MSI IVD

idylla by BIOCARTIS

TECHNICAL SHEET IDYLLA™ MSI TEST

The **Idylla™ MSI Test,** for use on the Idylla™ System, uses formalin-fixed, paraffin-embedded (FFPE) tissue sections of human CRC tumor, from which nucleic acids are liberated, then analyzed using PCR amplification of **seven monomorphic biomarkers** (ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2) and subsequent melt-curve analysis. The Idylla™ MSI Test reports results as either microsatellite stable (MSS), or microsatellite instability high (MSI-H) or invalid.

The Idylla™ MSI Test is indicated for use by healthcare professionals for the qualitative identification of microsatellite instability (MSI) in colorectal cancer (CRC) tumors, indicative of mismatch repair deficiency, and as an aid in the identification of probable Lynch syndrome to help identify patients that would benefit from additional genetic testing to diagnose Lynch syndrome.

The results from the Idylla™ MSI Test should be interpreted by healthcare professionals in conjunction with other clinical findings, family history, and other laboratory data. The Idylla™ MSI Test should not be used for diagnosis of CRC.

The clinical performance of this device to guide treatment decision for MSI high patients has not been established.

FEATURES

Idylla™ MSI Biomarkers						
ACVR2A	DIDO1	RYR3	SULF2	BTBD7	MRE11	SEC31A

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 (4-10 µm)
Neoplastic cells	≥ 33%, if less, macro-dissection is required
Tissue area	62.5–750 mm^2 (4 µm) 50–600 mm^2 (5 µm) 25-300 mm^2 (10 µm)

Total turnaround time	
Time	Approximately 150 minutes

Performance	
Clinical sensitivity, 33% neoplastic cell content	30% LoD
Between Laboratory Reproducibility (252 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)	

ACCURACY – CLINICAL PERFORMANCE EVALUATION

Overall percent agreement with OncoMate™ MSI Dx Analysis System and Germline NGS of respectively 98.57% and 90.22%.

98.57% overall concordance with OncoMate™ MSI Dx Analysis System (138/140)

Idylla™ MSI Test	OncoMate™ MSI				
	MSI-H	MSS	INVALID	NO CALL	TOTAL
MSI-H	31	1*	0	3	35
MSS	1**	107	0	0	108
Invalid	0	0	0	0	0
Total	32	108	0	3	143

* One (1) sample that tested MSS by Idylla™ MSI Test and MSI-H by the OncoMate™ MSI Dx Analysis System is a confirmed Lynch case by NGS.

** One (1) sample that tested MSI-H by Idylla™ MSI Test and MSS by the OncoMate™ MSI Dx Analysis System is a confirmed Lynch case by NGS.

90.22% overall concordance with Germline NGS (120/133)

Idylla™ MSI Test	Germline NGS			
	Lynch positive	Lynch negative	INVALID	TOTAL
MSI-H	23	11	1	35
MSS	2	97	9	108
Invalid	0	0	0	0
Total	25	108	10	143

Catalog number

Idylla™ MSI Test (510(k))	A0160/6

US.FL059.EN.R1.04/2024