

## Product update information for: Tru-Q products

### Dear Customer,

At Horizon we are constantly looking at ways to improve our products to give you even more confidence in your assay results. As a result of recent improvements, we wish to inform you that the expected allele frequency for some of the variants in Tru-Q products has been slightly modified.

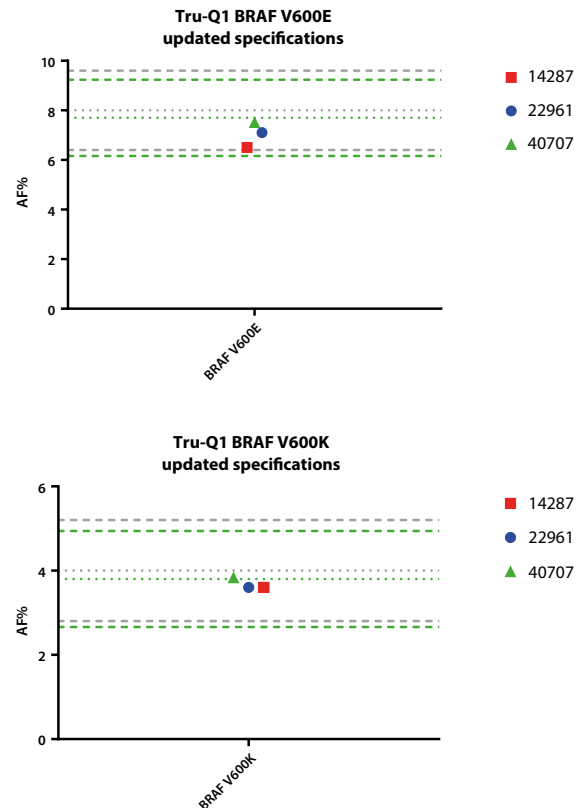
These changes will be effective for batches manufactured after the 31st March 2021

As the data below demonstrates, changes are minimal and should not impact use of the control.

### Tru-Q1

Changes made affect only BRAF V600E and BRAF V600K

Chromosome	Gene	Variant	Expected Allelic Frequency, %	New Expected Allele Frequency, %
7q34	BRAF	V600E	8.00%	<b>7.70%</b>
7q34	BRAF	V600K	4.00%	<b>3.80%</b>
7p12	EGFR	G719S	16.70%	16.70%
7p12	EGFR	T790M	4.20%	4.20%
13q12	FLT3	ΔI836	5.00%	5.00%
2q33.3	IDH1	R132C	5.00%	5.00%
9p24	JAK2	V617F	5.00%	5.00%
12p12.1	KRAS	G12A	5.00%	5.00%
12p12.1	KRAS	G12R	5.00%	5.00%
12p12.1	KRAS	G13D	25.00%	25.00%
15q22.31	MEK1	P124L	5.00%	5.00%
9q34.3	NOTCH1	L1600P	4.80%	4.80%
1p13.2	NRAS	Q61K	5.00%	5.00%
3q26.3	PIK3CA	H1047R	30.00%	30.00%

