng/µl (t	AF 12	in % PA	PASS	
COMMENTS/REMARKS	Quantity Allele	179 bp 23.9 ng/µl (t 18.0 ng/µl (c Mutation PIK3CA E54 PIK3CA H10	AF 12	2.1	PASS PASS ASS/FAIL PASS	
COMMENTS/REMARKS	Quantity Allele Frequency	179 bp 23.9 ng/µl (t 18.0 ng/µl (c Mutation PIK3CA E54 PIK3CA H10	AF 45G 12 047R 12	2.1	PASS PASS/FAIL PASS PASS	
COMMENTS/REMARKS	Allele Frequency Additional inform Copy numbers	179 bp 23.9 ng/µl (t 18.0 ng/µl (c) Mutation PIK3CA E54 PIK3CA H10 nation: (CN) of the re	AF 45G 12 047R 12	2.1	PASS PASS ASS/FAIL PASS PASS	
COMMENTS/REMARKS	Allele Frequency Additional inform Copy numbers	179 bp 23.9 ng/µl (t 18.0 ng/µl (c) Mutation PIK3CA E54 PIK3CA H10 nation: (CN) of the re	AF 45G 12 047R 12 espective med	2.1 2.9 surement	PASS PASS ASS/FAIL PASS PASS PASS	

Test Method

Quality Control

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 (μ I), 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.

Table 3 indicates the values of the QC assays performed by SensID GmbH with a DNA input

18 Mutation

¹⁴ Protocol NK603 – Community Reference Laboratory for GM Food and Feed

¹⁵Measured before filling in product tube

¹⁶not applicable

¹⁷ Wild Type



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PRODUCT	INFORMATION	AND (YTHAHC	CONTROL
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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

• Manufactured and sealed in class 2 safety cabinet

CONDITIONS • At room temperature

PACKAGE SIZE • 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 material¹⁹

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 | SensID GmbH

QUALITY CONTROL | Schillingallee 68, 18057 Rostock, Germany

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TEST METHOD AND

Page 8/16 Acceptance

ACCEPTANCE CRITERIA				criter	a	
		Fragment Len	gth Analysis	peak	size 167 bp ±	
	Fragmentation	Agilent High Sensitivity DNA Kit			10%	
		(Agilent Techn	(151 b _r	(151 bp - 181 bp)		
	Quantification	Total DNA med Spectrophoto ssDNA [ng/μl]	Total n.a. ²²	DNA:		
		dsDNA measu dsDNA BR Ass	rement: Qubit ay Kit (Invitrogen)	17.5 -	dsDNA: 17.5 – 22.5 ng/μl	
	Allele Frequency	ddPCR Analys using BioRad (s 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 (t 19.4 ng/µl (c		PASS		
	Allele Frequency	Mutation AF in % PIK3CA E545K 12.2 PIK3CA H1047Y 11.0		2.2	ASS/FAIL PASS PASS	
COMMENTS/REMARKS	Additional inform		espective med	asuremen	ts	
	Mutat	ion	CN wt ²³ /μl	CN mut		
	PIK3CA E545K PIK3CA H1047Y		2938 4187	409 520		
	- 11 - 11 - 11					

Test Method

Quality Control

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

²¹Measured before filling in product tube

²²not applicable ²³ Wild Type ²⁴ Mutation



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PRODUCT	INFORMATION	AND CHAL	ITY CONTROL
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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

• Manufactured and sealed in class 2 safety cabinet

CONDITIONS • At room temperature

PACKAGE SIZE • 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 $25 \mu l; (523 ng)$

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 material²⁵

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 | SensID GmbH

QUALITY CONTROL Schillingallee 68, 18057 Rostock, Germany

SITES

²⁵ ERM_AD442K



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TEST METHOD AND	Quality Control	Test Method		Acceptance	
ACCEPTANCE CRITERIA				criteria	
AGGET THROE GRATEFULLY	Fragmentation		ensitivity DNA Kit	peak size 167 bp ± 10%	
		(Agilent Techn	ologies)	(151 bp – 181 bp)	
	Quantification	Total DNA me Spectrophoto ssDNA [ng/µl]		Total DNA: n.a. ²⁸	
		dsDNA measu dsDNA BR Ass	rement: Qubit ay Kit (Invitrogen)	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 (t 20.9 ng/µl (¢		PASS	
COMMENTS/REMARKS	Allele Frequency Additional inform Copy numbers		AF in 46E 12.8 espective measu	PASS	
	of ~40 ng. The value measured replicates (are based on droplet measurements. The de Therefore, due to ass	values of the QC as for the respectiv CN values are roun digital (ddPCR) a etection of the amo ay properties, the	e mutation results from nded). CN concentration ssay counts dilution fa punt of CNs may vary de	CN mut ³⁰ /µl 821 ID GmbH with a DNA input on the mean value of five of values per microliter (µl), actors, and droplet volume pending on the assay used. In the observed number of	

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

Phone: +49 (0) 381 377 182 01

Net: www.sens-id.





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

BATCH NUMBER 00049

MANUFACTURING

• Manufactured and sealed in class 2 safety cabinet

CONDITIONS • At room temperature

PACKAGE SIZE

• 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 material31

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 | SensID GmbH

QUALITY CONTROL | Schillingallee 68, 18057 Rostock, Germany

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Acceptance criteria



TEST METHOD AND

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ACCEPTANCE CRITERIA					criteria		
		Fragment Length Analysis			peak size 167 bp ±		
	Fragmentation	Agilent High Sensitivity DNA Kit			10%		
	Quantification	(Agilent Technologies)			(151 bp - 181 bp)		
		Total DNA measurement:			Total DNA:		
		Spectrophotometry			n.a. ³⁴		
		ssDNA [ng/μl] = (A260-					
		A320)*38 ³² , ³³					
					dsDNA:		
		dsDNA measurement: Qubit			17.5 – 22.5 ng/μl		
	All 1- 5	dsDNA BR Assay Kit (Invitrogen)					
		ddPCR Analysis			AF 12.5% ±20%		
	Allele Frequency	using BioRad QX200™ System		m	(10.0-15.0%)		
		I		Į.			
RESULTS OF ANALYSIS		Result			PAS	S/FAIL	
	Fragmentation	178 bp			P	PASS	
		33.6 ng/µl (total DNA)					
	Quantity	21.6 ng/µl (dsDNA)			P	ASS	
	Allala	Mutation		AF in %	PASS/F	AIL	
	Allele	PIK3CA E545A ³⁵ 11.9			PASS		
	Frequency	PIK3CA C4	20R	14.1	PASS)	
COMMENTS/REMARKS	Additional inform	_L mation:					
	Copy numbers (CN) of the respective measurements						
	copy hambers (City of the respective measurements						
	Mutat	Mutation		I C	CN mut ³⁷ /μl		
	L L DU/7 O A EE / E A				774	1	

Test Method

Quality Control

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
conies and allele frequencies compared to the values given here

5711

2316

PIK3CA E545A

PIK3CA C420R

Phone: +49 (0) 381 377 182 01

771

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 $^{^{32}}$ Protocol NK603 – Community Reference Laboratory for GM Food and Feed 33 Measured before filling in product tube

³⁴not applicable

⁵⁷⁴ 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

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