FINAL REPORT

Patient:
Sex:
DOB:
Client:
Provider:

Tumor Site:
Specimen ID:
Collected:
Received:
Reported:

DecisionDx-SCC Result

Class 2A

Class 2A signature is associated with a higher risk of metastasis within 3 years.

Clinical Validity and Risk of Metastasis

Molecular Signature Result	3-year Metastasis-Free Survival (MFS)
Class 1 (Low Risk)	94.1%
Class 2A (Higher Risk)	**81.1%**
Class 2B (Highest Risk)	56.8%

The DecisionDx-SCC® test is validated to predict a patient's individual risk of metastasis (regional or distant) in two, multi-center studies evaluating 897 patients, from 58 centers, diagnosed with localized cutaneous squamous cell carcinoma (SCC) and one or more risk factors.

3-year metastasis-free survival (MFS) for the entire population was 87.5%. Patients without a metastatic event had a minimum of 3 years follow-up. Median time to metastasis was 0.73 years.

DecisionDx-SCC 3-Year MFS Rate (%) with BWH Staging

Class Result Distribution Overall Cohort (n=872*)	BWH T1 (n=444)	BWH T2a (n=335)	BWH T2b (n=93)
Overall 3-year MFS rate	93.7%	87.2%	67.7%
Class 1 (n=503)	97.3%	93.1%	81.1%
Class 2A (n=334)	**88.7%**	**81.9%**	**63.6%**
Class 2B (n=35)	66.7%	63.6%	41.7%

The DecisionDx-SCC test significantly improves risk stratification across BWH T-stages (T1, T2a, T2b)

BWH Risk Factors: Tumor size ≥2 cm, perineural invasion (PNI) ≥0.1mm, poor differentiation, invasion beyond subcutaneous fat; T1 (0 risk factors), T2a (1 risk factor), T2b (2-3 risk factors); T3 (4 risk factors or bone invasion).

*This table excludes patients staged BWH T3 (n=25).

DecisionDx-SCC 3-Year MFS Rate (%) with NCCN High-Risk (HR) and Very-High-Risk (VHR) Groups

Class Result Distribution Overall Cohort (n=882**)	NCCN HR (n=570)	NCCN VHR (n=312)
Overall 3-year MFS rate	93.5%	76.0%
Class 1 (n=498)	97.0%	85.4%
Class 2A (n=347)	**88.4%**	**72.2%**
Class 2B (n=37)	69.2%	50.0%

The DecisionDx-SCC test significantly improves risk stratification across NCCN HR and VHR patients

NCCN HR factors: Tumor size >2cm-≤4cm, tumor location on the head, neck, hands, genitals, feet or pretibial surface (areas H or M), poorly defined, immunosuppression, rapidly growing tumor, prior radiation therapy or chronic inflammation, neurological symptoms, 2-6mm depth, select histologic subtypes.

NCCN VHR Factors: Tumor size >4 cm (any location), poor differentiation, desmoplastic SCC, >6mm or invasion beyond subcutaneous fat, perineural invasion (PNI) ≥ 0.1mm, lymphatic or vascular involvement.

**This table excludes NCCN Low Risk patients (n=15).

Multivariate Comparison with Clinicopathologic Risk Factors

Risk Factor	Hazard Ratio (HR) with DecisionDx-SCC	p-Value
Class 1	1.0	-
Class 2A	**2.21**	**<0.001**
Class 2B	4.90	<0.001
Tumor Thickness (>6mm)	2.93	<0.001
Poor Differentiation	2.82	<0.001
Immunosuppression	2.17	<0.001
Invasion beyond subcuaneous fat	1.83	ns
Perineural involvement (>0.1 mm)	0.65	ns
Diameter (2-4 cm)	1.31	ns

This table presents multivariate risk of metastasis for individuals with a specific high-risk factor as hazard ratios (HR). In this analysis, HR represents independent risk added by each variable, and cumulative risk when multiple risk factors are present can be assessed by multiplying the HRs.

For example: A Class 2A result (2.21 HR) with poor differentiation (2.82 HR) would result in a HR of 6.23 (2.21 x 2.82) as these values are multiplicative.

Multivariate analysis demonstrated independence of Class 2A and Class 2B molecular results (HR 2.21 and 4.90, respectively). Tumor thickness (2.93), poor differentiation (2.82) and immunosuppression (2.17) were also statistically significant.

About the Test

The DecisionDx-SCC test is a qRT-PCR assay of 6 control and 34 discriminant genes (40 in total) that uses a neural network algorithm comprised of two gene expression signatures to classify patients into risk categories. The algorithmic score from both signatures is converted to results reflecting risk classification. DecisionDx-SCC is indicated for patients with cutaneous squamous cell carcinoma (SCC) and one or more high-risk factors (see Test Requisition Form). The test predicts individual metastatic risk to help inform risk appropriate management.

The 34 discriminating genes are: ACSBG1, ALOX12, APOBEC3G, ATP6V0E2, BBC3, BHLHB9, CEP76, DUXAP9, GTPBP2, HDDC3, ID2, LCE2B, LIME1, LOC100287896, LOC101927502, MMP10, MRC1, MSANTD4, NFASC, NFIC, PDPN, PI3, PLS3, RCHY1, RNF135, RPP38, RUNX3, SLC1A3, SPP1, TAF6L, TFAP2B, ZNF48, ZNF496 and ZNF839. Six control genes consist of BAG6, FXR1, KMT2C, KMT2D, MDM2, MDM4.

For additional information about the development, validation and clinical use of the DecisionDx-SCC test, including references, scan the QR code below.

<Signature>

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