MSI A0101/6 RUO

idylla by BIOCARTIS

TECHNICAL SHEET IDYLLA™ MSI ASSAY

The **Idylla™ MSI Assay** is a fully automated real-time PCR test for the qualitative detection of mutations in a panel of **seven monomorphic biomarkers** to identify the microsatellite status of tumor samples. The Assay has been optimized for use with formalin-fixed, paraffin-embedded (FFPE) tumor tissue sections from which nucleic acids are extracted, then analyzed using PCR amplification and subsequent melt-curve analysis. The Idylla™ MSI Assay reports the microsatellite status of valid results as Microsatellite Stable (MSS) or Microsatellite Instability-High (MSI-H).

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 to 10 µm)
Neoplastic cells	CRC: ≥20%, if less macrodissection is required EC: ≥40%, if less macrodissection is required
Tissue area	50-600 mm^2 (5 µm) 25-300 mm^2 (10 µm)
Total turnaround time	
Time	Approx. 150 minutes
Catalog number	
Idylla™ MSI Assay	A0101/6
Regulatory status	
Regulatory status	RUO



Idylla™ System is CE-marked in Europe in compliance with EU IVD Regulation 2017/746 (IVDR), listed as a class II device in the US under establishment registration 3009972873, and registered in many other countries. Idylla™ MSI Assay (A0101/6) is for Research Use Only (RUO), not for use in diagnostic procedures. The Biocartis and Idylla™ trademarks and logos are used trademarks owned by Biocartis. Idylla™ is available for sale in Europe, the US and many other countries. Please check availability with the local Biocartis representative.
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