

A NEW ERA  
IN MSI  
TESTING

# IDYLLA™ MSI TEST

NOW FDA 510(k)  
CLEARED



THINK IDYLLA™  
BECAUSE TIME MATTERS

# INDICATIONS FOR USE

For in vitro diagnostic use.

For use on the Biocartis Idylla™ System only.

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.

## THE IDYLLA™ DIFFERENCE



Molecular detection of seven monomorphic homopolymer biomarkers in one cartridge.



Directly from a minimum of 1 FFPE section. No need for paired normal tissue samples.



Less than **3 minutes** hands-on time. Assay turn-around time of **-150 minutes**.



Fully automated molecular walk-away system. On-demand testing.



Idylla™ has 98.57% overall percent agreement when compared with an FDA cleared molecular MSI detection method.



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To order your Idylla™ MSI 510(k) cleared Test,  
please contact [CustomerServiceUS@biocartis.com](mailto:CustomerServiceUS@biocartis.com)

The Idylla™ MSI Test and Idylla™ System are cleared in the US under K211181. Idylla™ is available for sale in EU, US and many other countries. Please check availability with a Biocartis representative. Biocartis and Idylla™ are registered trademarks in Europe, the US and many other countries. The Biocartis and Idylla™ trademarks and logos are used trademarks owned by Biocartis.

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