

BATCH CERTIFICATE

For Research Use Only

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	MSI-MSS FFPE Reference Set		
DESCRIPTION	The MSI FFPE Reference Set is a commutable control material for microsatellite instability (MSI) markers in FFPE format based on human microsatellite stable and microsatellite instable cell lines. It consists of a MSI positive FFPE control with MSI positive cells at a frequency of 16.67% and a MSI negative FFPE control with 0% MSI positive cells.		
CATALOG NUMBER	SID-000139		
MANUFACTURING CONDITIONS	· Manufactured according to DIN EN ISO 13485:2016		
PACKAGE SIZE AND TYPE	· Each in 1.5 ml tube with screw cap · Material: Polypropylen (PP)		
COMPONENTS	Name of product	MSI 16.67 % FFPE Reference Standard	MSI 0 % FFPE Reference Standard
	Catalog number	SID-000138	SID-000137
	Batch number	00381-R	00262-R
	Date of manufacture	16.06.2022	14.12.2021
	Expiry date	15.06.2024	13.12.2023
	Fraction of MSI	16.67%	0.00%
FORMAT	10 µm section / curl		
AVAILABLE MSI MARKERS	Loci tested: · Biocartis Panel: ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A, and SULF2 · NCI Panel: BAT25, BAT26, MONO-27, NR-21, NR-24 · Promega Panel (including NCI Panel): BAT25, BAT26, MONO-27, NR-21, Penta C, Penta D, NR-24		
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: ddPCR* (BioRad QX200™)		MSI 16.67 % FFPE Reference Standard: 13.00 - 20.00% MSI 0 % FFPE Reference Standard: 0.00 - 1.00%	
*Measured after extraction with Qiagen QIAamp DNA FFPE Tissue Kit					
RESULTS OF ANALYSIS	Quality control	Result		PASS / FAIL	
		MSI 16.67 % FFPE Reference Standard	MSI 0 % FFPE Reference Standard	MSI 16.67 % FFPE Reference Standard	MSI 0 % FFPE Reference Standard
	Quantification	201,9 ng/curl	212 ng/curl	PASS	PASS
	DNA Quality (DIN)	6,2	6,8	PASS	PASS
	Fraction of MSI	14,53 %	0,09 %	PASS	PASS

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

Björn Nowack, Managing Director

Date of batch release: 01.07.2022

Signature batch release: Björn Nowack

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