

Multiplex cfDNA in Synthetic Matrix II Reference Standard

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

PRODUCT INFORMATION	
Catalog ID	HD917
Batch ID	
Product Description	Multiplex I cfDNA Reference Standard Set in Synthetic Matrix II
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 in 1 mL
Expected DNA yield	≥ 120 ng per mL*
Average Fragment Length	170 bp
Buffer	Synthetic matrix II
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

*Represents 30% extraction yield performed using recommended 2 mL input with the 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
		Final Mut	Final WT	Final Total			Low	High	
5% Allele Frequency (Part No: HD912)									
EGFR	T790M				5.0		3.50	6.50	
EGFR	ΔE746-A750				5.0		3.50	6.50	
EGFR	L858R				5.0		3.50	6.50	
EGFR	V769-D770insASV				5.0		3.50	6.50	
NRAS	Q61K				6.3		4.40	8.20	
NRAS	A59T				6.3		4.40	8.20	
PIK3CA	E545K				6.3		4.40	8.20	
KRAS	G12D				6.3		4.40	8.20	
1% Allele Frequency (Part No: HD913)									
EGFR	T790M				1.0		0.60	1.40	
EGFR	ΔE746-A750				1.0		0.60	1.40	
EGFR	L858R				1.0		0.60	1.40	
EGFR	V769-D770insASV				1.0		0.60	1.40	
NRAS	Q61K				1.3		0.80	1.80	
NRAS	A59T				1.3		0.80	1.80	
PIK3CA	E545K				1.3		0.80	1.80	
KRAS	G12D				1.3		0.80	1.80	
0.1% Allele Frequency (Part No: HD914)									
EGFR	T790M				0.10		See below*		
EGFR	ΔE746-A750				0.10		See below*		
EGFR	L858R				0.10		0.05	0.15	
EGFR	V769-D770insASV				0.10		0.05	0.15	
NRAS	Q61K				0.13		0.07	0.20	
NRAS	A59T				0.13		See below*		
PIK3CA	E545K				0.13		See below*		
KRAS	G12D				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: HD915)									
EGFR	T790M				0.00		≤0.10		
EGFR	ΔE746-A750				0.00		≤0.10		
EGFR	L858R				0.00		≤0.01		
EGFR	V769-D770insASV				0.00		≤0.01		
NRAS	Q61K				0.00		≤0.01		
NRAS	A59T				0.00		≤0.10		
PIK3CA	E545K				0.00		≤0.10		
KRAS	G12D				0.00		≤0.10		

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: HD912)		
170bp ± 15% (144 bp - 195 bp)		
1% Allele Frequency (Part No: HD913)		
170bp ± 15% (144 bp - 195 bp)		
0.1% Allele Frequency (Part No: HD914)		
170bp ± 15% (144 bp - 195 bp)		
100% Wild Type (Part No: HD915)		
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: HD912)		
40 ng/μL ± 10% (36.0 – 44.0 ng/μL)		
1% Allele Frequency (Part No: HD913)		
40 ng/μL ± 10% (36.0 – 44.0 ng/μL)		
0.1% Allele Frequency (Part No: HD914)		
40 ng/μL ± 10% (36.0 – 44.0 ng/μL)		
100% Wild Type (Part No: HD915)		
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: HD912)		
≥ 120 ng per mL		
1% Allele Frequency (Part No: HD913)		
≥ 120 ng per mL		
0.1% Allele Frequency (Part No: HD914)		
≥ 120 ng per mL		
100% Wild Type (Part No: HD915)		
≥ 120 ng per mL		

FOR RESEARCH USE ONLY

Manufactured in the UK

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