Bringing Precision to MDx

Release Date	29.01.2025
Version / Index	1 1
Print Date	29.01.2025

BATCH CERTIFICATE

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	MSI 0 % FFPE Reference Standard		
DESCRIPTION	The MSI 0 % Reference Standard is a negative control for seven new microsatellite instability (MSI) markers in FFPE format containing DNA from human microsatellite stable cell lines.		
CATALOG NUMBER	SID-000137		
BATCH NUMBER	**00853**		
MANUFACTURING CONDITIONS	· Manufactured according to DIN EN ISO 13485:2016		
PACKAGE SIZE AND TYPE	· 1.5 ml tube with screw cap · Material: Polypropylen (PP)		
DATE OF MANUFACTURE	17.01.2025		
EXPIRY DATE	16.01.2027		
FORMAT	10 µm section / curl		
AVAILABLE MSI MARKERS	The MSI 0 % Reference Standard covers seven new microsatellite instability (MSI) markers: ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2.		
BLEND OF MSI CELL LINE	0 %		
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
	Quantification	dsDNA measurement: Qubit* dsDNA BR Assay Kit (Invitrogen)	dsDNA: ≥ 110.0 ng
	DNA Quality	Measurement of DNA Integrity Number (DIN): Tape Station* Genomic DNA ScreenTape (Agilent Technologies)	DIN: ≥ 5.0
	Fraction of MSI	Fraction analysis of MSI/MSS cell lines by ddPCR* (BioRad QX200™)	MSI Fraction 0.00 % (0.00 - 1.00 %)
	*Measured after extraction with Qiagen QIAamp DNA FFPE Tissue Kit		
RESULTS OF ANALYSIS	Quality control	Result	PASS / FAIL
	Quantification	186.7 ng/curl (dsDNA)	PASS
	DNA Quality (DIN)	8.2	PASS
	Fraction of MSI	0.10 %	PASS

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

Björn Nowack, Managing Director

Date of batch release: 22.01.2025

Signature batch release: Björn Nowack

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