

Non-Invasive Prenatal Testing (NIPT) Multiplex cfDNA in Synthetic Matrix II Reference Standard

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

PRODUCT INFORMATION	
Catalog ID	HD863
Batch ID	
Product Description	10% Fetal Fraction Trisomy 21 - Female Reference Standard in Synthetic Matrix II
Date of Manufacture	
Manufacturing QMS Status	ISO 9001

PROPERTIES	
Volume	1 tube of 1 mL
cfDNA quantity spiked into plasma	40 ng in 1 mL
Expected DNA yield	≥ 24 ng per 2mL*
Average Fragment Length	170 bp
Buffer	Synthetic matrix II
Storage Conditions	+4°C (2-8°C)
Use by	13 months from Date of Manufacture:

*Represents 30% extraction yield performed using recommended 2 mL input with the Qiagen kit (Cat. No. 55114)

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

ADDITIONAL INFORMATION

QUALITY CONTROL

Copy Number and Fetal Fraction: Droplet Digital™ PCR

Chr	Variant	Expected Copy Number/Fractional Abundance (%)	Actual Copy Number/Fractional Abundance (%)	Acceptance Criteria Copy Number / Fractional Abundance (%)		Pass/Fail
				Low	High	
Maternal – gDNA						
Chr13	N/A	2.11		1.79	2.42	
Chr18		2.09		1.78	2.40	
Chr21		1.93		1.64	2.22	
ChrX		1.96		1.66	2.25	
ChrY		0.00		≤0.10		
Fetal – gDNA						
Chr13	Trisomy 21 - Female	2.11		1.79	2.42	
Chr18		2.09		1.78	2.40	
Chr21		2.95		2.51	3.39	
ChrX		1.96		1.66	2.25	
ChrY		0.00		≤0.10		
10% Fetal Fraction (Pre-Fragmentation)						
Chr2	Trisomy 21 - Female	5.00 **		4.00	6.00	
10% Fetal Fraction (Post-Fragmentation, Extracted)						
Chr2	Trisomy 21 - Female	5.00 **		3.50	6.50	

**Fetal Fraction = Fractional abundance (%) of SNP in Chr2 measured by ddPCR x 2

QUALITY CONTROL (continued)

Post-Extraction Fragmentation Size: **HS D1000 DNA ScreenTape assay (Agilent Technologies)**
TapeStation software version 4.1.1

Acceptance Criteria	Reading (bp)	Pass/Fail
170bp ± 15% 144bp to 195bp		

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

Acceptance Criteria	Reading (ng/μL)	Pass/Fail
40 ng/μL ±10% (36.0 – 44.0 ng/μL)		

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

Acceptance Criteria	Reading (ng)	Pass/Fail
≥ 24 ng per 2 mL***		

***Represents 30% extraction yield performed using recommended 2ml input with the Qiagen kit (Cat. No. 55114)

FOR RESEARCH USE ONLY

Manufactured in the UK

Horizon Discovery

8100 Cambridge Research Park,
Waterbeach, Cambridge,
CB25 9TL, United Kingdom
www.horizondiscovery.com/

t + 44 (0) 1223 976 000
f + 44 (0) 1223 655 581
e orders@horizondiscovery.com