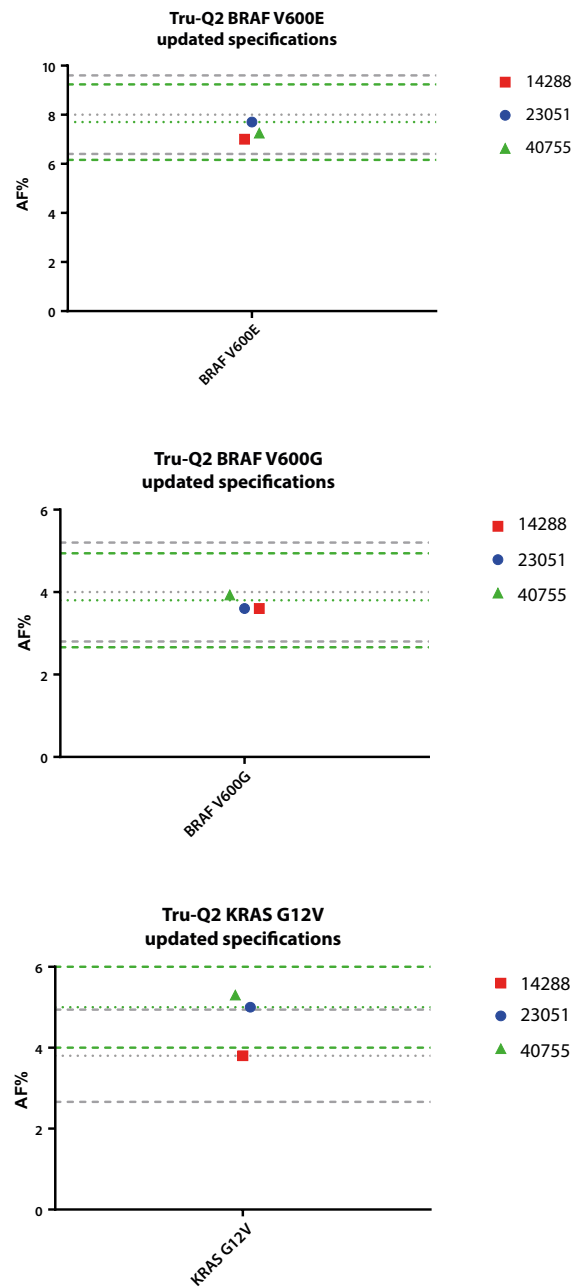


**Figure 1:** Updated BRAF V600E and V600K specifications for Tru-Q1. The graphs show batches of Tru-Q1 and the change in specifications. Gray lines relate to the original specifications and green lines show the new specifications. The dotted lines represent the expected allele frequency and the dashed lines exhibit the acceptance criteria.

## Tru-Q2

Changes made affect only BRAF V600G, KRAS G12V and BRAF V600E

Chromosome	Gene	Variant	Expected Allelic Frequency, %	New Expected Allele Frequency, %
2p23	ALK	F1174L	5.0%	5.0%
7q34	BRAF	V600E	8.0%	7.7%
7q34	BRAF	V600G	4.0%	3.8%
7p12	EGFR	G719S	16.7%	16.7%
7p12	EGFR	L858R	4.2%	4.2%
10q26	FGFR2	S252W	4.0%	4.0%
9q21	GNAQ	Q209L	5.0%	5.0%
15q26.1	IDH2	R140Q	5.0%	5.0%
12p12.1	KRAS	G12V	3.8%	5%
12p12.1	KRAS	G13D	25.0%	25.0%
12p12.1	KRAS	Q61L	5.0%	5.0%
1p13.2	NRAS	Q61L	5.0%	5.0%
3q26.3	PIK3CA	E545K	5.0%	5.0%
3q26.3	PIK3CA	H1047R	30.0%	30.0%

