Bringing Precision to MDx

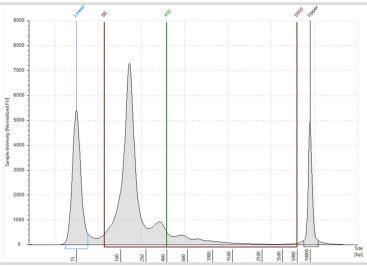
Release Date	19.08.2024
Version / Index	7 1
Print Date	20.08.2024

BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	Nucleosome ctDNA (human, BDXXP4)		
DESCRIPTION	Nucleosome ctDNA (human, BDXXP4) is highly characterized human DNA from cell line.		
CATALOG NUMBER	SID-000128		
BATCH NUMBER	**00752**		
MANUFACTURING CONDITIONS	· Manufactured and sealed in class 2 safety cabinet · Manufactured according to DIN EN ISO 13485:2016		
PACKAGE SIZE AND TYPE	· 2D barcoded tube with screw cap · Material: Polypropylen (PP)		
DATE OF MANUFACTURE	06.08.2024		
EXPIRY DATE	05.08.2026		
TARGET CONCENTRATION	20 ng/µl (dsDNA)		
TARGET QUANTITY	400 ng (dsDNA)		
NOMINAL VOLUME	20 µl		
QUALITY	DNA quantity metrologically traceable to internationally certified reference material (ERM_AD442K).		
STORAGE CONDITIONS	+ 2-8 °C		
MANUFACTURING SITE	SensID GmbH Schillingallee 68, 18057 Rostock, Germany		
TEST METHOD AND ACCEPTANCE CRITERIA	Quality control	Test method	Acceptance criteria
	Fragmentation	Fragment length analysis: Agilent D5000 ScreenTape System (Agilent Technologies)	Mononucleosomal peak size 137 – 167 bp
	Quality	Fragment length analysis: Agilent D5000 ScreenTape System (Agilent Technologies)	> 80 % of AUC* within 50 – 400 bp (from total 50 – 5,000 bp)
	Quantification	dsDNA measurement: Qubit dsDNA BR Assay Kit (Invitrogen)	dsDNA: 20.0 ng/µl (17.5 – 22.5 ng/µl)
	*AUC = area under the curve		

	Quality control	Result	PASS / FAIL
RESULTS OF ANALYSIS	Fragmentation	139 bp 	PASS
	Quality	87.8 %	PASS
	Quantification	21.0 ng/µl (dsDNA)	PASS
COMMENTS / REMARKS	not applicable		

Name and position/title of person authorising the batch release:

Björn Nowack, Managing Director

Date of batch release: 12.08.2024

Signature batch release: Björn Nowack

This document has been created electronically and is valid without signature.