



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 16.67 % FFPE Reference Standard
DESCRIPTION	The Idylla™ 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-000117
BATCH NUMBER	00264
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	15.12.2021
EXPIRY DATE	14.12.2023
FORMAT	10 µm section / curl
AVAILABLE MSI MARKERS	The Idylla™ 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



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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™)	MSI Fraction 16.67 % (13.0-20.0 %)
**Measured after extraction with Qiagen QIAamp DNA FFPE Tissue Kit			
RESULTS OF ANALYSIS	Quality control	Result	PASS / FAIL
	Quantification	152.7 ng (dsDNA)	PASS
	DNA Quality	7.0	PASS
	Fraction of MSI	14.05	PASS

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

Björn Nowack, Managing Director

Date of batch release: 07.02.2022

Signature batch release: Björn Nowack

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