

## Multiplex cfDNA Reference Standard

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

PRODUCT INFORMATION	
Catalog ID	HD780
Batch ID	
Product Description	<a href="#">Multiplex I cfDNA Reference Standard Set</a>
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: <a href="https://horizondiscovery.com/products/diagnostic-reference-standards/reference-standards-product-information">https://horizondiscovery.com/products/diagnostic-reference-standards/reference-standards-product-information</a>

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	

### Horizon Discovery

8100 Cambridge Research Park,  
Waterbeach, Cambridge,  
CB25 9TL, United Kingdom  
[www.horizondiscovery.com/](http://www.horizondiscovery.com/)

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f + 44 (0) 1223 655 581  
e [orders@horizondiscovery.com](mailto:orders@horizondiscovery.com)

**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	
<b>5% Allele Frequency (Part No: HD777)</b>									
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	
<b>1% Allele Frequency (Part No: HD778)</b>									
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	
<b>0.1% Allele Frequency (Part No: HD779)</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: HD776)</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) TapeStation software version 4.1.1

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

**FOR RESEARCH USE ONLY**

Manufactured in the UK

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