

## TECHNICAL SHEET IDYLLA™ MSI TEST



The **Idylla™ MSI Test** is intended for the qualitative detection of a novel panel of **seven monomorphic homopolymer biomarkers** for identification of colorectal cancers (CRC) with microsatellite instability (MSI). The Idylla™ MSI Test uses formalin-fixed, paraffin-embedded (FFPE) tissue sections from human CRC tissue, from which nucleic acids are liberated, then analyzed by PCR amplification and high-resolution melting detection. The Idylla™ MSI Test automates the entire process from FFPE sample preparation to reporting of MSI status.

### FEATURES

#### Idylla™ MSI Biomarkers

ACVR2A	2q22.3-q23.1
BTBD7	14q32.12
DIDO1	20q13.33
MRE11	11q21
RYR3	15q13.3-q14
SEC31A	4q21.22
SULF2	20q13.12

Sample Processing Control      The MSI specific software will automatically check the validity of the measured fluorescence profiles: presence of specific PCR amplicons will result in biomarker-specific fluorescence profiles, which eliminates the need for an additional sample processing control in the cartridge.

#### Specimen requirements

Sample type	FFPE tissue sections (5-10 µm)
Neoplastic cells	≥ 20%, if less, macrodissection is required
Tissue area	50-600 mm <sup>2</sup> (5 µm) 25-300 mm <sup>2</sup> (10 µm)

## Performance

Analytical sensitivity	10% LOD
Between Laboratory Reproducibility (480 results at 3 sites)	100% agreement for an MSS sample at approximately 125,000 and 500,000 cells/slice 100% agreement for an MSI-H sample at approximately 125,000 and 500,000 cells/slice
Between Lot Reproducibility (240 results on 3 lots)	100% agreement for an MSS sample at approximately 125,000 and 500,000 cells/slice 100% agreement for an MSI-H sample at approximately 125,000 and 500,000 cells/slice

## Total turnaround time

Time	150 minutes
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## ACCURACY - CLINICAL PERFORMANCE EVALUATION

Overall agreement with Promega MSI Analysis System v1.2 and Immunohistochemistry (IHC) of respectively 99.7% and 97.5%.

### 99.7% overall concordance with Promega MSI (322/323)

330 CRC samples		Promega MSI Analysis System v1.2		
		MSI-H	MSS	Failed
Idylla™ MSI Test	MSI-H	75	0	0
	MSS	<b>1<sup>(i)</sup></b>	247	5
	Invalid	0	0	2

<sup>(i)</sup> Failed in 1st Promega run; MSI-H in 2nd Promega run, and dMMR with IHC

### 97.5% overall concordance with IHC (310/318)

330 CRC samples		IHC MMR		
		dMMR	pMMR	Doubtful
Idylla™ MSI Test	MSI-H	72	0	3
	MSS	<b>8<sup>(ii)</sup></b>	238	7
	Invalid	0	2	0

<sup>(ii)</sup> 7 confirmed as MSS by Promega MSI Analysis System v1.2

## IDYLLA™ MSI PUBLICATIONS

Check our website: <https://www.biocartis.com/publications/articles-posters?cat=19> and subscribe to receive our newest publications.



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