BATCH CERTIFICATE

PRODUCT INFORMATION AND QUALITY CONTROL

NAME OF PRODUCT	Idylla™ MSI FFPE Reference Set		
DESCRIPTION	The Idylla™ MSI FFPE Reference Set is a commutable control material for seven microsatellite instability (MSI) markers in FFPE format based on human microsatellite stable cell lines. It consists of an MSI 16.67 % FFPE control with all MSI markers at an allele frequency of 16.67 % and an MSI 0 % control with 0 % allele frequency of all MSI markers.		
CATALOG NUMBER	SID-000114		
BATCH NUMBER	**00809**		
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)		
EXPIRY DATE	06.10.2026		
COMPONENTS	Name of product	Idylla™ MSI 16.67 % FFPE Reference Standard	Idylla™ MSI 0 % FFPE Reference Standard
	Catalog number	SID-000117	SID-000116
	Batch number	00807	00805
	Date of manufacture	08.10.2024	07.10.2024
	Expiry date	07.10.2026	06.10.2026
	Allele frequency of MSI markers	16.67 %	0.00 %
FORMAT	10 µm section / curl		
AVAILABLE MSI MARKERS	The Idylla™ MSI FFPE Reference Set covers seven new microsatellite instability (MSI) markers: ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2.		
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 ng	
	DNA Quality	Measurement of DNA Integrity Number (DIN): Tape Station Genomic DNA ScreenTape* (Agilent Technologies)	DIN: ≥ 5	
	Fraction of MSI	Fraction analysis of MSI/MSS cell lines by ddPCR* (BioRad QX200™)	Idylla™ MSI 16.67 % FFPE Reference Standard: 13.0 – 20.0 %	
			Idylla™ 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
		Idylla™ MSI 16.67 % FFPE Reference Standard	Idylla™ MSI 0 % FFPE Reference Standard	Idylla™ MSI 16.67 % FFPE Reference Standard	Idylla™ MSI 0 % FFPE Reference Standard
	Quantification	308.0 ng (dsDNA)	121.2 ng (dsDNA)	PASS	PASS
	DNA Quality (DIN)	7.9	8.2	PASS	PASS
	Fraction of MSI	16.21 %	0.23 %	PASS	PASS

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

Björn Nowack, Managing Director

Date of batch release: 16.12.2024

Signature batch release: Björn Nowack

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