

Accurately identify the risk of metastasis with

Decision Dx[®]-SCC

DecisionDx[®]-SCC complements traditional assessments, providing additional risk prediction to better inform choices about treatment and follow-up care.

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CASTLE
BIOSCIENCES

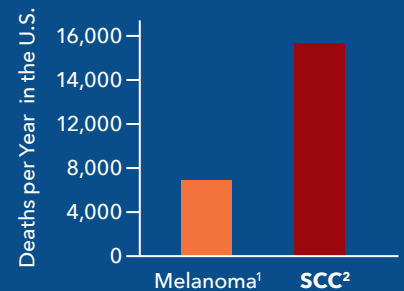


Cutaneous squamous cell carcinoma (SCC) is an emerging problem in the U.S.

Although most patients with SCC have an excellent prognosis, there is a subset of patients at risk of metastasis. Metastatic SCC is deadly.

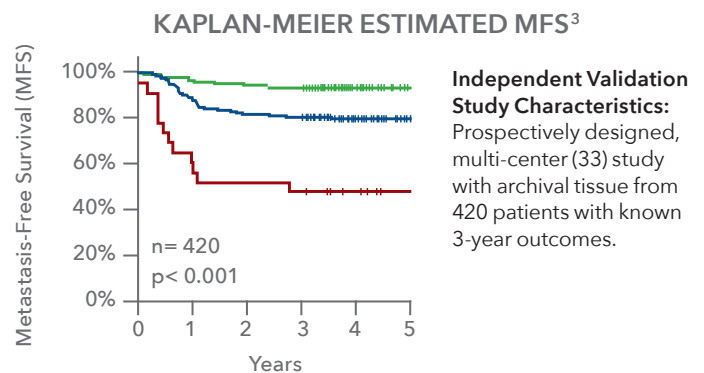
Patients with one or more risk factors suffer the majority of SCC mortality, however these factors alone are often not specific enough to determine their risk-appropriate treatment and further management.

DISEASE RELATED MORTALITY

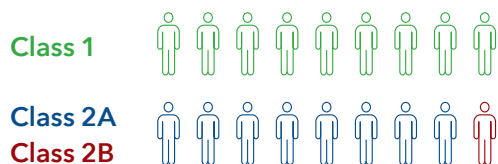


DecisionDx-SCC is a gene expression profile (GEP) test that is validated to predict metastatic risk for individual SCC patients with one or more risk factors.

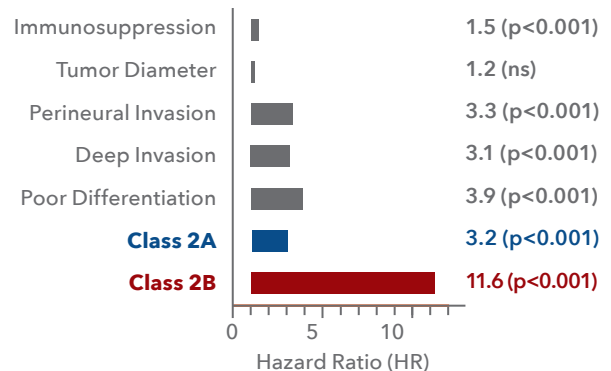
It is independently validated in a 420-patient cohort of high-risk SCC patients with 3-year outcomes. DecisionDx-SCC is the strongest independent predictor of metastasis in univariate (figure) and multivariate analysis (not shown).



COHORT CLASS RESULTS DISTRIBUTION



UNIVARIATE ANALYSIS³



RISK IDENTIFIED

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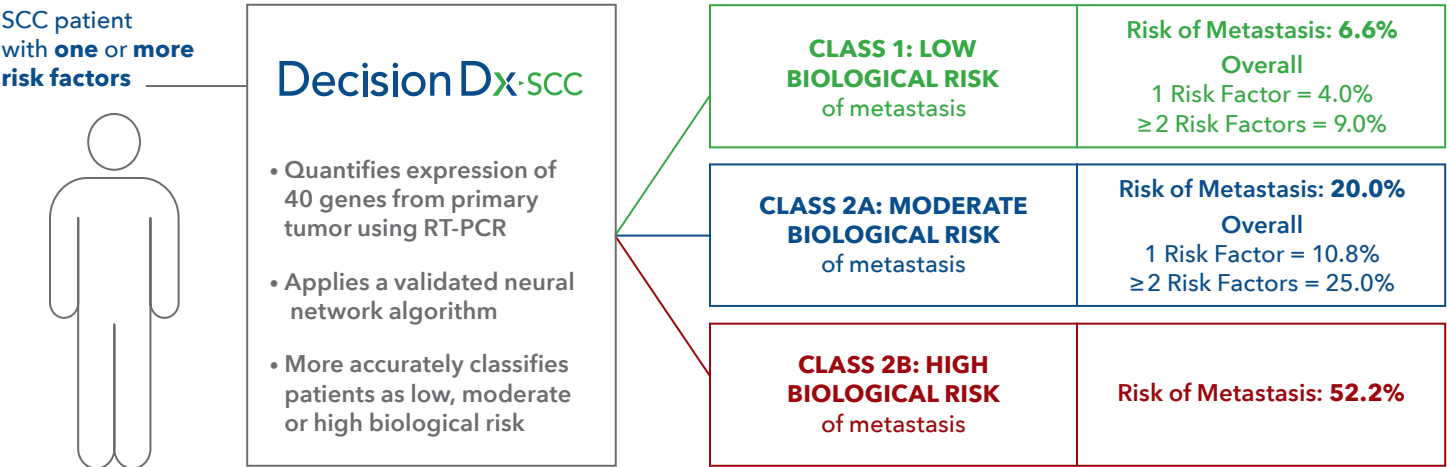
DecisionDx-SCC is the strongest independent predictor of SCC metastasis.

