

CERTIFICATE OF ANALYSIS

cfDNA Reference Standard Set in Synthetic Plasma

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

Manufacturing QMS Status	ISO 9001
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PROPERTIES

Volume	2 tubes of 1 ml per Allelic Frequency
cfDNA quantity spiked into plasma	800 ng per 2 ml
Expected DNA yield	≥ 240ng per 2 ml*
Fragmentation	Fragmented DNA (average size 170bp)
Buffer	Synthetic plasma
Storage Conditions	+4°C
Use By	Stable for 24 months from date of manufacture (as supplied)

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

QUALITY CONTROL

TEST	TEST METHOD AND ACCEPTANCE CRITERIA	PASS/FAIL
Allelic Frequency	Droplet Digital™ PCR <ul style="list-style-type: none"> For AF ≥ 5% < 10% ± 30% For AF ≥ 1% < 5% ± 40% For AF < 1% ± 50% 0% expected AF for wild type, up to 0.01% 0% expected AF for wild type, up to 0.1% [For targets unverified at 0.01%] 	Pass
Fragmentation Size	D1000 DNA ScreenTape assay (Agilent Tech) <ul style="list-style-type: none"> Fragmented DNA of average size 170bp ± 15% (144bp – 195bp) 	Pass
Quantification of cfDNA spiked into plasma	Qubit® dsDNA BR assay (Invitrogen) <ul style="list-style-type: none"> 40.0 ng/μL ± 10% (36.0 – 44.0 ng/μL) 	Pass
Quantification of extraction yield	Qubit® dsDNA BR assay (Invitrogen) <ul style="list-style-type: none"> ≥ 240 ng per 2 ml 	Pass

CUSTOMER SUPPORT

Technical	technical@horizondiscovery.com
Orders	orders@horizondiscovery.com

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