MSI-CDx A0220/6 IVD PMA

TECHNICAL SHEET IDYLLA™ CDx MSI TEST

For in vitro diagnostic use. For Prescription 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 panel of **seven monomorphic biomarkers** (ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2) for identification of microsatellite instability (MSI) in **colorectal cancer (CRC) tissue**. The Idylla™ CDx MSI Test uses formalin-fixed, paraffin embedded (FFPE) tissue sections from patients with CRC, from which nucleic acids are extracted, then analyzed using PCR amplification and subsequent melt-curve analysis. The Idylla™ CDx MSI Test reports MSI status as either Microsatellite Stable (MSS) or Microsatellite Instability-High (MSI-H) or invalid.

The test is intended as a companion diagnostic to identify CRC patients with MSI-H status, who may benefit from treatment with **OPDIVO® (nivolumab) as a monotherapy** and/or treatment with **OPDIVO (nivolumab) in combination with YERVOY® (ipilimumab)**.

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	Approximately 150 minutes					

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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) estimated from CA209-8HW

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

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Regulatory status

Regulatory status	IVD (PMA)

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