Merlin

A GENE EXPRESSION-BASED TEST

Does my patient need a sentinel lymph node biopsy?

The Merlin™ test helps identify patients who may forgo the SLNB due to their low risk for nodal metastasis.

merlinmelanomatest.com

Merlin

A GENE EXPRESSION-BASED TEST

The Merlin test addresses important challenges in dermatology practice

Sentinel lymph node biopsy (SLNB) referral can be challenging, especially for the groups of patients for which the guidelines recommend to "discuss and consider/offer" the surgery[1].

SLNB is considered the standard of care to determine the clinical stage of the disease and guide appropriate treatment decisions. Still, the SLNB is an invasive surgery that may expose a patient to >10% risk of complications, such as infection, seroma, hematoma and lymphedema[2].

Furthermore, studies show that the vast majority (80-85%) of melanoma patients who undergo surgery are negative for nodal metastasis (SLNB-)[3]. While few patients may benefit from this procedure, many may be able to avoid the surgery and its associated risks[2].

Merlin test at a glance

- Gene expression-based test to identify primary melanoma patients who may forgo the sentinel lymph node biopsy due to their low risk for nodal metastasis.
- Enhances clinicopathologic findings with critical tumor biology insights.
- Improved performance over clinicopathologic (CP) variables alone (e.g. nomograms like MIA and MSKCC4) for appropriately predicting SLN status[5].
- Validated in multicenter clinical trials in the U.S. and EU.
- Non-invasive as it uses the primary biopsy tissue.
- Turnaround time: 6 hours and 25 minutes.
- Developed by SkylineDx in collaboration with the Mayo Clinic (USA).

The Merlin test provides actionable information to complement clinical management decisions and help improve patient care.

Merlin test indication

Utility

Identify primary cutaneous melanoma patients who have a low risk for nodal metastasis and may forgo sentinel lymph node biopsy.

Intended use population

SLNB eligible patients:

- ✓ Newly diagnosed invasive malignant melanoma of the skin (AJCC 8th edition staging guidelines)
- ✓ Without clinical evidence of nodal involvement or distant metastasis (cN0M0)
- ✓ pT1b-pT3 melanomas (Breslow thickness ≥ 0.8mm to 4mm **or** <0.8mm with ulceration)
- ✓ pT1a (Breslow thickness < 0.8 mm) **and** one or more of the following:
  - Mitotic rate ≥ 2/mm^2
  - Patient age at time of primary biopsy < 40 years old
  - Presence of lymphovascular invasion

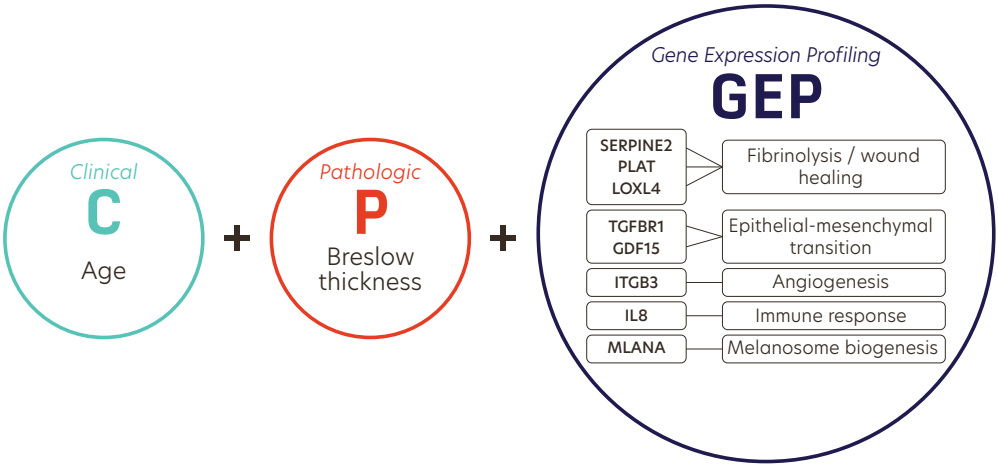
> The Merlin test seeks to improve risk assessment and individualized care for patients with a primary thin melanoma (pT1-pT3). Merlin can aid patients at risk of surgical complications, such as those with comorbidities or a lower extremity melanoma location. The addition of novel diagnostics like the Merlin test aims to positively impact patient care.

Alexander Meves, MD
Mayo Clinic, USA

Learn how your patient's melanoma behaves to complement clinical management decisions and improve patient care.

The Merlin test provides unique insights on the aggressiveness of your patient's melanoma

The test uses the CP-GEP model, an algorithm developed by logistic regression modelling. The combination of clinicopathologic factors – patient's age and Breslow thickness – with the gene expression profiling component of 8 specific genes involved in cancer metastasis and melanosome biogenesis, will allow you to better understand your patient's risk and may optimize a personalized treatment plan. No additional procedure is required to perform the test.



The Merlin test supports your decision-making

Validation studies in the Unites States and Europe confirm that the test accurately identifies patients who have a low risk for nodal metastasis. The Merlin test provides an easy to interpret binary result:

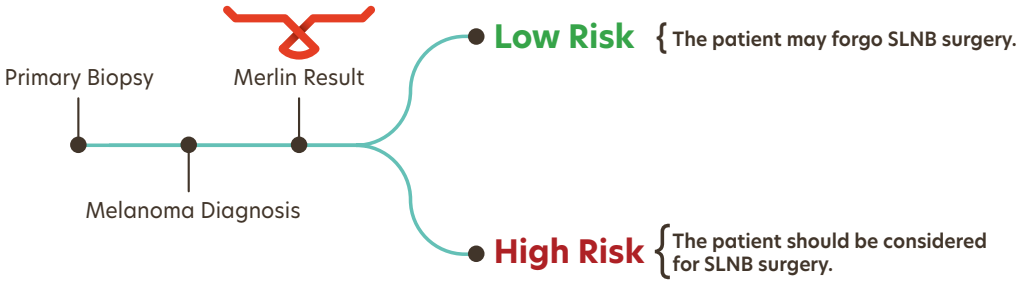
Low Risk

Your patient has a Low Risk of having nodal metastasis. The SLNB surgery may be avoided.

High Risk

Your patient has a High Risk of having nodal metastasis. The SLNB surgery should be considered according to national guidelines.

Merlin may reduce the number of SLNB-related complications by 59%[6].



We promise to provide personalized service

Outstanding customer service

We believe it is our job to make a difference by improving the quality of patients' lives. Thanks to the collaboration between SkylineDx and Biocartis, as we continue to innovate and serve your patients, we promise to provide the personalized service—expert, compassionate, and timely—that you and your patients deserve.

Ordering

To order the Merlin test or set up an account, please email **customerservice@biocartis.com** or visit our website **merlinmelanomatest.com**

Tissue requirements

- 5 x 10µm formalin fixed and paraffin embedded (FFPE) tissue of primary cutaneous melanoma biopsy.
- No macrodissection is required.

We welcome your inquiries.
To order Merlin or for additional information,
please contact us at:
email: **customerservice@biocartis.com**

References:

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