A NEW ERA IN MSI TESTING

IDYLLA™ MSI TEST
IDYLLA™ MSI TEST TISSUE SPECIMEN REQUIREMENTS

- 1 x 5 μm FFPE tissue section 50 - 600 mm²
- 1 x 10 μm FFPE tissue section 25 - 300 mm²
- Neoplastic cell content ≥ 20%
  - If < 20%, macrodissection needed

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
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

<table>
<thead>
<tr>
<th>Study</th>
<th># Samples</th>
<th>Reference method</th>
<th>Concordance</th>
<th>Failure rate Idylla™ vs. Reference method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Performance</td>
<td>330</td>
<td>Promega MSI</td>
<td>99.7% (322/323)</td>
<td>0.9% vs 5.5%</td>
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<tr>
<td></td>
<td></td>
<td>Immunohistochemistry</td>
<td>97.5% (310/318)</td>
<td>0.6% vs 3.0%</td>
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</tbody>
</table>

1. Data from Promega internal study.
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. 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. Clinical trials and pathophysiological studies indicate a wide distribution of MSI-H across tumor types. In addition to CRC, high incidences are observed in endometrial cancer (20-30%), and gastric cancer (15-20%). 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. Research studies have shown that MSI-H patients respond favorably to immune checkpoint inhibitors and checkpoint blockade therapy has recently been incorporated into clinical care for colorectal cancers. 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.\textsuperscript{1,12-14}

Idylla™ MSI Test shows high concordance of more than 97% and lower failure rates compared to standard methods.\textsuperscript{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
REFERENCES

(1) Clinical Performance Study showed 99.7% concordance for MSI testing vs Promega (unpublished data)
(6) Van Cutsem et al. (2016) ESMO Consensus Guidelines for the management of patients with mCRC. *Annals of Oncology* 27, 1386.
(13) De Craene et al. (2017) Detection of microsatellite instability (MSI) with a novel panel of biomarkers in gastric cancer samples. *Annals of Oncology* 28 (suppl_5): v209-v268. Data obtained with pre-final biomarker panel containing the 7 final biomarkers and several additional biomarkers that were not retained in the final product.

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