

Multiplex cfDNA Reference Standard

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

PRODUCT INFORMATION	
Catalog ID	HD780
Batch ID	
Product Description	Multiplex I cfDNA Reference Standard Set
Date of Manufacture	
Manufacturing QMS Status	ISO 13485

PROPERTIES	
Quantity	4 vials of 350 ng
Concentration	20 ng/μL
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	

Horizon Discovery

8100 Cambridge Research Park,
Waterbeach, Cambridge,
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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	
5% Allele Frequency (Part No: HD777)									
EGFR	L858R				5.0		3.50	6.50	
EGFR	ΔE746-A750				5.0		3.50	6.50	
EGFR	T790M				5.0		3.50	6.50	
EGFR	V769-D770insASV				5.0		3.50	6.50	
KRAS	G12D				6.3		4.40	8.20	
NRAS	Q61K				6.3		4.40	8.20	
NRAS	A59T				6.3		4.40	8.20	
PIK3CA	E545K				6.3		4.40	8.20	
1% Allele Frequency (Part No: HD778)									
EGFR	L858R				1.0		0.60	1.40	
EGFR	ΔE746-A750				1.0		0.60	1.40	
EGFR	T790M				1.0		0.60	1.40	
EGFR	V769-D770insASV				1.0		0.60	1.40	
KRAS	G12D				1.3		0.80	1.80	
NRAS	Q61K				1.3		0.80	1.80	
NRAS	A59T				1.3		0.80	1.80	
PIK3CA	E545K				1.3		0.80	1.80	
0.1% Allele Frequency (Part No: HD779)									
EGFR	L858R				0.10		0.05	0.15	
EGFR	ΔE746-A750				0.10		See below*		
EGFR	T790M				0.10		See below*		
EGFR	V769-D770insASV				0.10		0.05	0.15	
KRAS	G12D				0.13		See below*		
NRAS	Q61K				0.13		0.07	0.20	
NRAS	A59T				0.13		See below*		
PIK3CA	E545K				0.13		See below*		
*Observed AF (%) for 0.1% variants must be greater than observed AF (%) of the corresponding wild type assay									
100% Wild Type (Part No: HD776)									
EGFR	L858R				0.00		≤0.10		
EGFR	ΔE746-A750				0.00		≤0.10		
EGFR	T790M				0.00		≤0.10		
EGFR	V769-D770insASV				0.00		≤0.10		
KRAS	G12D				0.00		≤0.10		
NRAS	Q61K				0.00		≤0.10		
NRAS	A59T				0.00		≤0.10		
PIK3CA	E545K				0.00		≤0.10		

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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
5% Allele Frequency (Part No: HD777) 160 bp \pm 10% (144 bp – 176 bp)		
1% Allele Frequency (Part No: HD778) 160 bp \pm 10% (144 bp – 176 bp)		
0.1% Allele Frequency (Part No: HD779) 160 bp \pm 10% (144 bp – 176 bp)		
100% Wild Type (Part No: HD776) 160 bp \pm 10% (144 bp – 176 bp)		
Quantification: Qubit® dsDNA BR assay (Invitrogen)		
Acceptance Criteria	Reading	Pass/Fail
5% Allele Frequency (Part No: HD777) 20 ng/ μ L \pm 15% (17.0 – 23.0 ng/ μ L)		
1% Allele Frequency (Part No: HD778) 20 ng/ μ L \pm 15% (17.0 – 23.0 ng/ μ L)		
0.1% Allele Frequency (Part No: HD779) 20 ng/ μ L \pm 15% (17.0 – 23.0 ng/ μ L)		
100% Wild Type (Part No: HD776) 20 ng/ μ L \pm 15% (17.0 – 23.0 ng/ μ L)		

FOR RESEARCH USE ONLY

Manufactured in the UK

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