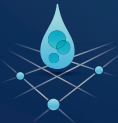


A NEW ERA
IN MSI
TESTING

IDYLLA™ MSI TEST



BIO CARTIS

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
- 1 x 10 μm FFPE tissue section
- Neoplastic cell content $\geq 20\%$
- If $< 20\%$, macrodissection needed

50 - 600 mm²
25 - 300 mm²



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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