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Multiplex cfDNA Reference Standard

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

PRODUCT INFORMATION	
Catalog ID	HD825
Batch ID	46503
Product Description	EGFR Multiplex cfDNA Reference Standard Set
Date of Manufacture	20-Oct-2020
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: https://horizondiscovery.com/products/diagnostic-reference-standards/reference-standards-product-information

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

ADDITIONAL INFORMATION

The products contains the additional EGFR variants listed in the table below.

AA Mutation	CDS mutation	GRCh37 Location	Cosmic ID	rsID	Cause
L844L	c.2532G>A	7:55259474	n/a	n/a	Engineering scar
Q787Q	c.2361G>A	7:55249063	COSV51769407	rs1050171	Endogenous variant

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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: HD821)									
EGFR	T790M	2176	119	2295	5.0	5.20	3.50	6.50	PASS
EGFR	L858R	2864	148	3012	5.0	4.90	3.50	6.50	PASS
EGFR	ΔE746-A750	1672	112	1784	5.0	6.25	3.50	6.50	PASS
EGFR	L861Q	2984	143	3127	5.0	4.57	3.50	6.50	PASS
EGFR	G719S	1916	104	2020	5.0	5.12	3.50	6.50	PASS
EGFR	C797S	3644	182	3826	5.0	4.77	3.50	6.50	PASS
EGFR	S464L	1672	90	1762	5.0	5.12	3.50	6.50	PASS
EGFR	G465R	2188	117	2305	5.0	5.08	3.50	6.50	PASS
EGFR	V769-D770insASV	1288	67	1355	5.0	4.93	3.50	6.50	PASS
EGFR	S768I	3372	180	3552	5.0	5.07	3.50	6.50	PASS
1% Allele Frequency (Part No: HD822)									
EGFR	T790M	2368	26	2394	1.0	1.06	0.60	1.40	PASS
EGFR	L858R	3148	31	3179	1.0	0.97	0.60	1.40	PASS
EGFR	ΔE746-A750	1792	22	1814	1.0	1.22	0.60	1.40	PASS
EGFR	L861Q	3228	30	3258	1.0	0.91	0.60	1.40	PASS
EGFR	G719S	2100	24	2124	1.0	1.14	0.60	1.40	PASS
EGFR	C797S	3908	37	3945	1.0	0.94	0.60	1.40	PASS
EGFR	S464L	1924	18	1942	1.0	0.93	0.60	1.40	PASS
EGFR	G465R	2516	22	2538	1.0	0.89	0.60	1.40	PASS
EGFR	V769-D770insASV	1568	14	1582	1.0	0.89	0.60	1.40	PASS
EGFR	S768I	3720	36	3756	1.0	0.97	0.60	1.40	PASS
0.1% Allele Frequency (Part No: HD823)									
EGFR	T790M	2476	4	2480	0.1	0.15	See below*		PASS
EGFR	L858R	3200	4	3204	0.1	0.11	0.05	0.15	PASS
EGFR	ΔE746-A750	1776	3	1779	0.1	0.19	See below*		PASS
EGFR	L861Q	3300	3	3303	0.1	0.08	0.05	0.15	PASS
EGFR	G719S	2144	4	2148	0.1	0.17	See below		PASS
EGFR	C797S	3916	4	3920	0.1	0.10	0.05	0.15	PASS
EGFR	S464L	2024	2	2026	0.1	0.11	See below*		PASS
EGFR	G465R	2556	2	2558	0.1	0.09	See below*		PASS
EGFR	V769-D770insASV	1580	2	1582	0.1	0.11	0.05	0.15	PASS
EGFR	S768I	3776	5	3781	0.1	0.12	0.05	0.15	PASS
*Observed AF (%) for 0.1% variants must be greater than observed AF (%) of the corresponding wild type assay									
100% Wild Type (Part No: HD824)									
EGFR	T790M	2576	0.3	2576	0.0	0.01	≤0.05		PASS
EGFR	L858R	3192	0.2	3192	0.0	0.01	≤0.01		PASS
EGFR	ΔE746-A750	1808	0.0	1808	0.0	0.00	≤0.05		PASS
EGFR	L861Q	3364	0.1	3364	0.0	0.00	≤0.01		PASS
EGFR	G719S	2132	0.4	2132	0.0	0.02	≤0.05		PASS
EGFR	C797S	4024	0.2	4024	0.0	0.00	≤0.01		PASS
EGFR	S464L	2004	0.1	2004	0.0	0.01	≤0.05		PASS
EGFR	G465R	2572	0.3	2572	0.0	0.01	≤0.05		PASS
EGFR	V769-D770insASV	1580	0.1	1580	0.0	0.01	≤0.01		PASS
EGFR	S768I	3784	0.1	3784	0.0	0.00	≤0.01		PASS

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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: HD821) 160 bp ± 10% (144 bp – 176 bp)	159 bp	PASS
1% Allele Frequency (Part No: HD822) 160 bp ± 10% (144 bp – 176 bp)	159 bp	PASS
0.1% Allele Frequency (Part No: HD823) 160 bp ± 10% (144 bp – 176 bp)	160 bp	PASS
100% Wild Type (Part No: HD824) 160 bp ± 10% (144 bp – 176 bp)	156 bp	PASS
Quantification: **Qubit® dsDNA BR assay (Invitrogen)**		
Acceptance Criteria	**Reading**	**Pass/Fail**
5% Allele Frequency (Part No: HD821) 20 ng/µL ± 15% (17.0 – 23.0 ng/µL)	18.5 ng/µL	PASS
1% Allele Frequency (Part No: HD822) 20 ng/µL ± 15% (17.0 – 23.0 ng/µL)	19.4 ng/µL	PASS
0.1% Allele Frequency (Part No: HD823) 20 ng/µL ± 15% (17.0 – 23.0 ng/µL)	19.3 ng/µL	PASS
100% Wild Type (Part No: HD824) 20 ng/µL ± 15% (17.0 – 23.0 ng/µL)	19.3 ng/µL	PASS

FOR RESEARCH USE ONLY

Manufactured in the UK

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