



Merlin

A GENE EXPRESSION-BASED TEST

Can my patient safely forgo a sentinel lymph node biopsy?



The Merlin™ Test helps identify patients who have a low risk for nodal metastasis and may therefore forgo the SLNB.



Merlinmelanomatest.com



Merlin

A GENE EXPRESSION-BASED TEST

The Merlin Test addresses important challenges in dermatology practice

Sentinel lymph node biopsy (SLNB) referral for physicians can be challenging. Especially for the groups of patients for which the guidelines recommend to “discuss and consider/offer” the surgery¹.

The 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 complications².

Furthermore, studies show that the wide majority (80-85%) of melanoma patients who undergo the surgery are negative for nodal metastasis (SLNB-)³. While some patients may require this procedure, many may be able to avoid the risk associated with the surgery such as infection, seroma, hematoma and lymphedema².

Merlin Test at a glance



Gene expression-based test to identify primary melanoma patients who are at low risk of nodal metastasis and may forgo the sentinel lymph node biopsy (SLNB).



Enhances clinicopathologic findings with critical tumor biology insights.



Improved performance over clinicopathologic (CP) variables only (e.g. nomograms like MIA and MSKCC⁴) for appropriately predicting SLN status⁵.



Validated in multicenter clinical trials in the U.S. and EU.



Non-invasive as it uses primary biopsy.



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 you improve patient care.

Merlin Test indication

Utility

Identify primary cutaneous melanoma patients who have a low risk for nodal metastasis and may therefore forgo the 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 $\geq 0.8\text{mm}$ to 4mm **or** $< 0.8\text{mm}$ with ulceration)
- pT1a (Breslow thickness $< 0.8\text{ mm}$) **and** one or more of the following:
 - Mitotic rate $\geq 2/\text{mm}^2$
 - 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. Reducing the need for surgery will facilitate clinical care delivery in lower resource settings, underserved populations, and during times of healthcare crises. The addition of novel diagnostics like the Merlin Test aims to positively impact patient care.

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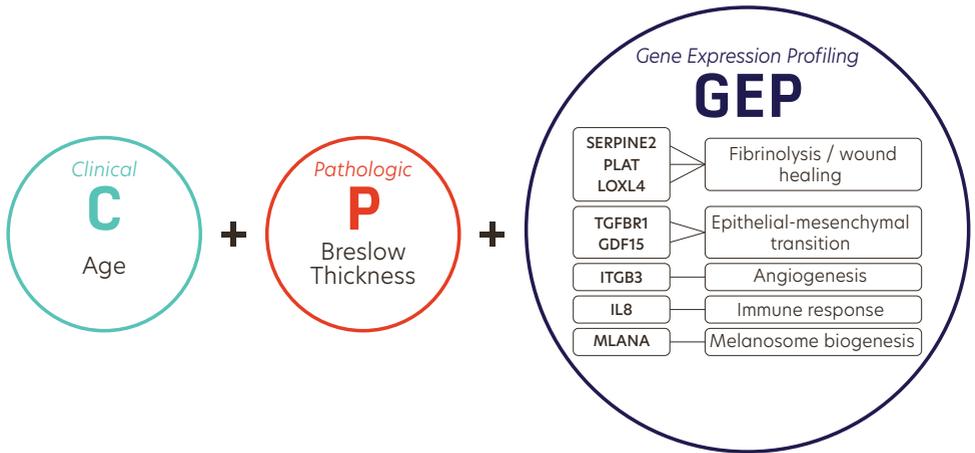


Learn how your patient's melanoma behaves by knowing their risk to complement clinical management decisions and improve patient care.

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

With the Merlin Test, you can gain a deeper understanding of your patient's cancer with no additional procedure required.

The Merlin 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.



Merlin Test may help reducing the number of unnecessary SLNB surgeries by ~ 40%⁵.



The Merlin Test supports your decision-making

The Merlin Test may help you optimize the clinical management of each patient. Validation studies in the United States and Europe confirm that the test accurately stratifies patients who have a low risk for nodal metastasis. The Merlin Test provides a 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 will be considered according to national guidelines.

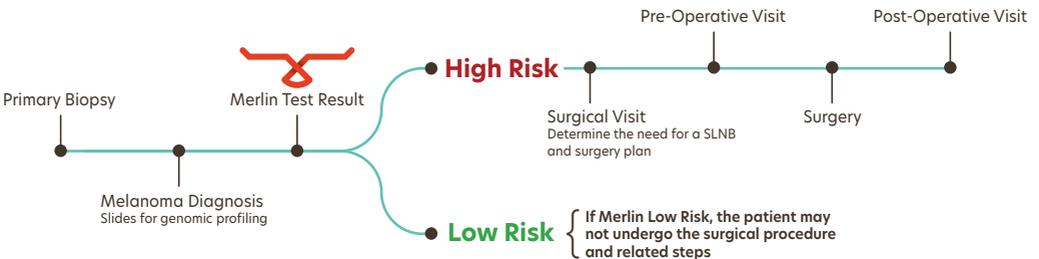
Low Risk Report

TEST REPORT		
		
Patient Information		
Name	Date of Birth	Case No.
Age at Biopsy	MIRN #	
Specimen Information		
Accession ID	Specimen Type	Date of Primary Biopsy
Receipt Date	Breast Thickness (mm)	Ulceration Status
Healthcare Provider Information		
Provider Name	Institution/Practice	
NPI	Client ID	
Merlin Predictive Result		
Low Risk		
Comments		

High Risk Report

TEST REPORT		
		
Patient Information		
Name	Date of Birth	Case No.
Age at Biopsy	MIRN #	
Specimen Information		
Accession ID	Specimen Type	Date of Primary Biopsy
Receipt Date	Breast Thickness (mm)	Ulceration Status
Healthcare Provider Information		
Provider Name	Institution/Practice	
NPI	Client ID	
Merlin Predictive Result		
High Risk		
Comments		

Merlin may reduce the number of SLNB-related complications by 59% if Merlin Low Risk patients would forgo the SLNB surgery⁶.



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 needed.

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

References:

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- 3 Morton DL, Thompson JF, Cochran AJ, et al. Final Trial Report of Sentinel-Node Biopsy versus Nodal Observation in Melanoma. *N Engl J Med*. 2014;370(7):599-609.
- 4 Johansson I, Tempel D, Dwarkasing D, et al. Validation of a clinicopathological and gene expression profile model to identify patients with cutaneous melanoma where sentinel lymph node biopsy is unnecessary. *EJSO*. 2021: DOI 10.1016/j.ejso.2021.11.010.
- 5 Bellomo D, Arias-Mejias S, Ramana C, et al. A model combining tumor molecular and clinicopathologic risk factors predicts sentinel lymph node metastasis in primary cutaneous melanoma. *JCO Precis Oncol*. 2020:DOI 10.1200/PO.19.00206.
- 6 Hieken T, Sadurni M, Quatrocchi E, et al. Complications of sentinel lymph node biopsy for primary cutaneous melanoma and the impact of molecular testing. *Int J Dermatol*. 2022.



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