



AJCC staging-only approach misses patients with aggressive tumor biology

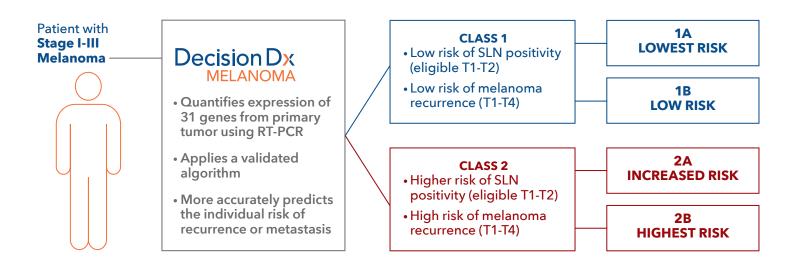
STAGE AT DIAGNOSIS* STAGE I 80% STAGE III MELANOMA DEATHS BY STAGE AT DIAGNOSIS*

STAGE I

*Excludes stage IV

- Early detection of disease and lower tumor burden are associated with better patient response to therapy and survival outcomes.¹⁻⁵
- Therefore, appropriate surveillance including imaging of high-risk patients is critical.¹⁻⁵
- AJCC clinicopathologic factors are helpful clinically but can miss patients with aggressive tumor biology. The majority of deaths occur in patients diagnosed with early stage disease when using only these factors for staging.⁶⁻⁸
- Prognostic accuracy needs to be improved to determine the most appropriate melanoma management strategy for each patient.

DecisionDx-Melanoma Informs Two Important Clinical Decisions Impacting Treatment Plans¹⁻⁵



STAGE II

STAGE III





Case Profile: 52-year-old male with melanoma on the right lower leg

Breslow depth: 1.2 mm

Clark level not reported

No ulceration (T2a)

Mitotic rate: <1/mm²

SLNB-eligible per NCCN: Yes



AJCC Clinical Stage: Stage IB (T2a)

Performed wide excision with sentinel lymph node biopsy per NCCN recommendation

- SLNB Negative
- Based on NCCN Guidelines for Stage IA/IB Patients with negative SLNB:
- Low frequency clinical follow-up every
 6-12 months (primarily with dermatology)
- No advanced imaging or blood tests recommended
- Ordered DecisionDx-Melanoma for additional information

DecisionDx-Melanoma Test Result: Class 2B (HIGHEST RISK)

Updated Plan:

- Patient sent to medical oncology for high intensity surveillance and clinical trial consideration
- Initial PET/CT scan intense, abnormal uptake on the left lateral deep cervical node
- Biopsy and removal of left lateral deep cervical nodes
- Upgraded to stage IV due to metastatic disease in contralateral nodes
- Offered immunotherapy for low-burden metastatic disease

Molecular		Recurrence-Free Survival at 5 years (Stage I and II)	Distant Metastasis-Free	Melanoma-Specific
Signature Result			Survival (Stage I and II)	Survival (Stage I and II)
Class 1	1A	95%	97%	99%
	1B	88%	90%	97%
Class 2	2A	77%	84%	97%
	2B	51%	65%	89%

tage I and II 9-12

Approximately 67% of patients in the clinical validation studies were clinically and/or pathologically node-negative (AJCC Stage I and II). The test is an independent predictor of risk of recurrence compared to traditional clinicopathologic factors.

Decision Dx-MELANOMA

Informs 2 Key Clinical Management Decisions 9-17

- Sentinel Lymph Node Biopsy (SLNB) patient selection
- Intensity of follow up, surveillance imaging and referral to surgical or medical oncology

Extensively Supported

- Over 25 peer-reviewed published studies including 2 meta-analyses¹⁸⁻¹⁹
- Achieves Level 1A evidence classification
- 230+ clinical US sites in collaboration with Castle Biosciences

Easily Integrates into Your Practice

- Online ordering available
- Results typically received within 5 days from sample receipt
- Favorable reimbursement profile now covered by Medicare and multiple private insurers

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