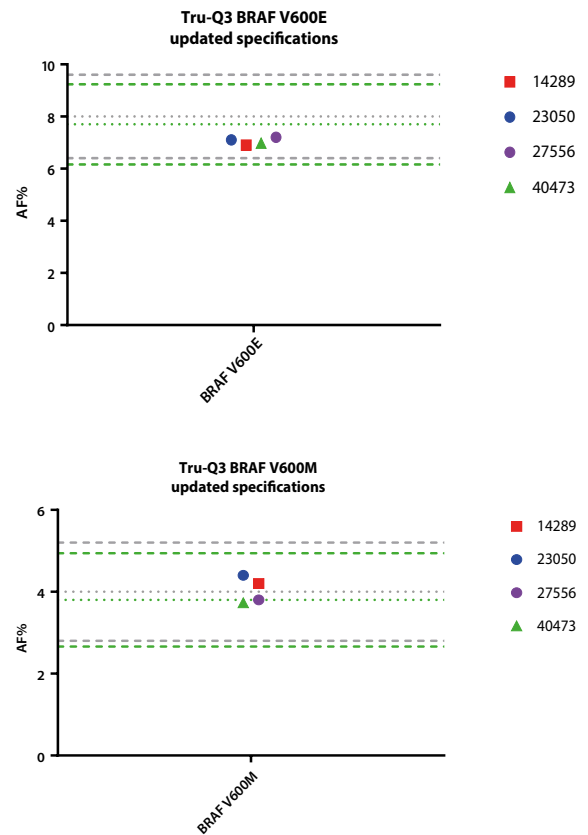


**Figure 2:** Updated BRAF V600E, V600G and KRAS G12V specifications for Tru-Q2. The graphs show batches of Tru-Q2 and the change in specifications. Gray lines relate to the original specifications and green lines show the new specifications. The dotted lines represent the expected allele frequency and the dashed lines exhibit the acceptance criteria.

## Tru-Q3

Changes made affect only BRAF V600M and BRAF V600E

Chromosome	Gene	Variant	Expected Allelic Frequency, %	New Expected Allele Frequency, %
7q34	BRAF	V600E	8.0%	7.7%
7q34	BRAF	V600M	4.0%	3.8%
7p12	EGFR	G719S	16.7%	16.7%
7p12	EGFR	ΔE746 - A750	4.2%	4.2%
13q12	FLT3	D835Y	5.0%	5.0%
19p13.3	GNA11	Q209L	5.0%	5.0%
2q33.3	IDH1	R132H	5.0%	5.0%
12p12.1	KRAS	A146T	5.0%	5.0%
12p12.1	KRAS	G12S	5.0%	5.0%
12p12.1	KRAS	G13D	25.0%	25.0%
7q31	MET	Y1253D	3.6%	3.6%
1p13.2	NRAS	Q61H	5.0%	5.0%
3q26.3	PIK3CA	E542K	5.0%	5.0%
3q26.3	PIK3CA	H1047R	30.0%	30.0%

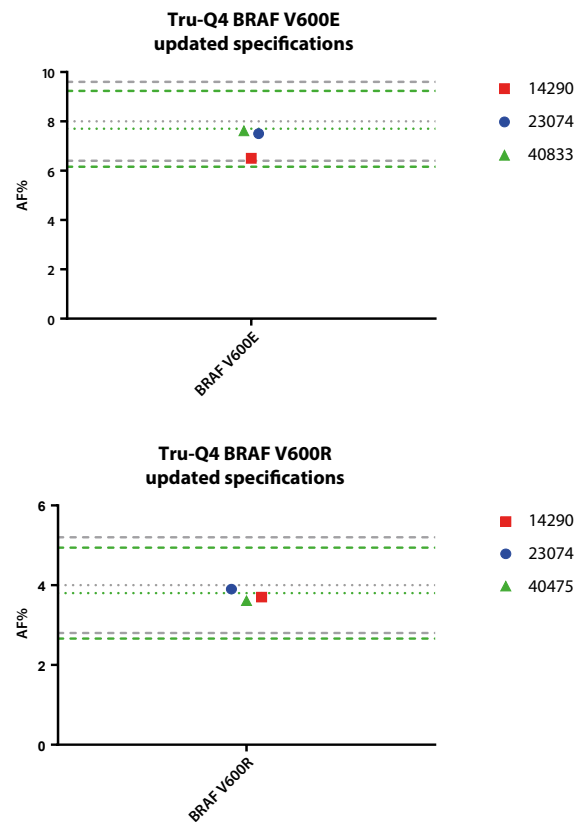


**Figure 3:** Updated BRAF V600E and V600M specifications for Tru-Q3. The graphs show batches of Tru-Q3 and the change in specifications. Gray lines relate to the original specifications and the green lines show the new specifications. The dotted lines represent the expected allele frequency and the dashed lines exhibit the acceptance criteria.

