

Multiplex cfDNA Reference Standard

IMPORTANT: Centrifuge tube prior to opening to prevent loss of product

PRODUCT INFORMATION

Catalog ID	HD833
Batch ID	40762
Product Description	OncoSpan cfDNA Reference Standard Set
Date of Manufacture	24-Sep-2019
Manufacturing QMS Status	ISO 13485

PROPERTIES

Quantity	350 ng
Concentration	20 ng/ μ L
Average Fragment Length	160 bp
Buffer	Tris-EDTA (10 mM Tris-HCl, 1 mM EDTA), pH 8.0
Storage Conditions	+4°C (2-8°C)
Use by	For the latest information on product shelf life, please visit our website: https://horizondiscovery.com/products/diagnostic-reference-standards/reference-standards-product-information

CUSTOMER SUPPORT

Technical Support	technical@horizondiscovery.com
Customer Service	orders@horizondiscovery.com

ADDITIONAL INFORMATION

N/A

Horizon Discovery

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QUALITY CONTROL

Allele Frequency (AF) and Genotype: Droplet Digital™ PCR

Gene	Variant	Copy Number (copies/μL)			Expected AF (%)	Actual AF (%)	Acceptance Criteria (%)		Pass/Fail
		WT	Mut	Total			Low	High	
BRAF	V600E	263.10	27.80	290.90	10.50	9.55	9.45	11.55	PASS
KIT	D816V	318.00	34.10	352.10	10.00	9.71	8.00	12.00	PASS
EGFR	ΔE746-A750	323.00	6.80	329.80	2.00	2.07	1.40	2.60	PASS
EGFR	p.L858R	524.00	12.70	536.70	3.00	2.37	2.10	3.90	PASS
EGFR	p.T790M	443.00	3.61	446.61	1.00	0.81	0.70	1.30	PASS
EGFR	p.G719S	293.30	90.70	384.00	24.50	23.60	22.05	26.95	PASS
KRAS	p.G13D	253.90	49.80	303.70	15.00	12.29	12.00	18.00	PASS
KRAS	p.G12D	380.00	25.30	405.30	6.00	6.26	4.80	7.20	PASS
NRAS	Q61K	386.00	54.30	440.30	12.50	12.34	11.25	13.75	PASS
PIK3CA	p.H1047R	275.30	51.60	326.90	17.50	15.80	15.75	19.25	PASS
PIK3CA	p.E545K	389.00	37.80	426.80	9.00	8.87	7.20	10.80	PASS

Allele Frequency (AF) and Genotype: Droplet Digital™ PCR (additional variants detected for information only)

Gene	Variant	Copy Number (copies/μL)			Expected AF (%)	Actual AF (%)
		WT	Mut	Total		
ALK	3'_UTR_insertion	322.20	33.90	356.10	10.00	9.51
APC	P.T1493T	241.30	135.40	376.70	35.00	35.90
BRCA2	p.K1691fs*15	244.30	119.50	363.80	32.50	32.90
CTNNB1	p.S33Y	354.90	114.50	469.40	32.50	31.00
CTNNB1	p.S45del	455.00	54.80	509.80	10.00	10.75
EGFR	p.Q787Q	532.00	94.30	626.30	15.00	15.05
FBXW7	p.S668fs*39	286.00	138.10	424.10	32.50	32.60
FLT3	p.P986fs*>8	471.00	53.00	524.00	10.00	10.12
KIT	p.L862L	357.00	27.00	384.00	7.50	7.03
MET	p.A1357A	623.00	46.00	669.00	7.00	6.88
MET	p.L238fs*25	352.00	25.70	377.70	7.00	6.82
NOTCH1	p.P668S	440.00	199.80	639.80	30.00	31.24
RET	p.L769L	222.80	130.60	353.40	60.00	63.00
TP53	p.P72R	421.00	30.00	451.00	92.50	93.33

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QUALITY CONTROL (continued)Fragmentation Size: **D1000 DNA ScreenTape assay (Agilent Technologies) TapeStation software version A.02.02**

Acceptance Criteria	Reading	Pass/Fail
160 bp \pm 10% (144 bp – 176 bp)	164 bp	PASS

Quantification: **Qubit® dsDNA BR assay (Invitrogen)**

Acceptance Criteria	Reading	Pass/Fail
20 ng/ μ L \pm 15% (17.0 – 23.0 ng/ μ L)	20.17 ng/ μ l	PASS

FOR RESEARCH USE ONLY

Manufactured in the UK

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