BECAUSE TIME MATTERS

IDYLLA™ CDx MSI TEST

Trust in Idylla™ CDx MSI Test to accommodate your mCRC MSI testing needs

idylla
by BIOCARTIS

THINK IDYLLA™
BECAUSE TIME MATTERS

Idylla™ CDx MSI Test (A0220/6) is CE-marked in Europe in compliance with the EU IVD Regulation 2017/746 (IVDR).

THE IDEAL SUSTAINABLE DIAGNOSTIC SOLUTION FOR LABS AND HCPS

CHALLENGES

RISING DEMAND FOR MOLECULAR TESTING PUTS PRESSURE ON LAB WORKFLOWS

Precision medicine depends on accurate biomarker detection. As therapies **increasingly rely on molecular diagnostics**, labs are looking for solutions that simplify workflows and keep workloads manageable.

GAPS IN MSI TESTING DRIVE DISPARITIES IN CRC OUTCOMES

Socio-economic and care-setting disparities in patient access to healthcare are associated with unequal access to MSI testing[1]. **Delayed testing access** may **prevent** stage IV CRC patients from receiving the **right frontline therapy** at the right time.

METHOD-DEPENDENT VARIABILITY MAY IMPACT PATIENTS AND LAB ECONOMICS

13% of MSI-H/dMMR patients enrolled in CheckMate-8HW were **false-positive** upon central confirmation, underscoring that lack of testing standardization may **compromise patient outcomes**[2] and can **drive up costs** from repeat or additional testing.

SOLUTIONS

EASY AND OPTIMIZED LAB WORKFLOWS

Idylla™ CDx MSI Test runs directly from **FFPE tissue sections** on the fully automated Idylla™ Platform. With just **three minutes of hands-on time** and no need for matched or external control samples, Idylla™ CDx MSI Test **streamlines** testing and **simplifies** workflows.

IDYLLA™ CDx MSI TEST CLOSES GAPS IN PATIENT ACCESS AND TIMELY TREATMENT

The Idylla™ CDx MSI Test delivers **accurate** MSI results in only three hours, in any lab. The Test achieved a **HR of 0.21** in Checkmate-8HW for patients treated frontline with nivolumab + ipilimumab vs ChT[2].

STANDARDIZATION AND HIGH PERFORMANCE

Idylla™ CDx MSI Test is **clinically validated**, eliminating the need for complex test adoption trajectories, while also providing **standardized and straightforward results** with a demonstrated overall **98.57% concordance** rate.

IDYLLA™ CDx MSI TEST

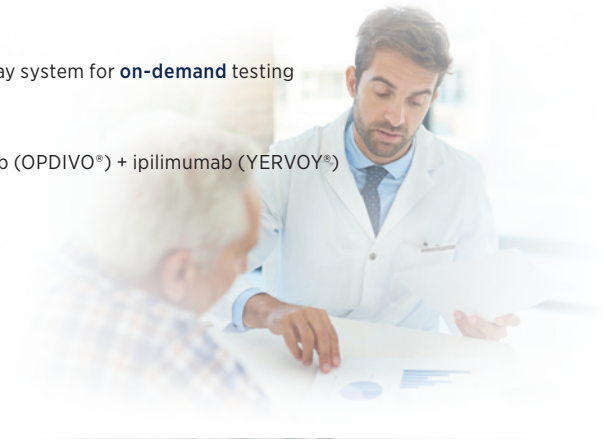
Standardized MSI detection in a single-use cartridge without the need for matched normal sample

< 3 minutes hands-on time (HoT) and **~150 minutes** turnaround time (TAT)

One FFPE tissue section with ≥ 33% neoplastic cells and tissue area 25-300 mm² (10 µm)

Fully automated molecular walk-away system for **on-demand** testing

CDx **Companion diagnostic** for nivolumab (OPDIVO®) + ipilimumab (YERVOY®)



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