

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	45462
Product Description	Multiplex I cfDNA Reference Standard Set in Synthetic Matrix II
Date of Manufacture	10-Sep-2020
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	
N/A	

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	286	5760	6046	5.0	4.73	3.50	6.50	PASS
EGFR	ΔE746-A750	386	6140	6526	5.0	5.91	3.50	6.50	PASS
EGFR	L858R	550	11380	11930	5.0	4.61	3.50	6.50	PASS
EGFR	V769-D770insASV	240	5722	5962	5.0	4.02	3.50	6.50	PASS
NRAS	Q61K	672	9400	10072	6.3	6.67	4.40	8.20	PASS
NRAS	A59T	786	11260	12046	6.3	6.53	4.40	8.20	PASS
PIK3CA	E545K	604	9100	9704	6.3	6.22	4.40	8.20	PASS
KRAS	G12D	630	9080	9710	6.3	6.48	4.40	8.20	PASS
1% Allele Frequency (Part No: HD913)									
EGFR	T790M	54	5860	5914	1.0	0.91	0.60	1.40	PASS
EGFR	ΔE746-A750	70	6560	6630	1.0	1.06	0.60	1.40	PASS
EGFR	L858R	126	11520	11646	1.0	1.08	0.60	1.40	PASS
EGFR	V769-D770insASV	40.6	5666	5707	1.0	0.71	0.60	1.40	PASS
NRAS	Q61K	108	9240	9348	1.3	1.15	0.80	1.80	PASS
NRAS	A59T	128	9620	9748	1.3	1.31	0.80	1.80	PASS
PIK3CA	E545K	114	9480	9594	1.3	1.19	0.80	1.80	PASS
KRAS	G12D	136	8940	9076	1.3	1.50	0.80	1.80	PASS
0.1% Allele Frequency (Part No: HD914)									
EGFR	T790M	9	7000	7009	0.10	0.13	See below*		PASS
EGFR	ΔE746-A750	9	8160	8169	0.10	0.11	See below*		PASS
EGFR	L858R	17.8	14640	14658	0.10	0.12	0.05	0.15	PASS
EGFR	V769-D770insASV	6.2	6820	6826	0.10	0.09	0.05	0.15	PASS
NRAS	Q61K	17	12080	12097	0.13	0.14	0.07	0.20	PASS
NRAS	A59T	26.2	11600	11626	0.13	0.22	See below*		PASS
PIK3CA	E545K	16.2	12100	12116	0.13	0.13	See below*		PASS
KRAS	G12D	18.2	11340	11358	0.13	0.16	See below*		PASS
*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	2.2	7180	7182	0.00	0.03	≤0.10		PASS
EGFR	ΔE746-A750	0	8100	8100	0.00	0.00	≤0.10		PASS
EGFR	L858R	0	14340	14340	0.00	0.00	≤0.01		PASS
EGFR	V769-D770insASV	0	6960	6960	0.00	0.00	≤0.01		PASS
NRAS	Q61K	0	12000	12000	0.00	0.00	≤0.01		PASS
NRAS	A59T	1.2	11960	11961	0.00	0.01	≤0.10		PASS
PIK3CA	E545K	2	12040	12042	0.00	0.02	≤0.10		PASS
KRAS	G12D	2.6	11500	11503	0.00	0.02	≤0.10		PASS

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)	168 bp	PASS
1% Allele Frequency (Part No: HD913) 170bp ± 15% (144 bp - 195 bp)	171 bp	PASS
0.1% Allele Frequency (Part No: HD914) 170bp ± 15% (144 bp - 195 bp)	171 bp	PASS
100% Wild Type (Part No: HD915) 170bp ± 15% (144 bp - 195 bp)	168 bp	PASS

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)	37.50 ng/μL	PASS
1% Allele Frequency (Part No: HD913) 40 ng/μL ± 10% (36.0 – 44.0 ng/μL)	38.50 ng/μL	PASS
0.1% Allele Frequency (Part No: HD914) 40 ng/μL ± 10% (36.0 – 44.0 ng/μL)	37.20 ng/μL	PASS
100% Wild Type (Part No: HD915) 40 ng/μL ± 10% (36.0 – 44.0 ng/μL)	38.60 ng/μL	PASS

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

Acceptance Criteria	Reading	Pass/Fail
5% Allele Frequency (Part No: HD912) ≥ 120 ng per mL	470 ng	PASS
1% Allele Frequency (Part No: HD913) ≥ 120 ng per mL	519 ng	PASS
0.1% Allele Frequency (Part No: HD914) ≥ 120 ng per mL	502 ng	PASS
100% Wild Type (Part No: HD915) ≥ 120 ng per mL	404 ng	PASS

FOR RESEARCH USE ONLY

Manufactured in the UK

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