## Tru-Q4

Changes made affect only BRAF V600R and BRAF V600E

Chromosome	Gene	Variant	Expected Allelic Frequency, %	New Expected Allele Frequency, %
9q34.1	ABL1	T315I	5.0%	5.0%
7q34	BRAF	V600E	8.0%	7.7%
7q34	BRAF	V600R	4.0%	3.8%
7p12	EGFR	G719S	16.7%	16.7%
7p12	EGFR	L861Q	4.2%	4.2%
15q26.1	IDH2	R172K	5.0%	5.0%
4q11-q12	KIT	D816V	5.0%	5.0%
12p12.1	KRAS	G12C	5.0%	5.0%
12p12.1	KRAS	G12D	5.0%	5.0%
12p12.1	KRAS	G13D	25.0%	25.0%
12p12.1	KRAS	Q61H	5.0%	5.0%
1p13.2	NRAS	Q61R	5.0%	5.0%
4q12	PDGFRA	D842V	5.0%	5.0%
3q26.3	PIK3CA	H1047R	30.0%	30.0%

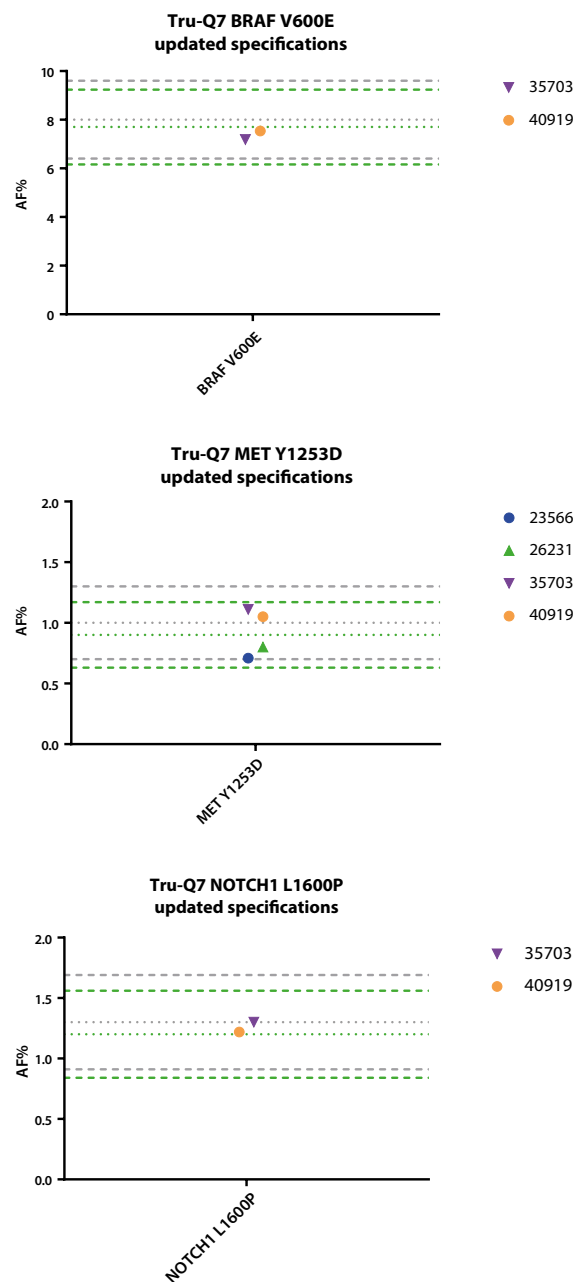


**Figure 4:** Updated BRAF V600E and V600R specifications for Tru-Q4. The graphs show batches of Tru-Q4 and the change in specifications. Gray lines relate to the original specifications and green lines show the new specifications. The dotted lines represent the expected allele frequency and the dashed lines exhibit the acceptance criteria.

