Using the DecisionDx-Melanoma Test in Clinical Practice

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DecisionDx-Melanoma Provides Individualized Results to Guide Patient Management

DecisionDx-Melanoma answers your critical clinical questions:

- **How do I manage early-stage patients?**
- **Does my patient need to be referred for SLNB consideration?**
- **How do I manage patients who are node-negative?**

→ **DecisionDx-Melanoma**

Traditional AJCC Staging alone does not always tell the full story of melanoma risk.
Approximately **two-thirds** of **melanoma deaths** occur in patients **originally diagnosed as Stage I–II**.[a,1-3]

[a]Excludes Stage IV.

Three Actionable Risk Prediction Results

1 Class Result

- Assesses the aggressiveness of the patient's tumor biology alone
- Informs risk of recurrence and/or metastasis to guide ongoing surveillance and imaging

2 i31-SLNB Result[4]

- Integrates the GEP score with i31-SLNB-specific clinicopathologic factors,[b] including ulceration, Breslow thickness, age, and mitotic rate, to provide a personalized likelihood of SLN positivity
- Supports surgical referral decisions for patients with a higher likelihood of a positive SLNB

3 i31-ROR Result[5]

- Integrates the GEP score with i31-ROR-specific clinicopathologic factors,[b] including ulceration, age, Breslow thickness, mitotic rate, SLN status, and tumor location, to provide individualized recurrence-risk estimates
- Supports patient discussions and shared treatment decision-making
- Identifies patients at high risk for recurrence even after a negative SLNB

[b]The i31-SLNB and i31-ROR results integrate different clinicopathologic factors.

DecisionDx-Melanoma risk results inform management decisions

Higher-risk results

- Support more frequent surveillance and imaging
- Prompt surgical referral for SLNB
- Drive referrals to oncology or multidisciplinary teams

Lower-risk results

- Provide reassurance and peace of mind to patients and providers
- Support appropriate de-escalation decisions
- Avoid unnecessary SLNB

How to Use DecisionDx-Melanoma to Guide Patient Management

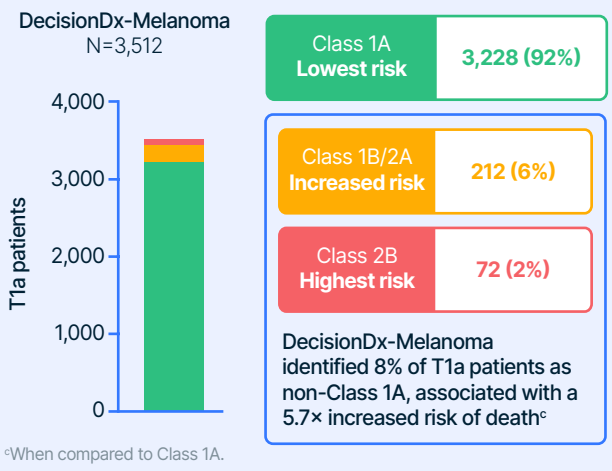
Early-Stage Patient

- Patients considered low risk based on AJCC staging and NCCN guidelines
- May include patients with thin tumors (<0.8 mm Breslow depth)

The Utility of the DecisionDx-Melanoma Class Result (Figure 1)

Class 1A Lowest Risk	**Standard follow-up** • Stage I/II: Symptom-guided imaging only • Stage >III: Imaging per surgical/medical oncology • Dermatology clinic visits approximately every 6 months/annually
Class 1B/2A Increased Risk **Class 2B** Highest Risk	**High-intensity surveillance** • Referral to medical oncology and/or multidisciplinary team • Frequent CT scans • Regular dermatology clinic visits

Figure 1: DecisionDx-Melanoma accurately identifies a subset of T1a patients with a high-risk of recurrence.[6]



[c]When compared to Class 1A.

Patient Under Consideration for SLNB

- Additional risk insight needed to support surgical decisions
- Potential to forgo unnecessary SLNB procedures if patient is low-risk

Current Guidelines for SLNB Patient Selection (Figure 2)

SLN Positivity Risk <5%	SLN Eligibility: NO
SLN Positivity Risk <5–10%	SLN Eligibility: YES, consider
SLN Positivity Risk >10%	SLN Eligibility: YES, offer

Figure 2: DecisionDx-Melanoma i31-SLNB result can accurately predict SLNB positivity.[7,8]

SLN positivity rates by i31-SLNB result	<5%	5–10%	>10%	Fold Difference <5% vs >10%
T1–T4 % SLN+	2.6%	7.0%	21.4%	8x higher
T1b–T2a % SLN+	1.4%	7.4%	18.5%	13x higher

Patients with <5% predicted risk had very low SLN positivity

Patients with >10% predicted risk had 8–13x higher SLN positivity

Node-Negative Patient

- Includes patients referred back to dermatology after negative SLNB
- Where further guidance is required on risk-appropriate management

The Utility of DecisionDx-Melanoma in Node-Negative Patients (Figure 3)

Lower risk Patients	Consider low-intensity management
Higher-risk Patients	Consider intensified management (follow-up, imaging, referral to medical oncology)

Figure 3: In a real-world cohort of 6,301 node-negative patients with melanoma, DecisionDx-Melanoma stratified melanoma-specific survival.[9]

DecisionDx-Melanoma result	Patients	5-year MSS
Class 1A	4,238	97.9%
Class 1B/2A	1,174	95.7%
Class 2B	889	85.8%

4.08x higher adjusted hazard of melanoma-specific death

Class 2B was associated with a 4.08-fold higher adjusted hazard of melanoma-specific death versus Class 1A among node-negative patients.[d] p<0.001

[d]Adjusted for age, ulceration, mitotic rate, and Breslow thickness.

The DecisionDx-Melanoma Test provides individualized results to guide risk-appropriate clinical management for patients with cutaneous melanoma.

References

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Abbreviations:

AJCC: American Joint Committee on Cancer; DMFS: distant metastasis-free survival; GEP: gene expression profile; i31: integrated 31-gene expression profile test; MSS: melanoma-specific survival; NCCN: National Comprehensive Cancer Network; RFS: recurrence-free survival; ROR: risk of recurrence; SLN: sentinel lymph node; SLNB: sentinel lymph node biopsy; vs: versus.