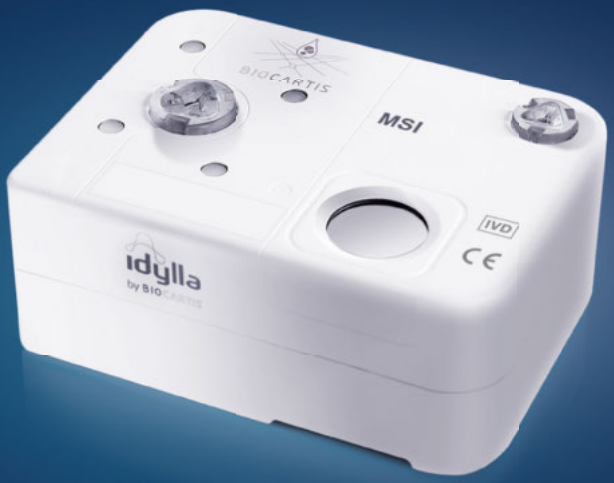
A NEW ERA IN MSI TESTING

IDYLLA™ MSI TEST



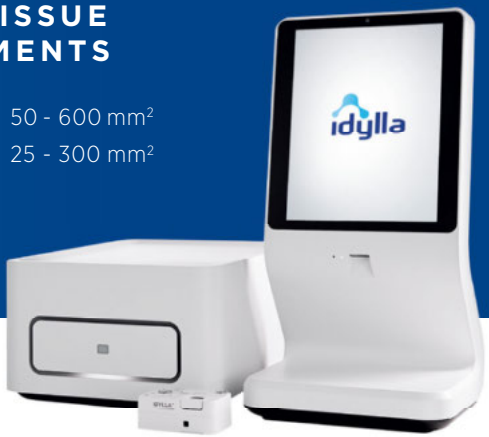
BIOCARTIS

INTRODUCING IDYLLA™ MSI TEST FAST AND ACCURATE INFORMATION ON MSI STATUS

- Fully-automated molecular testing platform
- Directly from 1 FFPE tissue section
- 7 novel tumor-specific biomarkers
- No need for paired normal tissue samples
- 150 minutes assay turnaround-time
- Unbiased result reporting
- 2 minutes hands-on-time

IDYLLA™ MSI TEST TISSUE SPECIMEN REQUIREMENTS

- 1 x 5 µm FFPE tissue section — 50 - 600 mm^2
- 1 x 10 µm FFPE tissue section — 25 - 300 mm^2
- Neoplastic cell content ≥ 20%
  - If < 20%, macrodissection needed



A NEW SET OF BIOMARKERS

The **Idylla™ MSI Test** has been developed using a new set of short homopolymers located in the **ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A & SULF2 genes.** These biomarkers are **tumor-specific,** show a high frequency in colorectal and endometrial cancers and are **stable** across **different ethnicities** ensuring excellent specificity of the test. In addition, these tumor-specific biomarkers do not require the analysis of paired normal tissue samples associated with traditional MSI/MMR testing, **improving operational efficiency.**

IDYLLA™ MSI TEST - EXCELLENT PERFORMANCE

Idylla™ MSI Test shows high concordance with lower failure rates compared to standard methods.[1]

Colorectal Cancer

Study	# Samples	Reference method	Concordance	Failure rate Idylla™ vs. Reference method
Clinical Performance Study	330	Promega MSI	**99.7% (322/323)**	**0.9% vs 5.5%**
		Immunohistochemistry	**97.5% (310/318)**	**0.6% vs 3.0%**

MSI BACKGROUND

Microsatellite instability (MSI) is defined as a length variation of DNA repeat regions found in microsatellites or homopolymers. MSI is caused by deficiency of the DNA mismatch repair system (dMMR) resulting in a distinct accumulation of insertions and deletions in microsatellite and homopolymeric regions.[2]

MSI can be sporadic or hereditary. MSI-high (MSI-H) is detected in approximately 15% of all colorectal cancers; 3% are associated with Lynch syndrome (LS), the other 12% have sporadic disease.[3]

Clinical trials and pathophysiological studies indicate a wide distribution of MSI-H across tumor types.[4] In addition to CRC, high incidences are observed in endometrial cancer (20-30%), and gastric cancer (15-20%).[5]

Guidelines recommend assessing the MSI status for all patients with colorectal or endometrial carcinomas for screening for Lynch syndrome as well as for prognostic stratification and immunotherapy.[6-9]

Research studies have shown that MSI-H patients respond favorably to immune checkpoint inhibitors[10,11], and checkpoint blockade therapy has recently been incorporated into clinical care for colorectal cancers.[7,8]

The Idylla™ MSI Test is only validated for the detection of MSI status in colorectal cancer.

THE IDYLLA™ ADVANTAGE

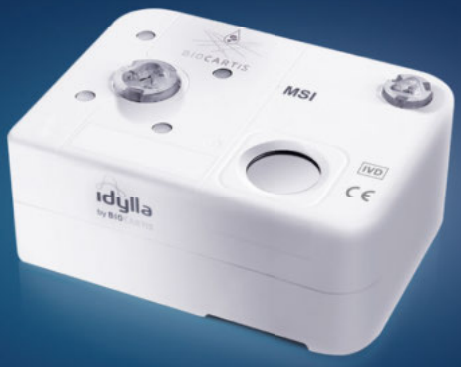
The fully automated Idylla™ MSI Test provides fast and accurate information on MSI status.[1,12-14]

Idylla™ MSI Test shows high concordance of more than 97% and lower failure rates compared to standard methods.[1]

No need for paired normal tissue sample.

"We are delighted with the **performance of the Idylla™ MSI Test** providing high quality results from minimal amount of tissue. The **ease of use** allows even laboratories with minimal histopathology experience to perform MSI testing in-house."

Sarah L. McCarron
Cancer Molecular Diagnostics,
St. James's Hospital, Dublin, Ireland



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