



## PRODUCT SPECIFICATION

### cfDNA Reference Standard

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

#### PRODUCT INFORMATION

Date Effective From	August 2015	Manufacturing QMS Status	ISO 9001
Quantity	350 ng per vial		
Buffer	Tris-EDTA (10 mM Tris-HCl, 1 mM EDTA), pH 8.0		
Storage Conditions	4 °C		
Use By	Stable for 12 months from date of manufacture (as supplied)* Please refer to product label for details of date of manufacture.		

#### QUALITY CONTROL

TEST	TEST METHOD	ACCEPTANCE CRITERIA
Allelic Frequency	Droplet Digital™ PCR	<ul style="list-style-type: none"> <li>0% expected frequency for wild type, up to 0.01%</li> <li>0% expected frequency for wild type, up to 0.1% [For targets unverified at 0.01%]</li> <li>For AF ≥ 5% &lt; 10% ± 30%</li> <li>For AF ≥ 1% &lt; 5% ± 40%</li> <li>For AF &lt;1% ± 50%</li> </ul>
Fragmentation Size	D1000 DNA ScreenTape assay (Agilent Tech)	<ul style="list-style-type: none"> <li>Fragmented DNA of average size 160bp ± 10%</li> <li>(35bp – 500bp) ≥92% of total material</li> </ul>
Quantification	Qubit® dsDNA BR assay (Invitrogen)	20.0 ng/μL ± 15% (17.0 – 23.0 ng/μL)

\* Stability estimate based on gDNA product stability.

#### CUSTOMER SUPPORT

Technical	<a href="mailto:technical@horizondiscovery.com">technical@horizondiscovery.com</a>
Orders	<a href="mailto:orders@horizondiscovery.com">orders@horizondiscovery.com</a>

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