

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	HD862
Batch ID	
Product Description	10% Fetal Fraction Trisomy 18 - Male 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 18 - Male	2.11		1.79	2.42	
Chr18		3.00		2.40	3.60	
Chr21		1.93		1.64	2.22	
ChrX		1.07		0.91	1.23	
ChrY		1.11		0.94	1.28	
10% Fetal Fraction (Pre-Fragmentation)						
ChrY	Trisomy 18 - Male	5.00 **		4.00	6.00	
10% Fetal Fraction (Post-Fragmentation, Extracted)						
ChrY	Trisomy 18 - Male	5.00 **		3.50	6.50	

**Fetal Fraction = Fractional abundance (%) of ChrY 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

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