CLASS 1: LOW BIOLOGICAL RISK Metastatic risk was less than half of the independent validation cohort
CLASS 2A: MODERATE BIOLOGICAL RISK Confirmatory of the strongest established factors (deep invasion, poor differentiation, BWH T2b/T3)
CLASS 2B: HIGH BIOLOGICAL RISK >50% risk of metastasis



Incorporation of risk factors with DecisionDx-SCC results provides superior patient classification compared to traditional risk factors alone.³

DecisionDx-SCC complements factors commonly used for risk assessment in SCC.



DecisionDx-SCC results can inform management decisions within established guidelines for SCC patients.^{4,5,6}

Established management options have potential for early detection of metastasis, improved response to therapy and improved survival.^{7,8}

DecisionDx-SCC test results are reported two ways: Independently and in combination with traditional risk factors.

TREATMENT PLANS MAY INCLUDE		
LOW INTENSITY	MODERATE INTENSITY	HIGH INTENSITY
<ul style="list-style-type: none">Surgery, if feasibleClinical nodal exam	<ul style="list-style-type: none">Surgery, if feasibleConsider nodal imagingConsider oncology referral	<ul style="list-style-type: none">Surgery, if feasibleNodal imagingConsultation: radiation oncologyConsultation: medical oncology

FOLLOW-UP PLANS MAY INCLUDE		
LOW INTENSITY	MODERATE INTENSITY	HIGH INTENSITY
<ul style="list-style-type: none">Clinical follow-up 1-2x per yearClinical nodal exam	<ul style="list-style-type: none">Clinical follow-up 2-4x per year for 3 yearsBaseline and annual nodal US/CT for 2 years	<ul style="list-style-type: none">Clinical follow-up ≥4x per year for 3 yearsBaseline and 2x per year nodal US/CT for 2 years

DecisionDx-SCC

For SCC patients with one or more of the following risk factors

Intended Use: DecisionDx-SCC is indicated for patients diagnosed with cutaneous squamous cell carcinoma (SCC) and one or more risk factors.^{4,9} DecisionDx-SCC predicts individual metastatic risk to inform risk-appropriate management.^{3,10}

HISTORY AND PHYSICAL EXAMINATION	SURGICAL AND PATHOLOGY FINDINGS
Tumor size ≥ 2 cm anywhere on the body	Perineural involvement: <ul style="list-style-type: none">• Large (≥ 0.1 mm) or named nerve involvement• Small (< 0.1 mm) in caliber
Tumor location on the head, neck, hands, genitals, feet or pretibial surface (areas H or M)	Poorly differentiated tumor histology
Immunosuppression	Depth: <ul style="list-style-type: none">• Invasion beyond subcutaneous fat• Breslow depth ≥ 2 mm• Clark level $\geq IV$
Rapidly growing tumor	Aggressive histologic subtype ^a
Tumor with poorly defined borders	Lymphovascular invasion
Tumor at site of prior radiation therapy or chronic inflammation	
Neurologic symptoms in region of tumor	
DecisionDx-SCC is not intended for use with locally recurrent tumor tissue.	

a) Any of: acantholytic, adenosquamous, desmoplastic, carcinosarcomatous, sclerosing, basosquamous, small cell, spindle cell, pagetoid, infiltrating, single cell, clear cell, lymphoepithelial or sarcomatoid subtypes^{4,9}

References:

1. SEER data release 2019
2. Mansouri B et al. *JAMA Dermatol* 2017.
3. Data on file, Castle Biosciences.
4. NCCN Guidelines for Squamous Cell Skin Cancer v2.2020.
5. Likhacheva A et al. *Pract Radiat Oncol* 2020.
6. Alam M et al. *J Am Acad Dermatol* 2018.
7. Ruiz ES et al. *J Am Acad Dermatol* 2017.
8. Harris BN et al. *JAMA Otolaryngol Head Neck Surg*. 2019.
9. Connolly SM et al. *J Am Acad Dermatol* 2012.
10. Wysong A et al. *J Am Acad Dermatol* 2020.

Patient Access: Castle Biosciences works with all insurance providers, including Medicare, Medicaid, commercial insurers, and the VA, to secure coverage and payment for the DecisionDx-SCC test. Castle will submit insurance claims and manage the insurance billing process on behalf of patients. The company also sponsors an industry-leading Patient Assistance Program with the belief that quality care should not depend on financial considerations.

You can get more information about insurance coverage, claims processing, and financial assistance by calling **866-788-9007** and selecting **option #3**.