



Management System
EN ISO 13485:2016
www.tuv.com
ID: 900009213
according to
directive 98/79/EC

Release Date 27.10.2022
Version / Index 2 1
Print Date 27.10.2022

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	00420		
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	16.06.2024		
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	00382	00380
	Date of manufacture	20.06.2022	17.06.2022
	Expiry date	19.06.2024	16.06.2024
	Allele frequency of MSI markers	16.67%	0%
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		



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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 - 20% Idylla™ MSI 0 % FFPE Reference Standard: 0-1%	
*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	218.1	140.0	PASS	PASS
	DNA Quality	6.1	5.5	PASS	PASS
	Fraction of MSI	15.38	0.66	PASS	PASS

Name and position/title of person authorising the batch release:
 Björn Nowack, Managing Director

Date of batch release: 20.10.2022
 Signature batch release: Björn Nowack

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