

Multiplex cfDNA Reference Standard

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

PRODUCT INFORMATION	
Catalog ID	HD817
Batch ID	
Product Description	Multiplex I cfDNA Reference Standard Set in Synthetic Matrix
Date of Manufacture	
Manufacturing QMS Status	ISO 9001

PROPERTIES	
Volume	1 tube of 1 mL per Allele Frequency
cfDNA quantity spiked into plasma	400 ng per 1 mL
Expected DNA yield	≥ 120 ng per 1 mL*
Average Fragment Length	170 bp
Buffer	Synthetic matrix
Storage Conditions	+4°C (2-8°C)
Use by	31-Mar-2022

*Represents 30% extraction yield performed using Qiagen kit (Cat. No. 55114)

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

ADDITIONAL INFORMATION	

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: HD812)									
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: HD813)									
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: HD814)									
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: HD815)									
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		

Horizon Discovery

 8100 Cambridge Research Park,
 Waterbeach, Cambridge,
 CB25 9TL, United Kingdom
www.horizondiscovery.com/

 t + 44 (0) 1223 976 000
 f + 44 (0) 1223 655 581
 e orders@horizondiscovery.com

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: HD812) 170bp ± 15% (144 bp - 195 bp)		
1% Allele Frequency (Part No: HD813) 170bp ± 15% (144 bp - 195 bp)		
0.1% Allele Frequency (Part No: HD814) 170bp ± 15% (144 bp - 195 bp)		
100% Wild Type (Part No: HD815) 170bp ± 15% (144 bp - 195 bp)		

Quantification of cfDNA spiked into matrix: **Qubit® dsDNA BR assay (Invitrogen)**

Acceptance Criteria	Reading	Pass/Fail
5% Allele Frequency (Part No: HD812) 40 ng/μL ± 10% (36.0 – 44.0 ng/μL)		
1% Allele Frequency (Part No: HD813) 40 ng/μL ± 10% (36.0 – 44.0 ng/μL)		
0.1% Allele Frequency (Part No: HD814) 40 ng/μL ± 10% (36.0 – 44.0 ng/μL)		
100% Wild Type (Part No: HD815) 40 ng/μL ± 10% (36.0 – 44.0 ng/μL)		

Quantification of extraction yield: **Qubit® dsDNA BR assay (Invitrogen)**

Acceptance Criteria	Reading	Pass/Fail
5% Allele Frequency (Part No: HD812) ≥ 120 ng per 1 mL		
1% Allele Frequency (Part No: HD813) ≥ 120 ng per 1 mL		
0.1% Allele Frequency (Part No: HD814) ≥ 120 ng per 1 mL		
100% Wild Type (Part No: HD815) ≥ 120 ng per 1 mL		

FOR RESEARCH USE ONLY

Manufactured in the UK

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