MSI-CDx A0220/6 CE 2797 IVD IVDR

idylla by BIOCARTIS

TECHNICAL SHEET IDYLLA™ CDx MSI TEST

For in vitro diagnostic use. For professional use only. For use on the Biocartis Idylla™ System only.

The **Idylla™ CDx MSI Test** is an in vitro diagnostic test intended for the qualitative detection of a novel panel of **seven (7) monomorphic biomarkers** for identification of microsatellite instability (MSI) in **colorectal cancer** tissue. The Idylla™ CDx MSI Test uses **formalin-fixed, paraffin embedded (FFPE) tissue** sections from human colorectal cancer (CRC), from which nucleic acids are liberated, then analyzed by PCR amplification and high-resolution melting detection. The Idylla™ CDx MSI Test automates the entire process from FFPE specimen processing to reporting of MSI status as either Microsatellite Stable (MSS) or Microsatellite Instability-High (MSI-H). The Idylla™ CDx MSI Test is intended for identification of adult patients with **MSI-H metastatic CRC**, for whom treatment with **OPDIVO® (nivolumab) in combination with YERVOY® (ipilimumab)** as a combination therapy is indicated with approved therapeutic product labeling.

FEATURES

Idylla™ CDx MSI biomarkers						
ACVR2A	BTBD7	DIDO1	MRE11	RYR3	SEC31A	SULF2

Sample processing control	The MSI-specific software automatically verifies the validity of the measured fluorescence profiles. For each of the seven biomarkers, the presence of biomarker-specific amplification curves confirms successful PCR amplification and proper assay performance. These curves function as internal controls, eliminating the need for a separate external sample-processing control within the cartridge.
Specimen requirements	
Sample type	1-5 FFPE tissue sections (4-10 µm)
Neoplastic cells	≥ 33%; if less, macrodissection 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	Approx. 150 minutes

Accuracy

98.57% overall percent agreement against the OncoMate™ MSI Dx Analysis System

Idylla™ MSI Test*	OncoMate™ MSI Dx				
	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

*Accuracy data were obtained with the Idylla™ MSI Test and are applicable to the Idylla™ CDx MSI Test.
**One (1) sample that tested MSS by Idylla™ MSI Test and MSI-H by the OncoMate™ MSI Dx Analysis System is a confirmed Lynch Syndrome 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 Syndrome case by NGS.

Clinical performance

PFS of first line OPDIVO® (nivolumab) in combination with YERVOY® (ipilimumab) established by CheckMate 8HW

Source	Arm B: nivolumab + ipilimumab			Arm C: Chemo			Hazard Ratio***	
	N	Median** (months)	95% CI	N	Median** (months)	95% CI	Estimate	95% CI
All CTA+ Randomized	200	N.A.*	(34.30 - N.A.*)	101	6.21	(4.70 - 9.00)	0.32	(0.22 - 0.45)
Idylla™ CDx MSI Test MSI-H and CTA+	147	N.A.*	(38.44 - N.A.*)	71	6.21	(4.70 - 9.03)	0.20****	(0.12 - 0.31)
Idylla™ CDx MSI Test MSS and CTA+	30	1.81	(1.45 - 5.75)	15	7.36	(4.01 - 12.88)	1.51	(0.68 - 3.33)

*N.A.: Not available since the median PFS is not reached **Median PFS is based on Kaplan-Meier Estimates ***Hazard Ratio (HR) is Arm B over Arm C from a Cox Model stratified by tumor sidedness (left vs. right) as entered into the Interactive Response Technology (IRT) system. ****The HR is based on the Idylla™ CDx MSI Test MSI-H and CTA+ subjects. The difference between the HRs (0.20 in the table above vs. 0.21 in the drug labeling) for the first line PFS comparison of nivolumab plus ipilimumab versus chemotherapy is due to the slightly different population since the intended use population in the drug labeling is based on at least one of the two centrally confirmed tests on the CTA+ randomized subjects (Idylla™ CDx MSI Test or MMR IHC Panel pharmDx).

Catalog number

Idylla™ CDx MSI Test	A0220/6

Regulatory status

Regulatory status	CE-IVD – IVDR certified

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