

## Multiplex cfDNA in Plasma Reference Standard

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

PRODUCT INFORMATION	
Catalog ID	HD816
Batch ID	
Product Description	<a href="#">Multiplex I cfDNA Reference Standard Set in Synthetic Plasma</a>
Date of Manufacture	
Manufacturing QMS Status	ISO 9001

PROPERTIES	
Volume	2 tubes of 1 mL per Allele Frequency
cfDNA Quantity spiked into Plasma	800 ng per 2 mL
Expected DNA Yield	≥ 240 ng per 2 mL*
Average Fragment Length	170 bp
Buffer	Synthetic plasma
Storage Conditions	+4°C
Use by	For the latest information on product shelf life, please visit our website: <a href="https://www.horizondiscovery.com/reference-standards/coa-information">https://www.horizondiscovery.com/reference-standards/coa-information</a>

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

CUSTOMER SUPPORT	
Technical Support	<a href="mailto:technical@horizondiscovery.com">technical@horizondiscovery.com</a>
Customer Service	<a href="mailto:orders@horizondiscovery.com">orders@horizondiscovery.com</a>

### ADDITIONAL INFORMATION

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#### Horizon Discovery

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**QUALITY CONTROL**

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

Gene	Variant	Expected AF (%)	Actual AF (%)	Acceptance Criteria (%)		Pass/Fail
				Low	High	
<b>5% Allele Frequency (Part No: HD812)</b>						
EGFR	L858R	5.0		3.5	6.5	
EGFR	ΔE746-A750	5.0		3.5	6.5	
EGFR	T790M	5.0		3.5	6.5	
EGFR	V769-D770insASV	5.0		3.5	6.5	
KRAS	G12D	6.3		4.4	8.2	
NRAS	Q61K	6.3		4.4	8.2	
NRAS	A59T	6.3		4.4	8.2	
PIK3CA	E545K	6.3		4.4	8.2	
<b>1% Allele Frequency (Part No: HD813)</b>						
EGFR	L858R	1.0		0.6	1.4	
EGFR	ΔE746-A750	1.0		0.6	1.4	
EGFR	T790M	1.0		0.6	1.4	
EGFR	V769-D770insASV	1.0		0.6	1.4	
KRAS	G12D	1.3		0.8	1.8	
NRAS	Q61K	1.3		0.8	1.8	
NRAS	A59T	1.3		0.8	1.8	
PIK3CA	E545K	1.3		0.8	1.8	
<b>0.1% Allele Frequency (Part No: HD814)</b>						
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						
<b>100% Wild Type (Part No: HD815)</b>						
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)**

Acceptance Criteria	Reading	Pass/Fail
<b>5% Allele Frequency (Part No: HD812)</b> 170 bp ± 15% (144 bp – 195 bp)		
<b>1% Allele Frequency (Part No: HD813)</b> 170 bp ± 15% (144 bp – 195 bp)		
<b>0.1% Allele Frequency (Part No: HD814)</b> 170 bp ± 15% (144 bp – 195 bp)		
<b>100% Wild Type (Part No: HD815)</b> 170 bp ±15% (144 bp – 195 bp)		

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

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

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

Acceptance Criteria	Reading	Pass/Fail
<b>5% Allele Frequency (Part No: HD812)</b> ≥ 240 ng per 2 mL		
<b>1% Allele Frequency (Part No: HD813)</b> ≥ 240 ng per 2 mL		
<b>0.1% Allele Frequency (Part No: HD814)</b> ≥ 240 ng per 2 mL		
<b>100% Wild Type (Part No: HD815)</b> ≥ 240 ng per 2 mL		

**FOR RESEARCH USE ONLY**

Manufactured in the UK

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