

BATCH CERTIFICATE

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	MSI 16.67 % FFPE Reference Standard		
DESCRIPTION	The MSI 16.67% Reference Standard is a positive control for seven new microsatellite instability (MSI) markers in FFPE format containing a blend of 16.67% of microsatellite instable cell lines.		
CATALOG NUMBER	SID-000138		
BATCH NUMBER	00598		
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	23.10.2023		
EXPIRY DATE	22.10.2025		
FORMAT	10 µm section / curl		
AVAILABLE MSI MARKERS	The MSI 16.67% Reference Standard covers seven new microsatellite instability (MSI) markers: ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2.		
BLEND OF MSI CELL LINE	16.67%		
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 16.67 % (13.00 - 20.00%)
*Measured after extraction with Qiagen QIAamp DNA FFPE Tissue Kit			
RESULTS OF ANALYSIS	Quality control	Result	PASS / FAIL
	Quantification	322.8 ng (dsDNA)	PASS
	DNA Quality (DIN)	7.2	PASS
	Fraction of MSI	16.91 %	PASS

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

Björn Nowack, Managing Director

Date of batch release: 30.10.2023

Signature batch release: Björn Nowack

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