## Tru-Q7

Changes made affect only MET L1253D, NOTCH1 L1600P\* and BRAF V600E

Chromosome	Gene	Variant	Expected Allelic Frequency, %	New Expected Allele Frequency, %
9q34.1	ABL1	T315I	1.30%	1.30%
2p23	ALK	F1174L	1.30%	1.30%
7q34	BRAF	V600E	<b>8.00%</b>	<b>7.70%</b>
7q34	BRAF	V600G	1.00%	1.00%
7q34	BRAF	V600K	1.00%	1.00%
7q34	BRAF	V600M	1.00%	1.00%
7q34	BRAF	V600R	1.00%	1.00%
7p12	EGFR	G719S	16.70%	16.70%
7p12	EGFR	L858R	1.00%	1.00%
7p12	EGFR	L861Q	1.00%	1.00%
7p12	EGFR	T790M	1.00%	1.00%
7p12	EGFR	ΔE746-A750	1.00%	1.00%
10q26	FGFR2	S252W	1.00%	1.00%
13q12	FLT3	D835Y	1.30%	1.30%
13q12	FLT3	ΔI836	1.30%	1.30%
19p13.3	GNA11	Q209L	1.30%	1.30%
9q21	GNAQ	Q209L	1.30%	1.30%
2q33.3	IDH1	R132C	1.30%	1.30%
2q33.3	IDH1	R132H	1.30%	1.30%
15q26.1	IDH2	R140Q	1.30%	1.30%
15q26.1	IDH2	R172K	1.30%	1.30%
9p24	JAK2	V617F	1.30%	1.30%
4q11-q12	KIT	D816V	1.30%	1.30%
12p12.1	KRAS	A146T	1.30%	1.30%
12p12.1	KRAS	G12A	1.30%	1.30%
12p12.1	KRAS	G12C	1.30%	1.30%
12p12.1	KRAS	G12D	1.30%	1.30%
12p12.1	KRAS	G12R	1.30%	1.30%
12p12.1	KRAS	G12S	1.30%	1.30%
12p12.1	KRAS	G12V	1.30%	1.30%
12p12.1	KRAS	G13D	25.00%	25.00%
12p12.1	KRAS	Q61H	1.30%	1.30%
12p12.1	KRAS	Q61L	1.30%	1.30%
15q22.31	MEK1	P124L	1.30%	1.30%
7q31	MET	Y1253D	<b>1.00%</b>	<b>0.90%</b>
9q34.3	NOTCH	L1600P*	<b>1.30%</b>	<b>1.20%</b>
1p13.2	NRAS	Q61H	1.30%	1.30%
1p13.2	NRAS	Q61K	1.30%	1.30%
1p13.2	NRAS	Q61L	1.30%	1.30%
1p13.2	NRAS	Q61R	1.30%	1.30%
4q12	PDGFRA	D842V	1.30%	1.30%
3q26.3	PIK3CA	E542K	1.30%	1.30%
3q26.3	PIK3CA	E545K	1.30%	1.30%
3q26.3	PIK3CA	H1047R	30.00%	30.00%



**Figure 5:** Updated BRAF V600E, MET Y1253D and NOTCH1 L1600P specifications for Tru-Q7. The graphs show batches of Tru-Q7 and the change in specifications. Gray lines relate to the original specifications and green lines show the new specifications. The dotted lines represent the expected allele frequency and the dashed lines exhibit the acceptance criteria.

\* NOTCH1 L1600P was previously referred to as NOTCH1 L1601P. Whilst the mutation is L1601P on a genetic level, it is also commonly referred to as L1600P

**For more information**

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To find the contact information in your country for your technology of interest, please visit us at [horizondiscovery.com/contact-us](https://horizondiscovery.com/contact-us)

Horizon Discovery, 8100 Cambridge Research Park, Waterbeach, Cambridge, CB25 9TL, United Kingdom

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